Secure Horizons Medical Management Guidelines Manual

DISCLAIMER

Secure Horizon's medical management guidelines represent the recommendation of the Secure Horizon's Medical Management Guideline (MMG) committee. They are based on the MMG committee's review of the available evidence as of the date of the medical management guideline. Medical management guidelines are subject to change based upon changes in state and federal laws and regulations, changes in scientific knowledge/technology, and evolving practice patterns.

Medical management guidelines contain clinical practice and utilization criteria to assist professionals in Secure Horizon's medical management practice when making medical necessity determinations prior to, subsequent to, or concurrent with the provisions of health care services. Medical management guidelines are developed using peer-reviewed medical literature, publications, reports, professional or governmental guidelines, and other authoritative medical sources that relate to medical treatment or service. Medical management guidelines are intended to support consistent, appropriate medical necessity determinations, but they do not replace an individualized case-by-case review and medical necessity determination for each Secure Horizons member.

Member benefit coverage and limitations may vary based on the member’s benefit plan. Refer to member specific Evidence of Coverage (EOC), Schedule of Benefits (SOB), or Certificate of Insurance (COI). If there is a discrepancy between a medical management guideline and the member’s EOC/SOB/COI, the member’s EOC/SOB/COI provision will govern. In addition, please consult with your local Medicare carrier to determine if a Local Coverage Determination is in place.
I. New Approved Guidelines:

Medical Management Guidelines
1. Breast Imaging
2. Hyperbaric Oxygen Therapy
3. Laparoscopic Radical Prostatectomy

Clinical Practice Guidelines
1. None

II. Re-Reviewed/Revised Guidelines:

Medical Management Guidelines
1. Cardiac Rehabilitation
2. Genetic Testing
3. Oxygen for Home Use
4. Polysomnography/Pulse Oximetry
5. Positron Emission Tomography/Combined PET-CT
6. Pulmonary Rehabilitation
7. Scanning Laser Glaucoma Testing
8. SNF Level of Care

Clinical Practice Guidelines
1. Cardiovascular Disease
2. Diabetes Management
3. Heart Failure Management
4. Preventive Health Recommendations

III. Retired Guidelines:

1. None
TITLE: Abdominal Panniculectomy

Authorized By: Medical Management Guideline Committee

Approval Date: 11/23/04        Revision Date: 11/22/05

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I. BACKGROUND

A. Description
Abdominal panniculectomy is defined as a surgical procedure to remove fatty tissue and excess skin from the lower to middle portions of the abdomen. A redundant panniculus is often associated with cutaneous inflammation, such as panniculitis, cellulitis, intertriginous dermatitis, or folliculitis. Blisters, abscesses, and gangrene may also develop. Patients with a large abdominal panniculus often also report severe, sustained low back pain that interferes with physical activity or activities of daily living (Gallagher and Gates, 2003). Stretching of the umbilicus in the panniculus may result in umbilical hernias. Abdominal panniculectomy is generally performed after obesity surgery following significant weight reduction (American Society of Plastic and Reconstructive Surgeons [ASPRS] 2004).

B. Benefit
PacifiCare covers abdominal panniculectomy when determined to be medically necessary and specific criteria are met. See the Secure Horizons Benefit...
Interpretation Policy (BIP) Cosmetic, Reconstructive or Plastic Surgery.

C. Local Carrier (Medicare) Determination
None

II. RECOMMENDATIONS

NOTE: Member benefit coverage and limitations may vary based on the member’s benefit plan. Refer to member specific Evidence of Coverage (EOC), Schedule of Benefits (SOB), or Certificate of Coverage (COC). If there is a discrepancy between this guideline and the member’s EOC/SOB/COC, the member’s EOC/SOB/COC provision will govern.

Abdominal panniculectomy is recommended for patients with abdominal panniculus who meet all of the following criteria (ASPRS 2004):

1. Uncontrollable (i.e., unresponsive to at least 6 months of comprehensive skin care) intertrigo of the skin folds of the panniculus
   AND
2. Panniculus hangs below the level of the inferior border of the pubic symphysis
   AND
3. The panniculus is interfering with activities of daily living
   • See appendix for corresponding list of activities

*Note: The above criteria should be documented in the patient’s medical records and through clinical photographs (ASPRS 2004).

*Note: If abdominal panniculectomy is performed following significant weight loss, the patient’s weight has to have been stable for at least 6 months.

III. STATE/MARKET APPLICATION CRITERIA

In applying this guideline, individual needs and an assessment of the local delivery system shall be considered.

• The following individual factors shall be considered: age, comorbidities, complications, progress of treatment, psychosocial situation, and home environment, when applicable.
• The following aspects of the local delivery system shall be considered: availability of local facilities and benefit coverage.

When utilization management guidelines cannot be applied appropriately, individual case discussions shall ensue.
IV. REFERENCES


V. APPENDIX/DEFINITIONS

Activities of Daily Living (Katz, 1976)

1. Bathing
2. Dressing
3. Toileting
4. Transferring (e.g. getting in/out of bed or a chair)
5. Continence
6. Feeding

Definitions (ASPRS 2004)

1. Cosmetic surgery: Performed to reshape normal structures of the body in order to improve the patient’s appearance and self-esteem.

2. Reconstructive surgery: Performed on abnormal structures of the body, caused by congenital defects, developmental abnormalities, trauma, tumors, or disease. Reconstructive surgery is generally performed to improve function, but may also be done to approximate normal appearance.

Approved by: Medical Management Guideline Committee

Date Approved: 11/22/05
I. BACKGROUND

A. Description

Traditionally, mammography has been the major imaging tool of choice in screening for breast cancer and identifying implant failure (i.e. leakage, rupture).

When used for breast cancer screening, the recommendation has been to have average-risk women screened annually or biannually beginning at age 40. However, the sensitivity of mammography in women that are younger or have dense breasts has been shown to be lower when compared to mammography results in older (≥50 years of age) women (BCBSA-TEC, 2003). Often times, many of these young women are at higher genetic risk for breast cancer. Women with a family history suggestive of a genetic predisposition to breast cancer should begin breast cancer screening 10 years prior to the youngest age that a family member was diagnosed with breast cancer.
The following imaging tools have been investigated with respect to their potential role in diagnosing and/or staging breast cancer as well as their role in examining implant failure:

1. **Screen Film Mammography (i.e. The Gold Standard)**
   Traditional radiologic mammograms can be categorized as either diagnostic or screening and must be performed in concordance with the Mammography Quality Standards Act [(MQSA; ACR, 2004)]. Screening mammography detects unsuspected breast cancer in asymptomatic women while diagnostic mammography provides specific analytic evaluation of patients with clinically detected or screen detected abnormalities (ACR, 2004; ACR, 2003).

2. **Full-field Digital Mammography**
   Recently, full-field digital mammography (FFDM) has been proposed as an alternative to screen film mammography (SFM) (BCBSA-TEC, 2002). FFDM has several advantages over SFM including increased image latitude and greater display of structure contrasts (Grainger, 2001). As with screen film mammography, digital mammography can be used either for screening or diagnostic purposes.

   Additionally, the images can be stored and retrieved electronically and its improved accuracy may reduce the number of followup procedures (NCI, 2002).

3. **Magnetic Resonance Imaging**
   Magnetic resonance imaging (MRI) is considered useful in detecting and characterizing breast disease, assessing local extent of disease, evaluating treatment response, and providing guidance for biopsy and localization (ACR, 2004).

   It is recommended that a dedicated breast coil be used for the procedure in addition to a recommendation that the facility administering the MRI have access to conventional breast imaging technology such as mammography (ACR, 2004). Since MRI uses magnetic field changes for imaging, ionizing radiation is not produced or emitted to the patient. Gadolinium contrast is typically used with injections being given intravenously either before or during the examination. (ECRI, 2002; BCBS-TEC, 2003).

   Many studies have found that when specifically used for breast cancer screening among high-risk women, MRI of the breast had a higher sensitivity but lower specificity when compared to results produced by the gold standard (i.e. screen film mammography).
4. **Positron Emission Tomography**

Positron emission tomography (PET) is a three-dimensional imaging technique intended to measure the level of physiologic and biochemical activity within tissue (Hayes, 2003). PET using fluorodeoxyglucose (FDG) as a radiotracer is generally used in disseminated disease (Abeloff: Clinical Oncology, 2004).

PET is used to distinguish between cancerous and non-cancerous tumors, for staging/restaging, and for diagnosis of breast cancer recurrence or distant metastasis (ECRI, 2003; American Cancer Society, 2005; Zangheri, et al., 2004).

5. **Combined Positron Emission Tomography-Computed Tomography**

Combined positron emission tomography and computed tomography (PET-CT) is an imaging technique that allows for the acquisition of physiologic data from PET and morphologic data from CT in a single scanning session. This can be used to diagnose, stage, and restage cancer as well as for treatment monitoring and radiotherapy planning (Hayes, 2004).

**B. Benefit**

Secure Horizons covers radiology and women’s preventive health screenings when determined to be medically necessary and specific criteria are met. See the Secure Horizons Benefit Interpretation Policies (BIPs) Radiology and Periodic Health Examination/Preventive Services.

**C. Local Carrier (Medicare) Determination**

Medicare currently does not have an existing national coverage determination for MRI of the breast. However, a policy does exist under one Local Carrier. Please see “RECOMMENDATIONS” below for exclusion/inclusion criteria. Detailed coverage and documentation information can be found on the following Local Carrier link. **NJ & NY**: [http://www.empiremedicare.com/newipolicy/policy/x21final.htm](http://www.empiremedicare.com/newipolicy/policy/x21final.htm).

**II. RECOMMENDATIONS**

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**A. Screen Film Mammography**
Screen film mammography of the breast **IS recommended** for the following:

   
   a. Annually for all female beneficiaries age 40 or older.
   
   b. One baseline screening for female beneficiaries between the ages of 35-39.

2. Breast cancer *diagnosis* if a beneficiary (CMS, 1978):
   
   a. Has distinct signs and symptoms for which a mammogram is indicated.
   
   b. Has a history of breast cancer.
   
   c. Is asymptomatic, but based on the patient’s history and other factors the physician considers significant, the physician’s judgment is that a mammogram is appropriate.

*Note:* A diagnostic mammography is a covered service if it is ordered by a physician (CMS, 1978).

*Note:* Screening and diagnostic mammograms must be furnished at FDA certified facilities for coverage (AMA, 2004).

*Note:* Also see CMS National Coverage Determination for Mammograms (220.4):


Screen film mammography of the breast **IS NOT recommended** for the following:

1. Asymptomatic women aged 50 and over
2. Asymptomatic women aged 40 or over whose mother or sisters have the disease

**B. FFDM**

FFDM of the breast **IS recommended** for the following:

   
   a. Annually for all female beneficiaries age 40 or older.
   
   b. One baseline screening for female beneficiaries between the ages of 35-39.

*Note:* FFDM has particular benefit over screen film mammography in women younger than age 50 or with very dense breasts (Pisano et al, 2005).

   
   a. Has distinct signs and symptoms for which a mammogram is indicated.
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b. Has a history of breast cancer.
c. Is asymptomatic, but based on the patient’s history and other factors the physician considers significant, the physician’s judgment is that a mammogram is appropriate.

*Note: A diagnostic mammography is a covered service if it is ordered by a physician (CMS, 1978).

*Note: Screening and diagnostic mammograms must be furnished at FDA certified facilities for coverage (AMA, 2004).

*Note: Also see CMS National Coverage Determination for Mammograms (220.4):

http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd

FFDM of the breast **IS NOT** recommended for the following:

1. Asymptomatic women aged 50 and over
2. Asymptomatic women aged 40 or over whose mother or sisters have the disease

C. MRI

MRI of the breast **IS** recommended for the following:

1. Cases where diagnosis is inconclusive, even after standard work-up (Empire, 1991).

2. Breast cancer screening (surveillance) in patients considered to be at a high genetic risk for breast cancer defined as (BCBSA-TSC, 2003):
   a. Having a confirmed presence of BRCA1 or BRCA2 mutation
   b. Having a high risk based on family history of a genetic mutation that increases the risk of developing breast cancer

3. Breast implants and **ANY ONE** of the following (MUSA, 2004; Empire, 1991):
   a. Palpable mass with inconclusive mammogram and ultrasound
   b. Confirmation of rupture that is moderately or strongly expected

4. Evaluation of the post-operative patient when scar tissue cannot be differentiated from tumors (Empire, 1991).

5. Determination of the extent of disease in patients with known malignancy, prior to treatment [to assure confinement to one segment of the breast; (Empire, 1991)].
6. Presurgical planning in patients with localized or locally advanced breast cancer who might be candidates for breast conservation surgery, when the results will be used to inform therapeutic decisions (Hayes, 2005).


MRI of the breast **IS NOT** recommended for the following:

1. Breast cancer screening for the low or average risk (asymptomatic) general population (ICSI, 2003; ACR, 2004; Hayes, 2005).
2. Breast cancer screening in patients who have breast characteristics such as dense breast tissue, implants, pain or treatment scarring (BCBSA-TEC, 2004).
3. Further evaluation of findings on conventional testing when short-interval follow-up or immediate biopsy is recommended (BCBSA-TEC, 2004).
4. Further evaluation of a suspicious breast lesion in order to avoid biopsy (BCBSA-TEC, 2004).
5. For use in distinguishing between malignant and benign lesions (Grainger, 2001).

*Note: Coverage is limited to MRI units that have received FDA premarket approval and are operated within the parameters specified by the approval (CMS, 1994). Breast MRI should be performed under the general supervision of a physician qualified in magnetic resonance imaging. A treating provider’s order is required (Empire, 1991).

MRI of the breast **IS NOT** recommended when the following contraindications are present (CMS, 1994):

1. Cardiac pacemakers
2. Metal clips on vascular aneurysms.
3. Viable pregnancy.
4. Life support systems and monitoring devices that employ ferromagnetic materials.

**D. PET**

PET for breast cancer **IS** recommended for the following as an adjunct to other imaging modalities (CMS, 2005):
1. Staging breast cancer patients with distant metastasis.
2. Restaging patients with loco-regional recurrence.
3. Monitoring tumor response to treatment for women with locally advanced and metastatic breast cancer when a change in therapy is contemplated.

PET for breast cancer IS NOT recommended for the following:
1. For initial diagnosis of breast cancer.
2. Staging of axillary lymph nodes.

*Note: Also see CMS National Coverage Determination for PET Scan (220.6):
http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd

E. Combined PET-CT

PET-CT for breast imaging IS recommended for the following (CMS, 2005):
1. Staging breast cancer patients with distant metastasis.
2. Restaging patients with loco-regional recurrence.
3. Monitoring tumor response to treatment for women with locally advanced and metastatic breast cancer when a change in therapy is contemplated.

PET-CT for breast imaging IS NOT recommended for the following (Hayes, 2004):
1. Identifying occult primary tumors in patients with metastases of unknown origin.
2. For planning radiotherapy
3. For any purpose in patients with a blood glucose level of >130 mg/dL

*Note: All recommendations are based on the use of fluorodeoxyglucose (FDG) as the radiotracer and glucose levels ≤130 mg/dL.

III. STATE/MARKET APPLICATION CRITERIA
Medical Management Guideline

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IV. REFERENCES


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V. APPENDIX/DEFINITIONS
I. BACKGROUND

A. Description

Cardiac rehabilitation services have been defined as comprehensive, long-term programs including medical education, prescribed exercise, cardiac risk factor modification, education, and counseling. These programs are intended to limit the physiologic and psychological effects of cardiac illness, reduce the risk for sudden death or reinfarction, control cardiac symptoms, stabilize or reverse the atherosclerotic process, and improve the psychosocial and vocational status of selected patients (AHRQ, 1995).

Core components of a comprehensive cardiac rehabilitation program include the following (Balady et al, 2000):

- Patient assessment
- Nutritional counseling
- Lipid management

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Medical Management Guideline

- Hypertension management
- Smoking cessation
- Weight management
- Diabetes management
- Psychosocial management
- Physical activity counseling
- Exercise training

Generally, cardiac rehabilitation programs are administered as a three-part process: phase 1, inpatient or recovery phase; phase II, outpatient or intermediate phase; and phase III, community-based or home long-term phase (HAYES, 2003).

In order to determine appropriate medical and surgical therapeutic strategies, patients at risk for proximate coronary events need to be identified. Risk stratification is based on the physiologic assessment of the cardiac patient and determines the presence and extent of myocardial ischemia, ventricular systolic dysfunction, and ventricular arrhythmias. Patients at low or moderate risk for proximate coronary events typically undergo early rehabilitative care, particularly early accelerated exercise. For many low-risk coronary patients, particularly those following myocardial revascularization procedures, rehabilitation often begins shortly after discharge from the hospital; many enter immediately what has traditionally been considered a Phase III program, that is, without intervening supervision in a Phase II component. Elderly coronary patients, those with significant comorbidity, high-risk patients with continuing ischemia, compensated heart failure, or serious arrhythmias, those with complications of myocardial infarction or CABG, and those with severe angina pectoris may require closer surveillance of their exercise training. ECG monitoring is currently generally recommended only for high-risk patients and selected patients who have problems in exercising (AHRQ, 1995).

For the year 2002, the American Heart Association (AHA) estimated a prevalence of coronary artery disease (CAD) of 13 million cases in the United States, including 7.1 million cases of myocardial infarction (MI) and 6.4 million cases of angina pectoris. According to the AHA, of 70.1 million Americans with one or more types of cardiovascular disease (CVD), 27 million are estimated to be age 65 and older (AHA, 2005).

B. Benefit

Secure Horizons covers cardiac rehabilitation programs when determined to be medically necessary and specific criteria are met.
C. Local Carrier (Medicare) Determination

II. RECOMMENDATIONS

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A. Outpatient Cardiac Rehabilitation

Outpatient cardiac rehabilitation services ARE recommended (CMS, 1989/2006):
1. For those members who have been referred by their attending physician and have one or more of the following:
   a. A documented diagnosis of an acute myocardial infarction (MI) within the past 12 months
   b. Coronary artery bypass surgery (CABG)
   c. Stable angina pectoris
   d. Heart valve repair/replacement
   e. Percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting
   f. Heart or heart lung transplant
2. When cardiac rehabilitation services meet ALL of the following criteria:
   a. The program is staffed by personnel necessary to conduct the program safely and effectively and who are trained in both basic and advanced life support techniques and in exercise therapy for coronary disease:
      1) A physician must be on the premises and available to perform medical duties
      2) Services of non-physician personnel must be furnished under the direct supervision of a physician
   b. Services must be provided either by the outpatient department of a hospital or in a physician-directed clinic
   c. The facility must have available for immediate use all medically necessary cardiopulmonary emergency diagnostic and therapeutic life saving equipment (e.g., oxygen, cardiopulmonary resuscitation equipment, defibrillator)

*Note: CMS has determined that the evidence is not adequate to conclude that cardiac rehabilitation is reasonable and necessary for congestive heart failure, and therefore we will not cover this indication (CMS, 1989/2006).
B. Cardiac Rehabilitation Services

Cardiac rehabilitation services include, but are not limited to (CMS, 1989/2006):

1. One baseline and one follow up stress test, using treadmill or bicycle ergometer with physician monitoring and written reports to:
   a. Evaluate chest pain, especially atypical chest pains
   b. Develop an exercise program for members with known cardiac disease
   c. Evaluate the pre- and/or post-operative tolerance of the coronary artery bypass surgery
      1) Continuous ECG monitoring during exercise
      2) Limited examination for physician follow-up to adjust medication or other treatment changes
      3) Psychotherapy or psychological testing if excessive anxiety or fear is associated with the cardiac disease or the member has a diagnosed mental, psycho-neurotic or personality disorder
      4) Physical and occupational therapy if there is an underlying medical condition other than cardiac (e.g., a member who is recovering from an acute phase of heart disease may have had a stroke which would require physical and/or occupational therapy)
      5) Member educational services regarding diet, nutrition and sexual activities

C. Duration

Services in connection with a cardiac rehabilitation program are reasonable and necessary for up to 36 sessions, usually 2-3 sessions per week for 12-18 weeks (CMS, 1989/2006)

1. Continued participation in cardiac exercise programs beyond 18 weeks will be covered only on a case-by-case basis in accordance with discharge guidelines (not to exceed a maximum of 72 sessions for 36 weeks).

D. Discharge Guidelines

Discharge guidelines from a cardiac rehabilitation program are as follows (CMS, 1989/2006)

1. Member has achieved a stable level of exercise tolerance without ischemia or dysrhythmia
2. Symptoms of angina or dyspnea are stable at the member’s maximum exercise level
3. Member’s resting blood pressure and heart rate are within normal limits
4. Member’s stress test is negative during exercise

III. STATE/MARKET APPLICATION CRITERIA
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IV. REFERENCES


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V. APPENDIX/DEFINITIONS

Approved by: Medical Management Guideline Committee Date Approved: 02/22/06
Medical Management Guideline

TITLE: Complex Decongestive Physiotherapy for Lymphedema

Authorized By: Medical Management Guideline Committee

Approval Date: 04/22/03    Revision Date: 05/25/04
                      05/24/05

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A. BACKGROUND

1. Description
Lymphedema is the accumulation of lymphatic fluid in a body part. Lymphedema is caused by reduced return of lymphatic fluid to the intravascular circulation, or by increased production of lymphatic fluid. Reduced return of fluid is considered low output failure and may be primary or secondary. Primary lymphedema involves impairment of lymphatic flow due to lymph vessel aplasia, hypoplasia, or hyperplasia and is congenital. Secondary lymphedema is caused by known precipitating factors such as surgical removal of the lymph nodes, fibrosis secondary to radiation, and traumatic injury to the lymphatic system. High output failure of the lymph circulation may occur when intact lymphatics are overwhelmed by capillary filtrate such as in ascities, anasarca, congestive heart failure, or venous insufficiency (TrailBlazer 2001).

Complex Decongestive Physiotherapy for Lymphedema – Secure Horizons
Medical Management Guideline

Complex decongestive physiotherapy (CDP) is used to treat primary and/or secondary lymphedema as a consequence of low output failure. The goal is to improve lymph flow and increase lymphatic microcirculation. Typically, CDP treatment consists of skin and nail care, gentle massage, application of compression dressings, muscle and joint exercises, and patient instruction for continuous self-treatment (TrailBlazer 2001).

2. Benefit
Secure Horizons covers complex decongestive physiotherapy (CDP) when determined to be medically necessary and specific criteria are met. See the Secure Horizons Benefit Interpretation Policy (BIP) Post Mastectomy Services.

B. RECOMMENDATIONS

NOTE: Member benefit coverage and limitations may vary based on the member’s benefit plan. Refer to member specific Evidence of Coverage (EOC), Schedule of Benefits (SOB), or Certificate of Coverage (COC). If there is a discrepancy between this guideline and the member’s EOC/SOB/COC, the member’s EOC/SOB/COC provision will govern.

1. CDP services are recommended 3 - 5 times per week, for 1 - 2 weeks for 60-75 minutes per treatment based on individual market Local Review Medical Policy (LMRP), when all of the following criteria are met (TrailBlazer 2001; Noridian 2000):
   a. A treating or consulting practitioner (MD, DO, Certified Nurse Practitioner, Certified Nurse Specialist, Certified Nurse Midwife or Physician Assistant) documents a diagnosis of lymphedema due to a low output cause and specifically orders CDP therapy
   b. The lymphedema causes a limitation of function related to self-care, mobility and/or safety
   c. The patient or patient caregiver has the ability to understand and provide home-based CDP
   d. CDP services are performed by a health care professional who has received CDP training
   e. The frequency and duration of the services are necessary and reasonable
   f. The patient's lymphedema is not reversible by exercise or elevation of the affected area
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g. The CDP services follow the Medicare criteria outlined for physical therapy (see Physical, Occupational and Speech Therapy BIP)

2. Each CDP treatment consists of 5 distinct steps (TrailBlazer 2001; Noridian 2000):
   a. Skin and nail care that includes treatment of infection and ulceration and use of low-pH lotions
   b. Gentle massage of edematous areas towards still functioning lymph vessels
   c. Multi-layered compression dressings of affected extremity to suppress formation of additional interstitial fluid
   d. Muscle contraction and joint mobility exercises, performed with the bandages in place, to mobilize fluid and prevent atrophy and stiffness
   e. Patient instruction for continuous self treatment

3. CDP is not recommended for the following (TrailBlazer, 2001; Noridian, 2000):
   a. Maintenance therapy
   b. Therapy limited to exercise or elevation of the affected area
   c. Therapy without ongoing patient education
   d. Treatment designed principally for temporary benefit
   e. CDP for patients who do not have the capacity or support system to supply self-treatment within a reasonable time

C. STATE/MARKET APPLICATION CRITERIA

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D. REFERENCES


Approved by: Medical Management Guideline Committee Date Approved: 05/24/05

Complex Decongestive Physiotherapy for Lymphedema – Secure Horizons
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A. BACKGROUND

1. Description
Medical nutritional therapy (MNT) services are defined as "nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional pursuant to a referral by a physician” (CFR 2003a).

For the purposes of this guideline, “diabetes” means diabetes mellitus consisting of two types. Type 1 is an autoimmune disease that destroys the beta cells of the pancreas, leading to insulin deficiency. Type 2 is familial hypoglycemia that occurs primarily in adults but can also occur in children and adolescents. It is caused by an insulin resistance with complex etiology. Gestational diabetes is any degree of...
glucose intolerance with onset or first recognition during pregnancy. The diagnostic criterion for a diagnosis of diabetes is a fasting glucose value of greater than or equal to 126mg/dl on glucose tolerance test (CFR 2003b).

For the purposes of this guideline, “renal disease” means chronic renal insufficiency, end-stage renal disease when dialysis is not received, or the medical condition of a beneficiary for 36 months after kidney transplant (CFR 2003b).

For the purposes of this guideline, “nutritional professional or registered dietitian” means an individual licensed or certified in a State prior to December 21, 2000; or an individual who, on or after December 22, 2000 meets all of the following (CFR 2003c):

- Holds a bachelors degree from an accredited college or university within the United States, or an equivalent foreign degree, with completion of the academic requirements of a program in nutrition or dietetics, as accredited by an appropriate national accreditation organization recognized for this purpose
- Has completed 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional
- Is licensed or certified by the state in which the services are performed. In a state without licensure or certification, the individual will be deemed to have met this requirement if he or she is recognized as a “registered dietitian” by the Commission on Dietetic Registration, or its successor organization, or has met the educational requirements and 900 hours of supervised dietetic practice

2. Benefit
Secure Horizons covers medical nutritional therapy for members with diabetes or renal disease when determined to be medically necessary and specific criteria are met. See the Secure Horizons Benefit Interpretation Policy (BIP) Diabetic Management Services and Supplies, and Dialysis.

B. RECOMMENDATIONS

NOTE: Member benefit coverage and limitations may vary based on the member’s benefit plan. Refer to member specific Evidence of Coverage (EOC), Schedule of Benefits (SOB), or Certificate of Coverage (COC). If there is a discrepancy between this guideline and the member’s EOC/SOB/COC, the member’s EOC/SOB/COC provision will govern.
A registered dietitian or a nutritional professional must render medical nutritional therapy (MNT). MNT consists of an initial visit assessment, follow-up visits for interventions, and reassessment as necessary during a 12-month period beginning with the initial assessment (“episode of care”) to assure compliance with dietary plan. The basic number of hours is 3 for the first year and 2 per year thereafter as determined to be medically necessary* by the contracted treating physician. All of the following conditions must be met (CMS NCD Manual):

a. The contracted treating physician must make a referral for MNT and indicate a diagnosis of diabetes or renal disease
b. The program meets the CMS guidelines
c. Services may be provided on an individual or group basis
d. For a member with a diagnosis of diabetes, diabetes self-management training (DSMT) and MNT services can be provided within the same time period and the maximum number of hours allowed under each benefit are covered. The only exception is that DSMT and MNT may not be provided on the same day to the same member
e. MNT services must be provided by a registered dietitian or nutrition professional (CFR 2003c)

*Additional hours are considered to be medically necessary and covered if the treating physician determines that there is a change in medical condition, diagnosis, or treatment regimen that requires a change in MNT and orders additional hours during that episode of care (CMS NCD Manual).

C. STATE/MARKET APPLICATION CRITERIA
In applying this guideline, individual needs and an assessment of the local delivery system shall be considered.
- The following individual factors shall be considered: age, comorbidities, complications, progress of treatment, psychosocial situation, and home environment, when applicable.
- The following aspects of the local delivery system shall be considered: availability of local facilities and benefit coverage.

When utilization management guidelines cannot be applied appropriately, individual case discussions shall ensue.
D. REFERENCES


Medical Management Guideline

TITLE: Diabetic Outpatient Self-Management Training

Authorized By: Medical Management Guideline Committee

Approval Date: 04/22/03       Revision Date: 05/25/04

05/24/05

Disclaimer

This medical management guideline represents the recommendation of the PacifiCare Medical Management Guideline (MMG) committee. It is based on the MMG committee's review of the available evidence as of the date of this medical management guideline.

This medical management guideline contains clinical practice and utilization criteria to assist professionals in PacifiCare’s medical management practice when making medical necessity determinations prior to, subsequent to, or concurrent with the provisions of health care services. This medical management guideline is intended to support consistent, appropriate medical necessity determinations, but it does not replace an individualized case-by-case review and medical necessity determination for each PacifiCare member.

Member benefit coverage and limitations may vary based on the member’s benefit plan. Please consult with your local Medicare carrier to determine if a Local Coverage Determination is in place.

A. BACKGROUND

1. Description
   Outpatient diabetic self-management training (ODSMT) consists of services intended to educate patients in the successful self-management of diabetes. The program includes instructions in self-monitoring of blood glucose, education about diet and exercise, an insulin treatment plan developed specifically for the patients, and motivation for patients to use the skills for self-management (CMS 2003).

2. Benefit
   Secure Horizons covers outpatient diabetic educational and outpatient diabetic self-management training when determined to be medically necessary and specific criteria are met. See the Secure Horizons Benefit Interpretation Policy (BIP) Diabetic Management, Services and Supplies.
B. RECOMMENDATIONS

NOTE: Member benefit coverage and limitations may vary based on the member’s benefit plan. Refer to member specific Evidence of Coverage (EOC), Schedule of Benefits (SOB), or Certificate of Coverage (COC). If there is a discrepancy between this guideline and the member’s EOC/SOB/COC, the member’s EOC/SOB/COC provision will govern.

1. ODSMT is covered for members who, within the 12-month period prior to the physician's order for training, meet one or more of the following criteria (CFR 2003):
   a. New onset diabetes
   b. Inadequate glycemic control demonstrated by a glycosylated hemoglobin (HbA1c) level of 8.5% or more on two consecutive HbA1c determinations, 3 or more months apart in the year before the member begins receiving training
   c. Change in treatment regime from no diabetic medications to any diabetic medication, or from oral diabetic medication to insulin
   d. High-risk for complications based on inadequate glycemic control (documented acute episodes of severe hypoglycemia or acute severe hyperglycemia occurring in the past year during which the beneficiary needed emergency room visits or a hospitalization)
   e. High-risk based on at least one of the following documented complications:
      1) Lack of feeling in the foot, or other complications such as foot ulcers, deformities, or amputation
      2) Pre-proliferative or proliferative retinopathy or prior laser treatment of the eye
      3) Kidney complications related to diabetes, when manifested by albuminuria, without other cause, or elevated serum creatinine

2. ODSMT must meet all of the following criteria:
   a. Training must be provided by a physician, individual or entity accredited by CMS to furnish outpatient diabetes self-management training
   Note: On October 26, 2001, the American Diabetes Association (ADA) was recognized by CMS as a national accreditation organization for the purposes of determining that an entity meets the necessary quality standards to furnish outpatient diabetes self-management and training services under Part B of the Medicare program (CMS 2001)
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b. Following an evaluation of the member's need for training, ODSMT is ordered by the physician (or qualified licensed practitioner) treating the member's diabetes

c. ODSMT is included in the comprehensive plan of care established by the physician (or qualified licensed practitioner). The treatment plan must meet the following requirements:
   1) Describes the content, number of sessions, frequency, and duration of the training as written by the physician (or qualified licensed practitioner) treating the member
   2) Provides that any changes to the plan of care are signed by the physician (or qualified licensed practitioner) treating the member (The plan of care must contain a signed statement certifying that the physician is indeed managing the member’s diabetic condition, and that the training described in the plan of care is needed to ensure therapy compliance or to provide the member with skills and knowledge to help manage their diabetes. The physician’s statement must identify the member’s specific medical conditions that the training will address)
   3) Is incorporated into the approved entity's medical record for the member

d. ODSMT is reasonable and necessary for treating or monitoring the condition of the member who meets the qualifying criteria listed above

3. Training is classified as either initial or follow-up (CFR 2003):
   a. Initial training must meet the following conditions:
      1) Furnished to the member who has not previously received initial training under this benefit
      2) Furnished within a continuous 12-month period
      3) Does not exceed a total of 10 hours
      4) Nine hours of the training are furnished in a group setting consisting of 2 to 20 individuals who need not all be Secure Horizons members
      5) Furnished in increments no less than one-half hour
      6) May include 1 hour of individual training for an assessment of the member's training needs
      7) Training on an individual basis is recommended when either of the following conditions are met:
         a) No group session is available within 2 months of the date the training is ordered
         b) The member's physician (or qualified licensed practitioner) documents in the member's medical record that the member has
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special needs resulting from conditions, such as severe vision, hearing, or language limitations that will hinder effective participation in a group training session and

c) Additional insulin instruction is needed (CMS 2003)

b. Follow-up training must meet the following criteria:
1) Consists of no more than 2 hours individual or group training for a member each year, where “group training” consists of 2 to 20 individuals who need not all be Secure Horizons members
2) It is furnished any time in a calendar year following the year in which the member completes the initial training
3) It is furnished in increments of no less than one-half hour
4) The physician (or qualified licensed practitioner) treating the member must document in the referral for training and the member's medical record, the specific medical condition that the follow-up training must address

C. STATE/MARKET APPLICATION CRITERIA
In applying this guideline, individual needs and an assessment of the local delivery system shall be considered.

- The following individual factors shall be considered: age, comorbidities, complications, progress of treatment, psychosocial situation, and home environment, when applicable.
- The following aspects of the local delivery system shall be considered: availability of local facilities and benefit coverage.

When utilization management guidelines cannot be applied appropriately, individual case discussions shall ensue.

D. REFERENCES

Medical Management Guideline


Approved by: Medical Management Guideline Committee Date Approved: 05/24/05

Diabetic Outpatient Self-Management Training – Secure Horizons
A. BACKGROUND

1. Description
Podiatry services include the treatment of disorders/ailments of the foot, heel, ankle, and leg by a medical doctor (MD), doctor of osteopathy (DO), or doctor of podiatric medicine (DPM).

Medically necessary foot care includes cutting/removing corns, warts, calluses, or nails for members with documented severe circulatory problems or decreased sensation in the legs or feet as a result of disease (e.g., diabetes, chronic thrombophlebitis).

Routine foot care includes, but is not limited to, the following: cutting and removing corns and calluses, trimming nails (including nail fungus conditions), cleansing and soaking feet, using skin creams to maintain skin tone of ambulatory or bedfast
patients, and other hygienic and preventive maintenance self-care performed in the absence of localized illness, injury, or symptoms involving the foot.

2. Benefit
Secure Horizons covers foot care and podiatry services when determined to be medically necessary and specific criteria are met. See the Secure Horizons Benefit Interpretation Policy (BIP) Foot Care and Podiatry Services.

3. Local Coverage Decisions
The following Local Coverage Decisions (LCDs) were identified as of May 2005:


“Indications:
The following is quoted from the Medicare Carrier’s Manual, Coverage and Limitations, Section B3 2323:
“B. Exceptions to Routine Foot Care Exclusion 3. Presence of Systemic Condition
The presence of a systemic condition such as metabolic, neurologic, or peripheral vascular disease may require scrupulous foot care by a professional that in the absence of such condition(s) would be considered routine (and, therefore, excluded from coverage). Accordingly, foot care that would otherwise be considered routine may be covered when systemic condition(s) result in severe circulatory embarrassment or areas of diminished sensation in the individual's legs or feet (emphasis added).

In these instances, certain foot care procedures that otherwise are considered routine (e.g., cutting or removing corns and calluses, or trimming, cutting, clipping, or debriding nails) may pose a hazard when performed by a nonprofessional person on patients with such systemic conditions.

C. Systemic Conditions
Although not intended as a comprehensive list, the following metabolic, neurologic, and peripheral vascular diseases (with synonyms in parentheses) most commonly represent the underlying conditions that might justify coverage for routine foot care.

*Diabetes Mellitus
Arteriosclerosis obliterans (A. S. O. arteriosclerosis of the extremities, occlusive peripheral arteriosclerosis)
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Buerger's Disease (Thromboangiitis obliterans)
*Chronic thrombophlebitis
Peripheral neuropathies involving the feet
  *associated with malnutrition and vitamin deficiency
    Malnutrition (general, pellagra)
    Alcoholism
    Malabsorption (celiac disease, tropical sprue)
Pernicious anemia
*associated with carcinoma
*associated with diabetes mellitus
*associated with drugs and toxins
*associated with multiple sclerosis
*associated with uremia (chronic renal disease)
associated with traumatic injury
associated with leprosy or neurosyphilis
associated with hereditary disorders
hereditary sensory radicular neuropathy
angiookeratoma corporis diffusum (Fabry's)
amyloid neuropathy

Where the patient's condition is one of those designated by an asterisk (*), routine procedures are covered only if the patient is under the active care of a doctor of medicine or osteopathy who documents the condition." (End of quote)

Routine foot care is also covered when the patient has had a non-traumatic amputation of a foot or integral skeletal portion thereof.

Limitations:
Noridian may make a presumption of coverage where the claim or other evidence available discloses certain physical and/or clinical findings consistent with the diagnosis and indicative of severe peripheral involvement. For purposes of applying this presumption, the following findings are pertinent.

Class A Findings:
- Non-traumatic amputation of foot or integral skeletal portion thereof

Class B Findings:
- Absent posterior tibial pulse
- Absent dorsalis pedis pulse
- Advanced trophic changes, such as: (three required)
  - Hair growth decreased or absent
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- Nail changes (thickening)
- Pigmentary changes (discoloration)
- Skin texture (thin, shiny)
- Skin color (rubor or redness)

Class C Findings:
- Claudication
- Temperature changes (e.g., cold feet)
- Edema
- Paresthesias (abnormal spontaneous sensations in the feet)
- Burning

The presumption of coverage may be applied when the physician rendering the routine foot care has identified:
1. a Class A finding; the Q7 Modifier,
2. two of the Class B findings; the Q8 Modifier, or
3. one Class B and two Class C findings; the Q9 Modifier

For purposes of applying the coverage presumption where the routine services have been rendered by a podiatrist, Noridian may deem the **active care** requirements (note under "Indications and Limitations of Coverage and/or Medical Necessity") met if the claim or other evidence available discloses that the patient has seen an MD or DO for treatment and/or evaluation of the complicating disease process during the six-month period prior to the rendition of the routine-type service.”

“Medicare covers routine foot care services only when the following conditions are met:
- The presence and documentation of one or more systemic condition(s) along with specific associated peripheral complications including clinically significant circulatory embarrassment;

    OR

- Clinically significant diminished or absent neurological sensations in an individual’s leg or foot;

    OR

- Patients undergoing active treatment for immunocompromised states (e.g., oral corticosteroid therapy; HIV; chemotherapy);

    OR

- Patients undergoing active anticoagulant therapy (e.g., heparin, coumadin)”

Foot Care and Podiatry Services – Secure Horizons
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Texas: Trailblazer – Routine Foot Care/Mycotic Nail Debridement (Trailblazer 2004)
“A presumption of coverage may be made by the carrier where the claim or other evidence available discloses certain physical and/or clinical findings consistent with the diagnosis and indicative of severe peripheral involvement. For purposes of applying this presumption, the following findings are pertinent:

- One of the following Class A findings;
- Two of the following Class B findings; or,
- One of the following Class B findings and two of the following Class C findings

Class A Findings:
- Non-traumatic amputation of foot or integral skeletal portion thereof

Class B Findings:
- Absent posterior tibial pulse;
- Absent dorsalis pedis pulse;
- Advanced trophic changes as evidenced by any three of the following:
  - Hair growth (decrease or increase);
  - Nail changes (thickening);
  - Pigmentary changes (discoloring);
  - Skin texture (thin, shiny); and/or,
  - Skin color (rubor or redness).

Class C Findings:
- Claudication;
- Temperature changes (e.g., cold feet);
- Edema;
- Paresthesias (abnormal spontaneous sensations in the feet): and/or,
- Burning”

B. RECOMMENDATIONS

*NOTE: Member benefit coverage and limitations may vary based on the member’s benefit plan. Refer to member specific Evidence of Coverage (EOC), Schedule of Benefits (SOB), or Certificate of Coverage (COC). If there is a discrepancy between this guideline and the member’s EOC/SOB/COC, the member’s EOC/SOB/COC provision will govern.*

Foot Care and Podiatry Services – Secure Horizons
1. **Medically Necessary Foot Care:**

   Foot care services are considered medically necessary when the following conditions are met (CMS 2002):

   1. Services are performed as a necessary and integral part of otherwise covered services such as diagnosis and treatment of ulcers, wounds, infections, and fractures.

   2. The presence of metabolic, neurologic, or vascular conditions that may require scrupulous foot care by a professional. Procedures that are otherwise considered routine are recommended when systemic condition(s), demonstrated through physical and/or clinical findings, result in severe circulatory embarrassment or areas of diminished sensation in the legs or feet and when such services may pose a hazard if performed by a nonprofessional. Patients with systemic conditions such as diabetes mellitus, chronic thrombophlebitis, and peripheral neuropathies involving the feet must be under the active care of a doctor of medicine or doctor of osteopathy who documents the condition in the patient’s medical record.

   *NOTE:* Active care is defined as treatment and/or evaluation of the complicating disease process during the six-month period prior to rendition of the routine care or care provided shortly after the services were furnished, usually as a result of a referral.

   3. Treatment of warts, including plantar warts, may be covered. Coverage is limited to those services provided for treatment of warts located elsewhere on the body.

   4. Treatment of fungal (mycotic) infection of the nail is limited to no more than once every 60 days unless medical documentation supports the need for more visits.

      a. For ambulatory members, the physician must document that both of the following criteria are met:

         1) There is clinical evidence of mycosis of the toenail
         2) The member has marked limitation of ambulation, pain, or secondary infection resulting from the thickening and dystrophy of the infected toenail plate

      b. For non-ambulatory members, the physician must document that both of the following criteria are met:

         1) There is clinical evidence of mycosis of the toenail
         2) The member has pain or secondary infection resulting from the thickening and dystrophy of the infected toenail plate
2. **Evaluation of diabetic neuropathy with loss of protective sensation (LOPS):**

Examination and treatment of the feet by a physician, no more often than every six (6) months, are recommended for members with a documented diagnosis of diabetic neuropathy with loss of protective sensation (LOPS) as long as the member has not seen a foot care specialist for some other reason in the interim (CMS NCD Manual).

LOPS is diagnosed through sensory testing with the 5.07 monofilament using established guidelines, such as those by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Five sites should be tested on the plantar surface of each foot. The areas must be tested randomly since the loss of protective sensation may be patchy in distribution, and the patient may get clues if the test is done rhythmically. Heavily callused areas should be avoided. As suggested by the American Podiatric Medicine Association, an absence of sensation at 2 or more sites out of 5 tested on either foot must be present and documented to diagnose peripheral neuropathy with loss of protective sensation (CMS NCD Manual).

The examination should include all of the following (CMS NCD Manual):
- Patient history
- Physical examination that must consist of at least the following elements:
  - Visual inspection of forefoot and hindfoot (including toe web spaces)
  - Evaluation of protective sensation
  - Evaluation of foot structure and biomechanics
  - Evaluation of vascular status and skin integrity
  - Evaluation of the need for special footwear
  - Patient education

Treatment should include, but is not limited to, the following (CMS NCD Manual):
- Local care of superficial wounds
- Debridement of corns and calluses
-Trimming and debridement of nails
C. STATE/MARKET APPLICATION CRITERIA

In applying this guideline, individual needs and an assessment of the local delivery system shall be considered.

- The following individual factors shall be considered: age, comorbidities, complications, progress of treatment, psychosocial situation, and home environment, when applicable.
- The following aspects of the local delivery system shall be considered: availability of local facilities and benefit coverage.

When utilization management guidelines cannot be applied appropriately, individual case discussions shall ensue.

D. REFERENCES


Medical Management Guideline


Approved by: Medical Management Guideline Committee

Date Approved: 05/24/05

Foot Care and Podiatry Services – Secure Horizons
TITLE: Genetic Testing and Genetic Counseling  

Authorized By: Medical Management Guideline Committee  

Approval Date: 04/22/03  Revision Dates: 07/22/03; 03/16/04; 02/22/05; 09/01/05; 02/22/06

Disclaimer  
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Member benefit coverage and limitations may vary based on the member’s benefit plan. Please consult with your local Medicare carrier to determine if a Local Coverage Determination is in place.

I. BACKGROUND

A. Description

1. Genetic Testing  
Genetic testing refers to the analysis of human DNA, RNA, genes, chromosomes, gene products, enzymes, or metabolites to detect inheritable and/or acquired alterations that cause or are likely to cause a particular disorder or condition (Genetics and Public Policy Center 2002).

Genetic testing is undertaken for several purposes, including the following (Genetics and Public Policy Center 2002):
- Carrier screening
- Prenatal diagnostic testing
- Newborn testing

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- Presymptomatic testing for estimating the risk of developing adult-onset cancers
- Confirmational diagnosis of a symptomatic individual

Common genetic tests include, but are not limited to, the following (Genome Programs 2003):
- Alpha-1-antitrypsin deficiency (AAT; emphysema and liver disease)
- Amyotrophic lateral sclerosis (ALS; Lou-Gehrig’s Disease: progressive motor function loss leading to paralysis and death)
- Ataxia telangiectasia (AT; progressive brain disorder resulting in loss of muscle control and cancers)
- Gaucher disease (GD; enlarged liver and spleen, bone degeneration)
- Charcot-Marie-Tooth (CMT; loss of feeling in ends of limbs)
- Congenital adrenal hyperplasia (CAH; hormone deficiency; ambiguous genitalia and male pseudohermaphroditism)
- Cystic fibrosis (CF; disease of lung and pancreas resulting in thick mucus accumulations and chronic infections)
- Duchenne muscular dystrophy/Becker muscular dystrophy (DMD; severe to mild muscle wasting, deterioration, weakness)
- Dystonia (DYT; muscle rigidity, repetitive twisting movements)
- Fanconi anemia, group C (FA; anemia, leukemia, skeletal deformities)
- Factor V-Leiden (FVL; blood-clotting disorder)
- Fragile X syndrome (FRAX; leading cause of inherited mental retardation)
- Hemophilia A and B (HEMA and HEMB; bleeding disorders)
- Hereditary Hemochromatosis (HFE; excess iron storage disorder)
- Huntington’s disease (HD; usually midlife onset; progressive, lethal, degenerative neurological disease)
- Myotonic dystrophy (MD; progressive muscle weakness; most common form of adult muscular dystrophy)
- Phenylketonuria (PKU; progressive mental retardation due to missing enzyme; correctable by diet)
- Adult Polycystic Kidney Disease (APKD; kidney failure and liver disease)
- Prader Willi/Angelman syndromes (PW/A; decreased motor skills, cognitive impairment, early death)
- Sickle cell disease (SS; blood cell disorder; chronic pain and infections)
- Spinocerebellar ataxias (SCA; e.g., Machado-Joseph disease [SCA3], DRPLA, and other progressive ataxias that may be associated with cerebellar atrophy, peripheral neuropathy, and/or ocular motor problems)
Spinal muscular atrophy (SMA; severe, usually lethal progressive muscle-wasting disorder in children)
- Thalassemias (THAL; anemias – reduced blood cell levels)
- Tay-Sachs Disease (TS; fatal neurological disease of early childhood; seizures, paralysis)

Susceptibility tests, which provide an estimated risk for developing a certain disorder, include, but are not limited to, the following (Genome Programs):
- Inherited breast and ovarian cancer (BRCA 1 and 2; early-onset tumors of breasts and ovaries)
- Hereditary nonpolyposis colon cancer (CA; early-onset tumors of colon and sometimes other organs)

2. Genetic Counseling
Genetic counseling refers to a process in which a genetic counselor educates individuals or families about a particular genetic disease or the risk of a predisposition for genetic disease in order to assist patients to make informed reproductive or medical decisions. Genetic counselors also provide supportive counseling and anticipatory guidance for individuals or families when a hereditary disorder or birth defect has occurred (National Society of Genetic Counselors 2003).

B. Benefit
Secure Horizons covers genetic testing when determined to be medically necessary and specific criteria are met. See the Secure Horizons Benefit Interpretation Policy (BIP) Genetic Testing.

C. Local Carrier (Medicare) Determination

II. RECOMMENDATIONS

NOTE: Member benefit coverage and limitations may vary based on the member’s benefit plan. Refer to member specific Evidence of Coverage (EOC), Schedule of Benefits (SOB), or Certificate of Coverage (COC). If there is a discrepancy between this guideline and the member’s EOC/SOB/COC, the member’s EOC/SOB/COC provision will govern.

A. General Recommendations for Genetic Testing
Genetic testing is recommended in the following instances (Genetics and Public Policy Center 2002; Kruse et al, 2002):
1. For members at direct risk of genetic disease
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2. For parent(s) and/or fetus after 3 consecutive spontaneous abortions to determine etiology
3. To screen newborns, children, or adolescents for disease to determine carrier status for inheritable disorders when there is immediate medical benefit or when the test results would be used to initiate medical interventions during childhood
4. To identify carriers of genetic disease when the member has a medical indication, i.e., high-risk status or a strong family history of genetic abnormality
5. To establish prenatal or clinical diagnoses
6. To direct clinical management

B. Recommendations for Specific Genetic Tests

Inheritable Diseases

Cystic Fibrosis Carrier Testing
Cystic fibrosis is a multisystem genetic disease that is inherited as an autosomal recessive disorder. In patients with cystic fibrosis, defective chloride transport across membranes causes dehydrated secretions, leading to tenacious mucus in the lungs, mucus plugs in the pancreas, and to the characteristically high sodium and chloride levels in the patients’ sweat (utilized in the diagnostic sweat test) (Gregg and Simpson, 2002). In Caucasian populations, particularly those of European or Ashkenazi Jewish descent, the cystic fibrosis carrier frequency is estimated to be 1/29. The cystic fibrosis gene is less frequent in Asian Americans (about 1/90), African Americans (about 1/65), and Hispanic Americans (about 1/46) (NIH 1997).

Cystic fibrosis carrier testing IS recommended for individuals of European or Ashkenazi Jewish descent who are seeking prenatal care or are planning a pregnancy.

*Note: Routine genetic screening for cystic fibrosis in newborns is not recommended.

Fragile X Syndrome: Diagnostic and Carrier Testing
Fragile X syndrome represents the most common cause of inherited mental retardation, accounting for approximately 40% of cases with X-linked mental retardation. Other symptoms include a wide range of cognitive, behavioral, and physical features, such as variable IQ, autistic-like qualities, hyperactivity, macroorchidism, macrocephaly, and prominent ears. Females are less severely affected, probably due to X-inactivation. The frequency of
fragile X syndrome is estimated to be 1/1,200 males and 1/2,500 females (CDC 2001; American College of Medical Genetics, 1994). The underlying gene abnormality can be classified as common, intermediate, premutation, and full mutation, with full mutation representing the disorder-causing form and intermediate representing the carrier form (CDC 2001).

Diagnostic testing for fragile X syndrome is recommended for (American College of Medical Genetics, 1994):
1. Individuals of either sex with mental retardation, developmental delay, or autism, particularly if they have any of the following:
   a. Physical or behavioral characteristics of fragile X syndrome
   b. Family history of fragile X syndrome
   c. Male or female relatives with undiagnosed mental retardation
2. Individuals seeking reproductive counseling who have either of the following:
   a. Family history of fragile X syndrome
   b. Family history of undiagnosed mental retardation
3. Fetuses of known carrier mothers
4. Patients who have had cytogenetic fragile X testing in the past with a result that is discordant with their phenotype, including patients with a strong clinical indication (including risk of being a carrier) who have had a negative or ambiguous test result, and patients with an atypical phenotype who have had a positive test result

*Note: Population carrier screening is not recommended.

**Factor V Leiden Mutation Testing**
Factor V Leiden mutation is an inheritable clotting disorder (hypercoagulability) that represents the most common risk factor for venous thrombosis. The mutation causes activated protein C resistance (an abnormally low anticoagulant response to activated protein C). The Factor V Leiden mutation is present in the heterozygous form in approximately 5% of Caucasian Americans and to a lesser degree in African-Americans and Asian-Americans. The relative risk of venous thrombosis is thought to be about 7-fold for heterozygous individuals and about 80-fold for homozygous individuals. The Factor V Leiden mutation is found in about 11-20% of individuals of all ages presenting with their first episode of venous thrombosis. Other thrombophilias include the G20210A prothrombin and MTHFR C667T mutations, and less frequently, deficiencies of protein C, protein S, and antithrombin III (American College of Medical Genetics, 2001).
Factor V Leiden mutation testing is recommended for (American College of Medical Genetics, 2001):
1. Individuals under age 50 with any venous thrombosis
2. Individuals with a venous thrombosis in unusual sites, such as the hepatic, mesenteric, or cerebral veins
3. Individuals with recurrent venous thrombosis
4. Individuals with venous thrombosis and a strong family history of thrombotic disease
5. Women with venous thrombosis during pregnancy or while taking oral contraceptives
6. Female smokers under age 50 with myocardial infarction

*Note:* Neither prenatal testing, nor routine newborn screening, nor random screening of the general population is recommended.

**Genetic Testing for Tay-Sachs Disease**
Tay-Sachs disease is a lysosomal storage disease caused by a deficient activity of the enzyme hexosaminidase A (Hex A) and is inherited as an autosomal recessive disorder. Tay-Sachs disease occurs most commonly among people with Ashkenazi Jewish or French-Canadian ancestry. In its most common form, the classical infantile type, Tay-Sachs disease results in progressive neurodegeneration and death within 5 years. However, there are also less severe juvenile, chronic, and adult-onset forms of the disease. Tay-Sachs disease is associated predominantly with one of 3 mutations in the HEXA gene, which codes for the Hex A enzyme. The initial screening test for mutation carriers usually consists of measurement of Hex A activity in serum. However, in some cases DNA analysis may be necessary to clarify undiagnostic or ambiguous enzyme test results, or to confirm positive test results in individuals who are not Ashkenazi Jewish or French-Canadian and may have very low Hex A levels but do not carry a HEXA gene mutation (pseudodeficiency) (Hayes 2003).

Genetic testing for Tay-Sachs disease is recommended for couples planning a pregnancy or in the early stages of pregnancy or to diagnose variant forms of Tay-Sachs disease when one or more of the following are met (Hayes 2003):
1. Individuals at risk for Tay-Sachs disease due to ethnic background or family history
2. Partners of Tay-Sachs disease carriers
3. Prenatal testing when both parents are known to be Tay-Sachs disease carriers
4. Individuals who have an ambiguous enzyme test in both serum and leukocytes
5. Individuals who have low in vitro Hex A activity and are suspected of having a variant form of Tay-Sachs disease, such as adult onset or chronic Tay-Sachs disease
6. Individuals who are suspected of having a pseudodeficiency condition (asymptomatic non-Jewish individuals with low in vitro Hex A activity)

*Note: Genetic testing for Tay-Sachs disease in the general population is not recommended.

Susceptibility

**Genetic Susceptibility to Breast and Ovarian Cancer**

Breast and ovarian cancer represent frequent causes of morbidity and mortality among women. In the United States, an estimated 215,990 new cases of invasive breast cancer are expected to occur during 2004, with an estimate of 40,580 deaths (40,110 women, 470 men). Ovarian cancer is less common, with an estimated 25,580 new cases expected in 2003, accounting for an estimated 16,090 deaths (ACS 2004). Genetic testing for susceptibility to breast and ovarian cancer is based on the identification of mutations in 2 independent genes, BRCA1 and BRCA2. At present, more than 1000 mutations in both BRCA1 and BRCA2 have been identified, however, accurate risk figures as well as the complete array of clinical features associated with each specific mutation have not yet been described. It is currently estimated that 5% to 10% of breast cancers and up to 10% of ovarian cancers in the general population are associated with inherited mutations that confer a very high risk of developing the disease (American College of Medical Genetics, 1999).

Genetic testing for breast and ovarian cancer susceptibility genes BRCA1 and BRCA2 IS recommended when both of the following criteria are met (American College of Medical Genetics, 1999):
1. An increased risk for a mutation is evident based on any the following:
   a. There are 3 or more affected first or second degree relatives on the same side of the family, regardless of age at diagnosis, or
   b. There are fewer than 3 affected relatives, but
      1) The patient was diagnosed at 45 years of age or less, or
      2) A family member has been identified with a detectable mutation, or
3) There are one or more cases of ovarian cancer at any age, and one or more members on the same side of the family with breast cancer at any age, or
4) There are multiple primary or bilateral breast cancers in the patient or one family member, or
5) There is breast cancer in a male patient, or in a male relative, or
6) The patient is at increased risk for specific mutation(s) due to ethnic background (for instance, Ashkenazi Jewish descent) and has one or more relatives with breast cancer or ovarian cancer at any age

2. Prior to BRCA1/BRCA2 testing, it is recommended that the member at increased risk undergo a process of pre-test education, provided by a healthcare professional trained/experienced in medical genetic counseling, in order to allow the member to make an informed choice (i.e., the education may help the member weigh the potential benefits of testing against the potential burdens of testing). Elements of pre-test education should include:
   a. Clarification of the patient’s increased risk status
   b. Explanation of how genetics affect cancer susceptibility
   c. Potential benefits, risks, and limitations of testing
   d. Possible outcomes of testing (positive, negative, or uncertain test results)
   e. Limited data on efficacy methods for early detection and prevention
   f. Possible psychological and social impact of testing
   g. Alternatives to genetic testing

*Note: Except in unusual circumstances, testing of individuals under the age of 18 years is not recommended, since there is no recommended intervention in childhood.

**Genetic Testing for Hereditary Colorectal Cancer**
Colorectal cancer represents the third most common cancer in men and women, with 106,370 new cases of colon cancer and 40,570 new cases of rectal cancer expected for the year 2004 in the United States. Colorectal cancer is expected to result in 56,730 deaths in 2003, accounting for about 10% of cancer deaths (ACS 2004). The 2 best described hereditary colorectal cancer syndromes for which genetic testing is available are familial adenomatous polyposis (FAP) and hereditary nonpolyposis colorectal cancer (HNPCC) (AGA 2001).
Genetic Testing for Familial Adenomatous Polyposis (FAP)
Genetic testing for FAP is based on testing for mutation of the adenomatous polyposis coli (APC) gene (AGA 2001).

Genetic testing for FAP IS recommended to diagnose and establish a detectable mutation in the pedigree for individuals meeting one of the following criteria:
1. Individuals affected with FAP (≥100 colorectal adenomas)
2. Individuals with first degree relatives diagnosed with FAP if a detectable mutation in the pedigree has been identified
3. Individuals with ≥20 cumulative colorectal adenomas (suspected attenuated FAP)
4. Individuals with first degree relatives diagnosed with attenuated FAP if a detectable mutation in the pedigree has been identified

Genetic Testing for Hereditary Nonpolyposis Colorectal Cancer (HNPCC)
Genetic testing for HNPCC is based on testing for germline mutation of the DNA mismatch repair genes (AGA 2001).

Genetic testing for HNPCC IS recommended for:
1. Affected individuals meeting all of the following Amsterdam I criteria:
   a. ≥3 relatives with colorectal cancer, one of whom is a first degree relative to other 2
   b. ≥2 generations affected
   c. ≥1 relative diagnosed at ≤50 years
2. Affected individuals meeting any of the following Bethesda Criteria:
   a. Affected individuals meeting the Amsterdam I criteria
   b. Individuals with 2 HNPCC cancers (including synchronous/metachronous colorectal cancers)
   c. Individuals with colorectal cancer and a first degree relative with colorectal cancer and/or an HNPCC-related extracolonic cancer and/or colorectal adenoma (cancer diagnosed at age <50 years and adenoma diagnosed at age <40 years)
   d. Individuals with colorectal or endometrial cancer at <50 years
   e. Individuals with right-sided colorectal cancer with undifferentiated pattern on histology at <50 years
   f. Individuals with signet-cell type colorectal cancer at <50 years
   g. Individuals with colorectal adenoma at <40 years
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3. Individuals with a first degree adult relative with a known mutation

Prenatal Screening and Testing

First-Trimester Screening for Fetal Aneuploidy
First-trimester screening for fetal aneuploidy involves the measurement of the serum analytes pregnancy-associated plasma protein-A (PAPP-A) and free beta-hCG in combination with ultrasonographic nuchal translucency measurement (ACOG 2004).

First-trimester screening for fetal aneuploidy using nuchal translucency, free beta-hCG, and PAPP-A IS recommended only in the following instances (ACOG 2004):
1. Appropriate ultrasound training and ongoing quality monitoring programs are in place
2. Sufficient information and resources are available to provide comprehensive counseling to women regarding the different screening options and limitations of these tests
3. Access to an appropriate diagnostic test is available when screening results are positive

*Note: Nuchal translucency measurement in the absence of serum screening IS NOT recommended.

Prenatal Genetic Testing
Prenatal genetic testing involves the analysis of fetal chromosomes obtained from fetal cells, or of metabolites in the amniotic fluid, or of DNA or proteins from amniocytes or chorionic villi. Techniques for fetal tissue sampling include amniocentesis, chorionic villus sampling (CVS), and percutaneous umbilical blood sampling (PUBS) (ACOG 2001).

Prenatal genetic testing IS recommended in any the following instances (ACOG 2001; Budorick and Boyle, 2003):
1. Mother ≥35 years of age or older at estimated date of delivery
2. Chromosome rearrangement in either parent
3. One major or 2 or more minor abnormalities on fetal ultrasound suggestive of aneuploidy (for the most common aneuploidies, major abnormalities on fetal ultrasound include cardiac defects, cystic hygroma, duodenal atresia, generalized hydrops, and facial abnormalities; minor abnormalities include nuchal thickening, choroid plexus cysts, foot deformities, limb shortening, and pyelectasis)
4. Previous child with a chromosomal abnormality
5. Previous pregnancy with a fetal diagnosis of sex chromosome aneuploidy, autosomal trisomy, or other chromosomal abnormality
6. Positive maternal serum-marker screening

Genetic Counseling
Genetic counseling IS recommended for individuals or families fulfilling any of the following criteria (GeneTests 2004):

Preconception/prenatal
1. Personal or family history of a known or suspected genetic disorder, birth defect, or chromosome abnormality
2. Mother will be 35 years or older at delivery
3. Abnormal results from a serum marker screen or fetal ultrasound
4. Exposure to known or suspected teratogen or mutagen
5. Mother has medical condition known to affect fetal development
6. Close biological relationship of parents
7. Ethnic predisposition to certain genetic disorders

Neonatal/pediatric
1. Abnormal newborn screening results
2. Major malformation in any organ system
3. Growth abnormalities
4. Developmental delay or mental retardation
5. Severe visual or hearing impairment
6. Known or suspected genetic disorder or chromosome abnormality
7. Family history of known or suspected genetic disorder, birth defect, or chromosome abnormality

Adolescent/adult
1. Mental retardation
2. Personal or family history of possibly hereditary cancers
3. Personal or family history of a known or suspected genetic condition or chromosome abnormality
4. Severe visual or hearing impairment
5. Development of a degenerative disease

III. STATE/MARKET APPLICATION CRITERIA
In applying this guideline, individual needs and an assessment of the local delivery system shall be considered.
• The following individual factors shall be considered: age, comorbidities,
complications, progress of treatment, psychosocial situation, and home environment, when applicable.

- The following aspects of the local delivery system shall be considered: availability of local facilities and benefit coverage.

When utilization management guidelines cannot be applied appropriately, individual case discussions shall ensue.

IV. REFERENCES


V. APPENDIX/DEFINITIONS
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TITLE: High-End Durable Medical Equipment (DME), Prosthetic Devices, and Orthoses

Authorized By: Medical Management Guideline Committee

Approval Date: 03/16/04    Revision Date: 05/25/04

05/24/05, 09/01/05

A. BACKGROUND

1. Description

Durable Medical Equipment (DME) is defined as equipment that is furnished by a supplier or a home health agency and that can withstand repeated use, is primarily and customarily used to serve a medical purpose, is generally not useful to the individual in the absence of an illness or injury, and is appropriate for use in the home (DMERC 2004a).

Prosthetic Devices are items which replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ. The test of permanence is considered met if the medical record, including the judgment of the attending physician, indicates that the...
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condition is of long and indefinite duration (DMERC 2004a).

An Orthosis (brace) is a rigid or semi-rigid device that is used for the purpose of supporting a weak or deformed body part or restricting or eliminating motion in a diseased or injured part of the body (DMERC 2004a).

High-End DME, Prosthetic Devices, and Orthoses are defined as items with a purchase price of at least $2,000 or a monthly rental expense of $500 or more (per Medicare fee schedule, 2004 First Quarter - CA). Items were grouped into functional classes for review; however, this is not an exhaustive list.

2. Benefit
Secure Horizons covers Durable Medical Equipment (DME), Prosthetic Devices, and Orthoses when determined to be medically necessary and specific criteria are met. See the Secure Horizons Benefit Interpretation Policies (BIPs) Durable Medical Equipment (DME), Orthotics, Prosthetics and Medical Supplies, and DME Grid.

Repairs, replacement and maintenance of DME, Orthoses and Prosthetic devices:
- May require pre-certification to be covered (Note: The Market pre-certification process varies)
- Repairs are covered when necessary to make the item/device serviceable and the estimated repair expense does not exceed the cost of purchasing or renting another item/device
  - Extensive maintenance is covered as repair when, based on the manufacturer's recommendations, the maintenance (e.g., breaking down sealed components, performing tests that require specialized testing equipment not available to the member) is to be performed by an authorized technician
  - Repairs and maintenance for rented items/devices are the responsibility of the item/device provider
- Replacements are covered for damage beyond repair with normal wear and tear, when repair costs exceed new purchase price, or when a change in the member's medical condition occurs
  - Replacement of artificial limbs or any part of such devices is covered when the condition of the device or part requires repairs that cost more than 60% of the cost of a replacement device or part

B. RECOMMENDATIONS

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**NOTE:** Member benefit coverage and limitations may vary based on the member’s benefit plan. Refer to member specific Evidence of Coverage (EOC), Schedule of Benefits (SOB), or Certificate of Coverage (COC). If there is a discrepancy between this guideline and the member’s EOC/SOB/COC, the member’s EOC/SOB/COC provision will govern.

This Medical Management Guideline addresses the following:

1. Air-fluidized Bed
2. Cochlear Implants
3. High Frequency Chest Wall Oscillation Devices (ex. ThAIRapy Vest)
4. Hospital Beds (Heavy Duty & Extra Heavy Duty)
5. Infusion Pumps
6. Mattresses- Pressure Reducing
7. Negative Pressure Wound Therapy (NPWT) Pump
8. Neuromuscular Electrical Stimulation (NMES)
9. Cervical Thoracic Lumbar Sacral Orthoses (CTLSO) and Thoracic Lumbar Sacral Orthoses (TLSO) for Adolescent Idiopathic Scoliosis
10. Pneumatic Compression Devices
11. Osteogenic Stimulation
12. Prostheses - Lower Limb
13. Prostheses - Facial
14. Prostheses - Upper Limb
15. Respiratory Assist Devices (RADs)
16. Speech Generating Devices
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17. Ultraviolet Light Therapy System (Cabinet)

18. Ventilators (Respirators)

19. Wheelchairs (Manual or Motorized/Power) and Power Operated Vehicles (POVs)

20. Whirlpool (Non-Portable)

21. Spinal Cord Stimulator

1. Air Fluidized Bed

Home use of an air-fluidized bed is recommended when all of the following criteria are met (CMS a):

a. The patient has a stage 3 (full thickness tissue loss) or stage 4 (deep tissue destruction) pressure sore

b. The patient is bedridden or chair bound as a result of severely limited mobility

c. The patient would require institutionalization in the absence of an air-fluidized bed

d. The air-fluidized bed is ordered in writing by the patient's attending physician based upon a comprehensive assessment and evaluation of the patient after completion of a course of conservative treatment designed to optimize conditions that promote wound healing

1) The conservative treatment course must have been at least one month in duration without progression toward wound healing. The month of conservative treatment may include some period in an institution as long as there is documentation available to verify that the necessary conservative treatment has been rendered

2) Conservative treatment must include:

• Frequent repositioning of the patient with particular attention to relief of pressure over bony prominences (usually every 2 hours)

• Use of a specialized support surface (Group 2) designed to reduce pressure and shear forces on healing ulcers and to prevent new ulcer formation

• Necessary treatment to resolve any wound infection

• Optimization of nutrition status to promote wound healing

• Debridement by any means (including wet to dry dressings, which does not require an occlusive covering) to remove devitalized tissue from the wound bed

• Maintenance of a clean, moist bed of granulation tissue with
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appropriate moist dressings protected by an occlusive covering, while the wound heals

e. A trained adult caregiver is available to assist the patient with activities of daily living, fluid balance, dry skin care, repositioning, recognition and management of altered status, dietary needs, prescribed treatments, and management and support of the air-fluidized bed system and its problems, such as leakage

f. A physician directs the home treatment regimen and re-evaluates and re-certifies the need for the air-fluidized bed on a monthly basis

g. All other alternative equipment has been considered and ruled out

Home use of an air-fluidized bed is not recommended under any of the following circumstances (CMS a):
a. The patient has co-existing pulmonary disease (the lack of firm back support makes coughing ineffective and dry air inhalation thickens pulmonary secretions)
b. The patient requires treatment with wet soaks or moist wound dressings that are not protected with an impervious covering, such as plastic wrap or other occlusive material
c. The caregiver is unwilling or unable to provide the type of care required by the patient on an air-fluidized bed
d. Structural support is inadequate to support the weight of the air-fluidized bed system, which generally weighs 1,600 pounds or more
e. Electrical system is insufficient for the anticipated increase in energy consumption

2. Cochlear Implants
Cochlear implants are recommended when criterion a or b and criteria c - g are met (CMS b):
a. Bilateral pre- or post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification. Limited benefit from amplification is defined by test scores of less than or equal to 40% correct in the best-aided listening condition on tape-recorded tests of open-set sentence cognition or
b. Hearing test scores of greater than 40% and less than or equal to 60% only when the provider is participating in, and patients are enrolled in, either an FDA-approved category B investigational device exemption clinical trial as defined at 42 CFR 405.201, a trial under the Centers for Medicare & Medicaid (CMS) Clinical Trial Policy as defined at section 310.1 of the National Coverage Determinations Manual, or a prospective, controlled comparative trial approved by CMS as consistent with the evidentiary requirements for National Coverage Analyses and meeting specific quality standards.

c. Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment that cannot be intensified with the appropriate hearing (or vibrotactile) aids

d. Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation

e. Freedom from middle ear infection, the cochlear opening is able to accommodate the implant, and freedom from tumors or lesions in the auditory nerve and acoustic areas of the central nervous system

f. No contraindications to surgery

g. The device must be used in accordance with the FDA approved labeling

3. **High Frequency Chest Wall Oscillation Devices (ex. ThAIRapy Vest)**
   Recommended for patients who meet either criterion a. or b. and criterion c. (DMERC 2005a):
   a. There is a diagnosis of cystic fibrosis
   b. There is a diagnosis of bronchiectasis characterized by daily productive cough for at least 6 continuous months or frequent (i.e., more than 2/year) exacerbations requiring antibiotic therapy, and confirmed by high resolution, spiral, or standard CT scan
   c. There must be well-documented failure of standard treatments, i.e., percussion and postural drainage therapy (Whitman et al, 1993), to adequately mobilize retained secretions, demonstrated by one of the following:
      - Decrease in FEV1 >10% (Wagener and Headly, 2003)
      - Increasingly frequent hospitalizations and/or emergency room visits
      - Increasing episodes of infection

4. **Hospital Beds (Heavy Duty & Extra Heavy Duty)**
   For heavy duty extra wide beds (DMERC 2004b):
   - Recommended for patients meeting criteria for a fixed height hospital bed and the patient’s weight is more than 350 pounds, but does not exceed 600 pounds

   For extra heavy duty beds (DMERC 2004b):
• Recommended for patients meeting criteria for a fixed height hospital bed and the patient’s weight exceeds 600 pounds

The criteria for a fixed height hospital bed are considered met if one or more of the following is present (DMERC 2004b):
• The patient has a medical condition which requires positioning of the body in ways not feasible with an ordinary bed
• The patient requires positioning of the body in ways not feasible with an ordinary bed in order to alleviate pain
• The patient requires the head of the bed to be elevated more than 30 degrees most of the time due to congestive heart failure, chronic pulmonary disease, or problems with aspiration. Pillows or wedges must have been considered and ruled out
• The patient requires traction equipment, which can only be attached to a hospital bed

5. Infusion Pumps
External Infusion Pumps are recommended for the following (DMERC 2005b):
a. Treatment of diabetes mellitus – continuous subcutaneous insulin infusion pump (CSII) and related drugs and supplies are recommended in the home setting only for diabetics if criterion A or B is met and if criterion C or D is met.
Criteria:
   A. C-peptide testing requirement – must meet criterion 1 or 2 and criterion 3:
      1) C-peptide level is less than or equal to 110% of the lower limit of normal of the laboratory’s measurement method.
      2) For patients with renal insufficiency and a creatinine clearance (actual or calculated from age, weight, and serum creatinine) less than or equal to 50ml/minute, a fasting C-peptide level is less than or equal to 200% of the lower limit of normal of the laboratory’s measurement method.
      3) A fasting blood sugar obtained at the same time as the C-peptide level is less than or equal to 225mg/dl.
   B. Beta cell autoantibody test is positive.
   C. The patient has completed a comprehensive diabetes education program, has been on a program of multiple daily injections of insulin (i.e., at least 3 injections per day) with frequent self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump, has documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump, and meets one or more of the following criteria while on the multiple daily injection regimen:
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• Glycosylated hemoglobin level (HbA1c) >7.0%
• History of recurring hypoglycemia
• Wide fluctuations in blood glucose before mealtime
• Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl
• History of severe glycemic excursions

D. The member has been on an external insulin infusion pump prior to enrollment in Medicare/Secure Horizons and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to Medicare/Secure Horizons enrollment

For continued coverage, both of the following criteria must be met:
• Continued coverage of the insulin pump would require that the patient has been seen and evaluated by the treating physician at least every 3 months
• The pump must be ordered by and follow-up care of the patient must be managed by a physician who manages multiple patients with CSII and who works closely with a team including nurses, diabetes educators and dietitians who are knowledgeable in the use of CSII

b. Treatment of iron poisoning – only external pumps when used in the administration of deferoxamine for the treatment of chronic iron overload

c. Chemotherapy – when used in the treatment of primary hepatocellular carcinoma or colorectal cancer when the disease is not resectable or the patient refuses surgery to remove the tumor

d. Treatment of intractable cancer pain – morphine infusion via an external infusion pump is recommended when used in the treatment of intractable pain caused by cancer in either an inpatient or outpatient setting including hospice

e. Postoperative disposable ambulatory regional anesthesia (PDARA) – as an adjunct to conventional strategies for the management of postoperative pain following spinal fusion; inguinal hernia repair; or shoulder, knee, or foot surgery (Hayes 2004)

f. Other uses – external infusion pumps are recommended if either of the following sets of criteria (1) or (2) are met:

1) • Parenteral administration of the drug in the home is reasonable and necessary
   • An infusion pump is necessary to safely administer the drug
   • The drug is administered by a prolonged infusion of at least 8 hours because of proven improved clinical efficacy
   • The therapeutic regimen is proven or generally accepted to have significant advantages over intermittent bolus administration regimens or infusions lasting less than 8 hours
2) • Parenteral administration of the drug in the home is reasonable and necessary
• An infusion pump is necessary to safely administer the drug
• The drug is administered by intermittent infusion (each episode of infusion lasting less than 8 hours) which does not require the patient to return to the physician's office prior to the beginning of each infusion
• Systemic toxicity or adverse effects of the drug is unavoidable without infusing it at a strictly controlled rate as indicated in the Physicians Desk Reference, or the U.S. Pharmacopeia Drug Information

Administration of other drugs, based on criteria set 1) or 2), using an external infusion pump is limited to certain situations. Refer to the Durable Medical Equipment Regional Carrier DMERC Local Medical Review Policy: External Infusion Pumps at http://www.cms.hhs.gov/med/results_index.asp?from="lmrpcontractor'&contractor=122&name=Electronic+Data+Systems+Corp%2E+%2877006%2C+DME+PSC%29&letter_range= 4 for specific criteria

Implantable Infusion Pumps are recommended for the following (DMERC 2002):

a. Chemotherapy – intra-arterial infusion of 5-FudR for the treatment of liver cancer for patients with primary hepatocellular carcinoma or Duke’s Class D colorectal cancer, in cases where metastases are limited to the liver and the disease is not resectable or the patient refuses surgery to remove the tumor

b. Treatment of severe spasticity – when used to administer antispasmodic drugs intrathecally (e.g., baclofen) to treat chronic spasticity in patients who have proven unresponsive to less invasive medical treatment as determined by the following criteria:
• As indicated by at least a 6-week trial, the patient cannot be maintained on noninvasive methods of spasm control such as oral antispasmodic drugs either because these methods fail to control adequately the spasticity or produce intolerable side effects; and
• Prior to pump implantation, the patient must have responded favorably to a trial intrathecal dose of the antispasmodic drug

c. Treatment of intractable chronic pain – when used to administer opioid drugs (i.e., morphine) intrathecally or epidurally for the treatment of severe chronic intractable pain of malignant or nonmalignant origin in patients who have a life expectancy of at least 3 months and have proven unresponsive to less invasive therapy as determined by the following criteria:
• The patient’s history must indicate that he/she would not respond adequately to noninvasive methods of pain control such as systemic
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opioids, including attempts to eliminate physical and behavioral abnormalities, which may cause an exaggerated reaction to pain; and

- A preliminary trial of intraspinal opioid drug administration must be undertaken with a temporary intrathecal/epidural catheter to substantiate adequately acceptable pain relief and degree of side effects, including effects on the activities of daily living and patient acceptance

d. Other uses – if the patient’s physician verifies all of the following:

- The drug is reasonable and necessary for the treatment of the individual patient’s condition
- It is medically necessary that the drug be administered by an implanted infusion pump
- The FDA-approved labeling for the pump specifies that the drug being administered and the purpose for which it is being administered is an indicated use of the pump

6. Mattresses- Pressure Reducing

Mattresses (Pressure Reducing) are recommended if the patient meets the following (DMERC 2003a):

- Criterion 1 and 2 and 3, or
- Criterion 4, or
- Criterion 5 and 6

Criteria:

1) Multiple stage II pressure ulcers (see Appendix I for details) located on the trunk or pelvis
2) Patient has been on a comprehensive ulcer treatment program for at least the past month, which has included the use of an appropriate Group 1 support surface. The comprehensive treatment should include the following:

- Education of the patient and caregiver on the prevention and/or management of pressure ulcers
- Regular assessment by a nurse, physician, or other licensed healthcare practitioner (usually at least weekly for a patient with a stage III or IV ulcer)
- Appropriate turning and positioning
- Appropriate wound care (for a stage II, III, or IV ulcer)
- Appropriate management of moisture/incontinence
- Nutritional assessment and intervention consistent with the overall plan of care
3) The ulcers have worsened or remained the same over the past month.
4) Large or multiple stage III or IV pressure ulcer(s) on the trunk or pelvis
5) Recent myocutaneous flap or skin graft for a pressure ulcer on the

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7. Negative Pressure Wound Therapy (NPWT) Pump
   Please refer to Medical Management Guideline Wound Treatment (Secure Horizons).

8. Neuromuscular Electrical Stimulation (NMES)
   NMES is recommended for the following (DMERC 2003b):
   • Treatment of disuse atrophy where nerve supply to the muscle is intact, including brain, spinal cord and peripheral nerves, and other non-neurological reasons for disuse atrophy, e.g., casting or splinting of a limb, contracture due to scarring of soft tissue as in burn lesions, and hip replacement surgery (until orthotic training begins)
   • To achieve walking in patients with spinal cord injury (commonly referred to as functional electrical stimulation [FES]). These devices are surface units that use electrical impulses to activate paralyzed or weak muscles in precise
sequence. Coverage for the use of NMES is limited to spinal cord injury (SCI) patients, for walking, who have completed a training program, which consists of at least 32 physical therapy sessions with the device over a period of 3 months. The trial period of physical therapy will enable the physician treating the patient for his or her spinal cord injury to properly evaluate the person's ability to use these devices frequently and for the long term. Coverage for NMES for walking will be limited to SCI patients with all of the following characteristics:

- Intact lower motor units (L1 and below) (both muscle and peripheral nerve)
- Muscle and joint stability for weight bearing at upper and lower extremities that can demonstrate balance and control to maintain an upright support posture independently
- Demonstrate brisk muscle contraction to NMES and sensory perception of electrical stimulation sufficient for muscle contraction
- High motivation, commitment and cognitive ability to use such devices for walking
- Transfer independently and can demonstrate independent standing tolerance for at least 3 minutes
- Demonstrate hand and finger function to manipulate controls
- At least 6-month post recovery spinal cord injury and restorative surgery
- No hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis
- Demonstrated a willingness to use the device long-term

Note: The physical therapy necessary to perform this training must be directly performed by the physical therapist as part of a one-on-one training program; this service cannot be done unattended.

9. **Cervical Thoracic Lumbar Sacral Orthoses (CTLSO) and Thoracic Lumbar Sacral Orthoses (TLSO) for Adolescent Idiopathic Scoliosis**

Brace options for the treatment of adolescent idiopathic scoliosis and kyphosis include the cervico-thoraco-lumbo-sacral orthosis (CTLSO) (e.g., Milwaukee brace), the thoracolumbo-sacral orthosis (TLSO) or underarm brace (e.g., Boston brace) and the Charleston nighttime bending brace (McLain and Karol, 1994; Patwardhan et al, 1996). The mechanisms of action for all orthoses are endpoint control, curve correction, and continuous transverse support. Endpoint control prevents sway of the vertebral column and reduces gross trunk motion while lumbar and thoracic pads reduce scoliotic curves and maintain curve reduction for the duration of wear, providing continuous lateral support at the apex of the reduced curve (Patwardhan et al, 1996).
Objectives of treatment include (McLain and Karol, 1994):

- Stopping the progression of scoliotic curvature
- Gaining permanent correction in anticipation of skeletal maturity
- Allowing for continued growth of the spine during adolescence

Orthotic devices are better at halting curvature progression than at correcting deformity, hence the degree of deformity seen at the start of bracing is usually about the same as the final outcome. Therefore, it is important to begin brace wear before curvature reaches an unacceptable magnitude (McLain and Karol, 1994).

General indications for orthotic treatment in idiopathic scoliosis are as follows (McLain and Karol, 1994):

- Skeletally immature patients, prior to Risser grade 5 (usually one year post menarche in girls)
- Children presenting with curvature of 20 to 30 degrees should also be observed, at least initially. During the observation period, roentgenograms should be obtained at 3 to 6 month intervals and compared with the original films. If the curvature increases by more than 5 degrees in a skeletally immature patient, bracing is recommended
- Children presenting with 25 degrees to 39 degrees curvature require prompt treatment. These patients are at high risk of progression of curvature
- Boys with progressive curvature in excess of 25 degrees, including those presenting at Risser grade 4
- Patients with Scheuermann’s Kyphosis including kyphosis of more than 50 degrees. To maintain correction, the brace should be worn until there is improvement in vertebral wedging to roughly 5 degrees. Bracing for longer than 18 months may be necessary to achieve this improvement

Note: In very young patients, bracing may retard progression long enough to allow further trunk growth before the inevitable fusion. Once curvature exceeds 40 degrees, surgical treatment may be the only means of controlling and correcting the deformity.

Immediate bracing is recommended for the following to allow significant trunk growth prior to surgical intervention (McLain and Karol, 1994):

- Skeletally immature patients (at Risser grades 0 to 2) presenting with 30 to 40 degrees curvature
- Flaccid paralysis and 20 degrees or more of curvature

The recommended duration of bracing varies from 16 hours/day to 23 hours/day.
Risser grades: Grading is based on the degree of bony fusion of the iliac apophysis, from grade 0 (no ossification) to grade 5 (complete bony fusion) (Reamy and Slakey, 2001).

10. **Pneumatic Compression Devices**

Pneumatic Compression Devices consist of an inflatable garment for the arm or leg and an electrical pneumatic pump that fills the garment with compressed air. The garment is intermittently inflated and deflated with cycle times and pressures that vary between devices.

Pneumatic Compression Devices are recommended for the following indications (CMS 2001):

a. Lymphedema – for the treatment of lymphedema in the home setting if the patient has undergone a 4-week trial of conservative therapy and the treating physician determines that there has been no significant improvement or if significant symptoms remain after the trial. The trial of conservative therapy must include use of an appropriate compression bandage system or compression garment, exercise and elevation of the limb. The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression.

b. Chronic venous insufficiency (CVI)* – for the treatment of CVI of the lower extremities with venous stasis ulcers in the home setting only if the patient has one or more venous stasis ulcer(s) which have failed to heal after a 6-month trial of conservative therapy directed by the treating physician. The trial of conservative therapy must include a compression bandage system or compression garment, appropriate dressings for the wound, exercise and elevation of the limb.

Pneumatic compression devices must be prescribed by a physician and used with appropriate physician oversight (i.e., physician evaluation of the patient’s condition to determine medical necessity of the device, assuring suitable instruction in the operation of the machine, a treatment plan defining the pressure to be used and the frequency and duration of use, and ongoing monitoring of use and response to treatment). The determination by the physician of the medical necessity of a pneumatic compression device must include all of the following (CMS 2001):

- The patient’s diagnosis and prognosis
- Symptoms and objective findings, including measurements which establish the severity of the condition
- The reason the device is required, including the treatments which have been tried and failed
- The clinical response to an initial treatment with the device. The clinical
response includes the change in pre-treatment measurements, ability to tolerate the treatment session and parameters, and ability of the patient (or caregiver) to apply the device for continued use in the home.

A segmented, calibrated gradient pneumatic compression device is recommended only when the individual has unique characteristics that prevent them from receiving satisfactory pneumatic compression treatment using a nonsegmented device in conjunction with a segmented appliance or a segmented compression device without manual control of pressure in each chamber (CMS 2002).

* Chronic Venous Insufficiency (CVI): CVI of the lower extremities is a condition caused by abnormalities of the venous wall and valves, leading to obstruction or reflux of blood flow in the veins. Signs of CVI include hyperpigmentation, stasis dermatitis, chronic edema and venous ulcers.

11. **Osteogenic Stimulation**
   a. Invasive electrical stimulation is recommended only for the following indications (DMERC 2001a; CMS c; Benefit Interpretation Policy, Osteogenic/Bone Stimulation – 12/18/03):
      1) Nonunion of long bone fractures
         Nonunion is considered to exist only when serial radiographs confirm that fracture healing has ceased for 3 or more months
            • Serial radiographs must include a minimum of 2 sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days
      2) Spinal fusion
         a) As an adjunct to spinal fusion for patients at high risk of pseudoarthrosis due to a previously failed spinal fusion at the same site. If this criterion is met, device may be implanted at time of spinal fusion surgery
         b) As an adjunct to multiple level fusion (3 or more vertebrae). If this criterion is met, device may be implanted at time of spinal fusion surgery
   b. Non-invasive electrical stimulation is recommended only for the following indications (DMERC 2003c):
      1) Nonunion of long bone fractures
         Nonunion is considered to exist only when serial radiographs confirm that fracture healing has ceased for 3 or more months
            • Serial radiographs must include a minimum of 2 sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days
      2) Spinal fusion
         a) Failed spinal fusion, if at least 9 months have passed since the last
surgery or
b) As an adjunct to spinal fusion for patients at high risk of pseudoarthrosis due to a previously failed spinal fusion at the same site. If this criterion is met, coverage is effective immediately following spinal fusion surgery or
c) As an adjunct to multiple level fusion (3 or more vertebrae). If this criterion is met, coverage is effective immediately following spinal fusion surgery

3) Failed fusion (other than spine)
a) Failed fusion of a joint other than the spine, if at least 9 months have passed since the last surgery

4) Congenital pseudoarthrosis

c. Non-invasive ultrasonic stimulation is recommended only for nonunion of long bone fractures when all of the following criteria apply CMS c):

1) Patient's nonunion bone fractures has failed at least one open surgical intervention for the treatment of fracture or for the treatment of nonunion bone fractures prior to surgical intervention
2) Nonunion of fracture documented by at least 2 sets of multiple view radiographs, taken at least 90 days apart, with a written physician interpretation indicating that the radiographs demonstrate no clinically significant evidence of fracture healing
   • Nonunion is considered to exist only when serial radiographs confirm that fracture healing has ceased for 3 or more months
3) Fracture is not of the skull or vertebrae
4) Fracture is not tumor related
5) Ultrasonic osteogenic stimulators are not used for fresh fractures and delayed unions
6) Ultrasonic osteogenic stimulators may not be used concurrently with other non-invasive osteogenic devices

Note: Long bones include the following: Clavicle, humerus, radius, ulna, femur, tibia, fibula, metacarpals, metatarsals, and phalanges (Stedman’s Medical Dictionary 1990).

12. Prostheses - Lower Limb
A lower limb prosthesis is recommended in the following instances (DMERC 2005c):

a. The patient will reach or maintain a defined functional state within a reasonable period of time; and
b. The patient is motivated to ambulate
Functional Levels:
A determination of the medical necessity for certain components/additions to the prosthesis is based on the patient's potential functional abilities. Potential functional ability is based on the reasonable expectations of the prosthetist and treating physician, considering factors including, but not limited to:
a. The patient's past history (including prior prosthetic use if applicable); and
b. The patient's current condition including the status of the residual limb and the nature of other medical problems; and
c. The patient's desire to ambulate

Clinical assessments of patient rehabilitation potential must be based on the following classification levels:
Level 0: Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.
Level 1: Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
Level 2: Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator.
Level 3: Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
Level 4: Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

The records must document the patient's current functional capabilities and his/her expected functional potential, including an explanation for the difference, if that is the case. Within the functional classification hierarchy, bilateral amputees often cannot be strictly bound by functional level classifications.

General:
Prostheses should be furnished incident to physicians' services or on a physician's order. Accessories (e.g., stump stockings for the residual limb, harness, including replacements) are also recommended when these appliances aid in or are essential to the effective use of the artificial limb (DMERC 2005c).

Note: Lower limb prostheses are not recommended for patients with
functional level 0 (DMERC 2005c).

Feet:
A determination of the type of foot for the prosthesis should be made by the treating physician and/or the prosthetist based upon the functional needs of the patient. Basic lower extremity prostheses include a SACH foot. Other prosthetic feet should be considered based upon functional classification (DMERC 2005c).
- An external keel SACH foot or single axis ankle/foot is recommended for patients whose functional level is 1 or above
- A flexible-keel foot or multiaxial ankle/foot is recommended for patients whose functional level is 2 or above
- A flex foot system, energy storing foot, multiaxial ankle/foot, dynamic response, or flex-walk system or equal, or shank foot system with vertical loading pylon, is recommended for patients whose functional level is 3 or above

Knees:
A determination of the type of knee for the prosthesis should be made by the treating physician and/or the prosthetist based upon the functional needs of the patient. Basic lower extremity prostheses should include a single axis, constant friction knee. Other prosthetic knees should be considered based upon functional classification (DMERC 2005c).
- A fluid, pneumatic, or electronic prosthetic knee is recommended for patients whose functional level is 3 or above (DMERC 2005c)
- A Microprocessor Control Feature (e.g., C-leg) is recommended for patients with documented evidence of all of the following (VATAP 2000):
  - Adequate cardiovascular reserve and cognitive learning ability to master the higher level of technology and to allow for faster than normal walking speed
  - Demonstrated ability to ambulate at a faster than baseline rate using a standard prosthetic application with a swing and stance control knee
  - Demonstrated need for long distance ambulation at variable rate (greater than 400 yards) on a daily basis (use of the limb in the home or for basic community ambulation is not sufficient to justify provision of the computerized limb over the standard)
  - Demonstrated need for regular ambulation on uneven terrain or for regular stairs (use of the limb for limited stair climbing in the home or employment environment is not sufficient evidence for provision of the computerized limb over the standard)
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- Lower extremity functional level 3 or above
  c. Other standard knee systems not fitting categories above are recommended for patients whose functional level is 1 or above (DMERC 2005c)

Ankles:
An axial rotation unit is recommended for patients whose functional level is 2 or above (DMERC 2005c).

Sockets:
Test (diagnostic) sockets for immediate prostheses are not medically necessary. No more than 2 test (diagnostic) sockets for an individual prosthesis are medically necessary without additional documentation. No more than two of the same socket inserts should be provided per individual prosthesis at the same time. Socket replacements are considered medically necessary if there is adequate documentation of functional and/or physiological need. There are situations where the explanation includes, but is not limited to, changes in the residual limb; functional need changes; or irreparable damage or wear/tear due to excessive patient weight or prosthetic demands of very active amputees (DMERC 2005c).

13. Prostheses - Facial
Facial prostheses are recommended for patients with loss or absence of facial tissue due to disease, trauma, surgery, or a congenital defect (DMERC 2003d).

14. Prostheses - Upper Limb
A determination of the medical necessity for the prosthesis is based on the patient's potential functional abilities. Potential function ability is based on the reasonable expectations of the prosthetist and treating physician, considering factors including, but not limited to, the following (Bodeau et al, 2002):
  a. The patient's past history (including prior prosthetic use if applicable); and
  b. The patient's current condition including the status of the residual limb and the nature of the other medical problems; and
  c. The patient's desire to use a prosthesis

Body Powered Prostheses - Upper Limb
Upper limb functional body-powered prostheses are powered and controlled by gross body movements, a harness, and cable system. The following are basic requirements necessary for a patient to be a candidate for a body-powered prosthesis (Advanced Arm Dynamics 2002):
  • Sufficient residual limb length
• Sufficient musculature
• Sufficient range of motion

A patient must possess at least one more of the following gross body movements to be able to control a body-powered prosthesis (Advanced Arm Dynamics 2002):
• Glenohumeral flexion
• Scapular abduction or adduction
• Chest expansion
• Shoulder depression and elevation

Myoelectric Prosthesis and Hybrid Prosthesis - Upper Limb
Myoelectric control is achieved using electrodes that measure the body’s electrical signal (EMG) produced by flexed muscle. Once recorded, the signal is amplified and then processed by a controller that switches the motors on or off in the hand, wrist or elbow to produce movement and function (Advanced Arm Dynamics 2002). The hybrid prosthesis utilizes a body-powered elbow and a myoelectrically-controlled terminal device (hook or hand). The hybrid prosthesis allows simultaneous control of elbow flexion and extension while opening or closing the electric terminal device or rotating the wrist (Motion Control 1997; Advanced Arm Dynamics 2002).

A patient must demonstrate the following to meet criteria for a myoelectric or hybrid prosthesis:
• The ability to separate contractions – contracting one muscle while maintaining the opposing muscle in a relaxed position (Advanced Arm Dynamics 2002)
• A 15mcV EMG difference between the contracted and relaxed muscles (Motion Control 1997)
• Motivation and psychological adjustment: consistent use of a conventional prosthesis for at least 6 months (Motion Control 1997)
• Capacity to support the weight of the prosthesis (the hybrid weighs less) – age and slight stature may determine whether a myoelectric prosthesis can be used (Motion Control 1997)
• Participation in activities of daily living that require a range of motion over head, down by the feet, and out to the sides of the body (Advanced Arm Dynamics 2002)
• Ability to maintain the battery system (Advanced Arm Dynamics 2002)

15. Respiratory Assist Devices (RADs)
The initial criteria (first 3 months) for RADs are as follows (DMERC 2005d):
a. For a RAD, the treating physician must fully document in the patient’s medical record symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc.

b. A RAD used to administer noninvasive positive pressure respiratory assistance (NPPRA) therapy is recommended for those patients with clinical disorder groups characterized as (1) restrictive thoracic disorders (i.e., progressive neuromuscular diseases or severe thoracic cage abnormalities), (2) severe chronic obstructive pulmonary disease (COPD), (3) central sleep apnea (CSA), or (4) obstructive sleep apnea (OSA) (RAD without back-up rate feature only) and who also meet the following criteria:

1) Restrictive Thoracic Disorders
   a) There is documentation in the patient’s medical record of a progressive neuromuscular disease (for example, amyotrophic lateral sclerosis) or a severe thoracic cage abnormality (for example, post-thoracoplasty for TB), and
   b) (1) An arterial blood gas PaCO2, done while awake and breathing the patient’s usual FIO2 is greater than or equal to 45 mm Hg, or (2) Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for at least five continuous minutes, done while breathing the patient’s usual FIO2, or (3) For a progressive neuromuscular disease (only), maximal inspiratory pressure is less than 60 cm H20 or forced vital capacity is less than 50% predicted, and
   c) COPD does not contribute significantly to the patient’s pulmonary limitation

If all of the above criteria are met, a RAD (based upon the judgment of the treating physician) is recommended for patients within this group of conditions for the first 3 months of NPPRA therapy (see below for continued coverage after the initial 3 months). If all of the above criteria are not met, then a RAD and related accessories are not considered medically necessary.

2) Severe COPD
   a) (1) An arterial blood gas PaCO2, done while awake and breathing the patient’s usual FIO2, is greater than or equal to 52 mm Hg, and (2) Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for at least five continuous minutes, done while breathing oxygen at 2 LPM or the patient’s usual FIO2 (whichever is higher), and
   b) Prior to initiating therapy, OSA (and treatment with CPAP) has been considered and ruled out
If all of the above criteria are met, a RAD is recommended for patients with documented severe COPD conditions for the first 3 months of NPPRA therapy (see below for continued coverage after the initial 3 months). If all of the above criteria are not met, then a RAD and related accessories is considered not medically necessary.

3) Central Sleep Apnea, i.e., apnea not due to airway obstruction
Prior to initiating therapy, a complete facility-based, attended polysomnogram must be performed documenting the following:
   a) The diagnosis of central sleep apnea (CSA), and
   b) The exclusion of obstructive sleep apnea (OSA) as the predominant cause of sleep-associated hypoventilation, and
   c) The ruling out of CPAP as effective therapy if OSA is a component of the sleep-associated hypoventilation, and
   d) Oxygen saturation less than or equal to 88% for at least 5 continuous minutes, done while breathing the patient’s usual FIO2, and
   e) Significant improvement of the sleep-associated hypoventilation with the use of a RAD on the settings that will be prescribed for initial use at home, while breathing the patient’s usual FIO2

If all of the above criteria are met, a RAD is recommended for patients with documented CSA conditions for the first 3 months of NPPRA therapy (see below for continued coverage after the initial 3 months). If all of the above criteria are not met, then a RAD and related accessories is considered not medically necessary.

4) Obstructive Sleep Apnea (OSA):
Criteria a) and b) are both met
   a) A complete facility-based, attended polysomnogram, has established the diagnosis of obstructive sleep apnea according to the following criteria:
      (1) The apnea-hypopnea index (AHI) is greater than or equal to 15 events per hour, or
      (2) The AHI is from 5 to 14 events per hour with documented symptoms of:
         (a) Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia, or
         (b) Hypertension, ischemic heart disease, or history of stroke, and
   b) A single level device (CPAP device) has been tried and proven ineffective

If the above criteria are met, a RAD (without backup rate feature) is recommended for the first 3 months of NPPRA therapy (see below for continued coverage after the initial 3 months). If all of the above criteria are not met, then a RAD and related accessories is considered not medically necessary.
continued coverage after the initial 3 months). A RAD (with back-up rate feature, used with noninvasive interface) is not medically necessary if the primary diagnosis is OSA.

Continued use of Respiratory Assist Devices (RADs) beyond first 3 months of therapy (DMERC 2005d):
Patients on a RAD for the first 3 months must be re-evaluated to establish the medical necessity beyond the first 3 months. There should be documentation in the patient’s medical record about the progress of relevant symptoms and patient usage of the device up to that time.

16. Speech Generating Devices
Speech generating devices are recommended when the patient's physician determines that the patient suffers from a severe speech impairment and that the medical condition warrants the use of a device that is characterized by the following (DMERC 2001b):

a. The device is a dedicated speech device used solely by an individual with a severe speech impairment

b. The device may have any of the following features:
   - Digitized speech output using pre-recorded messages and less than or equal to 8 minutes recording time
   - Digitized speech output, using pre-recorded messages, greater than 8 minutes recording time
   - Synthesized speech output, which requires message formulation by spelling and device access by physical contact with the device-direct selection techniques
   - Synthesized speech output, which permits multiple methods of message formulation and multiple methods of device access
   - Software that allows a laptop computer, desktop computer or personal digital assistant (PDA) to function as a speech generating device

A speech generating device is recommended when all of the following criteria are met:
a. Prior to the delivery of the SGD, the patient has had a formal evaluation of their cognitive and communication abilities by a speech-language pathologist (SLP). The formal, written evaluation must include, at a minimum, the following elements (DMERC 2004c):
   1) Current communication impairment, including the type, severity, language skills, cognitive ability, and anticipated course of the impairment
   2) An assessment of whether the individual's daily communication needs
could be met using other natural modes of communication
3) A description of the functional communication goals expected to be achieved and treatment options
4) Rationale for selection of a specific device and any accessories
5) Demonstration that the patient possesses treatment plan that includes a training schedule for the selected device
6) The cognitive and physical abilities to effectively use the selected device and any accessories to communicate
7) For a subsequent upgrade to a previously issued SGD, information regarding the functional benefit to the patient of the upgrade compared to the initially provided SGD; and,
   b. The patient's medical condition is one resulting in a severe expressive speech impairment; and,
   c. The patient's speaking needs cannot be met using natural communication methods; and,
   d. Other forms of treatment have been considered and ruled out; and,
   e. The patient's speech impairment will benefit from the device ordered; and,
   f. A copy of the SLP's written evaluation and recommendation have been forwarded to the patient's treating physician prior to ordering the device; and,
   g. The SLP performing the patient evaluation may not be an employee of or have a financial relationship with the supplier of the SGD.

17. Ultraviolet Light Therapy System (Cabinet)
   Ultraviolet Light Therapy systems are recommended for selected patients with generalized intractable psoriasis. Using appropriate consultation, it should be determined whether medical and other factors justify treatment at home rather than at alternative sites, e.g., outpatient department of a hospital (CMS d).

18. Ventilators (Respirators)
   Ventilators (respirators) are recommended for the treatment of neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease. This recommendation includes both positive and negative pressure types (CMS e).

19. Wheelchairs (Manual or Motorized/Power) and Power Operated Vehicles (POVs)
   Recommended if patient meets Mobility Assistive Equipment clinical criteria. Refer to Medlearn Matters MM3791 Mobility Assistive Equipment (MAE) @ http://www.cms.hhs.gov/MedlearnMattersArticles/downloads/MM3791.pdf

20. Whirlpool (Non-Portable)
   Medical necessity is determined by the following (CMS g):
   a. Evidence that a whirlpool bath offers substantial therapeutic benefit for the
patient’s medical condition
b. Verification that the patient is homebound or that treatment in the home is the least costly alternative

21. **Spinal cord stimulator**

Spinal cord stimulation blocks pain conduction pathways and stimulates endorphins. The neurostimulator electrodes used for this purpose are implanted percutaneously in the epidural space through a special needle. Some patients may need an open procedure. After placement of the electrodes, the patient is provided with an external neurostimulator, initially on a trial basis. The trial period of one week (i.e., 5 days) may be extended up to 2 weeks. If during the trial it is determined that the modality is not effective or it is not acceptable to the patient, the electrodes may be removed. If the trial has been successful, a spinal neurostimulator and pulse generator, activated through a radiofrequency device, is inserted subcutaneously and connected to the electrodes already in place (OK/NM Medicare Services, 2003).

Spinal cord stimulation is recommended for the following indications (OK/NM Medicare Services, 2003):

A. **Indications**
   1. To treat chronic pain caused by lumbosacral arachnoiditis that has not responded to medical management including physical therapy (presence of arachnoiditis is usually documented by the presence of high levels of proteins in the CSF and/or by myelography or MRI);
   2. To treat intractable pain caused by nerve root injuries, post-surgical or post-traumatic, including that of post-laminectomy syndrome (failed back syndrome);
   3. To treat intractable pain caused by complex regional pain syndrome I and II (term causalgia reflex sympathetic dystrophy changed to complex regional pain syndrome I and II);
   4. To treat intractable pain caused by phantom limb syndrome that has not responded to medical management;
   5. To treat intractable pain caused by end-stage peripheral vascular disease under the following circumstances:
      a. When the patient cannot undergo revascularization; or
      b. When revascularization has failed to relieve painful symptoms and the pain has not responded to medical management;
   6. To treat intractable pain caused by post herpetic neuralgia;
   7. To treat intractable pain caused by plexopathy
   8. To treat intractable pain caused by intercostal neuralgia that did not
respond to medical management and nerve blocks;
9. To treat intractable pain caused by cauda equina injury; and
10. To treat intractable pain caused by incomplete spinal cord injury.

B. Limitations
1. The implantation of the spinal cord stimulator is used after other treatment modalities, including medical management, and where applicable less invasive surgical procedures, like appropriate blocks, have been tried and did not prove to be satisfactory or these have been judged to be unsuitable/contraindicated for the given patient.
2. Patients have undergone careful screening, evaluation and diagnosis by a multi-discipline team prior to implantation of the temporary electrode (such screening must include psychological as well as physical evaluation).
3. All the facilities, equipment, professional and support personnel required for the proper diagnosis, treatment training, and follow-up of the patient (including that required to satisfy item #2) must be available.
4. Demonstration of pain relief with a temporary implanted electrode, prior to permanent implantation.

C. STATE/MARKET APPLICATION CRITERIA
In applying this guideline, individual needs and an assessment of the local delivery system shall be considered.

• The following individual factors shall be considered: age, comorbidities, complications, progress of treatment, psychosocial situation, and home environment, when applicable.
• The following aspects of the local delivery system shall be considered: availability of local facilities and benefit coverage.

When utilization management guidelines cannot be applied appropriately, individual case discussions shall ensue.

D. REFERENCES


Available at http://www.emedicine.com/pmr/topic174.htm

Available at http://www.cms.hhs.gov/manuals/103_cov_determ/ncd103index.asp

Centers for Medicare and Medicaid Services (CMS b). Medicare National Coverage Determinations. 50.3 Cochlear Implantation.
Available at http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd

Available at http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd

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Centers for Medicare and Medicaid Services (CMS f). Medicare National Coverage Determinations. 280.3 Mobility Assistive Equipment (MAE).
Available at http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd

Available at http://www.cms.hhs.gov/manuals/103_cov_determ/ncd103index.asp
Medical Management Guideline


High-End Durable Medical Equipment (DME) – Secure Horizons
Medical Management Guideline


Appendix I

Staging of Pressure Ulcers (DMERC 2003a)

Stage I
Observable pressure-related alteration of intact skin whose indicators as compared to the adjacent or opposite area on the body may include changes in one or more of the following: skin temperature (warmth or coolness), tissue consistency (firm or boggy feel), and/or sensation (pain, itching). The ulcer appears as a defined area of persistent redness in lightly pigmented skin, whereas in darker skin tones, the ulcer may appear with persistent red, blue, or purple hues.

Stage II
Partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion, blister, or shallow crater.

Stage III
Full thickness skin loss involving damage to, or necrosis of, subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.

Stage IV
Full thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures (e.g., tendon, joint capsule). Undermining and sinus tracts also may be associated with Stage IV ulcers.

Appendix II

Links to Durable Medical Equipment Regional Carrier (DMERC) policies:

**AZ, CA, NV, OR & WA:**
http://www.cms.hhs.gov/mcd/results_index.asp?from='lmrpcontractor'&contractor=122&name=Electronic+Data+Systems+Corp%2E+%2877006%2C+DME+PSC%29&letter_range=4

**CO, OK & TX:**
http://www.cms.hhs.gov/mcd/results_index.asp?from='lmrpcontractor'&contractor=121&name=TrustSolutions+%2877012%2C+DME+PSC%29&letter_range=4

Approved by: Medical Management Guideline Committee
Date Approved: 09/01/05
TITLE: Hyperbaric Oxygen Therapy
Authorized By: Medical Management Guideline Committee
Approval Date: 02/22/06

Disclaimer
This medical management guideline represents the recommendation of the PacifiCare Medical Management Guideline (MMG) committee. It is based on the MMG committee's review of the available evidence as of the date of this medical management guideline.

This medical management guideline contains clinical practice and utilization criteria to assist professionals in PacifiCare’s medical management practice when making medical necessity determinations prior to, subsequent to, or concurrent with the provisions of health care services. This medical management guideline is intended to support consistent, appropriate medical necessity determinations, but it does not replace an individualized case-by-case review and medical necessity determination for each PacifiCare member.

Member benefit coverage and limitations may vary based on the member’s benefit plan. Please consult with your local Medicare carrier to determine if a Local Coverage Determination is in place.

I. BACKGROUND

A. Description
Hyperbaric Oxygen (HBO) therapy is a method of treating both acute life-threatening conditions and chronic diseases by delivering oxygen at pressures above those that can be achieved at sea level (Marx, 2002). One hundred percent (100%) oxygen is inhaled inside a hyperbaric chamber at pressures greater than 1 atmosphere, which increases systemic oxygen content (ECRI, 2005). The elevated concentration and pressure of oxygen increase the plasma oxygen concentration 10 to 15 fold, increasing oxygen delivery to the tissues (Hayes, 2003). This has the effect of increasing oxygen in the tissues, preventing ischemic damage, preventing swelling, promoting revascularization and preventing reperfusion injury by inhibiting the inappropriate activation of leukocytes (ECRI, 2005). Most of the benefits of HBO are explained by the simple physical relationships determining gas concentration, volume, and pressure (Mechem CC et al., 2005). In the United States, over 500 hyperbaric facilities offer either single occupant (“monoplace”) or
Multiple occupant (“multiplace”) chambers (Mechem et al, 2005). HBO has been shown to be useful in treating dive injuries, carbon monoxide poisoning, necrotizing fasciitis, crush injuries, acute traumatic ischemia, and exceptional blood-loss anemia (Marx, 2002).

B. Benefit
Secure Horizons covers hyperbaric oxygen therapy when determined to be medically necessary and specific criteria are met.

C. Local Carrier (Medicare) Determination

II. RECOMMENDATIONS

NOTE: Member benefit coverage and limitations may vary based on the member’s benefit plan. Refer to member specific Evidence of Coverage (EOC), Schedule of Benefits (SOB), or Certificate of Coverage (COC). If there is a discrepancy between this guideline and the member’s EOC/SOB/COC, the member’s EOC/SOB/COC provision will govern.

HBO therapy when administered in a chamber (including a one man unit) IS recommended for ALL of the following conditions (CMS, 2003, ACHM, 2004):

1. Acute carbon monoxide intoxication with ONE of the following indications (Kao LW et al., 2004; Marx, 2002):
   a. Altered mental status
   b. Coma
   c. Focal neurologic deficits
   d. Pregnancy with CO-Hgb levels >15-20%
   e. History of loss of consciousness
2. Decompression illness
3. Gas embolism
4. Gas gangrene
5. Acute traumatic peripheral ischemia as an adjunctive treatment in combination with accepted standard therapeutic measures when loss of function, limb, or life is threatened.
6. Crush injuries and suturing of severed limbs as an adjunctive treatment in combination with accepted standard therapeutic measures when loss of function, limb, or life is threatened.
7. Progressive necrotizing infections (necrotizing fasciitis)
8. Acute peripheral arterial insufficiency
9. Preparation and preservation of compromised skin grafts

Hyperbaric Oxygen Therapy-Secure Horizons
10. Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management
11. Osteoradionecrosis as an adjunct to conventional treatment
12. Soft tissue radionecrosis as an adjunct to conventional treatment
13. Cyanide poisoning
14. Actinomycosis (only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment)
15. Diabetic wounds of the lower extremities- for criteria see Medical Management Guideline-Treatment of Wounds (Secure Horizons)

*Note: HBO therapy is to be used as an adjunctive treatment in combination with accepted standard therapeutic measures when loss of function, limb, or life is threatened (CMS, 2003).

*Note: HBO therapy should not be a replacement for other standard successful therapeutic measures. Treatment may range from less than 1 week to several months duration, the average being 2-4 weeks. Any use of HBO therapy for more than 2 months must be reviewed and documented as medically necessary before being reimbursed (CMS, 2003).

HBO therapy IS NOT recommended for the following conditions (CMS, 2003; ECRI, 2005):

1. Cutaneous, decubitus, and stasis ulcers
2. Chronic peripheral vascular insufficiency
3. Anaerobic septicemia and infection other than clostridial
4. Skin burns (thermal)
5. Senility
6. Myocardial infarction
7. Cardiogenic shock
8. Sickle cell anemia
9. Acute thermal and chemical pulmonary damage (i.e., smoke inhalation with pulmonary insufficiency)
10. Acute or chronic cerebral vascular insufficiency
11. Hepatic necrosis
12. Aerobic septicemia
13. Nonvascular causes of chronic brain syndromes such as Pick’s disease, Alzheimer’s disease, and Korsakoff’s disease
14. Tetanus
15. Systemic aerobic infection
16. Organ transplantation

Hyperbaric Oxygen Therapy-Secure Horizons
17. Organ storage
18. Pulmonary emphysema
19. Exceptional blood loss anemia
20. Multiple Sclerosis
21. Arthritic diseases
22. Acute cerebral edema
23. Stroke
24. Cerebral Palsy

*Note: Topical application of Oxygen does not meet the definition of HBO therapy and will NOT be covered. In addition, all other conditions/indications not specified as “RECOMMENDED” will NOT be covered by CMS (CMS, 2003).

Contraindications

**Absolute Contraindications** to HBO therapy include the following (Jallali N et al., 2005; Marx, 2002):

1. Untreated pneumothorax
2. Treatment with doxorubicin, bleomycin (Blenoxane), cisplatin (Cisplatinum), disulfiram (Antabuse), and mafenide acetate (Sulfamylon)

**Relative Contraindications** to HBO therapy include the following (Jallali N et al., 2005; Marx, 2002):

1. Any condition that leads to the inability to equalize pressure in the ears or sinuses
2. Upper respiratory infections
3. Otitis media
4. Acute or chronic sinusitis
5. Chronic obstructive pulmonary disease
6. Bone cysts
7. Malignancy

*Note: Prior to HBO therapy, treatment of absolute and/or relative contraindications is recommended (Marx, 2002).

III. **STATE/MARKET APPLICATION CRITERIA**

In applying this guideline, individual needs and an assessment of the local delivery system shall be considered.

- The following individual factors shall be considered: age, comorbidities,
complications, progress of treatment, psychosocial situation, and home environment, when applicable.

• The following aspects of the local delivery system shall be considered: availability of local facilities and benefit coverage.

When utilization management guidelines cannot be applied appropriately, individual case discussions shall ensue.

IV. REFERENCES


V. APPENDIX/DEFINITIONS
I. BACKGROUND

A. Description
In 2000, there were 513,000 new cases of prostate cancer diagnosed among men worldwide and by 2015, prostate cancer will become the most commonly diagnosed solid tumor in men (Menon M et al., 2005). In North American men, prostate cancer is the most commonly diagnosed cancer and the second leading cause of death (Hayes, 2005). According to the National Cancer Institute, prostate cancer will be diagnosed in approximately 16% of men during their lifetimes, and about 3.5% of men will die from the disease (ECRI, 2005).

Laparoscopic Radical Prostatectomy

The established treatment for localized prostate cancer is radical prostatectomy (RP) with a retropubic surgical approach (ECRI, 2005). However, this surgery is invasive and has resultant side effects that cause significant changes in quality of life. Therefore, many patients seek alternative treatments as opposed to undergoing...
RP (Menon M et al, 2005). Laparoscopic radical prostatectomy (LRP) was first performed in 1991 and was initiated as a minimally invasive alternative to retropubic RP (ECRI, 2005; Hayes, 2005). It is now routinely performed in a growing number of centers worldwide and is becoming standard in many institutions (Hoznek A et al., 2005; Joseph JV et al., 2005). During LRP, five small incisions are made. A laparoscope is inserted through one incision which allows for a magnified view of the internal anatomy. Small laparoscopic instruments are inserted through the remaining four incisions to perform the surgical dissection (ECRI, 2005). Advantages of this procedure include less intraoperative blood loss, shorter hospitalization time, less postoperative pain, faster recovery, improved cosmetic results, and better functional outcomes (ECRI, 2005).

**Robotically Assisted Prostatectomy**

Robotically-assisted LRP is now in widespread and rapidly expanding use (Smith JA et al., 2005). The da Vinci Surgical System was cleared by the U.S. Food and Drug Administration in 2000 for general laparoscopic surgeries. Since then, the system has been approved for use in several other areas including radical prostatectomy (FDA, 2005). The da Vinci robot is a master-slave device that allows the surgeon to manipulate instruments from a remote console. The robotic arms are activated by the hand movements of the surgeon and allow a degree of wrist flexion and precision that is not attainable with standard laparoscopic instruments (Smith JA, 2004). Furthermore, the magnified three-dimensional telescope provides a virtually unprecedented viewing of the operative field (Smith JA et al., 2005). This procedure offers the same proposed advantages as LRP. In fact, patient demand for robotically-assisted LRP has increased over the last few years (ECRI, 2005).

**B. Benefit**

Secure Horizons covers procedures for the treatment of prostate cancer when determined to be medically necessary and specific criteria are met.

**C. Local Carrier (Medicare) Determination**

CMS has not issued a National Coverage Determination (NCD) on this procedure. In addition, a Local Carrier Determination (LCD) has not been issued.

**II. RECOMMENDATIONS**

*NOTE: Member benefit coverage and limitations may vary based on the member’s benefit plan. Refer to member specific Evidence of Coverage (EOC), Schedule of Benefits (SOB), or Certificate of Coverage (COC). If there is a discrepancy between this guideline and the member’s EOC/SOB/COC, the member’s EOC/SOB/COC provision*
**Medical Management Guideline**

Indications for LRP (including robotically-assisted) are the same as for open RP (ECRI, 2005; Smith JA et al., 2005; NICE, 2003).

Laparoscopic Radical Prostatectomy (including robotically-assisted with the da Vinci system only) **IS** recommended for the treatment of prostate cancer when **ALL** of the following are met (Hayes, 2005; Hayes, 2004):

1. Members are appropriate candidates for open radical prostatectomy- for criteria see Milliman Care Guidelines, 9th edition
2. Have no indication of extensive fibrosis or scarring within the pelvic region
3. Are not at risk for periprostatic adhesions
4. Have no anatomic contraindications to laparoscopic surgery (see note below)
5. Surgeons performing procedure should be experienced and from reasonably high volume centers with reported cost-effectiveness and good outcomes

*Note: Factors to consider when using these techniques is tumor size, pelvic anatomy, tumor localization, and morbid obesity as they can create technical challenges (Smith JA et al., 2005; ECRI, 2005).

*Note: Per FDA requirements, surgeons must be trained (2-3 days) by the manufacturer on the use of a robotic surgical system before using it to treat patients. Centers considering offering robotically assisted RLP should ensure they have a sufficient patient volume to allow surgeons to achieve and maintain proficiency (ECRI, 2005).

Laparoscopic Radical Prostatectomy (including robotically-assisted with the da Vinci system only) **IS NOT** recommended for the treatment of prostate cancer for members with the following (ECRI, 2005):

1. Evidence of cancer spread beyond the prostate
2. Previous radiotherapy
3. Co-morbid conditions contradicting elective surgery

III. STATE/MARKET APPLICATION CRITERIA

In applying this guideline, individual needs and an assessment of the local delivery system shall be considered.

- The following individual factors shall be considered: age, comorbidities, complications, progress of treatment, psychosocial situation, and home environment, when applicable.
- The following aspects of the local delivery system shall be considered: availability of local facilities and benefit coverage.
When utilization management guidelines cannot be applied appropriately, individual case discussions shall ensue.

IV. REFERENCES


V. APPENDIX/DEFINITIONS
Medical Management Guideline

TITLE: Incontinence Control (Adult): Collagen Implants, Biofeedback, Sacral Nerve Stimulation, Non-Implantable Pelvic Floor Stimulator

Authorized By: Medical Management Guideline Committee

Approval Date: 04/22/03   Revision Date: 05/25/04 05/24/05

Disclaimer
This medical management guideline represents the recommendation of the PacifiCare Medical Management Guideline (MMG) committee. It is based on the MMG committee’s review of the available evidence as of the date of this medical management guideline.

This medical management guideline contains clinical practice and utilization criteria to assist professionals in PacifiCare’s medical management practice when making medical necessity determinations prior to, subsequent to, or concurrent with the provisions of health care services. This medical management guideline is intended to support consistent, appropriate medical necessity determinations, but it does not replace an individualized case-by-case review and medical necessity determination for each PacifiCare member.

Member benefit coverage and limitations may vary based on the member’s benefit plan. Please consult with your local Medicare carrier to determine if a Local Coverage Determination is in place.

A. BACKGROUND

1. Description
Urinary incontinence is defined as the inability to control urination, ranging from an occasional leakage of urine to complete inability to hold any urine. Urinary incontinence is estimated to affect approximately 13 million individuals in the United States, including 11 million women (Bachmann and Wiita, 2002). For the year 2001, the National Institutes of Health (NIH) estimated that, among community-dwelling adults, 35% of women 65 years of age or older and 10% of women younger than 65 years of age were affected by urinary incontinence. For men, the NIH estimated a prevalence of 22% among men 65 years of age or older and of 1.5% among men younger than 65 years of age. Among institutionalized adults 65 years of age or older, the NIH estimated a prevalence of 30% to 50% (NIH 2004).
Persistent urinary incontinence can be classified by symptoms as stress urinary incontinence (SUI), urge incontinence, overflow incontinence, and functional incontinence (Bachmann and Wiita, 2002).

SUI is defined as the involuntary loss of urine during activities that increase intra-abdominal pressure, such as coughing, laughing, or exercising. The underlying cause is usually urethral hypermobility resulting from a failure of the normal anatomic supports of the urethrovesical junction (bladder neck). Under normal circumstances, increased intra-abdominal pressure is distributed evenly across the bladder body and neck. In individuals with SUI, weakened proximal urethral support and temporary loss of urethral sphincteric function due to bladder neck descent result in a disproportionate rise in bladder pressure over urethral pressure leading to the involuntary loss of urine (Culligan and Heit, 2000). SUI is the most common type of urinary incontinence in women (Brubaker et al, 1999). Risk factors for developing SUI include a history of vaginal delivery, vaginal surgery, inadequate estrogen levels, and advanced age (Bachmann and Wiita, 2002).

Urge incontinence, or overactive bladder, is defined as the involuntary loss of urine preceded by a strong urge to void, whether or not the bladder is full. Although urge incontinence is sometimes the result of specific conditions, such as acute or chronic urinary tract infection (UTI), bladder cancer, or bladder stones, most cases result from idiopathic, spontaneous detrusor muscle contractions (Culligan and Heit, 2000). SUI and urge incontinence often occur simultaneously and the resulting condition is referred to as mixed urinary incontinence (Bachmann and Wiita, 2002).

2. **Benefit**
Secure Horizons covers the treatment of incontinence when determined to be medically necessary and specific criteria are met. See the Secure Horizons Benefit Interpretation Policy (BIP) *Incontinence Control (Adult).*

B. **RECOMMENDATIONS**

*NOTE: Member benefit coverage and limitations may vary based on the member’s benefit plan. Refer to member specific Evidence of Coverage (EOC), Schedule of Benefits (SOB), or Certificate of Coverage (COC). If there is a discrepancy between this guideline and the member’s EOC/SOB/COC, the member’s EOC/SOB/COC provision will govern.*

*Incontinence Control (Adult) – Secure Horizons*
1. **Collagen Implants:**
A collagen implant is a prosthetic device injected into the submucosal tissues of the urethra and/or bladder, neck and tissues adjacent to the urethra for the purpose of treating stress urinary incontinence resulting from intrinsic sphincter deficiency (ISD). ISD is a cause of stress urinary incontinence in which the urethral sphincter is unable to contract and generate sufficient resistance in the bladder, especially during stress maneuvers (CMS a).

1. Coverage of a collagen implant, and the procedure to inject it, is limited to the following types of patients with stress urinary incontinence due to ISD (CMS a):
   - Male or female patients with congenital sphincter weakness secondary to conditions such as myelomeningocele or epispadias;
   - Male or female patients with acquired sphincter weakness secondary to spinal cord lesions;
   - Male patients following trauma, including prostatectomy and/or radiation; and
   - Female patients without urethral hypermobility and with abdominal leak point pressures of 100cm H₂O or less

2. Evaluation of the member must include all of the following (CMS a):
   **Men:**
   a) A complete history and physical examination
   b) A cystometrogram to determine whether the bladder fills and stores properly
   c) A bladder stress test maneuver to determine whether the bladder can contract and generate sufficient pressure resistance

   **Women:**
   a) A complete history and physical examination that must include a pelvic examination
   b) A cystometrogram to identify any existing bladder or urethral support abnormalities
   c) An abdominal leak point pressure (ALLP) test

3. Prior to any collagen implant therapy, a skin test for collagen sensitivity must be administered and evaluated over a 4-week period (CMS a).
4. Members may have more than 5 treatment sessions if both of the following criteria are met (CMS a):
   a) At least 6 to 12 months have passed following successful treatment with collagen implants
   b) Further treatment is medically justified

Note: Collagen implantation is not recommended for members whose incontinence does not improve after receiving 5 collagen injection procedures (5 separate treatment sessions) (CMS a).

2. **Biofeedback:**
   Biofeedback for the treatment of urinary incontinence is used as a tool to help patients learn how to perform pelvic muscle exercise (PME). Biofeedback-assisted PME involves the use of an electronic or mechanical device to relay visual and/or auditory evidence of pelvic floor muscle tone with the goal of improving awareness of pelvic floor musculature (CMS b).

   Biofeedback is recommended for the treatment of stress and/or urge urinary incontinence for cognitively intact patients who have failed a documented trial of pelvic muscle exercise (PME) training. A failed trial of PME training is defined as no clinically significant improvement in urinary continence after completing 4 weeks of an ordered plan of pelvic muscle exercises designed to increase periurethral muscle strength (CMS b).

   Note: Home use of biofeedback is not recommended (CMS b).

3. **Sacral Nerve Stimulation:**
   Sacral nerve stimulation is a reversible, minimally invasive, therapeutic intervention that involves placing electrodes in contact with one side of the appropriate sacral nerve, most often S3, and applying chronic electrical stimulation. Under general anesthesia, a neurostimulator is implanted into a subcutaneous abdominal pouch to provide programmable stimulation. Device settings are adjusted by using a noninvasive programmer. Although the precise mechanism of action of SNS is not known, current research suggests that urinary continence is affected by the stimulation of afferent somatic sacral nerve fibers, which evoke spinal inhibitory systems that are capable of interrupting a detrusor muscle contraction (HAYES 2003).
Medical Management Guideline

SNS involves both a temporary test stimulation to determine if an implantable stimulator would be effective and a permanent implantation for appropriate candidates (CMS c).

Sacral nerve stimulation (SNS) is recommended for the treatment of urinary urge incontinence, urgency-frequency syndrome, and urinary retention when the following criteria are met (CMS c):

a) The patient must be refractory to conventional therapy (documented behavioral, pharmacologic and/or surgical corrective therapy) and be an appropriate surgical candidate such that implantation with anesthesia can occur

b) The patient must have had successful test stimulation in order to support subsequent implantation

c) Before a patient is eligible for permanent implantation, he/she must demonstrate a 50% or greater improvement through test stimulation (improvement is measured through voiding diaries)

d) The patient must be able to demonstrate adequate ability to record voiding diary data such that clinical results of the implant procedure can be properly evaluated

Note: Sacral nerve stimulation is not recommended for members with stress incontinence, urinary obstruction and specific neurologic diseases (e.g., diabetes with peripheral nerve involvement) which are associated with secondary manifestations of urinary urge incontinence, urgency-frequency syndrome and urinary retention (CMS c).

4. Non-implantable pelvic floor electrical stimulator:

A non-implantable pelvic floor electrical stimulator is a device that provides neuromuscular electrical stimulation through the pelvic floor with the intent of strengthening and exercising pelvic floor musculature. Stimulation is generally delivered by vaginal or anal probes connected to an external pulse generator. The methods of pelvic floor electrical stimulation vary in location, stimulus frequency (Hz), stimulus intensity or amplitude (mA), pulse duration (duty cycle), treatments per day, number of treatment days per week, length of time for each treatment session, overall time period for device use, and between clinic and home settings. In general, the stimulus frequency and other parameters are chosen based on the patient's clinical diagnosis (CMS d).
Medical Management Guideline

Non-implantable pelvic floor electrical stimulators for stress and/or urge urinary incontinence are recommended when both of the following criteria are met (CMS d):

a) Member is cognitively intact
b) Member has failed a documented trial of pelvic muscle exercise (PME) training (a failed trial of PME training is defined as no clinically significant improvement in urinary continence after completing 4 weeks of an ordered plan of PME designed to increase periurethral muscle strength)

Note: Non-implantable pelvic floor stimulators as described above are not recommended for the treatment of intrinsic sphincter deficiency (ISD).

C. STATE/MARKET APPLICATION CRITERIA

In applying this guideline, individual needs and an assessment of the local delivery system shall be considered.

- The following individual factors shall be considered: age, comorbidities, complications, progress of treatment, psychosocial situation, and home environment, when applicable.
- The following aspects of the local delivery system shall be considered: availability of local facilities and benefit coverage.

When utilization management guidelines cannot be applied appropriately, individual case discussions shall ensue.

D. REFERENCES


Medical Management Guideline


Approved by: Medical Management Guideline Committee Date Approved: 05/24/05

Incontinence Control (Adult) – Secure Horizons
A. BACKGROUND

1. Description
Orthognathic surgery is defined as the surgical correction of abnormalities of the mandible, maxilla, or both with the goal of improving function. The underlying skeletal abnormalities may be present at birth, they may become evident as the patient grows, or they may be the result of traumatic injuries. Such skeletal abnormalities may cause difficulties with eating or chewing, abnormal speech patterns, or dysfunction of the temporomandibular joint (TMJ) (AAOMS 2004).

Orthognathic surgery involves osteotomy in the affected jaw and subsequent repositioning of the bones using plates, screws, and wires. Some patients also require intermaxillary fixation with arch bars. Patients with deformities in both jaws may undergo simultaneous osteotomies (Patel, et al, 2004).
The number of patients in the United States who may benefit from orthognathic surgery has been estimated at 1.5 – 2 million patients. Approximately 1 million of these patients present with Class II deformities, while 0.5 million patients present with Class III deformities (see Appendix for classification information) (Patel et al, 2004).

The following terms describe the relationship between the dentition of the upper and lower arches (Patel et al, 2004):

- **Overjet**: Horizontal distance between the incisal edges of the maxillary incisor and the mandibular incisor
- **Overbite**: Vertical distance between the incisal edge of the maxillary incisor and the mandibular incisor
- **Crossbite**: Lingual-buccal malposition of the normal relationship between the upper and lower dentition (negative overjet)
- **Deep bite**: Excessive overbite
- **Open bite**: Negative overbite (teeth do not meet)

2. **Benefit**

Secure Horizons covers orthognathic surgery when determined to be medically necessary and specific criteria are met. See the Secure Horizons Benefit Interpretation Policy (BIP) *Orthognathic Surgery*.

B. **RECOMMENDATIONS**

*NOTE: Member benefit coverage and limitations may vary based on the member’s benefit plan. Refer to member specific Evidence of Coverage (EOC), Schedule of Benefits (SOB), or Certificate of Coverage (COC). If there is a discrepancy between this guideline and the member’s EOC/SOB/COC, the member’s EOC/SOB/COC provision will govern.*
Orthognathic surgery is recommended for patients meeting both of the following criteria (AAOMS 2004):

1. Skeletal deformities of the mandible, maxilla, or both, which cannot be adequately treated with dental or orthodontic treatment measures alone

AND

2. One of the following:
   a. Skeletal deformities of the mandible, maxilla, or both, which contribute to significant masticatory dysfunction:
      • Anterioposterior discrepancies:
        • Maxillary/mandibular incisor relationship: overjet of 5mm or more, or a 0 to negative value (norm 2mm)
        • Maxillary/mandibular anteroposterior molar relationship discrepancy of 4mm or more (norm 0 to 1mm)
        Note: These values represent 2 or more standard deviations from published norms.
      • Vertical discrepancies:
        • Presence of a vertical facial skeletal deformity that is 2 or more standard deviations from published norms for accepted skeletal landmarks
        • Open bite:
          • No vertical overlap of anterior teeth
          • Unilateral or bilateral posterior open bite greater than 2mm
        • Deep overbite with impingement or irritation of buccal or lingual soft tissues of the opposing arch
        • Supraeruption of a dentoalveolar segment due to lack of occlusion
      • Transverse discrepancies:
        • Presence of a transverse skeletal discrepancy that is 2 or more standard deviations from published norms
        • Total bilateral maxillary palatal cusp to mandibular fossa discrepancy of 4mm or greater, or a unilateral discrepancy of 3mm or greater, given normal axial inclination of the posterior teeth
      • Asymmetries:
        • Anterioposterior, transverse, or lateral asymmetries greater than 3mm with concomitant occlusal asymmetry
   b. Skeletal deformities of the maxilla, mandible, or both, associated with documented respiratory dysfunction, speech impairment, or difficulties with fluid intake or swallowing
C. STATE/MARKET APPLICATION CRITERIA

In applying this guideline, individual needs and an assessment of the local delivery system shall be considered.

• The following individual factors shall be considered: age, comorbidities, complications, progress of treatment, psychosocial situation, and home environment, when applicable.

• The following aspects of the local delivery system shall be considered: availability of local facilities and benefit coverage.

When utilization management guidelines cannot be applied appropriately, individual case discussions shall ensue.

D. REFERENCES


Appendix

Angle’s classification of malocclusion (Chang et al, 2004; Medline Plus 2003)
Angle’s classification describes 3 classes of malocclusion based on the occlusal relationship of the mesial-buccal cusp of the maxillary first molar to the buccal groove of the mandibular first molar.

Class I  The mesial-buccal cusp of the maxillary first molar is in contact with the mandibular first molar’s buccal groove (normal bite), but teeth are crowded or malpositioned.

Class II  The mesial-buccal cusp of the maxillary first molar lies in front of (or mesial to) the mandibular first molar’s buccal groove (retrognathism or overbite).

Class III The mesial-buccal cusp of the maxillary first molar lies behind (or distal to) the mandibular first molar’s buccal groove (prognathism or underbite).
I. BACKGROUND

A. Description
Osteoporosis is a skeletal disorder characterized by compromised bone strength predisposing a person to an increased risk of fracture. Bone strength reflects the integration of 2 main features: bone density and bone quality (NIH 2000).

By 2050, the number of people beyond age 65 years will increase from 32 million to 69 million, with more than 15 million exceeding 85 years of age (AACE 2003). Consequently, the incidence of osteoporosis is expected to rise over the next few decades. The public health and clinical importance of osteoporosis lies in the fractures associated with the disease. According to conservative estimates, a 50-year old Caucasian woman has a remaining lifetime risk of 40% for hip, vertebra or
wrist fractures (SAC/OSC 2002). Low bone mineral density (BMD) at the femoral neck: T-score of –2.5 or below (see Table 1) is found in 21% of postmenopausal Caucasian American women, 16% of postmenopausal Mexican American women and 10% of postmenopausal African American women (AACE 2003).

The World Health Organization (WHO) defines fragility fracture as a fracture caused by injury that would be insufficient to fracture normal bone: the result of reduced compressive and/or torsional strength of bone. Clinically, a fragility fracture may be defined as one that occurs as a result of minimal trauma, such as a fall from a standing height or less, or no identifiable trauma. The WHO definition is based on a comparison of a patient’s BMD with the mean for a normal young adult population of the same sex and race. The patient is assigned a “T-score,” which is the number of standard deviations above or below the mean BMD for normal young adults (see Table 1) (SAC/OSC 2002).

Normal: BMD is within 1 standard deviation of a “young normal” adult (i.e., T-score at –1.0 and higher).

Osteopenia: (low bone mass) BMD is between 1 and 2.5 SD lower than that of a “young normal” adult (T-score between –1 and –2.5). Osteopenia is also a term used by radiologists to indicate that the bones on a plain x-ray film appear to be of decreased mineral content.

Osteoporosis: BMD is 2.5 SD or lower than that of a “young normal” adult (T-score at or below –2.5).

The term “severe osteoporosis” has been used in the assessment of patients who have a T-score of –2.5 or below and who have also suffered a fragility fracture (SAC/OSC 2002).

### Table 1. World Health Organization’s Definition of Osteoporosis (AACE 2003)

<table>
<thead>
<tr>
<th>Bone Mass Density</th>
<th>T-score: number of standard deviations above or below the mean BMD for normal young adults</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>-1.0 or higher</td>
</tr>
<tr>
<td>Osteopenia</td>
<td>Between -1.0 and -2.5</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>-2.5 or lower</td>
</tr>
<tr>
<td>Severe osteoporosis</td>
<td>-2.5 or lower and one or more fractures</td>
</tr>
</tbody>
</table>

**Screening:**
Screening individuals for risk factors aids physicians in identifying those who

**Osteoporosis – Secure Horizons**
require further assessment and investigation to determine whether medical intervention is needed to reduce their risk of osteoporotic (fragility) fracture (SAC/OSC 2002).

Predictors of low BMD (NOF 2003):
• Body weight <127lbs
• Any fracture as an adult
• Advanced age
• Fracture in a first degree relative

Bone Mineral Density Screening:
Central (hip and spine) dual-energy X-ray absorptiometry (DXA) remains the most accurate tool for evaluating BMD in clinical settings. Patients should be monitored using central (total hip and spine) DXA in clinical settings after initiating therapy (SAC/OSC 2002) (see Table 2).
• Central sites are more likely to demonstrate response than peripheral sites and are preferred for baseline and serial measurements (AACE 2003)
• Peripheral site measurements should be limited to risk assessment (AACE 2003)
• Hip BMD is the best predictor of hip fracture and appears to predict other types of fractures as well as measurements made at other skeletal sites (AACE 2003)

| Table 2. Bone mineral density (BMD) measurement techniques (AACE 2003) |
|--------------------------|-----------------------------|-----------------|-----------------|
| Technique* | Site Measured | Unit of Measure | Utility |
| DXA | Posteroanterior spine, lateral spine, proximal femur, total body, forearm, heel, phalanges | Areal density (g/cm²) | Diagnosis and monitoring |
| DXA | Lateral spine, total body, forearm, heel, phalanges | Areal density (g/cm²) | Risk assessment |
| QCT | Spine | Volumetric density (g/cm³) | Diagnosis and monitoring |
| pQCT | Forearm, hip | Volumetric density (g/cm³) | Risk assessment |
| QUS | Heel, forearm, tibia, phalanges, metatarsals | SOS, BUA | Risk assessment |
| RA | Phalanges | Volumetric density (arbitrary units) | Risk assessment |

*DXA = dual x-ray absorptiometry; QCT = quantitative computed tomography; pQCT = peripheral quantitative computed tomography; QUS = quantitative ultrasonometry; RA = radiographic absorptiometry; SOS = speed of sound; BUA = broadband ultrasound attenuation.

Osteoporosis – Secure Horizons
Treatment:
The goal of prevention and management of osteoporosis is to retain bone mass and preserve structural integrity of the skeleton (SAC/OSC 2002). Treatment options include pharmacotherapy (see Tables 3 and 4) and lifestyle changes to include exercise and modified diet. Adequate intake of calcium and vitamin D in addition to exercise will benefit skeletal structure (NOF 2003).

### Table 3. FDA approved indications (as per package inserts)

<table>
<thead>
<tr>
<th>Indication</th>
<th>Bisphosphonates*</th>
<th>SERMs†</th>
<th>Parathyroid hormones*</th>
<th>Miacalcin†</th>
<th>Estrogens‡‡</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Actonel® (Risedronate)</td>
<td>Fosamax® (Alendronate)</td>
<td>Evista® (Raloxifene)</td>
<td>Forteo® (Teriparatide)</td>
<td>Miacalcin® (Calcitonin)</td>
</tr>
<tr>
<td>Prevention</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Treatment</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
| ERT=estrogen replacement therapy; HRT=hormone replacement therapy; SERMs=selective estrogen receptor modulators

*FDA (2004); †Novartis (2003)

‡‡The American Association of Clinical Endocrinologists (AACE 2003) recommends against prescribing ERT/HRT to asymptomatic women to prevent or treat osteoporosis or for prevention of heart disease or other chronic medical problems. When prescribed solely for the prevention of postmenopausal osteoporosis, therapy should only be considered for women at significant risk of osteoporosis and for whom non-estrogen medications are not considered to be appropriate

### Table 4. Pharmacotherapy: Summary of clinical efficacy (These are not head to head comparisons)

<table>
<thead>
<tr>
<th>Therapeutic Class</th>
<th>Effect on BMD</th>
<th>Effect on Fractures*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bisphosphonates (Actonel®, Fosamax®)</td>
<td>Increase bone density of the spine, trochanter, and femoral neck (Manson and Martin 2001; McClung et al, 2001)</td>
<td>Decrease the risk of vertebral and non-vertebral fractures (including hip fractures) by 40% to 50% (Black et al, 1996; Cummings et al, 1998; Harris et al, 2000)</td>
</tr>
<tr>
<td>SERMs (Evista®)</td>
<td>Increase bone density of the spine and femoral neck (Ettinger et al, 1999)</td>
<td>Decrease the risk of vertebral fracture by 30% to 50%; no significant reduction in nonvertebral fractures was seen (FDA 2004; Ettinger et al, 1999)</td>
</tr>
<tr>
<td>Parathyroid hormone (Forteo®)</td>
<td>Increases vertebral, femoral, and total-body mineral density (Neer et al, 2001)</td>
<td>Decreases the risk of vertebral and nonvertebral fractures by 65% and 53%, respectively (Neer et al, 2001)</td>
</tr>
<tr>
<td>Calcitonin (Miacalcin®)</td>
<td>Increases bone density in the spine, but less evidence is available on the effect of calcitonin on sites other than the spine (Novartis 2003; The Medical Letter, 2002))</td>
<td>In the PROOF trial, a 35% decrease in vertebral fractures and no significant reduction in nonvertebral fractures was observed (Chesnut et al, 2000). Calcitonin has analgesic effect and is often used in patients with acute symptomatic vertebral fractures</td>
</tr>
<tr>
<td>Estrogens</td>
<td>Decrease rate of bone loss; increase bone density of the spine and hip (Manson and Martin 2001)</td>
<td>The Women’s Health Initiative study showed a one third reduction in hip and clinical vertebral fractures and a 24% reduction for all fractures with an average of 5.2 years of use (Rossouw et al, 2002)</td>
</tr>
</tbody>
</table>
B. Benefit
Secure Horizons covers osteoporosis screening and bone density studies/bone mass measurement when determined to be medically necessary and specific criteria are met. See the Secure Horizons Benefit Interpretation Policy (BIP) Diagnostic and Therapeutic Radiology Services and the Clinical Practice Guideline Preventive Health Recommendations.

C. Local Carrier (Medicare) Determination
None

II. RECOMMENDATIONS

NOTE: Member benefit coverage and limitations may vary based on the member’s benefit plan. Refer to member specific Evidence of Coverage (EOC), Schedule of Benefits (SOB), or Certificate of Coverage (COC). If there is a discrepancy between this guideline and the member’s EOC/SOB/COC, the member’s EOC/SOB/COC provision will govern.

A. Screening

*Note: For recommendations, see Clinical Practice Guidelines-Preventive Health

B. Diagnosis

Bone mass measurement IS recommended when ALL of the following criteria and requirements are met (CMS a):

1. Bone mass measurement is a radiologic, radioisotopic or other procedure (e.g., DXA and single photon absorptiometry [SPA]) that meets all of the following criteria/requirements:
   a. Is performed with a bone densitometer (other than dual photon absorptiometry [DPA]) or a bone sonometer (i.e., ultrasound) device approved or cleared for marketing by the Food and Drug Administration (FDA)
   b. Is performed for the purpose of identifying bone mass or detecting bone loss or determining bone quality
   c. Includes a physician's interpretation of the results of the procedure

2. Bone mass measurements may be performed on a member who meets at least ONE of the following medical indications:
   a. A woman who has been determined by the physician or qualified non-physician practitioner treating her to be estrogen-deficient and at clinical risk for Osteoporosis – Secure Horizons
osteoporosis, based on her medical history and other findings (CMS a)

b. A member with vertebral abnormalities as demonstrated by an X-ray to be indicative of osteoporosis, osteopenia (low bone mass), or vertebral fracture (CMS a)
c. A member receiving (or expecting to receive) glucocorticoid (steroid) therapy equivalent to 5 mg of prednisone, or greater, per day, for more than 3 months (CMS a)
d. A member with primary hyperparathyroidism (CMS a)
e. A man who has been determined by the physician or qualified non-physician practitioner treating him to be androgen-deficient and at clinical risk for osteoporosis, based on his medical history and other findings (Mason 2003)
f. A member being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy (CMS a)

3. The bone mass measurement is ordered by the member's physician or qualified non-physician practitioner who is treating the member following an evaluation of the need for a measurement, including a determination as to the medically appropriate measurement to be used for the member. For the purposes of this guideline, a "qualified non-physician practitioner" includes physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives (CMS a)

4. The bone mass measurement is furnished by a qualified supplier or provider of such services under the appropriate level of supervision of a physician (CMS a)

5. Frequency Standard: Bone mass measurements are recommended once every 2 years (if at least 23 months have passed since the month the last bone mass measurement was performed), or sooner if medically necessary. Examples of situations where more frequent bone mass measurement procedures may be medically necessary include, but are not limited to, the following medical circumstances (CMS a):

- Monitoring members on long-term glucocorticoid (steroid) therapy of more than 3 months
- Allowing for a confirmatory baseline bone mass measurement (either central or peripheral) to permit monitoring of members in the future if the initial test was performed with a technique that is different from the proposed monitoring method (e.g., if the initial test was performed using bone sonometry and monitoring is anticipated using bone densitometry, baseline measurement using bone densitometry is recommended)

Bone biopsy is recommended when used for the qualitative evaluation of bone, not to exceed 4 bone biopsies for a member, unless there is special justification provided (CMS b)
C. Pharmacotherapy

1. Prevention For High Risk Individuals (individuals with reduced BMD, i.e., osteopenia)
   a. Bisphosphonates are first-line therapies in the prevention of postmenopausal osteoporosis (SAC/OSC 2002)
   b. Estrogen-receptor modulators (SERMs) are first-line therapies in the prevention of postmenopausal osteoporosis for women with a personal or strong family history of breast cancer (Mason 2003)
   c. Bisphosphonates are first-line therapies for the prevention of osteoporosis in patients requiring prolonged glucocorticoid therapy (SAC/OSC 2002)
   d. Estrogen and estrogen/progestin therapy, when prescribed solely for the prevention of postmenopausal osteoporosis, should be considered for women at significant risk of osteoporosis and for whom non-estrogen medications are not considered to be appropriate. In women with an intact uterus, a progestin must be added to estrogen therapy because unopposed estrogen increases the risk of endometrial cancer in postmenopausal women (AACE 2003)
   e. Age-appropriate calcium and vitamin D intake are recommended for the prevention of osteoporosis (AACE 2003)

2. Treatment
   a. Bisphosphonates are first-line therapies in the treatment of postmenopausal osteoporosis (SAC/OSC 2002)
   b. Estrogen-receptor modulators (SERMs) are first-line therapies in the prevention of postmenopausal osteoporosis for women with a personal or strong family history of breast cancer (Mason 2003)
   c. Bisphosphonates are first line therapies for patients with glucocorticoid induced osteoporosis (SAC/OSC 2002)
   d. Nasal calcitonin is a second-line therapy in the treatment of postmenopausal osteoporosis (SAC/OSC 2002)
   e. Parathyroid hormone is a second line therapy for individuals unable to tolerate anti resorptive therapy (AACE 2003)
   f. Estrogen and estrogen/progestin therapy should be considered for women for whom non-estrogen medications are not considered to be appropriate. In women with an intact uterus, a progestin must be added to estrogen therapy because unopposed estrogen increases the risk of endometrial cancer in postmenopausal women (AACE 2003)

III. STATE/MARKET APPLICATION CRITERIA

In applying this guideline, individual needs and an assessment of the local delivery system

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shall be considered.

- The following individual factors shall be considered: age, comorbidities, complications, progress of treatment, psychosocial situation, and home environment, when applicable.
- The following aspects of the local delivery system shall be considered: availability of local facilities and benefit coverage.

When utilization management guidelines cannot be applied appropriately, individual case discussions shall ensue.

IV. REFERENCES


(7): 637-645.


Medical Management Guideline


V. APPENDIX/DEFINITIONS

Approved by: Medical Management Guideline Committee Date Approved: 11/22/05
TITLE: Oxygen for Home Use

Authorized By: Medical Management Guideline Committee

Approval Date: 04/22/03 Revision Date: 10/28/03; 11/23/04
02/22/05; 02/22/06

Disclaimer
This medical management guideline represents the recommendation of the PacifiCare Medical Management Guideline (MMG) committee. It is based on the MMG committee’s review of the available evidence as of the date of this medical management guideline.

This medical management guideline contains clinical practice and utilization criteria to assist professionals in PacifiCare’s medical management practice when making medical necessity determinations prior to, subsequent to, or concurrent with the provisions of health care services. This medical management guideline is intended to support consistent, appropriate medical necessity determinations, but it does not replace an individualized case-by-case review and medical necessity determination for each PacifiCare member.

Member benefit coverage and limitations may vary based on the member’s benefit plan. Please consult with your local Medicare carrier to determine if a Local Coverage Determination is in place.

I. BACKGROUND

A. Description
Home use oxygen is available as compressed gas in cylinders, liquid oxygen in specialized containers, and from self-generating concentrators (Findeisen 2001). Concentrators are the primary stationary home oxygen systems in use today (Lewarski 2001).

In addition to stationary oxygen systems, there are a growing number of portable oxygen systems and ambulatory lightweight oxygen systems available. Portable systems weigh more than 10 pounds, are mounted on wheels, and allow some degree of mobility but can be difficult to maneuver. Ambulatory lightweight oxygen systems (less than 10 pounds) are constructed of lightweight materials and/or integrate oxygen-conserving devices in the system (O’Donohue 1997; Petty and Casaburi 2000).
Some examples of new ambulatory lightweight portable oxygen systems include the following (Lewarski 2001):

- Small, lightweight, alloy cylinders
- Small, lightweight, click-style regulators
- Pulse-dose oxygen conserving devices
- Demand oxygen conserving devices
- Oxygen concentrators capable of filling small cylinders
- Low-loss liquid conserving devices

Selecting the correct type of oxygen for a patient depends on a number of variables including prescribed liter flow, ambulatory requirements, patient’s clinical status, patient’s dexterity and aptitude, home environment, support systems and geography (Lewarski 2001; Petty and Casaburi 2000).

Compressed gas is a good choice for patients using oxygen at low flow rates and for those who live in areas with frequent power outages. The large H or K cylinder may be used as a primary delivery system or as a backup for other systems and will provide 3 days of oxygen at 2L/min (Findeisen 2001).

Liquid oxygen is the system of choice for high-volume users. A 100 pound liquid oxygen tank contains approximately 7 days of oxygen at 2L/min. Smaller liquid oxygen containers can be filled from a larger reservoir providing ambulatory capabilities (Findeisen 2001).

Concentrators are cost-efficient oxygen delivery systems for patients who need low-flow continuous oxygen. At flow rates of 1 to 2L/min delivered oxygen concentration is 94% to 95%. At flow rates of 3 to 5L/min delivered oxygen concentrations drop to 85% to 93% (Findeisen 2001).
### Table 1. Portable and Ambulatory Lightweight Oxygen Device Comparison

<table>
<thead>
<tr>
<th>Oxygen Delivery Model</th>
<th>Portability</th>
<th>Cost</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Concentrator, E Cylinder, Cart, Standard Regulator</td>
<td>C</td>
<td>1</td>
<td>Reliable easy use. 2L/min flow provides about 5.5 hours of continuous oxygen. Heavy: 12 – 15lbs. Meets criteria as portable but not ambulatory lightweight.</td>
</tr>
<tr>
<td>Standard Concentrator, D Cylinder (alloy), Oxygen Conserving Device, and Carrying Bag</td>
<td>A</td>
<td>2</td>
<td>2L/min flow provides about 5 to 12 hours of continuous oxygen. Meets weight definition for ambulatory oxygen: 8 – 9lbs. Some patients cannot tolerate conserving devices.</td>
</tr>
<tr>
<td>Standard Concentrator, Very Small cylinder, Oxygen Conserving Device and Carrying Bag</td>
<td>B</td>
<td>2.5</td>
<td>Limited oxygen available in small tanks, which are usually teamed with high-ratio conserving devices. Some patients cannot tolerate conserving devices.</td>
</tr>
<tr>
<td>Liquid Oxygen System: Standard Stationary liquid oxygen (35 – 50 liter) and Portable Liquid Oxygen (1 - 1.5 liter)</td>
<td>B+</td>
<td>4</td>
<td>Useful if continuous flow is required. 2L/min flow provides about 4 – 8 hours of continuous oxygen. Liquid oxygen is less cost effective, requiring specialized frequent deliveries due to constant loss of product due to warming and evaporation.</td>
</tr>
<tr>
<td>Dual System: Standard Concentrator and Portable Liquid Oxygen System (e.g., Helios)</td>
<td>A</td>
<td>5</td>
<td>Can be used for high flow frail patients ≥ 3L/min who require frequent ambulation and cannot tolerate a conserving device. Selective use only as this is a less cost effective system.</td>
</tr>
<tr>
<td>Stationary Liquid Oxygen System with Portable Liquid Oxygen and Conserving Device</td>
<td>A</td>
<td>4.5</td>
<td>This system has a conserving device built into the portable system. 2L/min flow provides 8 – 12 hours of continuous oxygen. Meets weight definition for ambulatory lightweight oxygen: 4 – 5 lbs.</td>
</tr>
<tr>
<td>Oxygen Concentrator with Transfill Ability, Oxygen Conserving Device, and Lightweight Cylinder (e.g., Oxylite)</td>
<td>A+</td>
<td>5</td>
<td>System diverts oxygen from concentrator to fill cylinders without affecting delivery to the patient. Used in conjunction with a lightweight cylinder and conserving device.</td>
</tr>
</tbody>
</table>

This comparison table was adapted from Lewarski, 2001, and offers a simplified reference and comparison of different oxygen systems. Actual costs are not represented. A+ = most portable, C = least portable, 1 = most cost effective, 5 = least cost effective.

### B. Benefit

Secure Horizons covers home oxygen and necessary accessories when determined to be medically necessary and specific criteria are met. See the Secure Horizons Benefit Interpretation Policies (BIPs) *Durable Medical Equipment (DME), Orthotics, Prosthetics and Medical Supplies*, and *DME Grid*.

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C. Local Carrier (Medicare) Determination
Medicare coverage of home oxygen and oxygen equipment is determined by Durable Medical Equipment Regional Carriers. Please see “RECOMMENDATIONS” below for exclusion/inclusion criteria. Detailed coverage and documentation information can be found on the following Durable Medical Equipment Regional Carrier links.

AZ, CA, NV, OR & WA:
http://www.cms.hhs.gov/mcd/results_index.asp?from=lmrpcontractor&contractor=122&name=Electronic+Data+Systems+Corp%2E+%2877006%2C+DME+PSC%29&letter_range=4

CO, OK & TX:
http://www.cms.hhs.gov/mcd/results_index.asp?from=lmrpcontractor&contractor=121&name=TrustSolutions+%2877012%2C+DME+PSC%29&letter_range=4

II. RECOMMENDATIONS

NOTE: Member benefit coverage and limitations may vary based on the member’s benefit plan. Refer to member specific Evidence of Coverage (EOC), Schedule of Benefits (SOB), or Certificate of Coverage (COC). If there is a discrepancy between this guideline and the member’s EOC/SOB/COC, the member’s EOC/SOB/COC provision will govern.

A. Oxygen for Home Use

Oxygen for home use and accompanying necessary accessories IS recommended when ALL of the following conditions are met (CMS, 1993; DMERC, 2004):

1. The treating physician has determined that the patient has a severe lung disease or hypoxia-related symptoms that might be expected to improve with oxygen therapy.
2. The member’s blood gas study meets the criteria stated below (See GROUP I, II)
3. The qualifying blood gas study was performed by a physician or by a qualified provider or supplier of laboratory services
4. The qualifying blood gas study was obtained under the following conditions:
   a. **Inpatient hospital stay:** The reported test must be the one obtained closest to, but no earlier than 2 days prior to the hospital discharge date
   OR
   b. **Non-Inpatient hospital stay:** The reported test must be performed while the patient is in a chronic stable state
5. Alternative treatment measures have been tried or considered and deemed clinically ineffective.

**Group I criteria include any of the following:**

1. Arterial PO₂ at or below 55 mm Hg or arterial oxygen saturation at or below
88%, taken at rest, breathing room air.
2. Arterial PO2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88%, for at least 5 minutes taken during sleep for a patient who demonstrates an arterial PO2 at or above 56 mm Hg or an arterial oxygen saturation at or above 89% while awake.
3. A decrease in arterial PO2 more than 10 mm Hg or a decrease in arterial oxygen saturation more than 5%, for at least 5 minutes taken during sleep with symptoms or signs reasonably attributable to hypoxemia.
4. Arterial PO2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88%, taken during exercise for a member who demonstrates a PO2 at or above 56 mm Hg or an arterial oxygen saturation at or above 89% during the day while at rest.

**Note:**
- In cases 1-4 above, initial coverage is limited to 12 months or the physician specified length of need, whichever is shorter.
- In case 4 above, supplemental oxygen is provided only for use during exercise if there is evidence that the use of oxygen improves the hypoxemia that was demonstrated during exercise when the member was breathing room air.
- For all sleep oximetry criteria described above, the 5 minutes does not have to be continuous.

**Group II criteria include the following:**
Members with arterial PO2 at 56-59 mm Hg or an arterial blood oxygen saturation of 89% at rest (awake), during sleep for a continuous period of at least 5 minutes, or during exercise (as described under Group I criteria), AND any of the following:
1. Dependent edema suggesting congestive heart failure (CHF).
2. Cor Pulmonale (pulmonary hypertension)
3. Erythrocythemia with a hematocrit greater than 56%.

**Note:**
- In cases 1-3 above, initial coverage is limited to 3 months or the physician specified length of need, whichever is shorter.
- For all sleep oximetry criteria described above, the 5 minutes does not have to be continuous.

**Liter Flow**

Liter flow greater than 4 LPM IS recommended for home use when Group I or Group II criteria for oxygen are met and the blood gas study is performed while the patient is on 4 LPM (DMERC 2004).
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Home oxygen is NOT recommended for members with the following (DMERC 2004; CMS, 1993):

1. An arterial PO2 at or above 60mm Hg or with arterial blood oxygen saturations at or above 90%.
2. Angina pectoris in the absence of hypoxemia.
3. Breathlessness without cor pulmonale or evidence of hypoxemia.
4. Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities but in the absence of systemic hypoxia.
5. Terminal illnesses that do not affect the respiratory system.

B. Oxygen Delivery Systems:

1. Stationary

Stationary compressed gaseous oxygen cylinders and oxygen concentrators, in addition to necessary accessories, ARE recommended as follows (O’Donohue 1997):
   a. The member does not routinely travel 50 feet beyond the delivery system OR
   b. The member only uses oxygen at night.

2. Portable

Portable oxygen concentrators and portable gaseous oxygen cylinders (i.e. ≥ 10 pounds) with standard regulators are systems that weigh 10 pounds or more and can be transported on wheels (O’Donohue 1997). These systems including necessary accessories ARE recommended when the following criteria are met (DMERC 2004):
   a. Patient is mobile within the home, occasionally going beyond 50 feet of the oxygen delivery system for fewer than 2 hours per day but more than 2 hours per week (DMERC 2004; O’Donohue 1997).
   b. Blood gas study was performed at rest (awake) or during exercise (DMERC 2004).

3. Liquid

Stationary or portable liquid oxygen systems in addition to necessary accessories, ARE recommended when substituted in section B.1 or B.2 above, when both of the following additional criteria are met (Lewarski 2001):
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a. Patient requires frequent ambulation
   AND
b. Patient requires continuous high flow oxygen ≥ 3L/min.
   AND
c. Patient cannot tolerate a conserving device.

4. Ambulatory

Ambulatory lightweight (< 10 pounds) gaseous oxygen systems (e.g., Oxylite) are designed to be carried by the patient. These systems, including necessary accessories, ARE recommended alone or combined with stationary systems when the following are clearly documented in writing by a physician qualified to make this assessment:

a. Patient is mobile within the home, regularly going beyond 50 feet of the oxygen delivery system for 2 hours or more per day (minimum 6 hours per week) (O’Donohue 1997).
b. Blood gas study performed at rest (awake) or during exercise.
   AND
c. Patient has upper body weakness and walks with an assistive device in the home.
   OR
d. Patient cannot maneuver within the home with standard portable oxygen or extension tubing on stationary oxygen equipment.

Ambulatory lightweight (< 10 pounds) liquid oxygen systems (e.g., Helios) are designed to be carried by the patient. These systems, including necessary accessories, ARE recommended when ALL of the following are clearly documented:

a. Patient cannot tolerate ambulatory lightweight gaseous oxygen systems (e.g., Oxylite).
b. Patient requires continuous high flow oxygen ≥ 3L/min
c. Patient meets criteria for ambulatory lightweight gaseous oxygen (see Ambulatory above).

5. Other Systems and Accessories

Oxygen and water vapor enriching systems ARE NOT recommended. Emergency or stand-by oxygen systems ARE NOT recommended (e.g., preset portable oxygen units) (DMERC 2004).
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Necessary accessories such as conservers ARE NOT separately payable unless used with a patient-owned system that was purchased prior to June 1, 1989 (DMERC 2004).

C. Home Use of Oxygen in Clinical Trials
The home use of oxygen is covered for those members with arterial oxygen partial pressure measurements from 56 to 65 mmHg or oxygen saturation at or above 89% who are enrolled subjects in clinical trials approved by CMS and sponsored by the National Heart, Lung, and Blood Institute [(NHLBI); CMS, 2006)]

III. STATE/MARKET APPLICATION CRITERIA
In applying this guideline, individual needs and an assessment of the local delivery system shall be considered.
- The following individual factors shall be considered: age, comorbidities, complications, progress of treatment, psychosocial situation, and home environment, when applicable.
- The following aspects of the local delivery system shall be considered: availability of local facilities and benefit coverage.

When utilization management guidelines cannot be applied appropriately, individual case discussions shall ensue.

IV. REFERENCES


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V. APPENDIX/DEFINITIONS

Approved by: Medical Management Guideline Committee

Date Approved: 02/22/06
I. BACKGROUND

A. Description

The terms plasmapheresis and plasma exchange are often used interchangeably in the literature. Other terms include apheresis and therapeutic pheresis. In plasma exchange, large volumes of patient plasma are exchanged with donor plasma or a plasma substitute. In plasmapheresis, the patient’s plasma is separated from the cellular components of the blood. Following fractionation, the cellular components are returned to the patient (HAYES 2001).

Extracorporeal immunoadsorption is another therapeutic blood component technique that contains highly purified staphylococcal protein A covalently bound
Plasmapheresis/plasma exchange can be used to treat more than 50 diseases. Records from the Swedish apheresis study group indicate that more than 70% of all patients were referred for 12 indications: Guillain Barré syndrome, hyperviscosity syndrome TTP/HUS, myasthenia gravis, hypercholesterolemia, lupus, rejection after transplantation, chronic inflammatory demyelinating polyneuropathy (CIDP), HLA-ab removal before transplantation, Wegener’s syndrome septic shock, and Goodpasture’s syndrome (Norda and Stegmayr, 2001).

Procedure risk factors considered to have potential for major complications include (NIH 1986):

- Citrate-induced hypocalcemia
- Replacement with fluids depleted of coagulation factors, proteins, or electrolytes
- Replacement fluids containing plasma as these have the capacity to transmit infection (e.g., hepatitis, CMV, HTLV-III)
- Allergic reactions leading to anaphylaxis
- Hemorrhage secondary to systemic anticoagulants
- Activation of coagulation, complement, fibrinolytic cascades, and/or aggregation of platelets
- Fluid imbalance
- Problems with vascular access

The positive effects of Plasmapheresis/plasma exchange, when observed are temporary. This limits its use in the treatment and management of chronic diseases. Plasmapheresis/plasma exchange is usually effective for conditions that may benefit from short term clinical improvements.

B. Benefit

N/A

C. Local Carrier (Medicare) Determination

None
II. RECOMMENDATIONS

**NOTE:** Member benefit coverage and limitations may vary based on the member’s benefit plan. Refer to member specific Evidence of Coverage (EOC), Schedule of Benefits (SOB), or Certificate of Coverage (COC). If there is a discrepancy between this guideline and the member’s EOC/SOB/COC, the member’s EOC/SOB/COC provision will govern.

Plasmapheresis/Plasma Exchange IS recommended for the following:

A. **Apheresis (therapeutic pheresis)**

Apheresis (therapeutic pheresis) is recommended for the following indications (CMS a):

1. Plasma exchange for acquired myasthenia gravis
2. Leukapheresis in the treatment of leukemia
3. Plasmapheresis in the treatment of primary macroglobulinemia (Waldenstrom) and treatment of hyperglobulinemias, including (but not limited to) multiple myeloma, cryoglobulinemia and hyperviscosity syndromes
4. Plasmapheresis or plasma exchange as a last resort treatment of thrombotic thrombocytopenic purpura (TTP)
5. Plasmapheresis or plasma exchange as a last resort treatment of life threatening rheumatoid vasculitis
6. Plasma perfusion using charcoal filters for treatment of pruritus of cholestatic liver disease
7. Plasma exchange in the treatment of Goodpasture’s Syndrome
8. Plasma exchange in the treatment of glomerulonephritis associated with antiglomerular basement membrane antibodies and advancing renal failure or pulmonary hemorrhage
9. Treatment of chronic relapsing polyneuropathy for patients with severe or life threatening symptoms who have failed to respond to conventional therapy
10. Treatment of life threatening scleroderma and polymyositis when the patient is unresponsive to conventional therapy
11. Treatment of Guillain-Barré Syndrome (GBS) in patients with GBS severe enough to prevent independent walking (severity grade 3-5)
12. Last resort treatment of systemic lupus erythematosus (SLE) after conventional therapy has failed to prevent clinical deterioration

B. **Extracorporeal Immunoadsorption (ECI) using Protein A Columns**

Plasmapheresis/Plasma Exchange – Secure Horizons
Extracorporeal immunoadsorption (ECI) using Protein A columns is recommended for the following indications (CMS b):

1. Idiopathic thrombocytopenic purpura (ITP)
2. Severe, rheumatoid arthritis when BOTH of the following conditions are met:
   a. Disease is active, as evidenced by all of the following:
      1) >5 swollen joints
      2) >20 tender joints
      3) >60 minutes of morning stiffness
   b. Patient has failed and adequate course of at least 3 Disease Modifying Anti-Rheumatic Drugs (DMARDs). Failure does not include intolerance.

C. Settings

Treatment may be delivered in a hospital or non-hospital setting. In a hospital setting, treatment can be provided on an inpatient or outpatient basis. In a non-hospital setting, CMS conditions must be met.

Apheresis is covered by CMS only when performed in the following settings:

1. In a hospital setting (either inpatient or outpatient), non-physician services furnished to hospital patients are covered and paid for as hospital services. When covered services are provided to hospital patients by an outside provider/supplier, the hospital is responsible for paying the provider/supplier for the services.

2. In a non-hospital setting, e.g. a physician-directed clinic (see CMS pub.14-3, §2050.4), apheresis is covered when the following conditions are met:
   a. A physician (or a number of physicians) is present to perform medical services and to respond to medical emergencies at all times during patient care hours
   b. Each patient is under the care of a physician
   c. All non-physician services are furnished under the direct, personal supervision of a physician.

III. STATE/MARKET APPLICATION CRITERIA

In applying this guideline, individual needs and an assessment of the local delivery system shall be considered.
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- The following individual factors shall be considered: age, comorbidities, complications, progress of treatment, psychosocial situation, and home environment, when applicable.
- The following aspects of the local delivery system shall be considered: availability of local facilities and benefit coverage.

When utilization management guidelines cannot be applied appropriately, individual case discussions shall ensue.

IV. REFERENCES


V. APPENDIX/DEFINITIONS

Approved by: Medical Management Guideline Committee

Date Approved: 11/22/05
I. BACKGROUND

1. Description

**Polysomnography**

Polysomnography is defined as the collective process of monitoring and recording physiologic data during sleep (AARC-APT 1995). It is used to evaluate abnormalities of sleep and other physiologic disorders related to sleep or wakefulness (Nowack 2004). Polysomnographic evaluations typically include the measurement of multiple channels of physiologic parameters, including at a minimum, but not limited to, the following 7 parameters (ASDA, 1997; Rowley et al, 2004):

- Electroencephalography (EEG)
- Electro-oculography (EOG)
- Electromyography (EMG)
- Electrocardiography (ECG) or heart rate
- Respiratory effort
- Air flow
- Oxygen saturation

Additional parameters (e.g., body position, limb movements) may be added in selected situations (AARC-APT 1995; ASDA, 1997).

In-laboratory polysomnography is performed in specialized hospital sleep laboratories, appropriately equipped hospital rooms, or stand-alone sleep centers, with a qualified technician continuously in attendance (AARC-APT 1995). A full-night polysomnogram usually provides an accurate representation of sleep characteristics. During split-night studies, baseline sleep is assessed in the first segment of the study, followed by CPAP titration during the second segment (Qureshi and Ballard, 2003).

Polysomnography is considered the standard approach to the diagnosis of sleep apnea, a sleep-related breathing disorder (Flemons et al, 2003). In adults, an apnea is defined as a cessation of respiration for a minimum of 10 seconds. A hypopnea is commonly defined as a reduction of airflow for a minimum of 10 seconds (Qureshi and Ballard, 2003). There are 3 different types of sleep apnea: obstructive sleep apnea (OSA), central sleep apnea, and mixed sleep apnea (ASDA, 1997). The most common form of sleep apnea, obstructive sleep apnea (OSA), is characterized by recurrent episodes of upper airway collapse and obstruction during sleep, associated with recurrent oxyhemoglobin desaturation and arousals from sleep. Central origin of an apnea is assumed when there is no concurrent respiratory effort (Qureshi and Ballard, 2003). Mixed sleep apnea represents a combination of OSA and central sleep apnea (ASDA, 1997).

The severity of OSA is often quantified using the apnea-hypopnea index (AHI), which is defined as the total number of apneas and hypopneas per hour of sleep. Other measures include the severity of oxygen desaturation during sleep, or the severity of daytime somnolence (Flemons et al, 2003).

OSA is estimated to affect from 2% to 4% of the population and is more common in males than females. Signs of OSA include excessive daytime sleepiness, loud snoring, and choking or gasping during sleep. Other signs of sleep apnea may include morning headaches, dry throat upon awakening, irritability, and problems with learning, memory, or concentration (NIH 2003). OSA may also be associated with other medical disorders, e.g., tonsillar enlargement (Phillips et al, 1998). OSA is frequently associated with systemic hypertension and a higher-than-normal incidence of stroke and myocardial infarction (Rowley et al, 2004).
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Treatment options for OSA include oral appliances, continuous positive airway pressure (CPAP), and surgical procedures (Rowley et al, 2004). CPAP machines blow pressurized air into the patient’s nostrils, thus acting as a pneumatic splint that keeps the pharyngeal airway open (Victor 2004).

**Pulse Oximetry**

Oximetry measures blood oxygen saturation by measuring the absorbance of light at different wavelengths. The pulse oximeter uses a non-invasive probe to determine the arterial blood concentrations of oxygenated hemoglobin and reduced (deoxygenated) hemoglobin, which have different light absorption spectra. A built-in calibration algorithm allows the calculation of oxygen saturation (SpO2) (Noridian, 2005).

2. **Benefit**

Secure Horizons covers the services necessary for the diagnosis and treatment of sleep apnea when determined to be medically necessary and specific criteria are met. See the Secure Horizons Benefit Interpretation Policy (BIP) *Sleep Apnea*.

3. **Local Carrier (Medicare) Determination**

Medicare coverage of pulse oximetry is covered under a Local Carrier Determination (LCD). Please see “RECOMMENDATIONS” below for exclusion/inclusion criteria. Detailed coverage and documentation information can be found at the following local carrier determination link. **AZ, NV, OR, WA:**

http://www.cms.hhs.gov/med/viewlcd.asp?lcd_id=15068&lcd_version=7&basket=lcd%3A15068%3A7%3APulse%2B%3AOximetry%3ACarrier%3ANoridian+Administrative+Services%7C%7C+LLC+%2800821%29%

II. **RECOMMENDATIONS**

*NOTE: Member benefit coverage and limitations may vary based on the member’s benefit plan. Refer to member specific Evidence of Coverage (EOC), Schedule of Benefits (SOB), or Certificate of Coverage (COC). If there is a discrepancy between this guideline and the member’s EOC/SOB/COC, the member’s EOC/SOB/COC provision will govern.*

**A. Pulse Oximetry**

Pulse oximetry **IS** recommended for the following (Hayes, 1999):

1. As a screening instrument in members whose history, clinical signs and symptoms, and collateral information are highly suggestive of OSA.

*Polysomnography/Pulse Oximetry in Sleep Apnea – Secure Horizons*
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Pulse Oximetry **IS NOT** recommended (CMS, 2005; Hayes, 1999):

1. As a tool for diagnosing OSA for CPAP and will not be covered by CMS.
2. For members who are strongly suspected to have OSA and have tested negative on a previous screening test.
3. For members with suspected OSA who exhibit few signs.

**B. Polysomnography**

*Note:* All sleep studies should be performed as split-night studies, unless specifically contraindicated.

In-laboratory polysomnography, performed with the constant presence of a trained individual monitoring technical adequacy, patient compliance, and relevant patient behavior, **IS** recommended for the following:

1. Diagnosis of sleep apnea in patients with suspected sleep apnea meeting the following criteria:
   a. Witnessed apnea during sleep with a minimum duration of 10 seconds **OR**
   b. • Symptoms/observations during sleep, such as severe and persistent snoring, breathing pauses, choking/gasping, restless sleep for at least one month, or documented nocturnal hypoxia by oximetry study (ASDA, 1997)
      AND
      • Symptoms/observations while awake, such as excessive daytime sleepiness for at least one month, obesity (BMI>30), hypertension (ASDA, 1997), or neck circumference >40cm (Guilleminault and Abad, 2004)

*Note:* Polysomnography **IS NOT** recommended for any of the criteria listed under 1.b. occurring alone.

*Note:* Excessive daytime sleepiness with sleep initiation insomnia should negate excessive daytime sleepiness as a criterion for determining need for the study. See “APPENDIX/DEFINITIONS” for definition of excessive daytime sleepiness.
2. CPAP titration in patients with documented diagnosis of a sleep-related breathing disorder for which CPAP is warranted (ASDA, 1997).

3. Follow-up after sleep apnea treatment in any of the following situations:
   - Insufficient response to CPAP or returning symptoms after good initial response to CPAP (ASDA, 1997)
   - After surgical treatment in patients with sleep apnea whose symptoms return despite a good initial response to treatment (ASDA, 1997)
   - To ensure satisfactory response to surgical treatment in patients with moderate to severe OSA (ASDA, 1997)
   - After substantial weight loss or weight gain in patients treated with CPAP to establish whether pressure adjustments are necessary
   - To ensure therapeutic benefit in patients with moderate to severe OSA after good clinical response to oral appliance treatment (ASDA, 1997)

   *Note:* Follow-up polysomnography is not recommended in patients treated with CPAP whose symptoms continue to be resolved with CPAP (ASDA, 1997).

4. Other situations:
   - Unexplained right heart failure
   - Unexplained pulmonary hypertension
   - Unexplained polycythemia
   - Nocturnal arrhythmias
   - Violent sleep behaviors

C. Portable Devices

Portable devices ARE NOT recommended for the diagnosis of sleep apnea and will not be covered by CMS. At this time, there is insufficient evidence to conclude that unattended multi-channel sleep study testing is reasonable and necessary in the diagnosis of OSA for CPAP therapy (CMS, 2005).

III. STATE/MARKET APPLICATION CRITERIA

In applying this guideline, individual needs and an assessment of the local delivery system shall be considered.

- The following individual factors shall be considered: age, comorbidities, complications, progress of treatment, psychosocial situation, and home environment, when applicable.
- The following aspects of the local delivery system shall be considered: availability of local facilities and benefit coverage.

*Polysomnography/Pulse Oximetry in Sleep Apnea – Secure Horizons*
Medical Management Guideline

When utilization management guidelines cannot be applied appropriately, individual case discussions shall ensue.

IV. REFERENCES


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V. APPENDIX/DEFINITIONS

Excessive Daytime Sleepiness:

Excessive daytime sleepiness is evidenced by one or more of the following:

a) Inappropriate daytime napping (e.g., during driving, conversation, or eating)
b) Sleepiness that interferes with daily activities (the following should be ruled out as a cause for these symptoms: poor sleep hygiene, medication, drugs, alcohol,

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hypothyroidism, other medical diagnoses, psychiatric, or psychological disorders, social or work schedule changes)

c) An Epworth Sleepiness Scale score greater than 10. This scale is a popular quick and easy self-administered questionnaire that asks patients their likelihood of falling asleep in 8 situations ranked from 0 (would never doze) to 3 (high chance of dozing). The numbers are then added together to give a total score between 0 and 24. A value of 10 or below is considered normal. The 8 situations are as follows:

1. Sitting and reading
2. Watching TV
3. Sitting inactive in a public place, e.g., theater
4. As a passenger in a car for one hour without a break
5. Lying down to rest in the afternoon when circumstances permit
6. Sitting and talking to someone
7. Sitting quietly after a lunch without alcohol
8. In a car while stopped for a few minutes in traffic

Approved by: Medical Management Guideline Committee

Date Approved: 02/22/06
TITLE: Positron Emission Tomography (PET)/Combined PET-CT (Computed Tomography)

Authorized By: Medical Management Guideline Committee

Approval Date: 04/22/03 Revision Date: 07/22/03; 10/28/03; 11/23/04
11/22/05; 02/22/06

Disclaimer
This medical management guideline represents the recommendation of the PacifiCare Medical Management Guideline (MMG) committee. It is based on the MMG committee's review of the available evidence as of the date of this medical management guideline.

This medical management guideline contains clinical practice and utilization criteria to assist professionals in PacifiCare’s medical management practice when making medical necessity determinations prior to, subsequent to, or concurrent with the provisions of health care services. This medical management guideline is intended to support consistent, appropriate medical necessity determinations, but it does not replace an individualized case-by-case review and medical necessity determination for each PacifiCare member.

Member benefit coverage and limitations may vary based on the member’s benefit plan. Please consult with your local Medicare carrier to determine if a Local Coverage Determination is in place.

I. BACKGROUND

A. Description

PET
Positron emission tomography (PET) is a noninvasive radionuclide imaging technique that reflects tissue physiology by depicting the accumulation of a radiotracer. PET is used to depict the blood perfusion of tissue or the metabolism of malignant tumors. The radiotracers, such as fluorodeoxyglucose (FDG), are unstable radionuclides and decay by emission of a positively charged electron (positron). The emitted positron collides with an electron and produces 2 annihilation photons that radiate at an angle of 180 degrees and are registered by scanning devices. The computed evaluation displays the distribution of the radionuclide in the investigated areas three-dimensionally (Stuckensen et al, 2000;
Combined PET-CT
Combined positron emission tomography (PET)/computed tomography (CT) systems, also called hybrid PET/CT systems, merge PET and CT technology into one system to produce fused images that provide both functional and anatomic information (ECRI, 2005). Traditionally, both types of information was merged using visual fusion by having an expert review the PET and CT images separately and mentally synthesize the data (Griffith, 2005). Recently introduced, combined PET-CT scanners integrate both scanning techniques into a single device in one examination (Hayes, 2004; ECRI, 2005). An advantage of combined PET-CT systems is the ability to accurately localize increased FDG activity to specific normal or abnormal anatomic locations (Kapoor et al, 2004).

B. Benefit
Secure Horizons covers FDG-PET and/or combined PET-CT scans when determined to be medically necessary and specific criteria are met. See the Secure Horizons Benefit Interpretation Policy (BIP) Diagnostic and Therapeutic Radiology Services.

C. Local Carrier (Medicare) Determination
None

II. RECOMMENDATIONS

NOTE: Member benefit coverage and limitations may vary based on the member’s benefit plan. Refer to member specific Evidence of Coverage (EOC), Schedule of Benefits (SOB), or Certificate of Coverage (COC). If there is a discrepancy between this guideline and the member’s EOC/SOB/COC, the member’s EOC/SOB/COC provision will govern.

A. PET
For all uses of PET relating to malignancies or other specific conditions, refer to CMS criteria at the corresponding link: (CMS, 2006):

PET Scans

PET (FDG) for Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung, and Testicular Cancers
PET (FDG) for Breast Cancer

PET (FDG) for Colorectal Cancer

PET (FDG) for Dementia and Neurodegenerative Diseases

PET (FDG) for Esophageal Cancer

PET (FDG) for Head and Neck Cancers

PET (FDG) for Lung Cancers

PET (FDG) for Lymphoma

PET (FDG) for Melanoma

PET (FDG) for Myocardial Viability

PET (FDG) for Refractory Seizures

PET (FDG) for Soft Tissue Sarcoma

PET (FDG) for Thyroid Cancer

PET for Perfusion of the Heart

PET (FDG) for all Cancer Indications Not Previously Specified

B. Combined PET-CT

Combined PET (FDG)-CT scanning techniques used for oncologic indications listed above ARE recommended for the following (Hayes, 2004; Kapoor et al, 2004):

1. Staging and restaging cancer in patients with a diagnosis or history of cancer who are referred for imaging in patients with a blood glucose level of ≤ 130 mg/dL.

Combined PET (FDG)-CT scanning techniques ARE NOT recommended for the following (Hayes, 2004):
1. Diagnosing cancer or potential cancer in patients with SPN or identifying occult primary tumors in patients with metastases of unknown origin.
2. Monitoring anticancer treatment with any radiotracer.
3. For planning radiotherapy in cancer patients with any radiotracer.
4. For assessing MBF in patients with known or suspected CAD with any radiotracer.
5. For any purpose in patients with a blood glucose level of >130 mg/dL.
6. Evaluation of mild cognitive impairment
7. Evaluation of early dementia

III. STATE/MARKET APPLICATION CRITERIA
In applying this guideline, individual needs and an assessment of the local delivery system shall be considered.
• The following individual factors shall be considered: age, comorbidities, complications, progress of treatment, psychosocial situation, and home environment, when applicable.
• The following aspects of the local delivery system shall be considered: availability of local facilities and benefit coverage.

When utilization management guidelines cannot be applied appropriately, individual case discussions shall ensue.

IV. REFERENCES


V. APPENDIX/DEFINITIONS

Approved by: Medical Management Guideline Committee Date Approved: 02/22/06
I. BACKGROUND

A. Description

Pulmonary Rehabilitation
The American Thoracic Society (ATS) defines pulmonary rehabilitation (PR) as a multidisciplinary program of care for patients with chronic respiratory impairment that is individually tailored and designed to optimize physical and social performance and autonomy. It is designed to reduce and control symptoms experienced by patients with debilitating pulmonary disease and to teach the patients to maximize their ability to carry out activities of daily living (ADLs). PR is designed to assist with dyspnea control, instruct in breathing retraining and enhance functional capacity for ADLs, and to train patients to self-manage daily living skills within the limitations of their pulmonary disease (ATS 1999; Mutual...
According to the American College of Chest Physicians (AACP) and the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR), PR has been used primarily for patients with chronic obstructive pulmonary disease. However, it has also been applied successfully to patients with other chronic lung conditions such as interstitial disease, cystic fibrosis, bronchiectasis, thoracic cage abnormalities, and neuromuscular disorders. PR is also employed as part of the evaluation, preparation for, and recovery from surgical interventions such as lung transplantation (AACP/AACVPR 1997).

**Outpatient Pulmonary Rehabilitation**
Outpatient PR, which can be hospital-based or community-based, is currently the most widely available and, as such, has the potential to benefit the most patients. The outpatient setting may include an outpatient hospital based clinic, comprehensive outpatient rehabilitation facility, physician’s office, alternate or extended care facility, or the patient’s home (ATS 1999; American Association for Respiratory Care [AARC] 2002).

**Benefits of Pulmonary Rehabilitation**
The potential benefits of PR are to improve maximal exercise tolerance and endurance, improve symptoms of perceived breathlessness and muscle fatigue during exercise, reduce shortness of breath with daily activities, and improve walking distance. PR does not improve pulmonary function nor does it result in an increase in survival. The American Thoracic Society reports a reduction in hospital days as a result of PR. The duration of benefit from PR program is variable and may extend to 1 year (ATS 1999).

**Essential Components of Pulmonary Rehabilitation**
Comprehensive PR programs generally have 4 essential components (ATS 1999):

**Exercise training:**
Exercise training is the foundation of PR. Exercise has not resulted in measurable effects on the underlying respiratory impairment, however, the positive effects of exercise on dyspnea underscores the importance of physical deconditioning as a co-morbid factor in advanced lung diseases. Exercise training is based on the general principles of exercise physiology:

- **Intensity**
  Most PR programs emphasize endurance training targeted at 60% of the maximal work rate, for about 20-30 minutes, repeated 2-5 times a week. Generally, this training is well tolerated.
Specificity
The training specificity refers to the benefit gained only in those activities involving the specific muscle groups that are trained.

Reversibility
The reversibility of training effects is well known. The training effects are maintained only as long as exercise is continued. The efforts at improving long-term adherence with exercise training at home are necessary for the long-term effectiveness of PR.

Education
Patient education is an integral component of PR. Patient education can be provided in small groups or on an individual basis, depending on the needs of the patient, the site, the resources, and the design of the rehabilitation program. The educational needs of the patient are determined at the initial evaluation and are re-assessed during the program. The topics frequently incorporated into the PR programs are breathing retraining, energy conservation, proper use of medications and treatments, and end-of-life planning.

Psychosocial/behavioral intervention
Psychologic and behavioral problems such as anxiety, depression, difficulties in coping with chronic lung disease, and the inability to cope with illness contribute to the handicap of advanced respiratory disease. Psychosocial and behavioral interventions in the form of regular patient education sessions or support groups focusing on specific problems are intended to relieve these problems. Instructions in progressive muscle relaxation, stress reduction, and panic control may help reduce dyspnea and anxiety. Because of the effects of the chronic respiratory disease on the patient’s family, participation of family members or friends in the PR support groups is encouraged.

Outcome assessment
Outcome assessment is an important component of PR for determining the patient’s responses and for evaluating the overall effectiveness of the program. Evaluation of the program serves as a tool for quality improvement.

B. Benefit
Secure Horizons covers pulmonary rehabilitation when determined to be medically necessary and specific criteria are met. See the Secure Horizons Benefit Interpretation Policy (BIP) Respiratory Therapy Services.
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C. Local Carrier (Medicare) Determination
Medicare coverage for pulmonary rehabilitation is determined by Fiscal Intermediaries. Please see “RECOMMENDATIONS” below for exclusion/inclusion criteria.
Detailed coverage information can be found at the following Fiscal Intermediary link (coverage for all states except NY) http://www.mutualmedicare.com/lmrp/final.html.

II. RECOMMENDATIONS

NOTE: Member benefit coverage and limitations may vary based on the member’s benefit plan. Refer to member specific Evidence of Coverage (EOC), Schedule of Benefits (SOB), or Certificate of Coverage (COC). If there is a discrepancy between this guideline and the member’s EOC/SOB/COC, the member’s EOC/SOB/COC provision will govern.

A. Pulmonary Rehabilitation (PR) Services

PR services ARE recommended for members who meet ALL of the following ( Mutual of Omaha, 2005):

1. Diagnosis of a chronic, but stable, respiratory system impairment that is under optimal medical management.
2. Patient should be medically stable and not limited by another serious or unstable medical and/or mental condition
3. Pulmonary Function Tests (PFTs) revealing Forced Vital Capacity (FVC), Forced Expiratory Volume in one second (FEV1), or Diffusing Lung Capacity for Carbon Monoxide (DLCO) (uncorrected for volume) <65% of predicted normal within one year prior to initiating PR.
4. Patients must have initial monitored exercise with pulse oximeter and ECG to observe for oxygen desaturation or arrhythmias. Oxygen, if needed, may be titrated during exercise.
5. Exhibit disabling symptoms which significantly impair the patient’s level of functioning.
6. Expectation of measurable improvement in a reasonable and predictable timeframe.
7. Be physically able, motivated and willing to participate in PR.

PR is NOT recommended for the following (ATS 1999; Mutual of Omaha, 2005):

1. Patients with conditions that might interfere with their rehabilitative process such as advanced arthritis, the inability to learn, or disruptive behavior
2. Patients with conditions that might place them at undue risk during exercise
training such as severe pulmonary hypertension, unstable angina, or recent myocardial infarction
3. Patients who continue to smoking or engage in substance abuse without desire to cease use or who refuse a smoking cessation program
4. A patient who would be expected to spontaneously return to his/her prior level of function without skilled therapeutic intervention.
5. Services for maintenance of a chronic baseline condition or functional level.
6. Patients where documentation does not support measurable benefit.
7. Patients who are unable or unwilling to use training.

B. Indications for referral (AARC, 2002):

The common indications for referral to a PR program include the presence of respiratory impairment potentially responsive to the PR techniques available. Such impairments include:

1. Dyspnea experienced during rest or exertion
2. Hypoxemia, Hypercapnia
3. Reduced exercise tolerance or a decline in the patient's ability to perform activities of daily living
4. Unexpected deterioration or worsening of symptoms against a background of long-standing dyspnea and a reduced but stable exercise tolerance level
5. Need for surgical intervention (pre- and postoperative lung resection, transplantation)
6. Chronic respiratory failure and the need to initiate mechanical ventilation
7. Increasing need for acute care intervention, including emergency room visits, hospitalizations and unscheduled physician office visits

The following are examples of diagnoses that support medical necessity for a referral to a PR program:
- Chronic bronchitis
- Emphysema
- Bronchiectasis
- Chronic obstructive pulmonary disease
- Pulmonary fibrosis
- Interstitial lung disease
- History of adult respiratory distress syndrome

C. Duration

The duration of outpatient PR program for SH members should not exceed 12 weeks
and may be accomplished in less time. Services beyond 12 weeks will be reviewed on an individual basis (Mutual of Omaha, 2005). Most patients who have completed a PR program in the past 2 years should not require another full PR program. Such cases should be considered on an individual basis through prior-authorization Home self-monitored exercises should continue after the formal program, but do not require skilled supervision or monitoring.

D. Required Documentation

PR should be individualized to a patient’s specific needs, furnished under a written plan of treatment with measurable goals and time frames, and established by the physician or therapist caring for the patient. All orders/plans for PR must specify the type, frequency, and duration of activity. A generic PR order is not acceptable.

The medical record documentation must include the following:
1. Comprehensive pulmonary evaluation including history and physical
2. Documentation supporting that patient meets the medical necessity coverage criteria
3. Individualized plan of care specific to the patient’s needs including measurable goals, treatment modalities, services and duration
4. Documentation of each pulmonary session reflecting the services provided
5. Multi-disciplinary assessment every 2 weeks documenting the patient’s progress and updated plan of care

III. STATE/MARKET APPLICATION CRITERIA

In applying this guideline, individual needs and an assessment of the local delivery system shall be considered.

- The following individual factors shall be considered: age, comorbidities, complications, progress of treatment, psychosocial situation, and home environment, when applicable.
- The following aspects of the local delivery system shall be considered: availability of local facilities and benefit coverage.

When utilization management guidelines cannot be applied appropriately, individual case discussions shall ensue.

IV. REFERENCES


2. American College of Chest Physicians (ACCP) and the American Association of


V. APPENDIX/DEFINITIONS
I. BACKGROUND

A. Description
Scanning laser glaucoma testing (SLGT) includes confocal scanning laser ophthalmoscopy and polarimetry. Both imaging methods are used for the evaluation of the retinal nerve fiber layer and the optic nerve head. As it has been shown that damage to the retinal nerve fiber layer and optic nerve head often precede visual field loss, SLGT may facilitate the diagnosis and monitoring of glaucoma (Zangwill et al, 2001).

Confocal scanning laser ophthalmoscopy is based on spot illumination and spot detection. The confocal optical systems illuminate only one spot of the retina at a time while eliminating out-of-focus scattered light (Schuman and Kim, 2000). These systems allow for layer-by-layer imaging within the retina and create a 3-dimensional map of the topography of the optic disc (Kesen et al, 2002). Examples
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of confocal scanning laser ophthalmoscopy devices include the Heidelberg Retina Tomograph (HRT) (Heidelberg Engineering, Carlsbad, California), the Zeiss Confocal Scanning Ophthalmoscope (Carl Zeiss, Inc., Princeton, New Jersey), and the Topographic Scanning System (TopSS) (Laser Diagnostic Technologies, Inc., San Diego, California).

Confocal scanning laser polarimetry measures the retinal nerve fiber layer thickness using 780nm near-infrared diode polarized light (Schuman and Kim, 2000). This technique measures the retardation of light that has double-passed the birefringent fibers of the retinal nerve fiber layer (Zangwill et al, 2001). The mechanism of confocal scanning laser polarimetry is based on the fact that the microtubules of the retinal nerve fiber layer, which are predominantly parallel, cause a change in the state of polarization of the light, called retardation, which is related to the thickness of the retinal nerve fiber layer. The reflected light is analyzed and displayed in the form of pixels representing the degree of retardation (Schuman and Kim, 2000). One device used in confocal scanning laser polarimetry is the GDx Nerve Fiber Analyzer (Laser Diagnostic Technologies, Inc., San Diego, California).

Glaucoma represents a group of optic neuropathies characterized by the development of visual field defects and visible optic nerve changes. These optic neuropathies are often classified as primary open angle glaucoma (POAG; the most common type of glaucoma), secondary open angle glaucoma, primary angle-closure glaucoma (PACG), secondary angle-closure glaucoma, congenital glaucoma, and juvenile glaucoma (Coleman and Wilson, 2000). The diagnosis of glaucoma is typically based on measurements of intraocular pressure, visual field analysis, and evaluations of the optic nerve head (Schuman and Kim, 2000). The most common type of glaucoma in the United States is POAG, with an estimated 2.2 million cases among Americans over the age of 40 years. The condition is more common in African and Hispanic Americans than in Caucasians (Prevent Blindness America/National Eye Institute, 2002).

POAG is characterized by glaucomatous optic nerve damage and visual field loss in the presence of open and normal-appearing anterior chamber angles. The condition has an adult onset, is typically bilateral, and has no symptoms until the disease has progressed and central vision loss has occurred. Although no definite cause-and-effect relationship has been established, elevated intra-ocular pressure is generally accepted as one of the most important risk factors for developing POAG (Coleman and Wilson, 2000). Characteristic changes in the optic nerve head include increased cupping or excavation, notching, thinning of the neuroretinal rim, disc hemorrhages, asymmetry of the amount of optic-nerve
c cupping between the 2 eyes of the patient, and loss of the retinal nerve fiber layer. The appearance of the optic nerve head is often described via the cup-to-disc ratio, which expresses the size of the cup as a proportion of the size of the optic nerve head (Coleman 1999).

PACG may or may not involve optic nerve damage. This condition is characterized by the closure of the anterior chamber angle due to relative pupillary block, which is the obstruction of the trabecular meshwork by the peripheral iris. Due to the inability of the aqueous humor to pass easily into the anterior chamber, the iris is bowed forward, which then obstructs the trabecular meshwork. PACG can occur as acute attacks characterized by elevated intra-ocular pressure, a mid-dilated pupil, a red eye, and nausea and vomiting (Coleman and Wilson, 2000).

B. Benefit

Secure Horizons covers SLGT when determined to be medically necessary and specific criteria are met. See the Secure Horizons Benefit Interpretation Policy (BIP) Vision Care and Services.

C. Local Carrier (Medicare) Determinations:
Medicare coverage for Scanning Laser Glaucoma Testing is determined by Local Carriers. Please see “RECOMMENDATIONS” below for exclusion/inclusion criteria. Detailed coverage information can be found at the following local carrier link. CO, AZ, WA, OR, NV: www.noridianmedicare.com/provider/pubs/med_b/policy/final/11state/b2005_10.html

II. RECOMMENDATIONS

NOTE: Member benefit coverage and limitations may vary based on the member’s benefit plan. Refer to member specific Evidence of Coverage (EOC), Schedule of Benefits (SOB), or Certificate of Coverage (COC). If there is a discrepancy between this guideline and the member’s EOC/SOB/COC, the member’s EOC/SOB/COC provision will govern.

SLGT as used below includes confocal laser scanning ophthalmoscopy (topography) and scanning laser polarimetry – nerve fiber analysis (Noridian 1998a and 1998b).

SLGT IS recommended for the early detection of glaucoma as follows (Noridian 1998a and 1998b):

1. One SLGT per year for glaucoma suspect patients or those with “mild damage”.

Scanning Laser Glaucoma Testing – Secure Horizons
2. One or two SLGTs per year for patients with “moderate damage”.
   
a. Patients with “moderate damage” may be followed with SGLT or visual field testing. If both tests are performed, only one each per year is recommended.

SLGT **IS NOT** recommended for the following:

1. Patients with “advanced damage.” For these patients, visual field testing is the preferred method.

2. To further validate a diagnosis that has already been confirmed by another information set, such as visual field testing.

3. Testing in the absence of glaucoma suspicion, mild damage, or moderate damage.

*Note:* See “APPENDIX/DEFINITIONS” for corresponding definitions.

### III. STATE/MARKET APPLICATION CRITERIA
In applying this guideline, individual needs and an assessment of the local delivery system shall be considered.

- The following individual factors shall be considered: age, comorbidities, complications, progress of treatment, psychosocial situation, and home environment, when applicable.
- The following aspects of the local delivery system shall be considered: availability of local facilities and benefit coverage.

When utilization management guidelines cannot be applied appropriately, individual case discussions shall ensue.

### IV. REFERENCES


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V. APPENDIX/DEFINITIONS

Definitions (Noridian 1998a and 1998b):

1. Glaucoma suspect or mild damage:
Any or all of the following:
   a) Intraocular pressure >22mm Hg as measured by applanation
   b) Symmetric or vertically elongated cup enlargement, neural rim intact, cup/disc ratio >0.4
   c) Focal optic disc notch
   d) Optic disc hemorrhage or history of optic disc hemorrhage
   e) Nasal step or small paracentral or arcuate scotoma
   f) Mild constriction of visual field isopters

2. Moderate glaucomatous damage:
Any or all of the following:
   a) Enlarged optic cup with neural rim remaining but sloped or pale, cup to disc ratio >0.5 but <0.9
   b) Definite focal notch with thinning or the neural rim
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c) Definite glaucomatous visual field defect, e.g., arcuate or paracentral scotoma, nasal step, pencil wedge, or constriction of isopters

3. Advanced glaucomatous damage:
Any or all of the following:
  a) Severe generalized constriction of isopters (i.e., Goldmann I4<10 degrees of fixation
  b) Absolute visual field defects within 10 degrees of fixation
  c) Severe generalized reduction of retinal sensitivity
  d) Loss of central visual acuity, with temporal island remaining
  e) Diffuse enlargement of optic nerve cup, with cup to disc ratio >0.8
  f) Wipe-out of all or a portion of the neural retinal rim

Approved by: Medical Management Guideline Committee  Date Approved: 02/22/06
Medical Management Guideline

TITLE: Skilled Nursing Facility (SNF) Level Selection for Patient Referral

Authorized By: Medical Management Guideline Committee

Approval Date: 10/22/02 Revision Date: 12/11/03
11/23/04
11/22/05
02/22/06

Disclaimer
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This medical management guideline contains clinical practice and utilization criteria to assist professionals in PacifiCare’s medical management practice when making medical necessity determinations prior to, subsequent to, or concurrent with the provisions of health care services. This medical management guideline is intended to support consistent, appropriate medical necessity determinations, but it does not replace an individualized case-by-case review and medical necessity determination for each PacifiCare member.

Member benefit coverage and limitations may vary based on the member’s benefit plan. Please consult with your local Medicare carrier to determine if a Local Coverage Determination is in place.

I. BACKGROUND

A. Description
A Skilled Nursing Facility (SNF) is a specially qualified, Medicare/Medicaid licensed and accredited facility that specializes in skilled care. A SNF has the staff and equipment to provide skilled nursing care and/or skilled rehabilitation services, and other related health services.

Skilled services and/or skilled rehabilitation services are services that are rendered under physician orders, require the skills of qualified technical or professional health personnel such as RNs, LVNs/LPNs, and/or therapists (physical, occupational, speech pathologists or audiologists), and must be

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provided directly by or under the supervision of these skilled nursing or skilled rehabilitation personnel. These services include but are not limited to (PacifiCare Ancillary Services Agreement 2005):

- **Physical Therapy** is the primary treatment for which an inpatient unit is required. Inability to transfer or ambulate due to paralysis, weakness or amputation are the usual indications. While the basic goal is independent ambulation at home, more limited goals such as the ability to transfer to a wheelchair, may be necessary.

- **Occupational Therapy**, though often needed and provided in the multidisciplinary program, never requires an inpatient rehabilitation unit except for cognitive deficits and training. The service is intended to address the upper extremity, activities of daily living, functional or vocational training, and can be provided in an outpatient setting.

- **Speech-language pathology services** require an inpatient rehabilitation unit only for inability to swallow and swallowing training. Cognitive deficits and training are often associated with a need for an inpatient rehabilitation unit. Other speech impairment treatments can be provided in an outpatient setting. When cognitive or swallowing training is necessary, it should be provided at least twice a day.

B. **Benefit**

PacifiCare’s SNF benefit may have specific limitations depending on the member’s employer group benefit package. See the Secure Horizons Benefit Interpretation Policy (BIP) Skilled Nursing Facility (SNF) Care.

C. **Local Carrier (Medicare) Determination**

None

II. RECOMMENDATIONS

**NOTE**: Member benefit coverage and limitations may vary based on the member’s benefit plan. Refer to member specific Evidence of Coverage (EOC), Schedule of Benefits (SOB), or Certificate of Coverage (COC). If there is a discrepancy between this guideline and the member’s EOC/SOB/COC, the member’s EOC/SOB/COC provision will govern.

A. **Patient Selection Criteria**
Care in a SNF is recommended if ALL of the following 3 factors are met (CMS, 2005):

1. The patient requires skilled nursing services or skilled rehabilitation services (i.e., services that must be performed by or under the supervision of professional or technical personnel)

2. The patient requires these skilled services on a daily basis. However, if skilled rehabilitation services are not available on a 7-day-a-week basis, a patient whose inpatient stay is based solely on the need for skilled rehabilitation services would meet the "daily basis" requirement when he needs and receives those services on at least 5 days a week. Accordingly, if a facility provides physical therapy on only 5 days a week and a patient in the facility requires and receives physical therapy on each of those days, the requirement that skilled rehabilitation services be provided on a daily basis is met. (If the services are available less than 5 days a week, though, the "daily" requirement would not be met.)

3. As a practical matter, considering economy and efficiency, the daily skilled services can be provided only on an inpatient basis in an SNF (the services must be furnished pursuant to a physician’s orders and be reasonable and necessary for the treatment of a patient’s illness or injury). As a "practical matter," daily skilled services can be provided only in an SNF if they are not available on an outpatient basis in the area in which the individual resides or transportation to the closest facility would be:
   1) An excessive physical hardship;
   2) Less economical; or
   3) Less efficient or effective than an inpatient institutional setting

*Note: The availability at home of capable and willing family or the feasibility of obtaining other assistance for the patient should be considered. Even though needed daily skilled services might be available on an outpatient or home care basis, as a practical matter, the care can be furnished only in the SNF if home care would be ineffective because the patient would have insufficient assistance at home to reside there safely.

B. Referral to Appropriate Level of Service
There are 4 levels of skilled care defined in PacifiCare’s standard contract language with SNF facilities (PacifiCare Ancillary Services Agreement 2005). Patients should be referred based on their needs for care and service.

*Note: A patient/member must first meet all the criteria for SNF care outlined above before a level of SNF coverage is determined.
1. Level 1 – Skilled Nursing Care
   Patients who meet all the above patient selection criteria for SNF care AND require ANY OF the following:
   a) Routine oral or Injectable drug administration
   b) Post-surgical patient training/education
   c) Bowel and bladder training
   d) Administration of insulin and training of newly diagnosed insulin dependent diabetic; administration of insulin dependent sliding scale insulin
   e) Nasogastric tube, gastrostomy or jejunostomy care including feedings
   f) Colostomy/ileostomy care during early postoperative period
   g) Foley catheter care with daily irrigation
   h) Stable tracheotomy care
   i) Wound Care of a Stage I-II decubitus ulcer(s), widespread skin disorder or post surgical dressing, two times daily (BID) in addition to any of the services above

2. Level 2 – Rehabilitation Skilled Nursing Care
   Patients who meet the patient selection criteria for SNF care, requiring service in Level 1 AND ANY of the following:
   a) New tracheostomy care requiring suctioning at a frequency of Q2 hours or less and mist treatment
   b) Continuous oxygen (3 liters/minute or more)
   c) Pulse oximetry
   d) Postural drainage and percussion
   e) New colostomy/ileostomy care
   f) Intravenous hydration
   g) Administration of 1 intravenous antibiotic up to 4 times daily
   h) Combined physical, occupational and/or speech-language pathology services for 1.5 to 2 hours per day, 6 days per week
   i) Wound care of a Stage II decubitus ulcer(s), widespread skin disorder or post-surgical dressing, at least 3 times per day in addition to any of the services above

3. Level 3 – Extensive Skilled Nursing Care
   Patients who meet the coverage criteria for SNF care, requiring service in Level 1 and Level 2 AND ANY of the following:
   a) Intravenous medication administration
   b) Total parenteral nutrition and lipid administration
   c) New tracheostomy care requiring suctioning and mist treatment more than
twice per day

d) Administration of 2 intravenous antibiotics up to four times daily
e) Combined physical, occupational and/or speech-language pathology services for 2.5 to 3 hours per day, 6 days per week
f) Isolation care (excluding universal precautions)
g) Wound Care of a Stage III-IV decubitus ulcer(s), widespread skin disorder or post surgical dressing, 3 or 4 times daily (TID/QID)

4. **Level 4 – Ventilator/Sub-Acute Care**

Patients who meet the coverage criteria for SNF care, requiring service in Levels 1-3 **AND ANY** of the following:

a) Ventilator care
b) Continuous oxygen/humidification over the tracheostomy site
c) Physical, occupational and/or speech-language pathology services three (3) or more hours per day, 6 days per week

C. **Location of Care and Services**

Inpatient skilled care and services are provided in a Medicare certified bed and a PacifiCare contracted SNF (PacifiCare Ancillary Services Agreement 2005). Covered services include, but are not limited to:

1. Semi-private room (private room if medically necessary)
2. Meals (regular and special dietary needs)
3. 24-hour nursing care (RN, LVN, CNA)
4. Medications and pharmacy supplies including administration
5. Respiratory and oxygen supplies and services (nursing or respiratory therapist performs treatment)
6. Nutrition services, including enteral nutrition
7. Administration of medications (oral, intramuscular, subcutaneous and intravenous)
8. Laboratory services
9. X-ray services
10. Medical/in-house supplies
11. Nursing supplies
12. Speech-language pathology services, occupational, and/or physical therapy including evaluations
13. Discharge planning, social services and case management
14. Durable medical equipment (DME)
15. Specialized Beds (i.e., Clinitron and floatation beds)
16. Total parenteral nutrition solutions
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17. Prosthetics and orthotics (including custom made)
18. Blood, blood products and supplies
19. Hemodialysis, peritoneal dialysis and supplies
20. CT and MRI scan
21. Third generation antibiotic medications

III. STATE/MARKET APPLICATION CRITERIA
In applying this guideline, individual needs and an assessment of the local delivery system shall be considered.
- The following individual factors shall be considered: age, comorbidities, complications, progress of treatment, psychosocial situation, and home environment, when applicable.
- The following aspects of the local delivery system shall be considered: availability of local facilities and benefit coverage.

When utilization management guidelines cannot be applied appropriately, individual case discussions shall ensue.

IV. REFERENCES

V. APPENDIX/DEFINITIONS

Approved by: Medical Management Guideline Committee  Date Approved: 02/22/06
TITLE: Treatment of Temporomandibular Joint Disorders

Authorized By: Medical Management Guideline Committee

Approval Date: 10/28/03  Revision Date: 08/24/04
09/01/05

Disclaimer
This medical management guideline represents the recommendation of the PacifiCare Medical Management Guideline (MMG) committee. It is based on the MMG committee’s review of the available evidence as of the date of this medical management guideline.

This medical management guideline contains clinical practice and utilization criteria to assist professionals in PacifiCare’s medical management practice when making medical necessity determinations prior to, subsequent to, or concurrent with the provisions of health care services. This medical management guideline is intended to support consistent, appropriate medical necessity determinations, but it does not replace an individualized case-by-case review and medical necessity determination for each PacifiCare member.

Member benefit coverage and limitations may vary based on the member’s benefit plan. Please consult with your local Medicare carrier to determine if a Local Coverage Determination is in place.

A. BACKGROUND

1. Description
Temporomandibular disorders (TMDs) comprise the disorders relating to the temporomandibular joint (TMJ) and/or the masticatory muscles (see Appendix I for details). Although the biological concept of the pathological condition of disc displacement (internal derangement) with typically coexisting osteoarthritis of the TMJ emphasizes these conditions as the underlying mechanism in the pathogenesis of TMJ-related pain and dysfunction, the relationship and interdependence of these conditions to the development of pain and dysfunction remains a controversy. Internal derangement with coexisting osteoarthritis is considered to be the most common reason for surgical treatment of the TMJ. Internal derangement has been defined as a localized mechanical fault of the joint, which interferes with its smooth action. The coexisting osteoarthritis has been
defined as a non-inflammatory disorder of a movable joint characterized by
deterioration and abrasion of the articular connective tissues and also by the
formation of new bone at the articular surfaces. Some of these changes may be
adaptive rather than degenerative or maladaptive. The American Society of
Temporomandibular Joint Surgeons and The American Society of Maxillofacial
Surgeons estimate the prevalence of internal derangement at approximately 8% among
asymptomatic children and adolescents (mean age, 11 years) and at
approximately 30% among asymptomatic adults. Among symptomatic patients
with TMJ pain, internal derangement is estimated to be present 80% to 90% of the
time but only a small and yet-to-be-determined fraction of patients with internal
derangement and osteoarthritis become sufficiently symptomatic to seek
treatment. In addition, patients with pain in the masticatory muscles may present
with referred pain in the TMJ region, even though the TMJ is not involved.
According to the American Society of Temporomandibular Joint Surgeons and the
American Society of Maxillofacial Surgeons, the average age of patients seeking
surgical care is around 30 years of age (Emshoff et al, 2002; Hall et al, 2001; Goss
1993).

Internal derangement can be divided into painless incoordination, anterior disc
displacement with reduction, and anterior disc displacement without reduction. In
painless incoordination, there is a momentary catching sensation during mouth
opening. In anterior disc displacement with reduction, the displaced disc is
recaptured into the normal position during mouth opening, which is characterized
by a clicking or popping sound. In anterior disc displacement without reduction,
the disc remains anteriorly displaced on attempted mouth opening, resulting in
restriction of jaw movement, or locking (Laskin 2001; Montgomery 2000).

Clinically, patients with internal derangement and coexisting osteoarthritis present
with pain in the preauricular region of the TMJ, headaches behind and around the
eyes, and pain radiating from the joint to the temple, ears, side of the neck, and
upper shoulder. The pain is typically aggravated by joint activities, such as
chewing or clenching, and the TMJ, masticatory muscles, sternocleidomastoid
muscle, and trapezius muscle are often tender to palpation. Patients often
experience clicking, popping, or locking caused by disc interference, which results
in reflex masticatory muscle spasm. Although a clicking sound in the TMJ also
occurs frequently in the healthy population, the sound is highly correlated with
disc displacement with reduction. Internal derangement may be classified using
the Wilkes staging system (see Appendix II for details), which is based on the
progression of gross pathology of internal derangement and osteoarthritis in the
joint and is used for diagnosis and for predicting treatment outcomes (Hall et al,
2001; Montgomery 2000).
Evaluation and diagnosis of TMJ disorders are usually based on history and physical examination as well as imaging studies. The American Society of Temporomandibular Joint Surgeons and the American Society of Maxillofacial Surgeons generally recommend bilateral imaging studies because of the high incidence of bilateral joint disease. Basic screening radiographs are used to show temporal bone and condylar morphology, while the disc and soft tissue structures may be imaged with magnetic resonance imaging (MRI) and, in selected cases, arthrography. In addition, computed tomography (CT) can provide information on bone abnormalities, such as ankylosis, dysplasias, growth abnormalities, fractures, and osseous tumors. In some cases, isotope bone scans may be used to provide information on metabolic activity and inflammation. In the evaluation of TMJ conditions other than internal derangement and osteoarthritis, such as rheumatoid arthritis, laboratory tests may also be indicated (Hall et al, 2001).

2. Benefit
Secure Horizons covers the treatment of TMJ disorders when determined to be medically necessary and specific criteria are met. See the Secure Horizons Benefit Interpretation Policy (BIP) Temporomandibular Joint (TMJ) Disorders.

B. RECOMMENDATIONS

NOTE: Member benefit coverage and limitations may vary based on the member’s benefit plan. Refer to member specific Evidence of Coverage (EOC), Schedule of Benefits (SOB), or Certificate of Coverage (COC). If there is a discrepancy between this guideline and the member’s EOC/SOB/COC, the member’s EOC/SOB/COC provision will govern.

In the treatment of disorders of the TMJ and related structures, treatment efforts are directed towards the following (Hall et al, 2001):

• Reduction of pain
• Improvement of dysfunction
• Slowing the progression of internal derangement and osteoarthritis

1. Nonsurgical treatment
Non-surgical treatment is recommended for all patients with symptomatic internal derangement with coexisting osteoarthritis. Most patients experience symptom improvement with conservative treatment. Therefore, the vast majority of TMD
patients should receive initial management with noninvasive and reversible therapies (Hall et al, 2001; NIH 1996).

Non-surgical treatment options include the following:

a. **Pharmacological agents** (Hall et al, 2001; NIH 1996)
   - Non-opiate and non-steroidal anti-inflammatory drugs (NSAIDs)
   - Low-dose tricyclic antidepressants to control pain from nighttime bruxism
   - Muscle relaxant medications
   - Antidepressant medication if clinical depression is an aggravating factor

b. **Maxillomandibular appliances**
   - Occlusal splints, orthotics, and bite guards (Hall et al, 2001)

Note: Other dental treatments, such as occlusal equilibrations, extensive dental restoration, or orthodontic treatments are not recommended as primary treatment (Hall et al).

c. **Physical therapy**
   Physical therapy for TMJ disorders may include the following (Clark et al, 1990):
   - Exercise therapy
   - Heat and cold therapy
   - Ultrasound treatment
   - Electrical stimulation

d. **Injections**
   - Injections of tender muscles, trigger areas, and/or joint spaces with local anesthetic solution for diagnosis and symptom relief (Hall et al, 2001)
   - Corticosteroid injections to reduce capsulitis (Hall et al, 2001)
   - Sodium hyaluronate (3 to 5 injections over 3 to 5 weeks, single course therapy) for symptom relief (HAYES 2004)

Note: Intracapsular injections of steroids should not be used routinely since they can cause condylar necrosis. Generally, 1 to 2 injections per joint over a lifetime should not be exceeded.
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e. **Behavior modification** (may only be covered if member has supplemental behavioral health benefit) (Hall et al, 2001; NIH 1996)
   - To avoid stress-related lifestyle habits, such as clenching and bruxism
   - Psychological consultation for stress management may be indicated

f. **Diet**
   - Non-chewing diet (liquid or pureed) to reduce joint loading from forces of mastication (Hall et al, 2001)

2. **Surgical Treatment**
Surgical treatment is recommended for carefully selected patients with documented internal derangement/osteoarthritis in whom severe pain and dysfunction persist after a trial of nonsurgical therapy. Most patients experience symptom improvement with conservative treatment. Therefore, the vast majority of TMD patients should receive initial management with noninvasive and reversible therapies. It is recommended that non-surgical treatment options be tried for a minimum of 1 to 6 months, depending on the severity of the symptoms and findings. Early surgical consultation is recommended particularly in cases of closed lock, where delay in treatment may accelerate the progression of internal derangement/osteoarthritis. Surgery should not be performed unless imaging studies have demonstrated derangement or pathologic condition amenable to surgery (Hall et al, 2001; NIH 1996; Goss 1993a; Goss 1993b).

Surgical treatment options include the following:

a. **Arthrocentesis**
Arthrocentesis represents a minimally invasive procedure involving puncture of the TMJ with intra-articular, non-arthroscopic irrigation (lavage) and lysis. The procedure allows for simultaneous tissue sampling and injection with therapeutic agents (Nitzan and Price, 2001; Nitzan 2003).
Arthrocentesis is considered to be the initial surgical therapy of choice. The technique has limitations in that it does not allow direct visualization and lysis of significant adhesions. Complications include bleeding into joint and the potential of scarring of articular surfaces during needle stick to access superior cavity.
Arthrocentesis is recommended for patients meeting the following criteria (Nitzan and Price, 2001):
- Pain at TMJ
- Limited maximal mouth opening with impeded lateral movement
- Unresponsive to non-surgical treatment for at least 1 month

b. Arthroscopy
Arthroscopy of the TMJ involves visualization of the superior joint space as well as lysis and lavage to release adhesions that may have formed secondary to macro- or microtrauma. Cautery of the posterior ligament may also be performed as part of arthroscopic treatment (Kryshtalskyj and Weinberg, 1996). Significant arthritic changes may preclude the arthroscopic approach (Gynther and Holmlund, 1998; Hase 2002; Reston and Turkelson, 2003).

Arthroscopy is recommended for patients meeting the following criteria:
- Severe pain or dysfunction caused by intra-articular pathology of the TMJ with joint space remaining (Israel 1999)
- No or mild arthritis of the TMJ (Gynther and Holmlund, 1998)
- Failed non-surgical treatment for up to 6 months (White 2003)

Note: A temporomandibular disorder secondary to acute trauma or acute closed lock (painful limited jaw opening) may require earlier intervention: (Hall et al, 2001).

c. Arthrotomy/Arthroplasty
Several types of arthrotomy procedures exist, including arthrotomy with discoplasty, condylectomy, or arthroplasty (Fricton et al, 2002). Arthrotomy/arthroplasty may include lysis of adhesions, disc repositioning and repair (discoplasty), retrodiscal ligament resection. Arthrotomy/arthroplasty is deemed appropriate when the disc is displaced but maintains a favorable morphology. Total collapse of the joint space, severe degenerative disease of the condyle and fossa, or a large disc perforation often indicate disease severe enough to require discectomy rather than arthroplasty (Goss 1993a).
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Arthrotomy/arthroplasty is recommended for patients meeting the following criteria:

- Severe pain or dysfunction caused by intra-articular pathology of the TMJ with no joint space remaining (e.g., extensive osteoarthritis) (Israel 1999)
- Failed non-surgical treatment for up to 6 months (White 2003)
- Failed minimally invasive procedures (e.g., arthrocentesis and arthroscopic lysis/lavage) (Kryshtalskyj and Weinberg, 1996)
- A thorough investigation as to why the symptoms have continued concludes extensive intra-articular pathology is the cause. The recurrence or persistence of symptoms after arthroscopic surgery is usually caused by failure to control the etiologic factors. Surgery will fail if causative factors, such as stress, muscle disorders, bruxism, and clenching are not managed adequately (Israel 1999)

Note: Alloplastic implants are not recommended for initial surgical treatment of joints with internal derangement/osteoarthritis. Prosthetic joint replacement may be indicated in cases of severe joint degeneration, destruction, or ankylosis (Hall et al, 2001; NIH 1996).

e. Other procedures
   Other surgical procedures include the following (Hall et al, 2001):
   - Condylotomy (indirect arthroplasty)
   - Coronoidotomy/coronoidectomy
   - Styloidectomy (for Eagle’s syndrome)
   - Procedures for recurrent dislocation

   Note: These procedures are performed less frequently and their appropriateness for an individual patient needs to be considered on a case-by-case basis.

C. STATE/MARKET APPLICATION CRITERIA
   In applying this guideline, individual needs and an assessment of the local delivery system shall be considered.
   - The following individual factors shall be considered: age, comorbidities, complications, progress of treatment, psychosocial situation, and home environment, when applicable.
• The following aspects of the local delivery system shall be considered: availability of local facilities and benefit coverage.

When utilization management guidelines cannot be applied appropriately, individual case discussions shall ensue.

D. REFERENCES


Available at http://consensus.nih.gov/ta/018/018_statement.htm


Appendix I

Temporomandibular (TMJ) and Related Musculoskeletal Disorders: Classification (Hall et al, 2001)

I. Intra-articular (Intracapsular) Pathology

A. Articular Disc
   1. Displacement
   2. Deformity
   3. Adhesions
   4. Degeneration
   5. Injury
   6. Perforation
   7. Anomalous development

B. Disc Attachments
   1. Inflammation
   2. Injury (laceration, hematoma, contusion)
   3. Perforation
   4. Fibrosis
   5. Adhesions

C. Synovium
   1. Inflammation/effusion
   2. Injury
   3. Adhesions
   4. Synovial hypertrophy/hyperplasia
   5. Granulomatous inflammation
   6. Infection
   7. Arthritides (rheumatoid, degenerative)
   8. Synovial chondromatosis
   9. Neoplasia

D. Articular Fibrocartilage
   1. Hypertrophy/hyperplasia
   2. Degeneration (chondromalacia)
      a. Fissuring
      b. Fibrillation
      c. Blistering
      d. Erosion
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E. Mandibular condyle and glenoid fossa (see also Musculoskeletal)
   1. Osteoarthritis (osteoarthritis, degenerative joint disease)
   2. Avascular necrosis (osteonecrosis)
   3. Resorption
   4. Hypertrophy
   5. Fibrous and bony ankylosis
   6. Implant arthropathy
   7. Fracture/dislocations

II. Extra-articular (Extracapsular Pathology)

A. Musculoskeletal
   1. Bone (temporal, mandible, styloid)
      a. Anomalous development (hypoplasia, hypertrophy, malformation, ankylosis)
      b. Fracture
      c. Metabolic disease
      d. Systemic inflammatory disease (connective tissue/arthritides)
      e. Infection
      f. Dysplasias
      g. Neoplasia

   2. Masticatory muscles and tendons
      a. Anomalous development
      b. Injury
      c. Inflammation
      d. Hypertrophy
      e. Atrophy
      f. Fibrosis, contracture
      g. Metabolic disease
      h. Infection
      i. Dysplasias
      j. Neoplasia
      k. Fibromyalgia

B. Central nervous system/peripheral nervous system
   1. Reflex sympathetic dystrophy
Appendix II

Staging of Internal Derangement of TMJ (Hall et al, 2001)

<table>
<thead>
<tr>
<th>Stage</th>
<th>Clinical</th>
<th>Imaging</th>
<th>Surgical</th>
</tr>
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<tbody>
<tr>
<td>I</td>
<td>Early</td>
<td>Painless clicking</td>
<td>Slightly forward disc, reducing*</td>
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<tr>
<td></td>
<td></td>
<td>No restricted motion</td>
<td>Normal osseous contours</td>
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<tr>
<td>II</td>
<td>Early/intermediate</td>
<td>Occasional painful clicking</td>
<td>Slightly forward disc, reducing*</td>
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<tr>
<td></td>
<td></td>
<td>Intermittent locking</td>
<td>Early disc deformity</td>
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<tr>
<td></td>
<td></td>
<td>Headaches</td>
<td>Normal osseous contours</td>
</tr>
<tr>
<td>III</td>
<td>Intermediate</td>
<td>Frequent pain</td>
<td>Anterior disc displacement, reducing*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Joint tenderness, headaches</td>
<td>early progressing to non-reducing late</td>
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<tr>
<td></td>
<td></td>
<td>Locking</td>
<td>Moderate to marked disc thickening</td>
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<tr>
<td></td>
<td></td>
<td>Restricted motion</td>
<td>Normal osseous contours</td>
</tr>
<tr>
<td>IV</td>
<td>Intermediate/late</td>
<td>Chronic pain, headache</td>
<td>Anterior disc displacement, non-reducing*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Restricted motion</td>
<td>Marked disc thickening</td>
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<td></td>
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<td>Abnormal bone contours</td>
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<tr>
<td>V</td>
<td>Late</td>
<td>Variable pain</td>
<td>Anterior disc displacement, non-reducing* with perforation and gross deformity</td>
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<tr>
<td></td>
<td></td>
<td>Joint crepitus</td>
<td>Degenerative osseous changes</td>
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<td>Painful function</td>
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*refers to disc position in relation to condyle when the mouth is open

Approved by: Medical Management Guideline  Date Approved: 09/01/05

Committee

Temporomandibular Joint Disorders – Secure Horizons
Patient Selection Criteria
Autologous Hematopoietic Progenitor Cell Transplantation

<table>
<thead>
<tr>
<th>Hodgkin’s Disease and Non Hodgkin’s Lymphoma</th>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
<td>One of the following</td>
</tr>
<tr>
<td></td>
<td>• Individuals with advanced Hodgkin’s Disease (stage III and IV) who failed to achieve a complete initial response or who have relapsed or refractory disease</td>
</tr>
<tr>
<td></td>
<td>• Individuals with relapsed or primary refractory intermediate or high grade (stage III or IV) Non-Hodgkin’s Lymphoma</td>
</tr>
<tr>
<td></td>
<td>• Individuals with Non-Hodgkin’s Disease in first remission with extensive stage IV disease and elevated LDH.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exclusions/Contraindications</th>
<th>Any single contraindication listed below shall preclude approval for transplantation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Sepsis or systemic infection unresponsive to treatment</td>
</tr>
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<td></td>
<td>• Malignant disease considered likely to limit successful clinical outcome or interfere with compliance with a disciplined medical regimen or rehabilitation after transplantation</td>
</tr>
<tr>
<td></td>
<td>• Malignancy: see ASTS guideline in appendix 1</td>
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<tr>
<td></td>
<td>• Neuropsychiatric disorders which are likely to lead to non-compliance or will inhibit rehabilitation of the patient</td>
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<td></td>
<td>• Inadequate pulmonary, hepatic, cardiac, or renal function</td>
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<td>• Patients with:</td>
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<td></td>
<td>- NYHA Class III or IV cardiac insufficiency or</td>
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<td></td>
<td>- LVEF &lt; 45%</td>
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<td></td>
<td>- PFT with DLCO &lt; 50</td>
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<td></td>
<td>- Substantial liver damage (SGOT or SGPT &gt; 300 IU or</td>
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<tr>
<td></td>
<td>- Total bilirubin &gt; 2mg/dl</td>
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<tr>
<td></td>
<td>- Serum creatinine &gt; 2.0 mg/dl and/or</td>
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<tr>
<td></td>
<td>creatinine clearance &lt; 50ml/minute</td>
</tr>
<tr>
<td></td>
<td>• Substance abuse (drug and alcohol free)</td>
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</table>

Patient Selection Criteria
Autologous Hematopoietic Progenitor Cell Transplantation
Multiple Myeloma | PacifiCare
--- | ---
**Indications** | Durie-Salmon stage II (intermediate tumor burden) or III (high tumor burden) disease that meets the following requirements
- Newly diagnosed or responsive multiple myeloma; This includes those patients with previously untreated disease, those with at least a partial response to prior chemotherapy (defined as a 50% decrease either in measurable paraprotein [serum and/or urine] or in bone marrow infiltration, sustained for at least one month), and those in responsive relapse
- Adequate cardiac, renal, pulmonary and hepatic function

**Exclusions/Contraindications** | Any single contraindication listed below shall preclude approval for transplantation.
- Refractory multiple myeloma
- Sepsis or systemic infection unresponsive to treatment
- Malignant disease considered likely to limit successful clinical outcome or interfere with compliance with a disciplined medical regimen or rehabilitation after transplantation
- Malignancy: see ASTS guideline in appendix 1
- Neuropsychiatric disorders which are likely to lead to non-compliance or will inhibit rehabilitation of the patient
- Inadequate pulmonary, hepatic, cardiac, or renal function
- Severe hepatic disease as evidenced:
  - SGOT or SGPT, total bilirubin or alkaline
  - 2.5 times normal
- Compromised renal function as evidenced by:
  - Serum creatinine > or = 2.0 mg/dl
  - Creatinine clearance < 55ml/min
- LVEF (MUGA or ECHO) < or = 45%
- PFT with DLCO < 50
- Substance abuse (drug and alcohol free)
### Patient Selection Criteria
#### Autologous Hematopoietic Progenitor Cell Transplantation

<table>
<thead>
<tr>
<th>Amyloidosis</th>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
<td>Primary amyloid light chain (AL) amyloidosis and all of the following:</td>
</tr>
<tr>
<td></td>
<td>• Amyloid deposition in 2 or fewer organs</td>
</tr>
<tr>
<td></td>
<td>• Cardiac left ventricular ejection fraction &gt;45%</td>
</tr>
<tr>
<td></td>
<td>• Autologous stem cell transplant must be used to effect hematopoietic reconstitution following severely myelotoxic doses of chemotherapy and/or radiotherapy used to treat malignancy</td>
</tr>
<tr>
<td><strong>Exclusions/Contraindications</strong></td>
<td>PHP does not specify</td>
</tr>
</tbody>
</table>

#### Patient Selection Criteria
#### Autologous Hematopoietic Progenitor Cell Transplantation

<table>
<thead>
<tr>
<th>Acute Leukemias, AML, ALL</th>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
<td>One of the following</td>
</tr>
<tr>
<td></td>
<td>• Individuals of any age with Acute Lymphocytic or Myeloid Leukemia in first remission who are at high-risk for relapse, based on cytogenetics and white blood count, when these patients are not eligible for allogeneic stem cell transplant (AISCT) due to age or lack of an HLA-matched related donor</td>
</tr>
<tr>
<td></td>
<td>• Acute Lymphocytic or Myeloid Leukemia in first or second remission</td>
</tr>
<tr>
<td></td>
<td>• Individuals with Acute Myelocytic Leukemia who fail to achieve a complete response after 4 weeks of induction therapy</td>
</tr>
<tr>
<td></td>
<td>HDC/AuSCT is not generally recommended for children with low-risk AML in first complete response (CR1), but is considered appropriate for children with high-risk AML in CR1 and for children with AML in CR2 when an HLA-matched donor is not available.</td>
</tr>
<tr>
<td></td>
<td>OR</td>
</tr>
<tr>
<td></td>
<td>• Adults at high risk of mortality from AISCT</td>
</tr>
<tr>
<td><strong>Exclusions/Contraindications</strong></td>
<td>Any single contraindication listed below shall preclude approval for transplantation</td>
</tr>
<tr>
<td></td>
<td>• Failure to harvest adequate stem cells</td>
</tr>
<tr>
<td></td>
<td>• Substance abuse (drug and alcohol free)</td>
</tr>
<tr>
<td></td>
<td>• Chronic Myeloid leukemia (CML)</td>
</tr>
<tr>
<td></td>
<td>• Chronic lymphoid Leukemia (CLL)</td>
</tr>
<tr>
<td></td>
<td>• Sepsis or systemic infection unresponsive to treatment</td>
</tr>
<tr>
<td></td>
<td>• Malignant disease considered likely to limit successful clinical outcome or interfere with compliance with a disciplined medical regimen or</td>
</tr>
</tbody>
</table>
Patient Selection Criteria
Autologous Hematopoietic Progenitor Cell Transplantation

<table>
<thead>
<tr>
<th>Patient Selection Criteria</th>
<th>Autologous Hematopoietic Progenitor Cell Transplantation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Breast Cancer</strong></td>
<td><strong>PacifiCare</strong></td>
</tr>
<tr>
<td>Indications</td>
<td>• High dose chemotherapy with autologous stem cell rescue (HDC/AuSCT) is not recommended for treatment of breast cancer</td>
</tr>
<tr>
<td></td>
<td>• HDC/AuSCT for breast cancer does not provide a significantly better survival outcome than standard-dose chemotherapy and is associated with a greater risk of treatment-related mortality</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pediatric Patient Selection Criteria</th>
<th>Autologous Hematopoietic Progenitor Cell Transplantation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Neuroblastoma</strong></td>
<td><strong>PacifiCare</strong></td>
</tr>
<tr>
<td>Indications</td>
<td>High-risk neuroblastoma as defined by one of the following:</td>
</tr>
<tr>
<td></td>
<td>• Patients of any age with stage 2B, 3, or 4S disease with MYCN amplification</td>
</tr>
<tr>
<td></td>
<td>• Patients &lt; 1 year of age with stage 4 disease with MYCN amplification</td>
</tr>
<tr>
<td></td>
<td>• Patients &gt; 1 year of age with stage 4 disease with or without MYCN amplification</td>
</tr>
<tr>
<td>Exclusions/Contraindications</td>
<td>Any single contraindication listed below shall preclude approval for transplantation:</td>
</tr>
<tr>
<td></td>
<td>• Sepsis or systemic infection unresponsive to treatment</td>
</tr>
<tr>
<td></td>
<td>• Malignant disease considered likely to limit successful clinical outcome or interfere with compliance with a disciplined medical regimen or rehabilitation after transplantation</td>
</tr>
<tr>
<td></td>
<td>• Malignancy: see ASTS guideline in appendix 1</td>
</tr>
<tr>
<td></td>
<td>• Neuropsychiatric disorders (applies to parents and/or caregivers) which are likely to lead to non-compliance or will inhibit rehabilitation of the patient</td>
</tr>
<tr>
<td></td>
<td>• Inadequate social support system</td>
</tr>
<tr>
<td></td>
<td>• Inadequate pulmonary, hepatic, cardiac, or renal function</td>
</tr>
<tr>
<td></td>
<td>• New York Heart Association Class 3 or 4 cardiac insufficiency or</td>
</tr>
<tr>
<td></td>
<td>• LVEF &lt; 45%</td>
</tr>
</tbody>
</table>
Patient Selection Criteria

Allogeneic Hematopoietic Progenitor Cell Transplantation

### Leukemia

<table>
<thead>
<tr>
<th>Indications</th>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td>One of the following:</td>
<td></td>
</tr>
<tr>
<td>Acute Leukemia (ALL, AML /ANLL) with one of the following:</td>
<td></td>
</tr>
<tr>
<td>- Failure to achieve complete remission after 4 weeks of induction therapy</td>
<td></td>
</tr>
<tr>
<td>- First complete remission: high risk disease</td>
<td></td>
</tr>
<tr>
<td>- Second or third complete remission or relapse</td>
<td></td>
</tr>
<tr>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>- Chronic Myeloid Leukemia (CML): Patients in their first or second chronic phase</td>
<td></td>
</tr>
<tr>
<td>All of the following</td>
<td></td>
</tr>
<tr>
<td>- Relatively normal performance status as judged by medical history, physical examination, and evaluation of pulmonary, hepatic, cardiac, and renal function</td>
<td></td>
</tr>
<tr>
<td>- There should be a source of hematopoietic stem cells from a compatible donor to rescue the patient from high-dose therapy and ensure hematologic and immunologic recovery: histocompatible or 6 antigen HLA matched donor. (at least 5 antigen match acceptable in some circumstances)</td>
<td></td>
</tr>
<tr>
<td>- Patient's disease should be responsive to chemotherapy with a dose-limiting toxicity of bone marrow suppression</td>
<td></td>
</tr>
<tr>
<td>- The transplant should be performed at a time during the course of the malignancy when the tumor burden is minimal and before the onset of tumor cell drug resistance</td>
<td></td>
</tr>
<tr>
<td>- Adults should be &lt;55 years old (graft vs. host disease is more common among older recipients)</td>
<td></td>
</tr>
</tbody>
</table>
### Progenitor Cell Transplantation Criteria – September 2005

#### Exclusions/Contraindications
- **Contraindications**—Any single contraindication listed below shall preclude approval for transplantation.
  - Chronic Myeloid Leukemia (CML) in blast crisis
  - Sepsis or systemic infection unresponsive to treatment
  - Malignant disease considered likely to limit successful clinical outcome or interfere with compliance with a disciplined medical regimen or rehabilitation after transplantation
  - Malignancy: see ASTS guideline in appendix 1
  - Neuropsychiatric disorders which are likely to lead to non-compliance or will inhibit rehabilitation of the patient
  - Inadequate pulmonary, hepatic, cardiac, or renal function
    - New York Hear Association Class 3 or 4 cardiac insufficiency or
    - LVEF < 45%
    - PFT with DLCO < 50
    - Substantial liver damage (SGOT or SGPT > 300 IU or
    - Total bilirubin > 2mg/dl
    - Serum creatinine > 2.0 mg/dl and/or
    - Creatinine clearance < 50ml/minute
  - Substance abuse (drug and alcohol free)

#### Patient Selection Criteria
**Allogeneic Hematopoietic Progenitor Cell Transplantation**

**Hodgkin’s Disease, Non-Hodgkin’s Lymphoma**

<table>
<thead>
<tr>
<th>Indications</th>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hodgkin’s Disease (HD)</strong> with one of the following:</td>
<td></td>
</tr>
<tr>
<td>- Patients with stage III or IV disease who fail to achieve a complete response to standard chemotherapy</td>
<td></td>
</tr>
<tr>
<td>- Patients with stage III or IV disease who relapse after remission</td>
<td></td>
</tr>
<tr>
<td>OR</td>
<td></td>
</tr>
<tr>
<td><strong>Non Hodgkin’s Lymphoma (NHL)</strong></td>
<td></td>
</tr>
<tr>
<td>- Patients who are responsive to chemotherapy but relapse after a remission</td>
<td></td>
</tr>
<tr>
<td>- Patients with refractory disease</td>
<td></td>
</tr>
<tr>
<td>- All of the following</td>
<td></td>
</tr>
<tr>
<td>- Relatively normal performance status as judged by medical history, physical examination, and evaluation of pulmonary, hepatic, cardiac, and renal function</td>
<td></td>
</tr>
<tr>
<td>- There should be a source of hematopoietic stem cells from a compatible donor to rescue the patient from high-dose therapy and ensure hematologic and immunologic recovery: histocompatible or 6 antigen HLA matched donor. (at least 5 antigen match acceptable in some circumstances)</td>
<td></td>
</tr>
<tr>
<td>- Patient's disease should be responsive to chemotherapy with a dose-limiting toxicity of bone marrow suppression</td>
<td></td>
</tr>
<tr>
<td>- The transplant should be performed at a time during the course of the malignancy when the tumor burden is minimal and before the onset of tumor cell drug resistance</td>
<td></td>
</tr>
<tr>
<td>- Adults should be &lt;55 years old (graft vs. host disease is more common among older recipients)</td>
<td></td>
</tr>
</tbody>
</table>

*Allogeneic stem cell transplantation for HD and NHL is an established therapy but only for a select group of patients. Due to the high morbidity and mortality, this treatment is often only selected for younger patients who have good prognostic variables and a suitable matched HLA donor.*
More often, HD and NHL are treated with HDC/AuSCT over allogeneic BMT.

<table>
<thead>
<tr>
<th>Exclusion/Contraindications</th>
<th>Contraindications—Any single contraindication listed below shall preclude approval for transplantation.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>▪ Sepsis or systemic infection unresponsive to treatment</td>
</tr>
<tr>
<td></td>
<td>▪ Malignant disease considered likely to limit successful clinical outcome or interfere with compliance with a disciplined medical regimen or rehabilitation after transplantation</td>
</tr>
<tr>
<td></td>
<td>▪ Malignancy: see ASTS guideline in appendix 1</td>
</tr>
<tr>
<td></td>
<td>▪ Neuropsychiatric disorders which are likely to lead to non-compliance or will inhibit rehabilitation of the patient</td>
</tr>
<tr>
<td></td>
<td>▪ Inadequate pulmonary, hepatic, cardiac, or renal function</td>
</tr>
<tr>
<td></td>
<td>- New York Hear Association Class 3 or 4 cardiac insufficiency or</td>
</tr>
<tr>
<td></td>
<td>- LVEF &lt; 45%</td>
</tr>
<tr>
<td></td>
<td>- PFT with DLCO &lt; 50</td>
</tr>
<tr>
<td></td>
<td>- Substantial liver damage (SGOT or SGPT &gt; 300 IU or</td>
</tr>
<tr>
<td></td>
<td>- Total bilirubin &gt; 2mg/dl</td>
</tr>
<tr>
<td></td>
<td>- Serum creatinine &gt; 2.0 mg/dl and/or</td>
</tr>
<tr>
<td></td>
<td>Creatinine clearance &lt; 50ml/minute</td>
</tr>
<tr>
<td></td>
<td>▪ Substance abuse (drug and alcohol free)</td>
</tr>
</tbody>
</table>
Patient Selection Criteria
Allogeneic Hematopoietic Progenitor Cell Transplantation

<table>
<thead>
<tr>
<th>Indications</th>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-myeloablative allogeic HSCT is recommended for the treatment of patients with hematological malignancies who are ineligible for conventional allogeic HSCT due to age, comorbidity, or previous treatment, if the non-myeloablative procedure is expected to result in improved patient outcomes compared with standard therapies.</td>
<td>The patient must have one of the following:</td>
</tr>
<tr>
<td>Non-myeloablative allogeneic HSCT is not recommended for the treatment of patients with solid tumors, as the currently available evidence is extremely limited.</td>
<td></td>
</tr>
<tr>
<td>Age &gt;45 years</td>
<td></td>
</tr>
<tr>
<td>Significant comorbidity, poor performance status, or pretreatment precluding conventional myeloablative conditioning regimens</td>
<td></td>
</tr>
<tr>
<td>Failure of previous conventional autologous or allogeneic HSCT due to relapse, rejection, or secondary malignancy</td>
<td></td>
</tr>
<tr>
<td>Exclusion</td>
<td></td>
</tr>
<tr>
<td>Patients with chemorefractory disease</td>
<td></td>
</tr>
<tr>
<td>Non-myeloablative allogeic HSCT for solid tumors</td>
<td></td>
</tr>
</tbody>
</table>

Patient Selection Criteria
Allogeneic Hematopoietic Progenitor Cell Transplantation

<table>
<thead>
<tr>
<th>Indications</th>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donor Lymphocyte Infusion for Relapsed Leukemia or Multiple Myeloma after Allogeneic Bone Marrow/Stem Cell Transplantation</td>
<td>Chronic myeloid leukemia (CML) in chronic phase</td>
</tr>
<tr>
<td></td>
<td>Relapse after allogeneic bone marrow/stem cell transplantation</td>
</tr>
</tbody>
</table>
Patient Selection Criteria:
Allogeneic Hematopoietic Progenitor Cell Transplantation

### Aplastic Anemia

<table>
<thead>
<tr>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td>- Individuals with severe aplastic anemia who have a HLA-identical sibling donor</td>
</tr>
<tr>
<td>- Individuals with severe aplastic anemia who have failed immunosuppressive therapy and have a HLA-nonidentical related donor or HLA-matched unrelated donor</td>
</tr>
</tbody>
</table>

### Wiskott-Aldrich Syndrome:

<table>
<thead>
<tr>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td>- Individuals with a HLA-identical sibling donor</td>
</tr>
<tr>
<td>- Individuals with a HLA-nonidentical related and HLA-identical unrelated donor</td>
</tr>
</tbody>
</table>

### Organ Toxicity Criteria

<table>
<thead>
<tr>
<th>Patient must have adequate organ function as defined by:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Renal Function</strong></td>
</tr>
<tr>
<td>a) Serum creatinine ≤ 2mg/dl or</td>
</tr>
<tr>
<td>b) Creatinine clearance &gt; 50-55 ml/min</td>
</tr>
<tr>
<td><strong>Liver Function</strong></td>
</tr>
<tr>
<td>a) Total bilirubin ≤ 2mg/dl and</td>
</tr>
<tr>
<td>b) SGOT/SGPT &lt; 2.5 x normal</td>
</tr>
<tr>
<td><strong>Cardiac Function</strong></td>
</tr>
<tr>
<td>a) Ejection fraction &gt; 45% by ECHO</td>
</tr>
<tr>
<td><strong>Pulmonary Function</strong></td>
</tr>
<tr>
<td>a) PFT with DLCO &gt; 50</td>
</tr>
</tbody>
</table>

PACIFICARE PREFERRED TRANSPLANT NETWORK
GUIDELINES FOR CANCER FREE WAITING PERIOD PRIOR TO TRANSPLANTATION
From The American Society of Transplant Surgeons (ASTS) Recommendations 2001

<table>
<thead>
<tr>
<th>SITE</th>
<th>WAITING PERIOD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bladder</td>
<td></td>
</tr>
<tr>
<td>In situ (noninvasive Papillomas)</td>
<td>None</td>
</tr>
<tr>
<td>Invasive</td>
<td>2 years</td>
</tr>
<tr>
<td>Renal</td>
<td></td>
</tr>
<tr>
<td>Incidental, asymptomatic</td>
<td>None</td>
</tr>
<tr>
<td>Large, infiltrating (≥ 5 cm)</td>
<td>2-5 years</td>
</tr>
<tr>
<td>Wilm’s tumor</td>
<td>2 years</td>
</tr>
<tr>
<td>Anogenital</td>
<td></td>
</tr>
<tr>
<td>Genital warts, squamous intraepithelial neoplasias</td>
<td>None following treatment of lesions</td>
</tr>
<tr>
<td>Uterus</td>
<td></td>
</tr>
<tr>
<td>In situ cervical</td>
<td>2 years</td>
</tr>
<tr>
<td>Invasive cervical</td>
<td>5 years</td>
</tr>
<tr>
<td>Uterine body</td>
<td>2 years</td>
</tr>
<tr>
<td>Thyroid / Endocrine</td>
<td>2 years</td>
</tr>
<tr>
<td>Testicular</td>
<td>2 years</td>
</tr>
<tr>
<td>Kaposi’s and other Sarcomas</td>
<td>2 years</td>
</tr>
<tr>
<td>Breast</td>
<td>5 years</td>
</tr>
<tr>
<td>Early stage</td>
<td>2 years</td>
</tr>
<tr>
<td>Colorectal</td>
<td></td>
</tr>
<tr>
<td>Dukes A or B1</td>
<td>2 years</td>
</tr>
<tr>
<td>Higher stages</td>
<td>5 years</td>
</tr>
<tr>
<td>SITE</td>
<td>WAITING PERIOD</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>--------------------------------------------------------</td>
</tr>
<tr>
<td>Prostate</td>
<td>2 years</td>
</tr>
<tr>
<td>• Local lesion</td>
<td>None following treatment of lesion</td>
</tr>
<tr>
<td>Liver (see indications for liver transplantation)</td>
<td>5-10 years for extrahepatic transplants</td>
</tr>
<tr>
<td>Lung</td>
<td>2 years</td>
</tr>
<tr>
<td>Lymphoma and post transplant Lymphoproliferative Disorders (PTLD)</td>
<td>2 years</td>
</tr>
<tr>
<td>Leukemia</td>
<td>2 years</td>
</tr>
<tr>
<td>Skin</td>
<td></td>
</tr>
<tr>
<td>• Malignant melanoma</td>
<td>5 years</td>
</tr>
<tr>
<td>• In situ melanoma (very thin)</td>
<td>2 years</td>
</tr>
<tr>
<td>• Squamous cell</td>
<td>2 years</td>
</tr>
<tr>
<td>• Basal cell</td>
<td>None</td>
</tr>
</tbody>
</table>
## Adult Patient Selection Criteria

### Kidney

<table>
<thead>
<tr>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td>- Irreversible, progressive, end-stage renal disease: creatinine clearance ≤ 20ml/min or on dialysis</td>
</tr>
<tr>
<td>- Stable psychosocial status</td>
</tr>
<tr>
<td>- Willingness to comply (patient and/or caregiver) with medical advice</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Absolute Contraindications</strong></td>
</tr>
<tr>
<td>- Active infection</td>
</tr>
<tr>
<td>- Insufficient cardiac reserve:</td>
</tr>
<tr>
<td>- Non-correctable CAD</td>
</tr>
<tr>
<td>- Recent MI</td>
</tr>
<tr>
<td>- Ejection fraction &lt; 35%</td>
</tr>
<tr>
<td>- Severe hepatic dysfunction</td>
</tr>
<tr>
<td>- Bilirubin &gt; 2.5mg/dl</td>
</tr>
<tr>
<td>- SGOT &gt; 2x</td>
</tr>
<tr>
<td>- INR ≥ 1.5</td>
</tr>
<tr>
<td>- Malignancy: see ASTS guideline in appendix 1</td>
</tr>
<tr>
<td>- Psychiatric illness or mental incompetence that would make compliance with medical regimen highly unlikely</td>
</tr>
<tr>
<td>- Lack of competent care giver</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Relative Contraindications</strong></td>
</tr>
<tr>
<td>- Life threatening co-existing systemic disease</td>
</tr>
<tr>
<td>- BMI ≥ 35</td>
</tr>
<tr>
<td>- Substance abuse (drug, alcohol and nicotine free for 6 months prior to transplantation)</td>
</tr>
<tr>
<td>- Age ≥ 65 years of age</td>
</tr>
<tr>
<td>- Insufficient cardiac reserve:</td>
</tr>
<tr>
<td>- Ejection fraction 35% - 50%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diseases associated with diminishing kidney function:</strong></td>
</tr>
<tr>
<td>Irreversible Chronic Renal Failure:</td>
</tr>
<tr>
<td>- Chronic pyelonephritis</td>
</tr>
<tr>
<td>- Chronic glomerulonephritis</td>
</tr>
<tr>
<td>- Diabetic nephropathy</td>
</tr>
<tr>
<td>- Goodpasture's disease</td>
</tr>
<tr>
<td>- Hypocomplementemic nephritis</td>
</tr>
<tr>
<td>- Steroid-resistant nephrotic syndrome</td>
</tr>
</tbody>
</table>
**Kidney** | **PacifiCare**
--- | ---
|  | Hypertensive nephrosclerosis
| Obstructive Uropathy: | Acquired
|  | Congenital
| Congenital Disorders: | Aplasia
|  | Hypoplasia
|  | Horseshoe kidney
| Hereditary Nephropathies: | Alport's syndrome
|  | Polycystic kidney disease
|  | Medullary cystic disease
| Metabolic Disorders: | Hyperoxaluria
|  | Nephrocalcinosis
|  | Gout
|  | Oxalosis
|  | Amyloidosis
|  | Cystinosis
| Irreversible Acute Failure: | Cortical necrosis
|  | Hemolytic uremic syndrome
|  | Acute and subacute glomerulonephritis
|  | Anaphylactoid purpura (Henoch-Schönlein)
|  | Acute tubular necrosis
| Trauma Requiring Nephrectomy | Renal artery occlusion
| Renal Vascular Diseases: | Renal vein thrombosis
| Tumors Requiring Nephrectomy: | Renal carcinoma
|  | Wilms' tumor
|  | Tuberous sclerosis
| Other: | Multiple myeloma in CR, and cleared by Oncology
|  | Macroglobulinemia
|  | Wegener's disease
|  | Scleroderma
|  | Lupus erythematosus
|  | Polyarteritis (periarteritis nodosa)
**Pediatric Patient Selection Criteria**

<table>
<thead>
<tr>
<th>Kidney</th>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
<td>All of the following:</td>
</tr>
<tr>
<td></td>
<td>• Irreversible, progressive, end-stage renal disease</td>
</tr>
<tr>
<td></td>
<td>• Age ≤ 18 years</td>
</tr>
<tr>
<td></td>
<td>• Stable psychosocial status</td>
</tr>
<tr>
<td></td>
<td>• Willingness to comply (patient and/or caregiver) with medical advice</td>
</tr>
<tr>
<td><strong>Absolute Contraindications</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Active infection</td>
</tr>
<tr>
<td></td>
<td>• Malignancy: see ASTS guideline in appendix 1</td>
</tr>
<tr>
<td></td>
<td>• Psychiatric illness or mental incompetence that would make compliance with medical regimen highly unlikely</td>
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<tr>
<td></td>
<td>• Lack of competent care giver</td>
</tr>
<tr>
<td><strong>Relative Contraindications</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Life threatening co-existing systemic disease</td>
</tr>
<tr>
<td></td>
<td>• Substance abuse (caregiver and/or patient drug, alcohol and nicotine free for 6 months prior to transplantation)</td>
</tr>
<tr>
<td></td>
<td>• BMI &gt; 35</td>
</tr>
</tbody>
</table>

**Diseases associated with diminishing kidney function:**

- Irreversible Chronic Renal Failure:
  - Chronic pyelonephritis
  - Chronic glomerulonephritis
  - Diabetic nephropathy
  - Goodpasture's disease
  - Hypocomplementemic nephritis
  - Steroid-resistant nephrotic syndrome
  - Hypertensive nephrosclerosis

- Obstructive Uropathy:
  - Acquired
  - Congenital

- Congenital Disorders:
  - Aplasia
  - Hypoplasia
  - Horseshoe kidney

- Hereditary Nephropathies:
  - Alport's syndrome
  - Polycystic kidney disease
  - Medullary cystic disease

- Metabolic Disorders:
  - Hyperoxaluria
  - Nephrocalcinosis
  - Gout
### Kidney

<table>
<thead>
<tr>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxalosis</td>
</tr>
<tr>
<td>Amyloidosis</td>
</tr>
<tr>
<td>Cystinosis</td>
</tr>
</tbody>
</table>

**Irreversible Acute Failure:**
- Cortical necrosis
- Hemolytic uremic syndrome
- Acute and subacute glomerulonephritis
- Anaphylactoid purpura (Henoch-Schönlein)
- Acute tubular necrosis

**Trauma Requiring Nephrectomy**

**Renal Vascular Diseases:**
- Renal artery occlusion
- Renal vein thrombosis

**Tumors Requiring Nephrectomy:**
- Renal carcinoma
- Wilms' tumor
- Tuberous sclerosis

**Other:**
- Multiple myeloma in CR, and cleared by Oncology
- Macroglobulinemia
- Wegener's disease
- Scleroderma
- Lupus erythematosus
- Polyarteritis (periarteritis nodosa)
## Adult Patient Selection Criteria

### Kidney-Pancreas

**Indications**
- Patients with Diabetes Mellitus type I, with imminent or established end-stage renal disease who have had or plan to have a kidney transplant
- Stable and adequate renal function, s/p renal transplant for pancreas after kidney transplant
- Stable psychosocial status
- Willingness to comply (patient and/or caregiver) with medical advice

Pancreas transplantation alone has not demonstrated an improvement in net health outcome. Therefore, pancreas transplantation without kidney transplantation (simultaneous or previous) is not recommended or approved for coverage.

### Absolute Contraindications
- Active infection
- Insufficient cardiac reserve:
  - Non-correctable CAD
  - Recent MI
  - Ejection fraction ≤ 45%
- Severe hepatic dysfunction
  - Bilirubin > 2.5mg/dl
  - SGOT > 2x
  - INR ≥ 1.5
- Malignancy: see ASTS guideline in appendix 1
- Active peptic ulcer disease
- BMI ≥ 35
- Psychiatric illness or mental incompetence that would make compliance with medical regimen highly unlikely
- Lack of competent care giver

### Relative Contraindications
- Age ≥ 55 years of age
- Insufficient cardiac reserve:
- Advanced neuropathy
- Ejection fraction 35-45% may receive sequential pancreas after kidney transplant with re-evaluation of LVEF prior to consideration for pancreas transplant
- Peripheral vascular disease
- Blindness secondary to advanced retinopathy associated with diabetes
- Substance abuse (drug, alcohol and nicotine free for 6 months prior to transplantation)
Pancreatic Islet Cell Transplantation Patient Selection Criteria

<table>
<thead>
<tr>
<th>Pancreatic Islet Cells</th>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications</td>
<td>Effective October 1, 2004, as a result of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Medicare will cover pancreatic islet cell transplantation for patients with type I diabetes who are participating in National Institutes of Health-sponsored clinical trials. Because this procedure meets significant cost criteria, Medicare Advantage (MA) organizations are not required to assume risk for the costs of this service until payments are appropriately adjusted.</td>
</tr>
</tbody>
</table>

| Absolute Contraindications | • PHP does not specify |
| Relative Contraindications   | • PHP does not specify |

Liver (Living or Cadaver) Patient Selection Criteria

<table>
<thead>
<tr>
<th>Liver (Living or Cadaver)</th>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications</td>
<td>All of the following:</td>
</tr>
<tr>
<td></td>
<td>• End-stage liver disease with a life expectancy of &lt; 12-24 months, which may be characterized by the following:</td>
</tr>
<tr>
<td></td>
<td>• Life threatening complication of chronic liver disease, including:</td>
</tr>
<tr>
<td></td>
<td>- Repeated episodes of infection</td>
</tr>
<tr>
<td></td>
<td>- Acute fulminant hepatic failure</td>
</tr>
<tr>
<td></td>
<td>- Variceal hemorrhage</td>
</tr>
<tr>
<td></td>
<td>- Decompensation of previously stable liver disease</td>
</tr>
<tr>
<td></td>
<td>- Severe impairment of quality of life directly related to the liver disease</td>
</tr>
<tr>
<td></td>
<td>• Stable psychosocial status</td>
</tr>
<tr>
<td></td>
<td>• Willingness to comply (patient and/or caregiver) with medical advice</td>
</tr>
</tbody>
</table>
### Liver (Living or Cadaver)

#### Absolute Contraindications
- Hepatocellular carcinoma except when all of the following are met:
  - Not a candidate for subtotal liver resection
  - Tumor-nodule is HCC stage I or II: one nodule <1.9cm; one nodule 2-5 cm; two or three nodules, all < 3.0 cm
  - No macrovascular involvement
  - No identifiable extrahepatic spread of tumor to surrounding lymph nodes, lungs, abdominal organs or bone
- Active infection
- Cholangiocarcinoma or metastatic tumor or active malignancy extending beyond the margins of the liver.
- Encephalopathy with evidence of irreversible brain damage
- Congenital anomalies that prevent surgery
- Severe hypoxemia
- Severe renal, neurological or cardiopulmonary disease
- Insufficient cardiac reserve:
  - Non-correctable CAD
  - Recent MI
  - Ejection fraction < 50%
- Malignancy: see ASTS guideline in appendix 1
- Psychiatric illness (mental incompetence not attributable to hepatic encephalopathy) that would make compliance with a disciplined medical regimen highly unlikely
- Lack of competent care giver

#### Relative Contraindications
- Intrahepatic or biliary sepsis
- Portal vein thrombosis
- Previous upper quadrant surgery – because of scarring and possible alterations to portal vein architecture
- Stage IV hepatic coma
- Substance abuse (drug, alcohol and nicotine free for 6 months prior to transplantation)
### Liver (Living or Cadaver)

<table>
<thead>
<tr>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diseases associated with diminishing liver function</td>
</tr>
<tr>
<td>• Primary or secondary biliary cirrhosis</td>
</tr>
<tr>
<td>• Cirrhosis</td>
</tr>
<tr>
<td>- Liver</td>
</tr>
<tr>
<td>- Alcoholic</td>
</tr>
<tr>
<td>- Cryptogenic</td>
</tr>
<tr>
<td>- Medication induced</td>
</tr>
<tr>
<td>• Post necrotic cirrhosis (hepatitis B surface antigen negative)</td>
</tr>
<tr>
<td>• Hepatitis</td>
</tr>
<tr>
<td>- Fulminant (viral)</td>
</tr>
<tr>
<td>- Chronic active</td>
</tr>
<tr>
<td>- Acute toxic</td>
</tr>
<tr>
<td>• Primary sclerosing cholangitis</td>
</tr>
<tr>
<td>• Wilson’s Disease</td>
</tr>
<tr>
<td>• Alpha-1 antitrypsin deficiency disease</td>
</tr>
<tr>
<td>• Fulminant liver necrosis</td>
</tr>
<tr>
<td>• Budd-Chiari syndrome</td>
</tr>
</tbody>
</table>

### Living Donor Selection Criteria

<table>
<thead>
<tr>
<th>Liver</th>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications</td>
<td>All of the following:</td>
</tr>
<tr>
<td></td>
<td>• Donor is healthy and should be &lt; 50 years of age</td>
</tr>
<tr>
<td></td>
<td>• Donor is able to give informed consent</td>
</tr>
<tr>
<td></td>
<td>• Donor is not subjected to any form of financial coercion</td>
</tr>
<tr>
<td></td>
<td>• Consent should clearly state risk to donor</td>
</tr>
<tr>
<td></td>
<td>• Donors required to undergo psychosocial evaluation</td>
</tr>
</tbody>
</table>
## Pediatric Patient Selection Criteria

### Liver

#### Indications
- All of the following:
  - End-stage liver disease, which may be characterized by the following:
    - Age \( \leq 18 \)
    - Life threatening complication of chronic liver disease, including:
      - Repeated episodes of infection
      - Acute fulminant hepatic failure
      - Variceal hemorrhage
      - Decompensation of previously stable liver disease
      - Severe impairment of quality of life directly related to the liver disease
    - Stable psychosocial status
    - Willingness to comply (patient and/or caregiver) with medical advice

#### Absolute Contraindications
- Active infection
- Active malignancy extending beyond the margins of the liver
- Encephalopathy with evidence of irreversible brain damage
- Congenital anomalies that prevent surgery
- Severe hypoxemia
- Severe renal, neurological or cardiopulmonary disease
- Malignancy: see ASTS guideline in appendix 1
- Psychiatric illness that would make compliance with a disciplined medical regimen highly unlikely
- Lack of competent care giver

#### Relative Contraindications
- Intrahepatic or biliary sepsis
- Portal vein thrombosis
- Previous upper quadrant surgery – because of scarring and possible alterations to portal vein architecture
- Stage IV hepatic coma
- Substance abuse (patient and/or care giver drug, alcohol and nicotine free for 6 months prior to transplantation)

#### Diseases associated with diminishing liver function
- Extrahepatic biliary atresia
- Biliary atresia
- Primary biliary cirrhosis
- Primary sclerosing cholangitis
- Alpha-1 antitrypsin deficiency disease
- Metabolic disease (Crigler-Najjar Syndrome)
## Adult Patient Selection Criteria

### Heart

<table>
<thead>
<tr>
<th>Indications</th>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td>All of the following:</td>
<td></td>
</tr>
<tr>
<td>- End stage heart disease (NYHA Class III or IV) and a likelihood of a 1-year survival of ≤50%</td>
<td></td>
</tr>
<tr>
<td>- Stable psychosocial status</td>
<td></td>
</tr>
<tr>
<td>- Willingness to comply (patient and/or caregiver) with medical advice</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Absolute Contraindications</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Active infection</td>
<td></td>
</tr>
<tr>
<td>Irreversible pulmonary hypertension</td>
<td></td>
</tr>
<tr>
<td>Transpulmonary gradient &gt; 16mmHg with use of vasodilators</td>
<td></td>
</tr>
<tr>
<td>Pulmonary artery systolic pressure &gt; 60 mmHg with use of vasodilators</td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus with end-organ dysfunction</td>
<td></td>
</tr>
<tr>
<td>Irreversible hypertension</td>
<td></td>
</tr>
<tr>
<td>Irreversible renal impairment</td>
<td></td>
</tr>
<tr>
<td>Irreversible hepatic dysfunction</td>
<td></td>
</tr>
<tr>
<td>Malignancy: see ASTS guideline in appendix 1</td>
<td></td>
</tr>
<tr>
<td>Psychiatric illness or mental incompetence that would make compliance with medical regimen highly unlikely</td>
<td></td>
</tr>
<tr>
<td>Lack of competent care giver</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Relative Contraindications</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age ≥ 65 years of age</td>
<td></td>
</tr>
<tr>
<td>Severe hypertension (not of cardiac origin) requiring multiple drug therapy</td>
<td></td>
</tr>
<tr>
<td>Significant peripheral vascular disease</td>
<td></td>
</tr>
<tr>
<td>Cerebroembolic disease</td>
<td></td>
</tr>
<tr>
<td>Pulmonary hypertension</td>
<td></td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease</td>
<td></td>
</tr>
<tr>
<td>Mean transpulmonary gradient between 13-15 mmHg with use of vasodilators</td>
<td></td>
</tr>
<tr>
<td>Severe renal impairment</td>
<td></td>
</tr>
<tr>
<td>- Creatinine &gt; 2mg/dl</td>
<td></td>
</tr>
<tr>
<td>- Creatinine clearance &lt; 50ml/min</td>
<td></td>
</tr>
<tr>
<td>- Severe hepatic dysfunction</td>
<td></td>
</tr>
<tr>
<td>- Bilirubin &gt; 2.5mg/dl</td>
<td></td>
</tr>
<tr>
<td>- SGOT &gt; 2x</td>
<td></td>
</tr>
<tr>
<td>- INR ≥ 1.5</td>
<td></td>
</tr>
<tr>
<td>Insulin dependent diabetes mellitus</td>
<td></td>
</tr>
<tr>
<td>Diverticulitis (recent history) or active peptic ulcer disease</td>
<td></td>
</tr>
<tr>
<td>BMI ≥ 35</td>
<td></td>
</tr>
<tr>
<td>Cachexia</td>
<td></td>
</tr>
<tr>
<td>Severe osteoporosis</td>
<td></td>
</tr>
</tbody>
</table>
### Heart

- Any co-existing systemic illness likely to limit or preclude survival and rehabilitation after transplantation
- Substance abuse (drug, alcohol and nicotine free for 6 months prior to transplantation)

### Diseases associated with diminishing heart function

- Cardiomyopathy
- Acute Massive Myocardial Infarction
- Life-threatening arrhythmias uncontrolled by conventional methods
- Valvular heart disease
- Severe limiting angina with diffuse coronary artery disease
- Severely impaired ventricular function
- Ischemic heart disease

### Cardiac failure can be defined as

- Left ventricular ejection fraction (LVEF) <20%
- Marked functional limitation as defined by peak oxygen consumption (VO2max) < 14 ml/kg of body weight per minute, measured during maximum exercise testing, following optimal medical therapy
- Severe activity-limiting myocardial ischemia not amenable to revascularization
- Recurrent ventricular arrhythmias refractory to conventional therapies
- Persistent or labile fluid imbalance that does not respond to therapy
# Ventricular Assist Device Patient Selection Criteria

<table>
<thead>
<tr>
<th>Indications</th>
<th>PacifiCare</th>
</tr>
</thead>
</table>
| **LVADs**                                                                  | **As a bridge to transplant when individual is actively listed for transplant and all of the following conditions are met:**  
1. LVAD must be used in accordance with its FDA-approved labeling instructions (as a temporary mechanical circulatory support for approved transplant candidates as a bridge to heart transplantation)  
2. Member is approved and listed as a candidate for heart transplantation at a PHP approved heart transplant center  
3. VAD is implanted at a PHP approved heart transplant center in a member who is listed by that center or at another PHP approved transplant center and the implanting center receives written permission from the center under which the member is listed  
**Note:**  
- VADs implanted in an emergency situation are not required to meet criteria 2 & 3 above.  
- The implanting site, if different from the PacifiCare approved heart transplant center, must receive written permission from the PacifiCare approved heart transplant center under which the member is listed  
**Support circulation of blood following open-heart surgery (post cardiotomy)**  
- Covered only if they have received approval from the FDA for that purpose and the VAD’s are used according to the FDA approved labeling instructions  
**LVADs are not covered when used as an artificial heart**  
**Destination Therapy:**  
- From October 1, 2003 until December 31, 2004: As destination therapy for members with end-stage heart failure, this procedure meets significant cost criteria. Therefore, Medicare Advantage (MA) organizations will not be required to assume risk for the costs of service until payments are appropriately adjusted.  
- As of January 1, 2005: this service is included in the MA organizations’ contracts and is a covered benefit under the contract. MA organizations must furnish, arrange, or pay for this service and MA enrollees are liable for the plan’s cost sharing for this service.  
**Absolute Contraindications**  
- PHP does not specify, since must meet cardiac transplant candidate criteria  
**Relative Contraindications**  
- PHP does not specify, since must meet cardiac transplant candidate criteria
## Pediatric Patient Selection Criteria

### Heart

**Indications**
- End stage heart disease
- Age ≤ 18 years of age
- Stable psychosocial status
- Willingness to comply (patient and/or caregiver) with medical advice

**Absolute Contraindications**
- Active infection
- Irreversible pulmonary hypertension
- Transpulmonary gradient > 15mm with use of vasodilators
- Diabetes mellitus with end-organ dysfunction
- Irreversible chronic obstructive pulmonary disease
- Irreversible renal impairment
- Irreversible hepatic dysfunction
- Malignancy: see ASTS guideline in appendix 1
- Psychiatric illness or mental incompetence that would make compliance with medical regimen highly unlikely
- Lack of competent care giver

**Relative Contraindications**
- Severe chronic obstructive pulmonary disease or chronic bronchitis uncorrected with pulmonary vasodilators
- Mean transpulmonary gradient between 13- 15 mmHG with use of nitroprusside
- Severe renal impairment
  - Creatinine > 2mg/dl
  - Creatinine clearance < 50ml/min
- Severe hepatic dysfunction
  - Bilirubin > 2.5mg/dl
  - SGOT > 2x
  - INR ≥ 1.5
- Insulin dependent diabetes mellitus
- Diverticulitis (recent history) or active peptic ulcer disease
- Severe chromosomal abnormalities and associated developmental delay
- BMI ≥ 35
- Any co-existing systemic illness likely to limit or preclude survival and rehabilitation after transplantation
- Substance abuse (caregiver and/or patient drug, alcohol and nicotine free for 6 months prior to transplantation)
**Heart**

<table>
<thead>
<tr>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diseases/processes associated with diminishing heart function:</td>
</tr>
<tr>
<td>• Cardiomyopathy (dilated, hypertrophic, restrictive)</td>
</tr>
<tr>
<td>• Congenital Heart disease</td>
</tr>
<tr>
<td>• Retransplantation</td>
</tr>
<tr>
<td>The following may be helpful in identifying the child or adolescent with end-stage cardiac disease who should benefit from a heart transplant:</td>
</tr>
<tr>
<td>• Progressive deterioration of ventricular function or functional status despite optimal medical therapy, including digitalis, diuretics and ACE inhibitors</td>
</tr>
<tr>
<td>• Growth failure secondary to CHF unresponsive to conventional medical therapy</td>
</tr>
<tr>
<td>• Malignant arrhythmias or survival of cardiac arrest, unresponsive to conventional medical therapy and not likely to be successfully treated with implantable cardioverter defibrillator</td>
</tr>
<tr>
<td>• Need for ongoing intravenous inotropic support</td>
</tr>
<tr>
<td>• Unacceptable poor quality of life</td>
</tr>
<tr>
<td>• Progressive pulmonary HTN that would predictably preclude heart transplantation at a later date</td>
</tr>
</tbody>
</table>

---

**Adult Patient Selection Criteria**

<table>
<thead>
<tr>
<th>Lung</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications</td>
</tr>
<tr>
<td>All of the following:</td>
</tr>
<tr>
<td>• Presence of end-stage lung disease refractory to other available medical and surgical approaches</td>
</tr>
<tr>
<td>• Projected life expectancy of &lt; 2 years</td>
</tr>
<tr>
<td>• Stable psychosocial status</td>
</tr>
<tr>
<td>• Willingness to comply (patient and/or caregiver) with medical advice</td>
</tr>
<tr>
<td>Diseases associated with need for single lung transplant:</td>
</tr>
<tr>
<td>• Idiopathic pulmonary fibrosis</td>
</tr>
<tr>
<td>• COPD due to emphysema</td>
</tr>
<tr>
<td>• Alpha 1 Antitrypsin Deficiency</td>
</tr>
<tr>
<td>• Primary pulmonary HTN</td>
</tr>
<tr>
<td>• Sarcoidosis without systemic disease</td>
</tr>
<tr>
<td>• Radiation fibrosis</td>
</tr>
<tr>
<td>• Bronchiectasis</td>
</tr>
<tr>
<td>• Bronchiolitis obliterans</td>
</tr>
<tr>
<td>• Secondary pulmonary HTN due to correctable congenital heart defects</td>
</tr>
<tr>
<td>Disease associated with need for double Lung transplant:</td>
</tr>
<tr>
<td>• Cystic fibrosis</td>
</tr>
<tr>
<td>• Bronchiectasis</td>
</tr>
<tr>
<td>• COPD due to emphysema</td>
</tr>
<tr>
<td>• Alpha 1 Antitrypsin Deficiency &lt; 50 years</td>
</tr>
<tr>
<td>Lung</td>
</tr>
<tr>
<td>------</td>
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<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

**Absolute Contraindication**

|      | - Irreversible co-existing end-stage organ failure  |
|      | - Active malignant disease  |
|      | - Uncontrolled hypertension that requires more than two drugs for adequate control  |
|      | - Malignancy; see ASTS guideline in appendix 1  |
|      | - Cerebroembolic disease  |
|      | - Severe cardiac, renal or hepatic disease  |
|      | - Insufficient cardiac reserve:  |
|      |   - Non-correctable CAD  |
|      |   - Recent MI  |
|      |   - Ejection fraction < 50%  |
|      | - Severe renal impairment  |
|      |   - Creatinine > 2mg/dl  |
|      |   - Creatinine clearance < 50ml/min  |
|      | - Severe hepatic dysfunction  |
|      |   - Bilirubin > 2.5mg/dl  |
|      |   - SGOT > 2x  |
|      |   - INR ≥ 1.5  |
|      | - Active peptic ulcer disease  |
|      | - Active infection  |
|      | - Irreversible coagulopathies  |
|      | - Neuromuscular and musculoskeletal disorders that prohibit ambulation  |
|      | - Psychiatric illness or mental incompetence that would make compliance with medical regimen highly unlikely  |
|      | - Lack of competent care giver  |

**Relative Contraindications**

|      | - Age ≥ 65 years for single-lung transplant, ≥ 60 years for double-lung transplant  |
|      | - BMI ≥ 35  |
|      | - Cachexia  |
|      | - Current significant acute illness that is likely to contribute to a poor outcome  |
|      | - Osteoporosis  |
|      | - Substance abuse (drug, alcohol and nicotine free for 6 months prior to evaluation)  |
# Pediatric Patient Selection Criteria

<table>
<thead>
<tr>
<th>Lung</th>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications</td>
<td>All of the following</td>
</tr>
<tr>
<td></td>
<td>• End-stage lung disease refractory to other available medical and surgical approaches</td>
</tr>
<tr>
<td></td>
<td>• Declining functional status</td>
</tr>
<tr>
<td></td>
<td>• Age ≤ 18 years of age</td>
</tr>
<tr>
<td></td>
<td>• Pulmonary capacity suggestive of a short life expectancy, &lt; 2 years</td>
</tr>
<tr>
<td></td>
<td>• Stable psychosocial status</td>
</tr>
<tr>
<td></td>
<td>• Willingness to comply (patient and/or caregiver) with medical advice</td>
</tr>
<tr>
<td>Absolute Contraindication</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Irreversible co-existing end-stage organ failure</td>
</tr>
<tr>
<td></td>
<td>• Malignancy: see ASTS guideline in appendix 1</td>
</tr>
<tr>
<td></td>
<td>• Active infection</td>
</tr>
<tr>
<td></td>
<td>• Severe thoracic scoliosis that affects chest mechanics</td>
</tr>
<tr>
<td></td>
<td>• Portal hypertension</td>
</tr>
<tr>
<td></td>
<td>• Psychiatric illness or mental incompetence that would make compliance with medical regimen highly unlikely</td>
</tr>
<tr>
<td></td>
<td>• Lack of competent care giver</td>
</tr>
<tr>
<td>Relative Contraindications</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• High dose steroid therapy</td>
</tr>
<tr>
<td></td>
<td>• BMI ≥ 35</td>
</tr>
<tr>
<td></td>
<td>• Cachexia</td>
</tr>
<tr>
<td></td>
<td>• Diabetes mellitus</td>
</tr>
<tr>
<td></td>
<td>• Current significant acute illness that is likely to contribute to a poor outcome</td>
</tr>
<tr>
<td></td>
<td>• Co-existing end-stage organ disease</td>
</tr>
<tr>
<td></td>
<td>• Left ventricular dysfunction</td>
</tr>
<tr>
<td></td>
<td>• Congestive cardiomyopathy</td>
</tr>
<tr>
<td></td>
<td>• Substance abuse (caregiver and/or patient drug, alcohol and nicotine free for 6 months prior to evaluation)</td>
</tr>
<tr>
<td>Diseases associated with diminishing lung function:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Pulmonary fibrosis</td>
</tr>
<tr>
<td></td>
<td>• Interstitial lung disease</td>
</tr>
<tr>
<td></td>
<td>• Idiopathic pulmonary alveolar microlithiasis</td>
</tr>
<tr>
<td></td>
<td>• Pulmonary alveolar proteinosis</td>
</tr>
<tr>
<td></td>
<td>• Cystic fibrosis</td>
</tr>
<tr>
<td></td>
<td>• Obliterative bronchiolitis</td>
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<tr>
<td></td>
<td>• Bronchopulmonary deficiencies</td>
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<tr>
<td></td>
<td>• Congenital surfactant deficiencies</td>
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<tr>
<td></td>
<td>• Collagen vascular disease</td>
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<tr>
<td></td>
<td>• Pulmonary vascular disease</td>
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<tr>
<td></td>
<td>• Primary pulmonary HTN</td>
</tr>
<tr>
<td></td>
<td>• Eisenmenger’s syndrome</td>
</tr>
<tr>
<td></td>
<td>• Inadequate pulmonary vascular bed</td>
</tr>
<tr>
<td></td>
<td>• Congenital diaphragmatic hernia</td>
</tr>
</tbody>
</table>
## Adult Patient Selection Criteria

### Heart - Lung

<table>
<thead>
<tr>
<th>Indications</th>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td>All of the following:</td>
<td></td>
</tr>
<tr>
<td>- End-stage cardiopulmonary disease with severe disability (New York Heart</td>
<td>Association class III or IV refractory to all other medical or surgical</td>
</tr>
<tr>
<td>Heart Association class III or IV refractory to all other medical or</td>
<td></td>
</tr>
<tr>
<td>surgical treatments)</td>
<td></td>
</tr>
<tr>
<td>- Life expectancy of 6 – 24 months with a deteriorating status</td>
<td></td>
</tr>
<tr>
<td>- Absence of other debilitating medical illnesses</td>
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</tr>
<tr>
<td>- Stable psychosocial status</td>
<td></td>
</tr>
<tr>
<td>- Willingness to comply (patient and/or caregiver) with medical advice</td>
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</tr>
</tbody>
</table>

### Absolute Contraindication

- Irreversible co-existing end-stage organ failure
- Malignancy: see ASTS guideline in appendix 1
- Uncontrolled hypertension that requires more than two drugs for adequate control
- Thromboembolic disease, especially recurrent pulmonary emboli
- History of CVA resulting in significant impairment
- Severe renal or hepatic disease
- Severe renal impairment
  - Creatinine $> 2$mg/dl
  - Creatinine clearance $< 50$ml/min
- Severe hepatic dysfunction
  - Bilirubin $> 2.5$mg/dl
  - SGOT $> 2x$
  - INR $\geq 1.5$
- Active peptic ulcer disease
- Active infection
- Irreversible coagulopathies
- Neuromuscular and musculoskeletal disorders that limit ambulation
- Diabetes mellitus with end organ dysfunction
- Psychiatric illness or mental incompetence that would make compliance with medical regimen highly unlikely
- Lack of competent care giver
- Treatment with $\geq 50$ mg of prednisone per day due to high likelihood of tracheal and bronchial dehiscence

### Relative Contraindications

- Age $\geq 55$ years of age
- Previous thoracic or cardiac surgery
- The following collagen vascular diseases:
  - Rheumatoid arthritis with disabling joint disease
  - Lupus and lupus anti-coagulant
- Active peptic ulcer disease
- $\text{BMI} \geq 35$
Heart - Lung  | PacifiCare
---|---
- Cachexia  
- High dose, ≥ 30 mg per day of prednisone or chronic steroid therapy  
- Substance abuse (drug, alcohol and nicotine free for 6 months prior to evaluation)

### Diseases associated with diminishing heart-lung function
- Eisenmenger’s complex (cardiac abnormality associated with primary pulmonary hypertension)  
- Cardiomyopathy associated with irreversible secondary pulmonary hypertension  
- Cardiomyopathy associated with congenital heart disease  
- Untreatable primary lung disease associated with:  
  - Severe secondary right heart failure  
  - Bronchopulmonary dysplasia  
  - Cystic fibrosis  
  - Sarcoidosis  
  - Idiopathic pulmonary fibrosis  
  - Emphysema  
  - Primary pulmonary hypertension  
  - Asbestosis  
  - Bronchiectasis  
  - Wegener’s eosinophilic granulomatosis
### GUIDELINES FOR CANCER FREE WAITING PERIOD PRIOR TO TRANSPLANTATION

From The American Society of Transplant Surgeons (ASTS) Recommendations 2001

<table>
<thead>
<tr>
<th>SITE</th>
<th>WAITING PERIOD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bladder</strong></td>
<td></td>
</tr>
<tr>
<td>• In situ (noninvasive Papillomas)</td>
<td>None</td>
</tr>
<tr>
<td>• Invasive</td>
<td>2 years</td>
</tr>
<tr>
<td><strong>Renal</strong></td>
<td></td>
</tr>
<tr>
<td>• Incidental, asymptomatic</td>
<td>None</td>
</tr>
<tr>
<td>• Large, infiltrating (≥ 5 cm)</td>
<td>2-5 years</td>
</tr>
<tr>
<td>• Wilmi’s tumor</td>
<td>2 years</td>
</tr>
<tr>
<td><strong>Anogenital</strong></td>
<td></td>
</tr>
<tr>
<td>Genital warts, squamous intraepithelial neoplasias</td>
<td>None following treatment of lesions</td>
</tr>
<tr>
<td><strong>Uterus</strong></td>
<td></td>
</tr>
<tr>
<td>• In situ cervical</td>
<td>2 years</td>
</tr>
<tr>
<td>• Invasive cervical</td>
<td>5 years</td>
</tr>
<tr>
<td>• Uterine body</td>
<td>2 years</td>
</tr>
<tr>
<td><strong>Thyroid / Endocrine</strong></td>
<td>2 years</td>
</tr>
<tr>
<td><strong>Testicular</strong></td>
<td>2 years</td>
</tr>
<tr>
<td><strong>Karposi’s and other Sarcomas</strong></td>
<td>2 years</td>
</tr>
<tr>
<td><strong>Breast</strong></td>
<td>5 years</td>
</tr>
<tr>
<td>• Early stage</td>
<td>2 years</td>
</tr>
<tr>
<td><strong>Colorectal</strong></td>
<td></td>
</tr>
<tr>
<td>• Dukes A or B1</td>
<td>2 years</td>
</tr>
<tr>
<td>• Higher stages</td>
<td>5 years</td>
</tr>
<tr>
<td><strong>Prostate</strong></td>
<td>2 years</td>
</tr>
<tr>
<td>• Local lesion</td>
<td>None following treatment of lesion</td>
</tr>
<tr>
<td><strong>Liver (see indications for liver transplantation)</strong></td>
<td>5-10 years for extrahepatic transplants</td>
</tr>
<tr>
<td><strong>Lung</strong></td>
<td>2 years</td>
</tr>
<tr>
<td><strong>Lymphoma and post transplant Lymphoproliferative Disorders (PTLD)</strong></td>
<td>2 years</td>
</tr>
<tr>
<td><strong>Leukemia</strong></td>
<td>2 years</td>
</tr>
<tr>
<td><strong>Skin</strong></td>
<td></td>
</tr>
<tr>
<td>• Malignant melanoma</td>
<td>5 years</td>
</tr>
<tr>
<td>• In situ melanoma (very thin)</td>
<td>2 years</td>
</tr>
<tr>
<td>• Squamous cell</td>
<td>2 years</td>
</tr>
<tr>
<td>• Basal cell</td>
<td>None</td>
</tr>
</tbody>
</table>
TITLE: Out-of-Area Emergency/Urgently Needed Services and Transportation

Authorized By: Medical Management Guideline Committee

Approval Date: 01/28/03  Revision Date: 03/16/04
11/23/04
11/22/05

Disclaimer
This medical management guideline represents the recommendation of the PacifiCare Medical Management Guideline (MMG) committee. It is based on the MMG committee's review of the available evidence as of the date of this medical management guideline.

This medical management guideline contains clinical practice and utilization criteria to assist professionals in PacifiCare’s medical management practice when making medical necessity determinations prior to, subsequent to, or concurrent with the provisions of health care services. This medical management guideline is intended to support consistent, appropriate medical necessity determinations, but it does not replace an individualized case-by-case review and medical necessity determination for each PacifiCare member.

Member benefit coverage and limitations may vary based on the member’s benefit plan. Please consult with your local Medicare carrier to determine if a Local Coverage Determination is in place.

I. BACKGROUND

A. Description
Out-of-area services are services incurred while a member is temporarily outside the service area (outside a 30-mile radius of the member’s assigned PMG/IPA). Out-of-area coverage includes coverage for emergency conditions, urgently needed services, and post stabilization care. Once the member’s condition is stable, follow-up care is provided by the member’s PMG/IPA.

Out-of-area transportation services include services involved in the transport of the member, via ground or air, from the out-of-area facility to the member’s assigned service area.
Medical Management Guideline

B. Benefit
Secure Horizons covers out-of-area emergency/urgently needed services and out-of-area ambulance transportation when determined to be medically necessary and specific criteria are met in accordance with the Federal and State regulations and requirements. In addition, Secure Horizons covers maintenance dialysis when the member is temporarily outside of the service area for 6 months or less. See the Secure Horizons Benefit Interpretation Policy (BIP) *Emergency and Urgent Services*.

Secure Horizons covers ambulance transportation by ground or air to the nearest appropriate facility when a condition requiring medically necessary covered services exists and other means of transportation would be contraindicated. See the Secure Horizons Benefit Interpretation Policy (BIP) *Ambulance Transportation*.

C. Local Carrier (Medicare) Determination
None

II. RECOMMENDATIONS

*NOTE:* Member benefit coverage and limitations may vary based on the member’s benefit plan. Refer to member specific Evidence of Coverage (EOC), Schedule of Benefits (SOB), or Certificate of Coverage (COC). If there is a discrepancy between this guideline and the member’s EOC/SOB/COC, the member’s EOC/SOB/COC provision will govern.

The appropriateness of out-of-area services will be based on the following:

A. Emergency/urgently needed services
   1. Requested services are medically necessary
   2. Requested services are considered covered benefits by Secure Horizons
   3. Requested services are necessary to enable the member to return to the service area, or to prevent serious deterioration of the member’s condition
   4. Determine a coordination plan. The treating physician must be in agreement with the Plan’s proposed coordination plan. If not, a contracting/participating physician, ideally with privileges at the facility, will assume care of that member and authorize transfer of the member back to the service area. If not, the Plan must attempt to reach an agreement with the treating physician concerning appropriateness of discharge or transfer for the member. Until such agreement is reached, the Plan, in the majority of cases, may be financially responsible for such services until an agreement is reached.
B. Transportation

1. Determine transportation method for member transfer. A consensus among the treating physician, the PCP or Plan specialist, and the Plan’s Medical Director is required regarding the member’s medical stability for transfer and the proposed transportation method.

   Ambulance services ARE NOT covered for any of the following:
   1. Member initiated for social or convenience reasons that are not primarily medical (e.g., moving to be closer to family)
   2. Moving from one contracting facility to another contracting facility unless the transfer is necessary to deliver medical services

C. Patient Management

Management of the patient should be based on the following:

1. Post-stabilization care cannot be limited except when there is a contracting/participating physician who will assume appropriate care of the member who remains out-of-area
2. All medically necessary covered benefits requested and ordered by the treating physician are covered without distinction that the member is out-of-area
3. Denial of coverage may be issued if:
   a. The care or services requested are not a Plan covered benefit
   b. The services were not medically necessary
   c. Services could await the member’s return to the service area without putting the member in danger of serious deterioration or bodily functional loss
   d. The treating physician is in agreement with the transfer; there is a physician willing to accept the member’s care, but the member refuses. If the member can reasonably return to the service area but the member refuses, the Plan must explain the denial of continued out-of-area coverage and give the member a written notice and a reasonable time in which to return to the service area
4. The Plan is responsible for medically necessary nurse-companion or other medical or health care services that are ordered by a treating physician and/or are a condition of the member’s discharge
5. Return transportation to the service area if the member can return safely by common carrier, including medically necessary special accommodations that are not health services (e.g., first class airline ticket seat or two or three economy seats for the member to elevate extremity) are the responsibility of the member
6. Secure Horizons members’ post stabilization care must be authorized within the regulatory time frame (within 1 hour of the request). Post stabilization care must be
related to emergent or urgently needed services required to treat the member’s medical condition

7. Secure Horizons members’ post stabilization care may be assumed or limited by:
   a. The Secure Horizons physician at the hospital the member is in, if the physician has privileges
   b. Through transfer after consultation with the treating physician by a Secure Horizons physician assuming the care
   c. The member’s discharge from the facility

III. STATE/MARKET APPLICATION CRITERIA
In applying this guideline, individual needs and an assessment of the local delivery system shall be considered.
   • The following individual factors shall be considered: age, comorbidities, complications, progress of treatment, psychosocial situation, and home environment, when applicable.
   • The following aspects of the local delivery system shall be considered: availability of local facilities and benefit coverage.

When utilization management guidelines cannot be applied appropriately, individual case discussions shall ensue.

IV. REFERENCES
1. Evidence of Coverage for AZ, CA, CO, NV, OK, OR, TX, WA.
2. Konowiecki & Rank LLP Memorandum Out of Area Benefit Determinations

V. APPENDIX/DEFINITIONS

Approved by: Medical Management Guideline Committee    Date Approved: 11/22/05
TITLE: Varicose Veins of the Leg – Surgical Treatment

Authorized By: Medical Management Guideline Committee

Approval Date: 09/01/05

Disclaimer

This medical management guideline represents the recommendation of the PacifiCare Medical Management Guideline (MMG) committee. It is based on the MMG committee’s review of the available evidence as of the date of this medical management guideline.

This medical management guideline contains clinical practice and utilization criteria to assist professionals in PacifiCare’s medical management practice when making medical necessity determinations prior to, subsequent to, or concurrent with the provisions of health care services. This medical management guideline is intended to support consistent, appropriate medical necessity determinations, but it does not replace an individualized case-by-case review and medical necessity determination for each PacifiCare member.

Member benefit coverage and limitations may vary based on the member’s benefit plan. Please consult with your local Medicare carrier to determine if a Local Coverage Determination is in place.

A. BACKGROUND

1. Description

The venous system of the lower extremity consists of the superficial, communicating, and deep veins. The superficial vein system comprises the greater and lesser saphenous veins and their tributaries and connects to the deep venous system through smaller communicating or perforator veins. The deep veins are classified as either intra- or intermuscular. The greater saphenous vein (GSV) connects to the deep venous system at the saphenofemoral junction (SFJ) in the groin. The lesser saphenous vein connects to the deep venous system at the saphenopopliteal junction in the knee area (Valencia et al, 2001).

All 3 venous systems are equipped with one-way bicuspid valves, which allow blood to flow in a cephalad direction and, normally, prevent reflux. Blood is moved from the legs to the heart predominantly by the pumping action of the leg muscles. As the calf muscles contract, the deep veins are compressed, resulting in a transient rise of pressure in the deep system propelling blood in a cephalad
direction. As pressure rises in the deep system, the venous valves close, preventing retrograde flow. The subsequent fall in deep vein pressure as the system empties allows the valves to open and drive blood from the superficial into the deep system (Valencia et al, 2001).

In an unhealthy venous system, venous pressure in the deep system may either fall only minimally or not at all on ambulation, a condition also called venous hypertension or chronic venous insufficiency, and the sustained ambulatory pressure may ultimately be transmitted to the superficial system. Chronic venous insufficiency is the result of one of 4 pathophysiologic mechanisms: (1) dysfunction of the valves in the superficial and/or communicating veins due to congenital or acquired incompetence; (2) dysfunction of the valves in the deep system due to congenital absence, inherent weakness, or thrombotic damage; (3) deep venous outflow obstruction rather than valvular incompetence; and (4) muscle dysfunction and calf muscle pump failure from inflammatory conditions of the joints or muscles, fibrosis, or neuropathies (Valencia et al, 2001).

Reflux in the GSV has been shown to be an important component of the pathophysiology of primary venous insufficiency (Merchant et al, 2002). Chronic venous insufficiency, most commonly due to saphenous vein reflux, may lead to venous dilation, edema, skin pigmentation, and ulceration. As a result of venous dilation, varicose veins may occur, which are defined as dilated, palpable subcutaneous veins generally larger than 4mm (Porter and Moneta, 2000). The clinical severity of varicose disease can be graded according to the clinical, etiologic, anatomic, and pathophysiologic (CEAP) scoring system and its modifications, such as the venous clinical severity score (Rutherford et al, 2000). The standard treatment for GSV reflux is surgical stripping of the GSV from the groin to just below the knee with high ligation of the SFJ (Rautio et al, 2002; Sybrandy et al, 2002).

Symptomatic venous insufficiency is estimated to affect about 10-15% of adult men and 20-25% of adult women (Weiss and Weiss, 2002). The American College of Phlebology (ACP) estimates that more than 80 million Americans are affected by some form of venous disorder (ACP 2005).

Non-surgical treatment options include weight reduction, leg elevation, walking, and gradient compression (Valencia et al, 2001). Surgical treatment of varicose veins of the leg is intended to improve venous circulation by correcting venous insufficiency through removal of major reflux pathways (Feied et al, 2004). Surgical treatment options focus on treating the saphenous vein reflux as well as the varicosities. Treatment options to eliminate saphenous vein reflux include
surgical vein stripping and endovenous radiofrequency and laser ablation (Mozes et al, 2005). Treatment options for varicosities include stab avulsion, or ambulatory phlebectomy, and sclerotherapy (Teruya and Ballard, 2004; Sadick and Wasser, 2004).

2. **Local Coverage Determinations**
The following Local Coverage Determinations (LCDs) were identified as of June 21, 2005:

Oklahoma: Blue Cross and Blue Shield of Arkansas: Non Operative Treatment of Varicose Veins (OK/NM Medicare Services, 2005)

"Indications and Limitations of Coverage and/or Medical Necessity:
This LCD addresses sclerotherapy, endoluminal radiofrequency ablation (ERFA) and laser system ablation of varicose veins.

I. **Indications**
Conservative measures often yield satisfactory results in treatment of varicose veins. The surgical treatment of varicose veins may be medically necessary when ALL of the following criteria (1-4) are met.

1. One of the following indications (A-E) is present:
   A. Persistent symptoms interfering with activities of daily living in spite of conservative/non-surgical management. Symptoms include aching, cramping, burning, itching and/or swelling during activity or after prolonged standing;
   B. Significant recurrent attacks of superficial phlebitis;
   C. Hemorrhage from a ruptured varix;
   D. Ulceration from venous stasis (usually in conjunction with deep venous insufficiency) where incompetent varices are a contributing factor; or
   E. Symptomatic incompetence of the greater or lesser saphenous veins (with symptoms as in A above)

2. A trial of conservative, non-operative treatment for at least three months has failed. This would include mild exercise, avoidance of prolonged immobility, periodic elevation of legs, and compressive stockings.

3. The patient’s anatomy is amenable to ERFA or laser ablation, including ALL of the following:
   A. Non-aneurysmal saphenous vein(s);
   B. Maximum saphenous vein diameter of 12mm (for ERFA only); and
Medical Management Guideline

C. Absence of vein tortuosity which would impair catheter advancement.

4. All significant abnormalities and possible causes of the symptoms are addressed, as outcomes of the procedure are dependent on thoroughness of both diagnosis and the treatment itself.”

“The treatment of veins that are distended, lengthened and tortuous (i.e., varicose veins) by the injection of an irritant solution to encourage obliteration of the veins by thrombosis and subsequent scarring…”

“Indications and Limitations of Coverage and/or Medical Necessity:
The following quotes should be considered before applying sclerotherapy to varicose veins of the leg. M.W. Flye in Sabistan (1) states that “The enthusiasm for sclerotherapy varies, but many authorities do not use it as the primary treatment for incompetent varicose veins, since the recurrence rate may be high… Recurrence is a particular problem when sclerotherapy is used for large-caliber veins. In addition, sclerosing solutions can cause allergic reactions.” L.J. Greenfields, in Schwartz (2), states that “It [sclerotherapy] is useful primarily for managing of smaller varicose veins and for recurrent or persistent varicosities after operative treatment.” S.J. Burnham, in Rutherford (3), states that “This procedure [sclerotherapy] is contraindicated in limbs with saphenofemoral incompetence.”


B. RECOMMENDATIONS

NOTE: Member benefit coverage and limitations may vary based on the member’s benefit plan. Refer to member specific Evidence of Coverage (EOC), Schedule of Benefits (SOB), or Certificate of Coverage (COC). If there is a discrepancy between this guideline and the member’s EOC/SOB/COC, the member’s EOC/SOB/COC provision will govern.

Varicose Veins – Surgical Treatment – Secure Horizons
Note: The following treatments are recommended for patients with varicose veins defined as dilated greater than 4mm and tortuous as documented in the physical exam (photographs may be submitted).

Procedures to eliminate saphenous reflux

1. **Saphenous vein stripping**
   For saphenous vein stripping, a 2- to 3-cm incision is made at the groin crease and the SFJ is exposed by dissection. After ligation and division of the SFJ and all associated tributaries, a stripping instrument is inserted into the GSV at the groin and is threaded through the incompetent vein distally to the level of the upper calf, where it is brought out through a small incision. An inverting head is then attached to the stripping instrument at the groin and secured to the proximal end of the vein. The vein is inverted into itself while tearing away from each tributary and perforator vessel as the stripping instrument is pulled downward through the leg and out through the incision in the upper calf (Feied et al, 2004).

Saphenous vein stripping, with or without perforator vein ligation, is recommended for patients with venous insufficiency meeting all of the following criteria (Milliman USA 2004a):
   - Symptomatic chronic venous insufficiency, as indicated by the presence of any one of the following:
     - Severe and disabling symptoms
     - Refractory dependent edema
     - Skin changes suggestive of venous disease (e.g., pigmentation, lipodermatosclerosis, thickening, eczema, cellulitis)
     - Venous stasis ulcer, recurrent or persistent
   - Incompetent saphenous vein with duplex scanning
   - Failure of conservative treatment, including compression stocking, tried for a minimum of 3 months

2. **Endovenous ablation (radiofrequency or laser)**
   Endovenous radiofrequency ablation is a catheter-based technique intended to eliminate or significantly diminish saphenous vein reflux using controlled, heat-induced collagen-denaturation contraction to reduce vein luminal diameter. During the procedure, percutaneous access is gained below the SFJ and the catheter is inserted into the GSV to the SFJ under ultrasound guidance. Once the therapeutic temperature of 85°C is achieved, the catheter is withdrawn at 2.5-3.0 cm/min, while a vein wall temperature within 3°C of the therapeutic value is always maintained (Manfrini et al, 2000). The combination of collagen contraction,
thrombosis in the residual lumen, and intimal damage results in obliteration of the vein while the collagen contraction of the vein wall minimizes the likelihood of recanalization of the treated vein (Sybrandy et al, 2002; Weiss and Weiss, 2002).

Endovenous laser ablation uses laser energy (810nm or 940nm) delivered by a 600µm fiber. Percutaneous access is gained at the level of the knee and an endovenous catheter is advanced under ultrasound guidance (NICE 2004a). The bare-tipped laser fiber is positioned 1cm to 2cm below the SFJ and then slowly withdrawn as laser energy is delivered in a pulsed fashion (Proebstle et al, 2002; Bush et al, 2005). The laser energy causes the formation of steam bubbles, leading to endothelial damage, thrombotic occlusion, and collagen contraction (Proebstle et al, 2003; Perkowski et al, 2004; Corcos et al, 2005). As a result, the vein wall thickens and the vein lumen contracts (Teruya and Ballard, 2004; Min et al, 2003).

Endovenous ablation, using radiofrequency or laser energy, for the treatment of varicose veins of the leg is recommended for ambulatory patients meeting all of the following criteria:

- Symptomatic chronic venous insufficiency, as indicated by the presence of any one of the following (Milliman USA 2004a):
  - Severe and disabling symptoms
  - Refractory dependent edema
  - Skin changes suggestive of venous disease (e.g., pigmentation, lipodermatosclerosis, thickening, eczema, cellulitis)
  - Venous stasis ulcer, recurrent or persistent
- Incompetent saphenous vein with duplex scanning (Milliman USA 2004a)
- Failure of conservative treatment, including compression stocking, tried for a minimum of 3 months (Milliman USA 2004a)
- Patient’s anatomy is amenable to endovenous ablation, including all of the following (OK/NM Medicare Services, 2005):
  - Non-aneurysmal saphenous vein(s)
  - Absence of vein tortuosity which would impair catheter advancement
  - Maximum saphenous vein diameter of 12mm (radiofrequency ablation only)
- All significant abnormalities and possible causes of the symptoms have been addressed (OK/NM Medicare Services)
Procedures to eliminate varicosities

1. **Stab avulsion/ambulatory phlebectomy**
   Stab avulsion, or ambulatory phlebectomy, allows for removal of short segments of varicose veins through tiny incisions. For this procedure, a microincision is made over the vessel using a small blade or a large needle. A phlebectomy hook is then introduced into the microincision, and the vein is removed through the microincision (Feied et al, 2004; Weiss et al, 2004).

   Ambulatory phlebectomy is recommended for patients with varicose veins and venous insufficiency meeting all of the following criteria (Milliman USA 2004a):
   - Symptomatic chronic venous insufficiency, as indicated by the presence of any one of the following:
     - Severe and disabling symptoms
     - Refractory dependent edema
     - Skin changes suggestive of venous disease (e.g., pigmentation, lipodermatosclerosis, thickening, eczema, cellulitis)
     - Venous stasis ulcer, recurrent or persistent
   - Incompetent saphenous vein with duplex scanning
   - Failure of conservative treatment, including compression stocking, tried for a minimum of 3 months

2. **Sclerotherapy and foam sclerotherapy**
   Sclerotherapy represents the targeted elimination of intracutaneous, subcutaneous, and/or trans fascial varicose veins (perforating veins) (Rabe et al, 2004).
   Sclerotherapy uses sclerosing agents that are injected into the vessel causing endothelial damage and subsequent vein collapse. Types of sclerosing agents include detergents, osmotic agents, and chemical irritants (Parsons 2004). For foam sclerotherapy, a detergent-like sclerosing agent is first transformed into a fine-bubbled foam by forcibly mixing it with air (Rabe et al, 2004).

   Sclerotherapy, using liquid or foam sclerosants, is recommended for patients with varicose veins and venous insufficiency meeting any one of the following criteria (Milliman USA 2004b):
   - Recurrent or residual symptomatic varicosities after vein stripping
   - Bleeding varices
   - Large varices around a skin ulcer
Note: Limited research is available on the following procedures, which are therefore **not** generally recommended at this time:
- Transilluminated powered phlebectomy (Hayes 2002)
- Subfascial endoscopic perforator vein surgery (SEPS) (NICE 2004b)
- Sclerotherapy plus ligation at the SFJ (Milliman USA 2004c)

C. **STATE/MARKET APPLICATION CRITERIA**

In applying this guideline, individual needs and an assessment of the local delivery system shall be considered.
- The following individual factors shall be considered: age, comorbidities, complications, progress of treatment, psychosocial situation, and home environment, when applicable.
- The following aspects of the local delivery system shall be considered: availability of local facilities and benefit coverage.

When utilization management guidelines cannot be applied appropriately, individual case discussions shall ensue.

D. **REFERENCES**


*Varicose Veins – Surgical Treatment – Secure Horizons*


Medical Management Guideline


Medical Management Guideline


Approved by: Medical Management Guideline Committee Date Approved: 09/01/05
A. BACKGROUND

1. Description
Vision impairment rehabilitation is designed to improve the performance of activities of daily living in patients with vision impairment or vision loss whose vision cannot be corrected to normal or near normal by standard restorative processes. Vision impairment ranging from low vision to total blindness may result from primary eye disorders, such as macular degeneration, retinitis pigmentosa, or glaucoma, or as a condition secondary to another primary diagnosis, such as diabetes mellitus, acquired immune deficiency syndrome (AIDS), infection, etc. Vision rehabilitation in these patients is intended to maximize the use of residual vision and to provide practical adaptations and training to increase functional ability, personal safety, and independence (NHIC 2005).

Vision rehabilitation services are provided by a multi-disciplinary team, usually consisting of an optometrist or ophthalmologist and other trained individuals, such as...
Medical Management Guideline

as occupational therapists, rehabilitation teachers, physical therapists, orientation and mobility specialists, social workers, and rehabilitation counselors (Wilkinson 2003). Vision rehabilitation services begin with a low vision evaluation performed by an optometrist or ophthalmologist with specialized training. The low vision evaluation focuses on the patient’s functional ability and assesses near and distance acuity, visual fields, and contrast sensitivity (Lighthouse International 2004). The optometrist or ophthalmologist then defines the patient’s treatment objectives and determines the patient’s treatment plan (Wilkinson 2003).

Vision rehabilitation services typically consist of the following components (Lighthouse 2004):

- Orientation and mobility instruction: to develop a patient’s ability to use auditory, tactile, and other sensory data to keep them oriented in space
- Skills of daily living – rehabilitation teaching: to teach patients the safe and modified use of everyday equipment, such as stoves, microwaves, and knives, as well as safe child and elder care practices, and medication management
- Psychosocial services: to address the emotional and social needs of vision impaired patients

2. Benefit
Secure Horizons covers vision impairment rehabilitation when determined to be medically necessary and specific criteria are met. See the Secure Horizons Benefit Interpretation Policy (BIP) Vision Care and Services.

3. Local Coverage Decisions
The following Local Coverage Decision (LCD) was identified as of June 2005:

Excerpts:
“Low Vision Rehabilitation services are provided by an ophthalmologist, optometrist, or non-eye care physician; by a non-physician under the direct supervision of the ophthalmologist, optometrist, or non-eye care physician; or by an occupational therapist or physical therapist by prescription from the ophthalmologist, optometrist, or non-eye care physician. Providers performing the evaluation and management of patients with vision loss must possess an understanding of clinical optics and the training skills necessary to design, execute, and adjust a low vision rehabilitation plan. These services should not be performed without proper training.”
“Low Vision Rehabilitation services should be provided in accordance with a physician’s written evaluation and treatment plan. The treatment plan should include:

- An initial assessment that documents the level of visual impairment and the underlying disease if established;
- A plan of care identifying specific goals to be fulfilled during rehabilitation;
- The definition of specific rehabilitative services to be provided during the course of rehabilitation;
- A reasonable estimate of when the goals will be reached, and the frequency at which the services will be provided.”

“Low Vision Rehabilitation is indicated in those patients who exhibit one of the following:

- A best corrected visual acuity of less than 20/60 in the better or only seeing eye
- Constriction of visual fields or peripheral visual field defect
- A scotoma or central visual field defect
- A homonymous or heteronymous bilateral visual field defect”

Patients must possess the cognitive and physical skills necessary to benefit from rehabilitation services.”

- “Advisors with expertise with Visual Rehabilitation have recommended that most patients require 30 or less units of visual rehabilitation at a particular level of visual function to achieve most goals. If additional services were needed, we would expect documentation including a new or amended treatment plan to explain the need for extended services.
- If significant changes or worsening of the visual status can be documented, additional Low Vision Rehabilitation services, provided to improve the overall functioning of the patient, will be a covered benefit.
- We would expect that individuals performing Low Vision Rehabilitation are appropriately trained to perform this service. Individuals, other than licensed physical therapists or occupational therapists, who perform these services incident to a physician, should be certified by an organization such as the Joint Commission of Allied Health Personnel in Ophthalmology or the American Optometric Association Commission on Paraoptometric Certification.”
B. RECOMMENDATIONS

**NOTE:** Member benefit coverage and limitations may vary based on the member’s benefit plan. Refer to member specific Evidence of Coverage (EOC), Schedule of Benefits (SOB), or Certificate of Coverage (COC). If there is a discrepancy between this guideline and the member’s EOC/SOB/COC, the member’s EOC/SOB/COC provision will govern.

Vision impairment rehabilitation is recommended for patients with vision impairment who meet all of the following criteria (CMS 2002a):

- Patient should have a potential for restoration or improvement of lost functions
- Patient should be expected to improve significantly within a reasonable and generally predictable amount of time
- Services should be provided by a physician, a qualified occupational or physical therapist, or by an employee of a physician under the physician’s direct supervision and incident to the physician’s services

Note: Vision impairment rehabilitation should be provided for 30 units or less at a particular level of visual function (NHIC 2005).

Note: For patients with a primary vision impairment diagnosis (e.g., macular degeneration, retinitis pigmentosa, or glaucoma), services should be provided pursuant to a written treatment plan established by a physician and implemented by a qualified occupational or physical therapist (or a person supervised by a qualified therapist) or incident to physician services (CMS 2002a).

Definition of levels of vision impairment (CMS 2002b):
- **Moderate** Best corrected visual acuity is less than 20/60
- **Severe** Best corrected visual acuity is less than 20/160, or (legal blindness) visual field is 20 degrees or less
- **Profound** Best corrected visual acuity is less than 20/400, or (moderate blindness) visual field is 10 degrees or less
- **Near-total** Best corrected visual acuity is less than 20/1000, or (severe blindness) visual field is 5 degrees or less
- **Total** No light perception (total blindness)
C. STATE/MARKET APPLICATION CRITERIA
In applying this guideline, individual needs and an assessment of the local delivery system shall be considered.

- The following individual factors shall be considered: age, comorbidities, complications, progress of treatment, psychosocial situation, and home environment, when applicable.
- The following aspects of the local delivery system shall be considered: availability of local facilities and benefit coverage.

When utilization management guidelines cannot be applied appropriately, individual case discussions shall ensue.

D. REFERENCES


Approved by: Medical Management Guideline Committee

Date Approved: 09/01/05
Medical Management Guideline

TITLE: Treatment of Wounds
Authorized By: Medical Management Guideline Committee
Approval Date: 05/25/04    Revision Date: 08/24/04
                      02/22/05

Disclaimer
This medical management guideline represents the recommendation of the PacifiCare Medical Management Guideline (MMG) committee. It is based on the MMG committee's review of the available evidence as of the date of this medical management guideline.

This medical management guideline contains clinical practice and utilization criteria to assist professionals in PacifiCare’s medical management practice when making medical necessity determinations prior to, subsequent to, or concurrent with the provisions of health care services. This medical management guideline is intended to support consistent, appropriate medical necessity determinations, but it does not replace an individualized case-by-case review and medical necessity determination for each PacifiCare member.

Member benefit coverage and limitations may vary based on the member’s benefit plan. Please consult with your local Medicare carrier to determine if a Local Coverage Determination is in place.

A. BACKGROUND

1. Description
Normal wound healing is a complex process involving an immediate sequence of cell migration leading to tissue repair and wound closure. This sequence consists of removal of debris, control of infection, clearance of inflammation, angiogenesis, deposition of granulation tissue, contraction, remodeling of the connective tissue matrix, and maturation. If wounds fail to undergo this sequence, chronic wounds may result. Clinically, chronic wounds are associated with pressure, trauma, venous insufficiency, diabetes mellitus, vascular disease, or prolonged immobilization (Joseph et al, 2000). The most common chronic ulcers are lower extremity ulcers related to venous insufficiency, followed by diabetic (neuropathic) ulcers of the foot and pressure (decubitus) ulcers on any part of the body (Mostow 2003).
Medical Management Guideline

2. **Benefit**
Secure Horizons covers the treatment of wounds when determined to be medically necessary and specific criteria are met. See the Secure Horizons Benefit Interpretation Policies (BIPs) *Hyperbaric Oxygen Therapy (HBO)* and *Durable Medical Equipment (DME), Prosthetics, Corrective Appliances and Medical Supplies Grid (DME GRID)*.

B. **RECOMMENDATIONS**

*NOTE: Member benefit coverage and limitations may vary based on the member’s benefit plan. Refer to member specific Evidence of Coverage (EOC), Schedule of Benefits (SOB), or Certificate of Coverage (COC). If there is a discrepancy between this guideline and the member’s EOC/SOB/COC, the member’s EOC/SOB/COC provision will govern.*

Wound care relies on a number of general principles. Primary goals are relieving pain, correcting nutritional deficiencies, maintaining a moist wound environment, shielding the wound from further damage, removing necrotic debris, promoting granulation tissue, and protecting the wound from bacterial contamination (Thomas and Kamel, 2000).

The following treatments are recommended:

1. **Hyperbaric oxygen therapy**

   Hyperbaric oxygen therapy involves the systemic administration of 100% gaseous oxygen in chambers pressurized above 1 atmosphere absolute (ATA). The therapy is intended to improve wound healing by increasing oxygenation of the area surrounding the wound, thus lessening the impairment of leukocyte bacteriocidal activities caused by reduced oxygen supply (Wang et al, 2003).

   a. Hyperbaric oxygen therapy is recommended when all of the following criteria are met:
      - Patient has type 1 or type 2 diabetes and has a lower extremity wound that is due to diabetes (CMS a; ADA 1999) and
      - Patient has a wound classified as Wagner grade 3 (see Appendix I for details) or higher (CMS a)
      - Hyperbaric oxygen therapy is used as adjunctive therapy to standard wound therapy (CMS a)
      - Patient has failed an adequate course of standard wound therapy (CMS a; ADA 1999), as demonstrated by the absence of any measurable signs of healing for at least 30 consecutive days of
treatment with standard wound therapy (CMS a). Standard wound therapy in patients with diabetic wounds should include the following (CMS a):

- Assessment of vascular status and correction of any vascular problems in the affected limb if possible
- Optimization of nutritional status
- Optimization of glucose control
- Debridement by any means to remove devitalized tissue
- Maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings and appropriate off-loading
- Necessary treatment to resolve any infection that might be present

Note: Wounds must be evaluated at least every 30 days during administration of hyperbaric oxygen therapy. Continued treatment with hyperbaric oxygen therapy is not recommended if measurable signs of healing have not been demonstrated within any 30-day period of treatment (CMS a).

b. Hyperbaric oxygen therapy is recommended for the following indications if used as adjunctive treatment to accepted standard therapeutic measures when loss of function, limb, or life is threatened (CMS a; Wang et al, 2003):

- Gas gangrene
- Acute traumatic peripheral ischemia
- Crush injuries and suturing of severed limbs
- Progressive necrotizing infections (necrotizing fasciitis)
- Preparation and preservation of compromised skin grafts
- Soft tissue radionecrosis

2. Electrical stimulation and electromagnetic therapy

Electrical stimulation uses electrical current applied through electrodes, which are placed directly on the skin close to the wound (CMS b). The electrical current is intended to increase the migration of neutrophils and macrophages and to stimulate fibroblasts. In addition, electrical stimulation might also enhance wound healing by improving blood flow. The devices used for electrical stimulation for wound healing are based on 4 major types: (1) low intensity direct current (LIDC); (2) high voltage pulsed current (HVPC); (3) alternating current (AC); and transcutaneous electrical nerve stimulation (TENS) (Gardner et al, 1999).
Electromagnetic therapy is distinct from other forms of electrotherapy in that it uses a field of electricity and not a direct electrical effect to promote wound healing (Fleming and Cullum, 2001).

Electrical stimulation or electromagnetic therapy is recommended for the following indications (CMS b; CMS 2004):

- Chronic (not healed within 30 days of occurrence) Stage III and Stage IV pressure ulcers (see Appendix I for details)
- Arterial ulcers
- Diabetic ulcers
- Venous stasis ulcers

For all indications, the following criteria must be met (CMS b; CMS 2004):

- Electrical stimulation or electromagnetic therapy is used as adjunctive therapy to standard wound therapy
- Patient has failed an adequate course of standard wound therapy as demonstrated by the absence of any measurable signs of healing (decrease in wound size in surface area or volume, decrease in amount of exudates, decrease in amount of necrotic tissue) for at least 30 consecutive days of treatment with standard wound therapy. Standard wound therapy should include the following:
  - Optimization of nutritional status
  - Debridement by any means to remove devitalized tissue
  - Maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings
  - Necessary treatment to resolve any infection that may be present
  - For patients with pressure ulcers: frequent repositioning (usually every 2 hours)
  - For patients with arterial ulcers: establishment of adequate circulation
  - For patients with diabetic ulcers: off-loading of pressure and good glucose control
  - For patients with venous ulcers: use of a compression system

Note: Continued treatment with electrical stimulation or electromagnetic therapy is not recommended if measurable signs of healing have not been demonstrated within any 30-day period of treatment. Electrical stimulation or electromagnetic therapy should be discontinued when the wound demonstrates a 100% epithelialized wound bed. Electrical stimulation or electromagnetic therapy should be performed by a physician, physical therapist, or incident to a physician service (CMS b; CMS 2004).
3. Skin substitutes for wound healing
   a. Apligraf

Apligraf is an allogeneic, bilayered skin substitute containing both dermal and epidermal components. The dermal layer contains living fibroblasts and the epidermal layer is composed of live, differentiating keratinocytes and a well-differentiated stratum corneum. The fibroblasts and keratocytes are derived from human male neonatal foreskin. Apligraf is applied to a prepared wound bed using sterile techniques (HAYES 2004).

Apligraf used in conjunction with standard wound therapy is recommended for the following indications:

1. Venous leg ulcers
   Apligraf in conjunction with standard therapy is recommended for patients meeting all of the following criteria (HAYES 2004):
   - Partial or full-thickness Venous leg ulcer(s) of more than 3 months duration (Noridian 2001)
   - Ulcer(s) have not responded to documented conservative measures for greater than 2 months duration (Noridian 2001)

2. Full-thickness, neuropathic diabetic foot ulcers
   Apligraf in conjunction with standard therapy is recommended for patients with type 1 or type 2 diabetes mellitus who meet all of the following criteria (HAYES 2004):
   - Partial or full-thickness, neuropathic diabetic foot ulcer(s) of more than 4 weeks duration (Noridian 2001)
   - No tendon, muscle, capsule, or bone exposure (HAYES 2004)
   - Ulcer(s) have not responded to documented conservative measures for greater than 1 month duration (Noridian 2001)
   - Appropriate steps to off-load pressure during treatment are taken (Noridian 2001)
   - Ulcer is free of infection and underlying osteomyelitis (Noridian 2001)
   - Treatment of underlying disease is provided and documented in conjunction with Apligraf treatment (Noridian 2001)

Notes (Noridian 2001):
- Measurements should be taken of the initial ulcer size, the size following cessation of conservative management, and the size at the beginning of skin substitute treatment.
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- Use of Apligraf should be limited to 3 separate applications to any given ulcer
- Minimum time periods between applications should be 6 weeks for venous stasis ulcers and 3 weeks for neuropathic diabetic foot ulcers
- For venous stasis ulcers, 2 applications of Apligraf are recommended. If after 12 weeks of compression treatment and 2 applications of Apligraf a 50% or greater improvement is noted and documented, a third application of Apligraf is recommended. Otherwise, reapplication of the skin substitute is not recommended and other treatment modalities should be considered
- Re-treatment for venous stasis ulcers within 1 year is not recommended
- For neuropathic diabetic foot ulcers, if after 9 weeks of treatment and 3 applications of Apligraf satisfactory healing process is not noted, reapplication of Apligraf is not recommended and other treatment modalities should be considered

4. Negative Pressure Wound Therapy (NPWT) Pump

   An NPWT pump and supplies are recommended for treating ulcers and wounds in the home setting when either criterion A or B is met (DMERC 2004):

   A. The patient has a chronic Stage III or IV pressure ulcer (see Appendix I for details), neuropathic (for example, diabetic) ulcer, venous or arterial insufficiency ulcer, or a chronic (being present for at least 30 days) ulcer of mixed etiology. A complete wound therapy program described by criterion 1) and criteria 2), 3), or 4) below, as applicable depending on the type of wound, should have been tried or considered and ruled out prior to application of NPWT

   Criteria:
   1) For all ulcers or wounds, the following components of a wound therapy program must include a minimum of all of the following general measures, which should either be addressed, applied, or considered and ruled out prior to application of NPWT:
      - Documentation in the patient’s medical record of evaluation, care, and wound measurements by a licensed medical professional
      - Application of dressings to maintain a moist wound environment
      - Debridement of necrotic tissue if present
      - Evaluation of and provision for adequate nutritional status
   2) For Stage III or IV pressure ulcers:
      - The patient has been appropriately turned and positioned
      - The patient has used a Group 2 or 3 support surface for pressure
ulcers on the posterior trunk or pelvis (a Group 2 or 3 support surface is not required if the ulcer is not on the trunk or pelvis)

- The patient’s moisture and incontinence have been appropriately managed

3) For neuropathic (for example, diabetic) ulcers:
- The patient has been on a comprehensive diabetic management program
- Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities

4) For venous insufficiency ulcers:
- Compression bandages and/or garments have been consistently applied
- Leg elevation and ambulation have been encouraged

B. For ulcers and wounds encountered in an inpatient setting when treatment continuation is ordered beyond discharge to the home setting when either criterion 1) or 2) is met:

1) An ulcer or wound (described under A above) is encountered in the inpatient setting and, after wound treatments described under A-1) through A-4) have been tried or considered and ruled out, NPWT is initiated because it is considered in the judgment of the treating physician, the best available treatment option

2) The patient has complications of a surgically created wound (for example, dehiscence) or a traumatic wound (for example, pre-operative flap or graft) where there is documentation of the medical necessity for accelerated formation of granulation tissue which cannot be achieved by other available topical wound treatments (for example, other conditions of the patient that will not allow for healing times achievable with other topical wound treatments)

C. STATE/MARKET APPLICATION CRITERIA
In applying this guideline, individual needs and an assessment of the local delivery system shall be considered.

- The following individual factors shall be considered: age, comorbidities, complications, progress of treatment, psychosocial situation, and home environment, when applicable.
- The following aspects of the local delivery system shall be considered: availability of local facilities and benefit coverage.

When utilization management guidelines cannot be applied appropriately, individual
case discussions shall ensue.

D. REFERENCES


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Appendix I

Staging of Pressure Ulcers (DMERC 2004)

Stage I  Observable pressure-related alteration of intact skin whose indicators as compared to the adjacent or opposite area on the body may include changes in one or more of the following: skin temperature (warmth or coolness), tissue consistency (firm or boggy feel), and/or sensation (pain, itching). The ulcer appears as a defined area of persistent redness in lightly pigmented skin, whereas in darker skin tones, the ulcer may appear with persistent red, blue, or purple hues.

Stage II  Partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion, blister, or shallow crater.

Stage III  Full thickness skin loss involving damage to, or necrosis of, subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.

Stage IV  Full thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures (e.g., tendon, joint capsule). Undermining and sinus tracts also may be associated with Stage IV ulcers.

Wagner Classification of Diabetic Foot Ulcers (Oyibo et al, 2001)

Grade 0  Pre-or post-ulcerative lesion
Grade 1  Partial/full-thickness ulcer
Grade 2  Probing to tendon or capsule
Grade 3  Deep ulcer with osteitis
Grade 4  Partial-foot gangrene
Grade 5  Whole-foot gangrene
Appendix II

Links to Durable Medical Equipment Regional Carrier (DMERC) policies:

AZ, CA, NV, OR & WA:
http://www.cms.hhs.gov/mcd/results_index.asp?from='lmrpcontractor'&contractor=122&name=Electronic+Data+Systems+Corporation+%2877006%29+DME+PSC+letter_range=4

CO, OK & TX:
http://www.cms.hhs.gov/mcd/results_index.asp?from='lmrpcontractor'&contractor=121&name=TrustSolutions+%2877012%29+DME+PSC+letter_range=4

Approved by: Medical Management Guideline Committee
Date Approved: 02/22/05

Treatment of Wounds – Secure Horizons
**PacifiCare Health Plans**

*Asthma Practice Guidelines: Outpatient Management of Asthma 2005-2006*

**Authorized By:** Medical Management Guideline Committee  
**Approval Date:** 10/10/02  
**Revision Date:** 11/23/04; 11/22/05

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### Stepwise Approach to Managing Asthma Long Term for Adults and Children > 5 years old

<table>
<thead>
<tr>
<th>Classification</th>
<th>Symptoms/Day</th>
<th>PEF Variability</th>
<th>Medications Required to Maintain Long-Term Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Daily Medications</td>
</tr>
<tr>
<td><strong>Step 4</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe Persistent</td>
<td>Continual</td>
<td>≤ 60%</td>
<td>• <strong>Preferred treatment:</strong></td>
</tr>
<tr>
<td></td>
<td>Frequent</td>
<td>&gt;30%</td>
<td>→ High-dose inhaled corticosteroids,</td>
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<td></td>
<td></td>
<td>AND Long-acting inhaled beta2-agonists.</td>
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<td></td>
<td>AND if needed,</td>
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<tr>
<td></td>
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<td></td>
<td>→ Corticosteroid tablets or syrup long-term (2 mg/kg/day,</td>
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<td></td>
<td></td>
<td>generally do not exceed 60 mg/day.) (Make repeat attempts</td>
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<td>to reduce systemic corticosteroids and maintain control with</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>high-dose inhaled corticosteroids.)</td>
</tr>
<tr>
<td><strong>Step 3</strong></td>
<td>Daily</td>
<td>≥60% - &lt;80%</td>
<td>• <strong>Preferred treatment:</strong></td>
</tr>
</tbody>
</table>
| Moderate Persistent     | >1 night/week         | >30%            | → Low-to-medium dose inhaled corticosteroids and long-
|                         |                       |                 | acting inhaled beta2-agonists.                      |
|                         |                       |                 | • Alternative treatment (listed alphabetically):      |
|                         |                       |                 | → Increase inhaled corticosteroids within medium-dose |
|                         |                       |                 | range OR                                             |
|                         |                       |                 | → Low-to-medium dose inhaled corticosteroids and either |
|                         |                       |                 | leukotriene modifier or theophylline.               |
|                         |                       |                 | If needed (particularly in patients with recurring severe |
|                         |                       |                 | exacerbations):                                     |
|                         |                       |                 | • **Preferred treatment:**                           |
|                         |                       |                 | → Increase inhaled corticosteroids within medium-dose |
|                         |                       |                 | range and add long-acting inhaled beta2-agonists.   |
|                         |                       |                 | • Alternative treatment:                            |
|                         |                       |                 | → Increase inhaled corticosteroids within medium-dose |
|                         |                       |                 | range and add either leukotriene modifier or theophylline. |
| **Step 2**              | >2/week but <1x/day   | ≥ 80%           | • **Preferred treatment:**                           |
| Mild Persistent         | >2 nights/month       | 20-30%          | → Low dose inhaled corticosteroids.                 |
|                         |                       |                 | • Alternative treatment (listed alphabetically):      |
|                         |                       |                 | → Cromolyn, leukotriene modifier, nedocromil, OR sustained |
|                         |                       |                 | release theophylline to serum concentration of 5-15 mcg/mL. |
| **Step 1**              | ≤ 2 days/week         | ≥ 80%           | • **No daily medication needed.**                    |
| Mild Intermittent       | ≤ 2 nights/month      | <20%            | • Severe exacerbations may occur, separated by long periods of normal lung function and no symptoms. A course of systemic corticosteroids is recommended. |

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**Quick Relief for All Patients**

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*Clinical Practice Guidelines – Outpatient Management of Asthma*

Authorized by: Medical Management Guideline Committee. Approved: 10/10/02. Revised: 11/23/04; 11/22/05
Short-acting bronchodilator: 2-4 puffs short-acting inhaled beta2-agonists as needed for symptoms. Intensity of treatment will depend on severity of exacerbation; up to 3 treatments at 20-minute intervals or a single nebulizer treatment as needed. Course of systemic corticosteroids may be needed. Use of short-acting beta2-agonists >2 times a week in intermittent asthma (daily, or increasing use in persistent asthma) may indicate the need to initiate (increase) long-term control therapy.

**Goals of Therapy: Asthma Control**

- Minimal or no chronic symptoms day or night
- Minimal use of short-acting inhaled beta2-agonist
- No limitations on activities; no school/work missed
- Minimal or no adverse effects from medications
- Maintain (near) normal pulmonary function

**Note:**

- This stepwise approach is meant to assist, not replace, the clinical decision-making required to meet individual needs.
- Classify severity: assign patient to most severe step in which any feature occurs (PEF is % of personal best; FEV1 is % predicted).
- Gain control as quickly as possible (consider a short course of systemic corticosteroids); then step down to the least medication necessary to maintain control.
- Minimize use of short-acting inhaled beta2-agonists. Over-reliance on short-acting inhaled beta2-agonists (e.g., use of short-acting inhaled beta2-agonist every day, increasing use or lack of expected effect, or use of approximately one canister a month even if not using it every day) indicates inadequate control of asthma and the need to initiate or intensify long-term control therapy.
- Provide education on self-management and controlling environmental factors that make asthma worse (e.g., allergens and irritants).
- Refer to an asthma specialist if there are difficulties controlling asthma or if step 4 care is required. Referral may be considered if step 3 care is required.

**Step Down**

Review treatment every 1-6 months; a gradual stepwise reduction in treatment may be possible.

**Step Up**

If control is not maintained, consider step up. First, review patient medication technique, adherence, and environmental control.

### PacifiCare Health Plans

*Asthma Practice Guidelines: Outpatient Management of Asthma 2005-2006*

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**Stepwise Approach to Managing Infants and Children 0-5 years old with Acute or Chronic Asthma**

<table>
<thead>
<tr>
<th>Classification</th>
<th>Symptoms/Day</th>
<th>Symptoms/Night</th>
<th>Daily Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Step 4</strong></td>
<td>Continual</td>
<td>Frequent</td>
<td><strong>Preferred treatment:</strong></td>
</tr>
<tr>
<td>Severe Persistent</td>
<td></td>
<td></td>
<td>→High-dose inhaled corticosteroids, AND →Long–acting inhaled beta2-agonists.</td>
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<tr>
<td></td>
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<td></td>
<td>AND if needed, →Corticosteroid tablets or syrup long-term (2 mg/kg/day, generally do not exceed 60 mg/day.) (Make repeat attempts to reduce systemic corticosteroids and maintain control with high-dose inhaled corticosteroids.)</td>
</tr>
</tbody>
</table>

| **Step 3**     | Daily        | >1 night/week  | **Preferred treatment:**  |
| Moderate Persistent |             |                | →Low-dose inhaled corticosteroids and long-acting inhaled beta2-agonists OR →Medium-dose inhaled corticosteroids. |
|                | >2/week but <1x/day |                | **Preferred treatment:**  |
|                | >2 night/week  |                | →Low-dose inhaled corticosteroids and either leukotriene receptor antagonist or theophylline. |

| **Step 2**     | ≤2 days/week | ≤2 night/month | **Preferred treatment:**  |
| Mild Persistent |            |                | →Low dose inhaled corticosteroids (with nebulizer or MDI with holding chamber with or without face mask or DPI). |
|                |            |                | **Preferred treatment:**  |
|                |            |                | →Low dose inhaled corticosteroids (with nebulizer or MDI with holding chamber) OR leukotriene receptor antagonist. |

| **Step 1**     | ≤2 days/week | ≤2 night/month | **No daily medication needed.** |
| Mild Intermittent |            |                | |

**Quick Relief for All Patients**

- Bronchodilator as needed for symptoms. Intensity of treatment will depend upon severity of exacerbation.
  - **Preferred treatment:** Short-acting inhaled beta2-agonists by nebulizer or face mask and space/holding chamber
- With viral respiratory infection
  - Bronchodilator q 4-6 hours up to 24 hours (longer with physician consult); in general, repeat no more than once every 6 weeks.
  - Consider systemic corticosteroid if exacerbation is severe or patient has history of previous severe exacerbations.
- Use of short-acting beta2-agonists >2 times a week in intermittent asthma (daily, or increasing use in persistent asthma) may indicate the need to initiate (increase) long-term control therapy.
**Goals of Therapy: Asthma Control**

| Minimal or no chronic symptoms day or night | Minimal use of short-acting inhaled beta2-agonist |
| Minimal or no exacerbations | Minimal or no adverse effects from medications |
| No limitations on activities; no school/parent’s work missed |

**Note:**
- This stepwise approach is meant to assist, not replace, the clinical decision-making required to meet individual needs.
- Classify severity: assign patient to most severe step in which any feature occurs.
- There are very few studies on asthma therapy for infants.
- Gain control as quickly as possible (a course of short systemic corticosteroids may be required); then step down to the least medication necessary to maintain control.
- Minimize use of short-acting inhaled beta2-agonists. Over-reliance on short-acting inhaled beta2-agonists (e.g., use of short-acting inhaled beta2-agonist every day, increasing use or lack of expected effect, or use of approximately one canister a month even if not using it every day) indicates inadequate control of asthma and the need to initiate or intensify long-term control therapy.
- Provide parent education on asthma management and controlling environmental factors that make asthma worse (e.g., allergens and irritants).
- Consultation with an asthma specialist is recommended for patients with moderate or severe persistent asthma. Consider consultation for patients with mild persistent asthma.

**Step Down**
Review treatment every 1-6 months; a gradual stepwise reduction in treatment may be possible.

**Step Up**
If control is not maintained, consider step up. First, review patient medication technique, adherence, and environmental control.

---

Assessment Measures
Periodic assessments and ongoing monitoring of asthma are recommended to determine if the goals of therapy are being met.

- Monitoring the signs and symptoms of asthma
- Monitoring pulmonary function; spirometry and peak flow monitoring
  
  Spirometry is recommended
  - at the time of initial assessment,  
  - after treatment is initiated and symptoms and PEF have stabilized, and 
  - at least every 1 to 2 years to assess the maintenance of airway function. (Spirometry may be indicated more often than every 1-2 years, depending on the clinical severity and response to management.)

  For routine monitoring at most outpatient visits, measurement of PEF with a peak flow meter is generally a sufficient assessment of pulmonary function, particularly in mild intermittent, mild persistent, and moderate persistent asthma.

- Monitoring quality of life/functional status
- Monitoring history of asthma exacerbations
- Monitoring pharmacotherapy
- Monitoring patient-provider communication and patient satisfaction

Factors Contributing to Asthma Severity

<table>
<thead>
<tr>
<th>Allergens and Irritants</th>
<th>Educate patients with asthma at any level of severity on the importance of avoiding:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Exposure to allergens to which they are sensitive.</td>
</tr>
<tr>
<td></td>
<td>• Exposure to environmental tobacco smoke.</td>
</tr>
<tr>
<td></td>
<td>• Exertion when levels of air pollution are high.</td>
</tr>
<tr>
<td></td>
<td>• Use of nonselective beta-blockers.</td>
</tr>
<tr>
<td></td>
<td>• Sulfite-containing and other foods to which they are sensitive.</td>
</tr>
<tr>
<td></td>
<td>• Exposure to cold air, by covering their nose and mouth on cold or windy days.</td>
</tr>
</tbody>
</table>

  Immunotherapy may be considered for asthma patients when:
  • there is clear evidence of a relationship between symptoms and exposure to an unavoidable allergen to which the patient is sensitive,
  • symptoms occur all year or during a major portion of the year, and
  • there is difficulty controlling symptoms with pharmacologic management.

<table>
<thead>
<tr>
<th>Viral Infections</th>
<th>Annual influenza vaccine is recommended for patients with persistent asthma.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Refer to PHP Preventive Health Recommendations</strong></td>
</tr>
</tbody>
</table>

| Smoking          | Advise patients not to smoke, and to avoid smoke exposure. Tobacco smoke is a major precipitant of asthma symptoms in children and adults. |

<table>
<thead>
<tr>
<th>Other Factors Contributing to Asthma Severity</th>
<th>Medical management and treatment for rhinitis, sinusitis and GERD.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult patients with asthma should be questioned regarding precipitation of bronchoconstriction by aspirin and other nonsteroidal anti-inflammatory drugs. If they</td>
<td></td>
</tr>
</tbody>
</table>
have experienced a reaction to any of these drugs, they should be informed of the potential for all these drugs to precipitate severe and even fatal exacerbations. Adult patients with severe persistent asthma or nasal polyps, should be counseled regarding the risk of using these drugs.

### Managing Exacerbations

<table>
<thead>
<tr>
<th>Acute Exacerbations</th>
<th>Educate patients on early management of acute exacerbations (home management).</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Teach all patients how to monitor symptoms to recognize early signs of deterioration</td>
</tr>
<tr>
<td></td>
<td>- Teach all patients with moderate-to-severe persistent asthma and those with a history of severe exacerbations how to monitor their peak flow.</td>
</tr>
<tr>
<td></td>
<td>- Give a written action plan to be followed in the event of an exacerbation, especially to patients with moderate-to-severe persistent asthma and any patient with a history of severe exacerbations.</td>
</tr>
<tr>
<td></td>
<td>- Teach patient to seek medical help early if an asthma attack is severe; or therapy does not give rapid, sustained improvement; or there is further deterioration.</td>
</tr>
<tr>
<td></td>
<td>- Advise patients with moderate-to-severe persistent asthma or a history of severe exacerbations to have the medication (e.g., corticosteroid tablets or liquid) and equipment (e.g., peak flow meter or nebulizer for young children) for treating exacerbations at home/school or work.</td>
</tr>
</tbody>
</table>

Rapid deterioration can occur. Special attention is required for:

- Patients at high risk for asthma-related death
- Infants, due to greater risk for respiratory failure.

#### Antibiotics

Not recommended for treatment of acute asthma exacerbations except as needed for comorbid conditions.

**Education and counseling**

<table>
<thead>
<tr>
<th>Education &amp; Self-management</th>
<th>Teach self-management, tailoring the approach to the needs of the patient, and reinforce at every opportunity:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Basic facts about asthma</td>
</tr>
<tr>
<td></td>
<td>- Roles of medications</td>
</tr>
<tr>
<td></td>
<td>- Skills: inhaler/spacer/holding chamber use, self-monitoring</td>
</tr>
<tr>
<td></td>
<td>- Environmental and control measures</td>
</tr>
<tr>
<td></td>
<td>- When and how to take rescue actions.</td>
</tr>
</tbody>
</table>

Maintain sensitivity to cultural beliefs and practices, and jointly develop treatment goals.
**Self-Management Tools/Asthma Action Plans**

The use of written self-management (action) plans as part of an overall effort to educate patients in self-management is recommended, especially for moderate-to-severe persistent or for patients with a history of severe exacerbations. Review and refine at subsequent visits.

Provide appropriate patients with a daily asthma diary.

**Peak Flow Monitoring**

Patients with moderate-to-severe persistent asthma should learn how to monitor their Peak Expiratory Flow (PEF) and have a peak flow meter at home.

Peak Flow monitoring during exacerbations of asthma is recommended for patients with moderate-to-severe persistent asthma to:
- Determine severity of the exacerbation
- Guide therapeutic decisions.

Long-term daily monitoring is helpful in:
- Detecting early changes in disease status that require changes.
- Evaluate responses to changes in therapy.
- Provide assessment of severity for patients with poor perception of airflow obstruction.
- Afford a quantitative measure of impairment.

If long-term daily peak flow monitoring is not used, a short-term (2-3 week) period of peak flow monitoring is recommended to:
- Evaluate responses to changes in chronic maintenance therapy.
- Identify temporal relationship between changes in PEF and exposure to environmental or occupational irritants or allergens.
- Establish the patient’s personal best PEF.

Long-term peak flow monitoring for patients with mild intermittent or mild persistent asthma is usually not recommended unless the patient/family and/or physician find it useful in guiding therapeutic decisions.

Any patient who develops severe exacerbations may benefit from peak flow monitoring.

**Special Populations**

**Children**

Infants and Young Children (5 years of age or younger):

Initiation of long-term control therapy should be considered strongly for infants and young children who in the past year have had more than three episodes of wheezing that lasted more than 1 day and affected sleep, and who in addition have identifiable risk factors for the development of asthma.

School-age Children and Adolescents:

Pulmonary function testing should be performed using comparison data from an appropriate reference population.
## PacifiCare Health Plans

### Asthma Practice Guidelines: Outpatient Management of Asthma 2005-2006

Provide a written asthma management plan for the student’s school (including action plan, long-term control medication and prevention of exercise-induced bronchospasm if appropriate, and trigger factors to avoid) as well as plans to ensure reliable, prompt access to medications. Promote active participation in physical activities, exercise, and sports.

| Older Adults | Due to a high prevalence of other obstructive lung diseases, a trial of systemic steroids will determine disease reversibility and the extent of therapeutic reversibility.
Asthma medications may have increased adverse effects in the elderly; adjustments in the medication plan may be necessary.
Medications for other diseases may exacerbate asthma; adjustments may need to be made. |
|---|---|

| Pregnancy | Adequate control is essential to ensure an adequate oxygen supply to the fetus. For most drugs used to treat asthma and rhinitis, there is limited evidence to suggest an increased risk to the fetus with the exception of brompheniramine, epinephrine, and alpha-adrenergic compounds (other than pseudoephedrine). |

### Special Situations

#### Managing Special Situations

- **Seasonal Asthma**: Treat according to the step-wise approach for long-term management. If the patient has seasonal asthma on a predictable basis, daily long-term anti-inflammatory therapy should be initiated prior to the anticipated onset of symptoms and continued throughout the season.

- **Cough Variant Asthma**: Seen especially in young children, cough is the principal symptom, occurring frequently at night. Monitor day and afternoon PEF variability and/or therapeutic trials with anti-inflammatory or bronchodilator medications may be helpful in diagnosis. Treat according to step-wise approach to long-term management of asthma.

- **Exercise-Induced Bronchospasm (EIB)**: Anticipate in all asthma patients. Recommended prevention is inhaled beta2-agonists (effective with 80% of patients), cromolyn or nedocromil taken shortly before exercise, or long-term control therapy if appropriate. Teachers and coaches should be notified that a child has EIB.

- **Surgery**: Evaluation before surgery should include review of symptoms, medication use, and measurement of pulmonary function. Attempt to improve lung function to predicted values or personal best. For patients who have received systemic corticosteroids during the past 6 months, give hydrocortisone intravenously during the surgical period with a rapid reduction in dose following surgery.

This guideline is intended to provide information to aid health care providers and it is not a substitute for clinical judgement in treating individual patients. It is subject to updating pending the release and review of additional data, based upon changes in scientific knowledge and technology.
References


STRATEGIES FOR CLINICAL PRACTICE

CVD Prevention Strategies

- Assess and stratify women into high, intermediate, lower or optimal risk categories.
- Lifestyle approaches (smoking cessation, regular exercise, weight management, and heart healthy diet) to prevent CVD are recommendation for all women and a top priority in clinical practice.
- Other CVD risk-reducing interventions should be prioritized on the basis of strength of recommendations.
- Highest priority for risk intervention in clinical practice is based on risk stratification.
- Avoid interventions designated as Class III.

Spectrum of CVD Risk

<table>
<thead>
<tr>
<th>Risk Group</th>
<th>Framingham Global Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>(10-y absolute CHD risk)</td>
<td></td>
</tr>
</tbody>
</table>
Clinical Examples

High Risk: >20%
- Established CHD
- Cerebrovascular disease
- Peripheral arterial disease
- Abdominal aortic aneurysm
- Diabetes mellitus
- Chronic kidney disease

Intermediate Risk: 10% to 20%
- Subclinical CVD (e.g., coronary calcification)
- Metabolic syndrome
- Multiple risk factors
- Markedly elevated levels of a single risk factor
- First degree relatives

Lower Risk: <10%
- May include women with multiple risk factors, metabolic syndrome, or 1 or no risk factors

Optimal Risk: < 10%
- Optimal levels of risk factors and heart-healthy lifestyle
<table>
<thead>
<tr>
<th>CLINICAL RECOMMENDATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lifestyle Interventions</strong></td>
</tr>
<tr>
<td>• Cigarette smoking: Encourage women not to smoke and to avoid environmental tobacco. (Class I, Level B)</td>
</tr>
<tr>
<td>• Physical activity: Encourage women to accumulate a minimum of 30 minutes of moderate-intensity physical activity. (Class I, Level B)</td>
</tr>
<tr>
<td>• Cardiac rehabilitation: Should be considered for women with a recent acute coronary syndrome or coronary intervention, new-onset or chronic angina should participate in a comprehensive risk-reduction regimen. (Class I, Level B)</td>
</tr>
<tr>
<td>• Heart healthy diet: Encourage overall healthy eating that includes a variety of fruits, vegetables, grains, low-fat or nonfat dairy products, fish, legumes, and sources of protein low in saturated fat. Limit saturated fat intake to &lt;10% of calories, limit cholesterol intake to &lt;300mg/d, and limit intake of trans fatty acids. (Class I, Level B)</td>
</tr>
<tr>
<td>• Weight maintenance/reduction: Encourage weight maintenance/reduction through an appropriate balance of physical activity, caloric intake, and formal behavioral programs when indicated to maintain/achieve a BMI between 18.5 and 24.9 and a waist circumference &lt;35 in. (Class I, Level B)</td>
</tr>
<tr>
<td>• Psychosocial factors: Women with CVD should be evaluated for depression and refer/treat when indicated. (Class IIA, Level B)</td>
</tr>
<tr>
<td>• Omega 3 fatty acids: As an adjunct to diet, supplementation may be considered in high risk women.</td>
</tr>
<tr>
<td>• Folic acid: As an adjunct to diet, supplementation may be considered in high risk women (except after revascularization procedure) if a higher-than-normal level of homocysteine has been detected (Class IIb, Level B).</td>
</tr>
</tbody>
</table>

| **Major Risk Factor Interventions** |
| • Blood pressure: Encourage an optimal blood pressure of 120/80mmHg through lifestyle approaches (Class I, Level B). |
| o Pharmacotherapy is indicated when blood pressure is >140/90mmHg. Thiazide diuretics should be a part of the drug regimen for most patients unless |

*Clinical Practice Guidelines – Cardiovascular Disease Prevention in Women*

Authorized by: Medical Management Guideline Committee. Approved: 03/16/04. Revised: 2/22/06
### Lipids:

Optimal levels of lipids and lipoproteins in women are LDL-C <100mg/dL, HDL-C >50mg/dL, triglycerides <150mg/dL, and non-HDL-C (total cholesterol minus HDL) <130mg/dL and should be encouraged through lifestyle approaches (Class I, Level B).

- **High Risk Women:**
  - If LDL-C is elevated, saturated fat intake should be reduced to <7% of calories, cholesterol to <200mg/d, and trans fatty acid intake should be reduced.
  - Initiate LDL-C lowering therapy (preferably a statin) simultaneously with lifestyle therapy if LDL-C >100mg/dL (Class I, Level B) and initiate statin therapy in high risk women when LDL-C <100mg/dL unless contraindicated (Class I, Level B). Initiate niacin or fibrate therapy when HDL-C is low, or non-HDL-C elevated in high risk women (Class I, Level B).

- **Intermediate Risk Women:**
  - Initiate LDL-C lowering therapy (preferably a statin) if LDL-C level is >130mg/dL on lifestyle therapy (Class I, Level A), or niacin or fibrate therapy when HDL-C is low or non-HDL-C elevated after LDL-C goal is reached.

- **Lower Risk Women:**
  - Consider LDL-C lowering therapy in low risk women with 0 or 1 risk factors when LDL-C is >190mg/dL or if multiple risk factors are present when LDL-C is >160mg/dL (Class I, Level B) or niacin or fibrate therapy when HDL-C is low or non-HDL-C elevated after LDL-C goal is reached (Class IIa, Level B).

### Diabetes:

Lifestyle and pharmacotherapy should be used to achieve near normal A1C (<7%) in women with diabetes (Class I, Level B).
| Preventive Drug Interventions | • Aspirin:  
  o High Risk: Aspirin therapy (75 to 162 mg), or clopidogrel if a patient is intolerant to aspirin, should be used in high risk women unless contraindicated (Class I, Level A).  
  o Intermediate Risk: Consider aspirin therapy (75 to 162 mg) in intermediate risk women as long as blood pressure is controlled and benefit is likely to outweigh risk of gastrointestinal side effects (Class IIa, Level B).  
• Beta-Blockers: Should be used indefinitely in all women who have had a myocardial infarction or who have chronic ischemic syndromes unless contraindicated (Class I, Level A).  
• ACE Inhibitors: Should be used (unless contraindicated) in high risk women (Class I, Level A).  
• ARBs: Should be used in high risk women with clinical evidence of heart failure or an ejection fraction <40% who are intolerant to ACEI (Class I, Level B). |
| --- | --- |
| Atrial Fibrillation/Stroke Prevention | • Warfarin – Atrial fibrillation: Among women with chronic or paroxysmal atrial fibrillation, warfarin should be used to maintain the INR at 2.0 to 3.0 unless they are considered to be at low risk for stroke (<1%/y) or high risk of bleeding (Class I, Level A).  
• Aspirin – Atrial fibrillation: Aspirin (325 mg) should be used in women with chronic or paroxysmal atrial fibrillation with a contraindication to warfarin or at low risk for stroke (<1%) (Class I, Level A). |
| Class III Interventions | • Hormone Therapy: Combined estrogen plus progestin hormone therapy should not be initiated to prevent CVD in post menopausal women (Class III, Level A). Combined estrogen plus progestin hormone therapy should not be continued to prevent CVD in |
postmenopausal women (Class III, Level C). Other forms of menopausal hormone therapy (e.g., unopposed estrogen) should not be initiated or continued to prevent CVD in postmenopausal women pending the results of ongoing trials (Class III, Level C).

- Antioxidant Supplements: Antioxidant vitamin supplements should not be used to prevent CVD pending the results of ongoing trials (Class III, Level A).
- Aspirin - Lower Risk: Routine aspirin use in lower risk women is not recommended pending the results of ongoing trials (Class III, Level B).

### CLASSIFICATION AND LEVELS OF EVIDENCE

<table>
<thead>
<tr>
<th>Classification</th>
<th>Level of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>A</td>
</tr>
<tr>
<td>Intervention is useful and effective</td>
<td>Sufficient evidence from multiple randomized trials</td>
</tr>
<tr>
<td>Class IIa</td>
<td></td>
</tr>
<tr>
<td>Weight of evidence is in favor of usefulness/efficacy</td>
<td></td>
</tr>
<tr>
<td>Class IIb</td>
<td></td>
</tr>
<tr>
<td>Usefulness/efficacy is less well established by evidence/opinion</td>
<td></td>
</tr>
<tr>
<td>Class III</td>
<td></td>
</tr>
<tr>
<td>Intervention is not useful/effective and may be harmful</td>
<td></td>
</tr>
</tbody>
</table>
As a guideline, this document is intended to provide information to aid health care providers and is not a substitute for clinical judgment in treating individual patients. It is subject to updates pending the release of additional data, based upon changes in scientific knowledge and technology.

References:

### CLASSIFICATION OF COPD BY SEVERITY

<table>
<thead>
<tr>
<th>Stage</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>0: At Risk</td>
<td>Chronic symptoms (cough, sputum production); lung function is still normal</td>
</tr>
<tr>
<td>I: Mild COPD</td>
<td>Mild airflow limitation</td>
</tr>
<tr>
<td></td>
<td>FEV(_1)/FVC &lt;70% but FEV(_1) ≥ 80% predicted – and usually, but not always,</td>
</tr>
<tr>
<td></td>
<td>chronic cough and sputum production.</td>
</tr>
<tr>
<td></td>
<td>• At this stage, the individual may not be aware that his or her lung function is</td>
</tr>
<tr>
<td></td>
<td>abnormal</td>
</tr>
<tr>
<td>II: Moderate COPD</td>
<td>Worsening airflow limitation</td>
</tr>
<tr>
<td></td>
<td>50% ≤ FEV(_1) &lt;80% predicted, and usually the progression of symptoms, with</td>
</tr>
<tr>
<td></td>
<td>SOB typically developing on exertion</td>
</tr>
<tr>
<td>III: Severe COPD</td>
<td>Further worsening of airflow limitation</td>
</tr>
<tr>
<td></td>
<td>30% &lt; FEV(_1) &lt; 50% predicted, increased SOB, and repeated exacerbations</td>
</tr>
<tr>
<td></td>
<td>which have an impact on patient’s quality of life</td>
</tr>
<tr>
<td></td>
<td>• Exacerbations of symptoms, which have an impact on a patient’s quality of life</td>
</tr>
<tr>
<td></td>
<td>and prognosis, are especially seen in patients with FEV1 &lt; 50% predicted.</td>
</tr>
<tr>
<td>IV. Very Severe COPD</td>
<td>Severe airflow limitation</td>
</tr>
<tr>
<td></td>
<td>FEV(_1) &lt; 30% predicted or FEV(_1) &lt;50% plus chronic respiratory failure.</td>
</tr>
<tr>
<td></td>
<td>Patients may have very severe (Stage IV) COPD even if the FEV(_1) is &gt;30% predicted,</td>
</tr>
<tr>
<td></td>
<td>whenever these complications are present.</td>
</tr>
<tr>
<td></td>
<td>• At this stage, quality of life is very appreciably impaired and exacerbations</td>
</tr>
<tr>
<td></td>
<td>may be life-threatening</td>
</tr>
</tbody>
</table>
### DIAGNOSIS IN EARLY, ASYMPTOMATIC STAGE

**Detailed Medical History**
- Exposure to risk factors, including intensity and duration
- Past medical history, including asthma, allergy, sinusitis or nasal polyps, respiratory infections, and other respiratory diseases
- Family history of COPD or other chronic respiratory disease
- Pattern of symptom development
- History of exacerbations or previous hospitalizations for respiratory disorder
- Presence of comorbidities, such as heart disease and rheumatic disease, that may also contribute to restriction of activity
- Appropriateness of current medical treatments
- Impact of disease on patient’s life, including limitation of activity; missed work and economic impact; effect on family routines; and feelings of depression or anxiety
- Social and family support available to the patient
- Possibilities for reducing risk factors, especially smoking cessation.

**Key indicators for considering a COPD diagnosis**
- Chronic Cough: Present intermittently or every day. Often present throughout the day: seldom only nocturnal
- Chronic sputum production: Any pattern of chronic sputum production may indicate COPD
- Acute Bronchitis: Repeated episodes
- Dyspnea that is: Progressive (worsens over time). Persistent (present every day). Worse on exercise. Worse during respiratory infections.

**Spirometry**
Perform on any patient with chronic cough, chronic sputum production, or dyspnea and/or a history of exposure to risk factors. Diagnosis of COPD is confirmed with Spirometry. A reduced FEV1/FVC (less than 70%) indicates airflow limitation and the possibility of COPD.

**Lung Sounds**
Assess for decreased breath sounds, inspiratory and/or expiratory wheezes, inspiratory crackles (The absence of these auscultory changes does not exclude a COPD diagnosis)

**Radiographic Studies**
Chest X-ray is helpful in excluding alternative diagnoses. CT of the chest is not routinely recommended
## Electrocardiogram
ECG is normal in the early stages of COPD, but peaked P-waves in II, III, AVF, decreased voltage of QRS, and right axis deviation are often noted in advanced stages of disease. Supraventricular arrhythmias are commonly found, especially during exacerbations.

## Laboratory Screening
Alpha-1 antitrypsin deficiency screening: Perform when COPD develops in patients under 45 years of age or in patients with a strong family history of COPD. Arterial Blood gases (ABG’s) in patients with an FEV₁ of <40% predicted or clinical signs of respiratory failure or right heart failure. Hematocrit-polycythemia can develop in the presence of arterial hypoxemia. Polycythemia can be identified by a hematocrit of >55%.

## Sleep Disorders
Sleep studies may be indicated when hypoxemia or right heart failure develops in the presence of relatively mild air flow limitation or when the patient has symptoms suggestive of sleep apnea.

## IMMUNIZATIONS

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Indicates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza</td>
<td>Annually</td>
</tr>
<tr>
<td>Pneumococcal</td>
<td>All persons ≥ 65 years; second dose if initial vaccination was ≥ 5 years previously and &lt;65 years at time of initial vaccination</td>
</tr>
</tbody>
</table>

## EDUCATION/COUNSELING

### Smoking/Tobacco
Abstinence is the single most effective way to reduce exposure to COPD risk factors. Quitting smoking can prevent or delay the development of airflow limitations or reduce its progression. Refer patient to PacifiCare customer service to verify availability of tobacco cessation programs.

### Education
Educate the patient and family about COPD pathophysiology and medication regimen compliance. Educate patient of symptoms that may indicate worsening condition.

### Nutrition/Activity/Exercise
Advise patient to follow an appropriate diet to maintain appropriate weight. Encourage regular exercise. Counsel on recreation, leisure and work activity.

### Alcohol
Patients should be warned against excessive alcohol consumption due to disordered sleep patterns and potential for respiratory depression.

### Use of Medication
Patient should be educated at each visit on correct dosages of various medications, adherence to the regimen, inhaler technique, effectiveness of the current regimen at controlling symptoms And side effects of medications.

## PSYCHOLOGICAL ASSESSMENT

### Depression Screen
Formal depression screening (utilizing a tool which is professionally recognized and tested for reliability and validity e.g., Geriatric Depression Scale). Psychiatric morbidity such as Depression and/or Anxiety is common in advanced COPD. Assess regularly for signs and symptoms that would indicate re-screening is needed.
### MEDICATIONS BY STAGE OF DISEASE PROGRESSION

<table>
<thead>
<tr>
<th>Stage 0: At Risk</th>
<th>None</th>
</tr>
</thead>
</table>
| **Stage I: Mild COPD** | Short-acting inhaled therapy as needed to control dyspnea or coughing spasms is sufficient (If inhaled bronchodilators are not available, regular treatment with slow-release Theophylline should be considered)  
- Fenoterol, Salbutamol (albuterol), Terbutaline |
| **Stage II: Moderate COPD** | If symptoms are not adequately controlled with as-needed short-acting bronchodilators, adding regular treatment with long-acting inhaled bronchodilator is recommended. For patients who need additional symptom control adding Theophylline leads to additional benefits. For patients already on short or long-term bronchodilators, the use of a short-acting bronchodilator may also be used. In general, nebulized therapy for a stable patient is not appropriate unless it has shown to be better than conventional dose therapy  
- Tiotropium + Albuterol (as rescue medication) or;  
- Salmeterol or formoterol + ipratropium, albuterol or combination |
| **Stage III: Severe COPD** | In patients with a post-bronchodilator FEV₁ <50% predicted and a history of repeated exacerbations, regular treatment with inhaled glucocorticosteroids reduce frequency of exacerbations and improve health status. In these patients, regular use of an inhaled glucocorticosteroid should be added to regular bronchodilator treatment. Chronic treatment with oral glucocorticosteroids should be avoided  
- Tiotropium + Salmeterol or formoterol (short-acting can be added as rescue medication; inhaled corticosteroids if repeated exacerbations) or;  
- Salmeterol or formoterol + tiotropium (short-acting can be added as rescue medication; inhaled corticosteroids if repeated exacerbations) |
| **Stage IV: Very Severe COPD** | In patients with FEV₁/FVC <70% and FEV₁ <30% predicted may add long term oxygen and:  
- Tiotropium + Salmeterol or formoterol (short-acting inhaled agent can be added as rescue remedy); may add  
- Inhaled corticosteroid (low-dose methylxanthine can be added if response to inhaled bronchodilator therapy is insufficient) |
| **Mucolytic drugs** | A few patients with viscous sputum may benefit from use of a mucolytic agent, however, the overall benefits are very small thus their widespread use is not recommended |
### MANAGEMENT OF STABLE COPD

<table>
<thead>
<tr>
<th><strong>Education</strong></th>
<th>Information and advice about reducing risk factors. Information about the nature of COPD. Instruction on how to use inhalers and other treatments. Recognition and treatment of exacerbations. Strategies for minimizing dyspnea.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pulmonary function</strong></td>
<td>A patient’s decline in lung function is best tracked by periodic spirometry testing. Usefulness of information from spirometry testing declines if performed more frequently than once annually.</td>
</tr>
<tr>
<td><strong>Pulse oximetry</strong></td>
<td>Measure “at rest” and “ambulating” to establish the presence of hypoxemia.</td>
</tr>
</tbody>
</table>

### MANAGEMENT OF ADVANCED COPD

<table>
<thead>
<tr>
<th><strong>Assessment</strong></th>
<th>Regular monitoring of the patient’s lung sounds, pulmonary function, oxygenation, and ambulatory ability. Monitor for signs of respiratory failure or right heart failure; central cyanosis, ankle swelling, and an increase in jugular venous pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Education</strong></td>
<td>All topics for stable COPD plus information about complications, oxygen treatment, advanced directives and end-of-life decisions</td>
</tr>
<tr>
<td><strong>Oxygen</strong></td>
<td>Consider for patients with Stage IV: Very Severe COPD. Oxygen administration can be offered in three ways: long-term continuous therapy, during exercise and to relieve acute dyspnea. The primary goal of Oxygen therapy is to keep the SaO₂ at least 90%. Long-term therapy is usually administered to those patients whose PaO₂ is at or below 55 mmHg or SaO₂ at or below 88%</td>
</tr>
<tr>
<td><strong>Pulmonary Rehabilitation</strong></td>
<td>Consider referral. Should be a comprehensive program including exercise training, nutrition counseling and education</td>
</tr>
</tbody>
</table>

### MANAGEMENT OF ACUTE EXACERBATIONS IN THE OUTPATIENT SETTING

<table>
<thead>
<tr>
<th><strong>Medical History</strong></th>
<th>History prior to the exacerbation, increased breathlessness, wheezing, chest tightness, increased cough and sputum production, fever, malaise, insomnia, fatigue, sleepiness and confusion may indicate an acute exacerbation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assessment</strong></td>
<td>Physical exam, CBC, CXR, ECG (to rule out hypertrophy, arrhythmias, ischemia)</td>
</tr>
<tr>
<td><strong>Adjust medications</strong></td>
<td>Increase dose and/or frequency of bronchodilator therapy. May add an anticholinergic until symptoms improve. High dose nebulizer therapy as needed for several days. Long term use of nebulizer therapy is not recommended. Systemic glucocorticosteroids can be added to the Antibiotics indicated for suspected bacterial infection only. If patient unresponsive to antibiotic therapy a sputum C&amp;S may be indicated</td>
</tr>
<tr>
<td><strong>Indications for emergent hospitalization</strong></td>
<td>Increased intensity of symptoms, Severe COPD, cyanosis, peripheral edema, failure to respond to initial treatment, significant co-morbidities, new arrhythmias, diagnostic uncertainty, older age, insufficient home support</td>
</tr>
</tbody>
</table>
ITEMS TO INCLUDE IN FOLLOW-UP ASSESSMENT POST DISCHARGE FROM HOSPITAL

- Ability to cope in usual environment
- Measurement of FEV₁
- Reassessment of inhaler technique
- Understanding of recommended treatment regimen
- Need for long-term oxygen therapy and/or home nebulizer (for patients with very severe COPD)

This guideline is intended to provide information to aid health care providers and it is not a substitute for clinical judgment in treating individual patient. It is subject to updating pending the release and review of additional data, based upon changes in scientific knowledge and technology.

References:

- 2004/2005 ACIP recommendations
Cardiovascular Health Practice Guidelines

Outpatient Management of Heart Failure - 2006

Approved by the Medical Management Guideline Committee
Approval Date: 5/21/98 Revised: 4/13/00, 4/11/02, 3/16/04, 2/22/05, 2/22/06

<table>
<thead>
<tr>
<th>PHYSICAL ASSESSMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>History</strong></td>
</tr>
<tr>
<td>Inquire about history of hypertension, diabetes, hypercholesterolemia, coronary artery disease, alcohol, tobacco use and illicit drug use. The history should include specific consideration of non-cardiac diseases such as collagen vascular disease, bacterial or parasitic infection, and thyroid excess or deficiency.</td>
</tr>
<tr>
<td><strong>Vital Signs</strong></td>
</tr>
<tr>
<td>Assess at each visit:</td>
</tr>
<tr>
<td>Weigh and review patient’s self-reported daily weight record</td>
</tr>
<tr>
<td>Pulse rate</td>
</tr>
<tr>
<td>Blood pressure</td>
</tr>
<tr>
<td>Respiratory rate</td>
</tr>
<tr>
<td><strong>Cardiac</strong></td>
</tr>
<tr>
<td>Assess at each visit:</td>
</tr>
<tr>
<td>Jugular vein distention</td>
</tr>
<tr>
<td>Cardiac gallop (third or fourth heart sound)</td>
</tr>
</tbody>
</table>
Extremities | Assess at each visit for peripheral edema.
---|---
Lung | Assess at each visit for pulmonary rales.

**Functional Capacity**
Inquire at each visit about the type, severity, and duration of symptoms that occur during activities of daily living and that may impair patient’s functional capacity.

**PSYCHOLOGICAL ASSESSMENT**

**Depression Screen**
A high index of suspicion for depression should be maintained. Assess regularly and initiate treatment as needed.

* Refer to PHP Preventive Health Guidelines

**TESTS**

**Evaluation of ventricular function**
Perform echocardiography or other studies to evaluate cardiac structure and function and repeat as clinically indicated.

**STAGING AND RECOMMENDED THERAPY**

**Stage A**
Patients at high risk for HF but without structural heart disease or symptoms of HF (e.g., patients with systolic hypertension, coronary artery disease, diabetes mellitus metabolic syndrome, or history of cardio toxic drugs, alcohol abuse or family history of

- Treat hypertension
- Encourage smoking cessation
- Treat lipid disorders
- Encourage regular exercise
- Discourage alcohol intake, illicit drug use
- Control metabolic syndrome
- ACEI or ARB in patients with a history of atherosclerotic vascular disease, diabetes mellitus, hypertension and associated cardiovascular risk factors
<table>
<thead>
<tr>
<th>Stage B</th>
<th>Patients with a structural disorder of the heart but without symptoms of HF (e.g., patients with LVSD, left ventricular remodeling including LV hypertrophy and low ejection fraction, previous MI; asymptomatic valvular disease)</th>
</tr>
</thead>
</table>
| | • All measures in Stage A  
  • ACEI or ARB in patients with either a history of recent or remote MI or with low ejection fraction  
  • Beta-Blockers in patients either with recent history of MI or with low ejection fraction |
| Stage C | Patients with past or current symptoms of HF associated with structural heart disease (e.g., patients with known structural heart disease, shortness of breath and fatigue due to LVSD, reduced exercise tolerance. Asymptomatic patients who are under-going treatment for prior symptoms of HF) |
| | • All measures in Stage A and B  
  • Dietary salt restriction  
  • Drugs for routine use:  
    - Diuretics, in patients who have evidence of fluid retention  
    - ACEI  
    - Beta-blockers, in patients with no or minimal fluid retention  
  • Drugs in selected patients:  
    - Aldosterone antagonist  
    - ARBS  
    - Hydralazine/nitrates  
    - Digitalis  
  • Devices in selected patients:  
    - Biventricular pacing  
    - Implantable defibrillators |
| Stage D | • All measures under Stage A, B and C |
| **End-stage disease; Refractory HF requiring specialized interventions** (e.g., patients who have marked symptoms at rest despite maximal medical therapy - recurrent hospitalizations or cannot be safely discharged from the hospital without special interventions) | • Decisions regarding appropriate level of care  
• Options:  
  o Mechanical assist devices  
  o Heart transplantation  
  o Continuous intravenous inotropic infusions for palliation  
  o Hospice care |
|---|---|
| **THERAPY** | **ACE Inhibitors (ACEI) / ARB**  
In the absence of contraindications, start ACEI in patients with any of the following: Stages C or D chronic HF, Stage B HF with either a history of recent or remote MI or with low ejection fraction, and Stage A HF with a history of atherosclerotic vascular disease, diabetes or hypertension and associated cardiovascular risk factors.  
Note: Treat all patients indefinitely post MI; start early in stable high-risk patients (anterior MI, Killip class II [S3 gallop, rales, radiographic HF]). Angiotensin Receptor Blockers (ARB) should be considered in patients who are intolerant to ACEI. |
| **Beta-Blockers** | Initiate and continue indefinitely in patients with any of the following: Stages C or D HF, Stage B HF with recent history of MI or with low ejection fraction. Start in all post-MI and acute ischemic syndrome patients if not contraindicated. Continue indefinitely.  
Note: Observe usual contraindications. Use as needed to manage blood pressure or symptoms in all other patients. |
<p>| <strong>Diuretics</strong> | Begin in patients who have evidence of fluid retention, unless contraindicated. Consider spironolactone in patients with recent or current NYHA Class IV symptoms, preserved renal function and a normal potassium concentration. |</p>
<table>
<thead>
<tr>
<th><strong>Digitalis</strong></th>
<th>Initiate in patients for the treatment of symptoms of HF, unless contraindicated</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Antiplatelet Agents/anticoagulants</strong></td>
<td>Start and continue indefinitely aspirin 81 to 325 mg/d if not contraindicated. Consider clopidogrel 75 mg/d or warfarin if aspirin contraindicated. (ASA is recommended in the presence of comorbid conditions such as CAD, stroke, etc.)</td>
</tr>
<tr>
<td><strong>Hydralazine/Nitrate</strong></td>
<td>Initiate in patients with reduced LVEF who are already taking an ACEI and beta-blocker for symptomatic HF and who have persistent symptoms. Current medical studies suggest this combination should be considered for African-American patients.</td>
</tr>
<tr>
<td><strong>Aldosterone Antagonist</strong></td>
<td>Initiate in selected patients with moderately severe to severe symptoms of HF and reduced LVEF who can be carefully monitored for preserved renal function and normal potassium concentration. Creatinine should be less than or equal to 2.5 mg/dL in men or less than or equal to 2.0 mg/dL in women and potassium should be less than 5.0 mEq/L.</td>
</tr>
</tbody>
</table>
| **Devices** | - Implantable cardioverter-defibrillator is recommended as secondary prevention to prolong survival in patients with current or prior symptoms of HF and reduced LVEF who have a history of cardiac arrest, ventricular fibrillation, or hemodynamically destabilizing ventricular tachycardia.  
- Patient with LVEF less than or equal to 35%, sinus rhythm, and NYHA functional class III or ambulatory class IV symptoms despite recommended, optimal medical therapy and who have cardiac dyssynchrony, which is currently defined as a QRS duration greater than 0.12 ms, should be considered for cardiac resynchronization therapy unless contraindicated. |

**RISK INTERVENTION AND RECOMMENDATIONS**

| **Diabetes Management** | Goal: A1C < 7%. Appropriate hypoglycemic therapy to achieve near-normal fasting plasma glucose, as indicated by A1C. |
| **Blood Pressure Control** | Goal: <140/90 mm Hg, or <130/85 mm Hg if heart failure or renal insufficiency, <130/80 mm |
**Hg if diabetes.**
Initiate lifestyle modification (weight control, physical activity, alcohol moderation, and moderate sodium restriction) in all patients with blood pressure $\geq 130/80$ mm Hg.
Add blood pressure medications, individualized to patient if blood pressure is higher than established goals.

| **Lipid Management** | Primary Goal:  
LDL $< 100$ mg/dL  
Assess fasting lipid profile in all patients. Start dietary therapy ($<7\%$ saturated fat and $<200$ mg cholesterol). Add drug therapy according to the ATPIII guidelines.  
Secondary Goal:  
If TG $\geq 200$ mg/dL, then non-HDL should be $<130$ mg/dL  
Emphasize weight management and physical activity. |
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<tbody>
<tr>
<td><strong>Smoking/Tobacco</strong></td>
<td>Assess smoking status at each visit. All smokers should be counseled on tobacco cessation. Refer to stop smoking program and, if necessary, recommend smoking cessation aids. Follow up on progress at each visit.</td>
</tr>
<tr>
<td><strong>Routine Weight Monitoring</strong></td>
<td>Educate patient to routinely monitor weight and maintain a weight log. Instruct patient on weight variances that should be reported to the provider.</td>
</tr>
<tr>
<td><strong>Symptom Recognition</strong></td>
<td>Educate patient of symptoms to report to provider that may indicate worsening condition.</td>
</tr>
<tr>
<td><strong>Low sodium diet</strong></td>
<td>Advise patient/caregiver on lower sodium diet. The most commonly recommended limit is 2000 mg of sodium daily. Consider referring to a dietitian if extremely low sodium diet is prescribed or if patient/caregiver fails to adhere to diet after initial instructions.</td>
</tr>
</tbody>
</table>
Activity and exercise

Advise patient to follow an appropriate exercise regimen. Encourage regular exercise. Counsel on recreation, leisure, and work activity. Address sexual activity, sexual difficulties, and coping strategies.

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References:

## MEDICATIONS

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>RECOMMENDATIONS</th>
</tr>
</thead>
</table>
| Beta-Blockers | Indicated in post-MI (ST-elevation MI (STEMI) and non-STEMI) and unstable angina. Prescribe to all patients without a contraindication to beta-blocker therapy, except low risk patients (i.e., those without previous infarction, anterior infarction, advanced age or complex ventricular ectopy). Treatment should begin within a few days of the event and continued indefinitely. **Contraindications:**  
- Cardiogenic shock  
- Sick sinus syndrome  
- History of asthma/severe COPD  
- Hypersensitivity to beta-blockers  
- HR <50 bpm  
- P-R interval >.24 seconds  
- Second or third degree AV block  
**Precautions and Close Monitoring:**  
- Diabetes Mellitus  
- Severe LV dysfunction with CHF  
- SBP <100 mmHg  
- HR <60 bpm  
- Peripheral vascular disease  
- Peripheral hypoperfusion |

Patients receiving beta-blockers should be advised:  
- Side effects may occur during initiation of therapy but do not prevent long term use  
- Use is intended as long term therapy  
- Abrupt discontinuation should be avoided  
- Self monitor for evidence of hypotension and bradycardia

| Nitrates | Indicated in treatment and prophylaxis of angina. Patients should be given oral, sublingual or spray NTG and instructed in its use. **Contraindications:**  
- Concomitant phosphodiesterase type 5 inhibitors such as Viagra.  
- Hypersensitivity to nitrates, severe anemia, increased intracranial pressure. |
## Calcium Channel Blockers

For ischemic symptoms when beta-blockers are not successful or contraindicated. Short acting dihydropyridine antagonists (e.g., nifedipine) should be avoided.

**Contraindications:**
- Sick Sinus syndrome
- Second or third degree AV block
- Hypotension (< than 90 mm Hg systolic)
- Hypersensitivity to the drug
- Severe left ventricular dysfunction
- Atrial flutter or atrial fibrillation and an accessory bypass tract

## Antiplatelet Drugs

**Aspirin**

Indicated in post-MI (STEMI and non-STEMI) and unstable angina. Prescribe 75 to 325 mg/d in the absence of contraindications.

**Absolute Contraindications**
- Hypersensitivity to salicylates or nonsteroidal anti-inflammatory drug products

**Antiplatelet Drugs:**

Prescribe Clopidogrel 75 mg daily when aspirin is not tolerated due to hypersensitivity or gastrointestinal intolerance. The combination of aspirin and clopidogrel for 9 months after unstable angina/NSTEMI.

## Anticoagulation Therapy

Consider long-term anticoagulation post-MI for the following patients:
- Post-MI patients who are unable to take aspirin daily* or other antiplatelet agents
- Post-MI patients with persistent atrial fibrillation
- Post-MI patients with left ventricular thrombus

## ACE Inhibitors

Indicated in post-MI stable high-risk patients (elderly, anterior infarction, previous infarction), CHF, LV dysfunction (EF ≤40%), hypertension, or diabetes unless contraindicated. **

Continue indefinitely for all patients with left ventricular systolic dysfunction (EF ≤40%) or symptoms of heart failure. Use as needed to manage blood pressure or symptoms in all other patients.

**Contraindications:**
- History of intolerance or adverse reaction to ACE inhibitors
- Elevated levels of serum potassium (K+ >5.5 mEq/L)
- Renal artery stenosis
- Symptomatic hypotension
- Shock
- Pregnancy
### Precautions and Close Monitoring:
- SBP <90 mmHg
- Elevated levels of serum creatinine (SCr >3) or creatinine clearance <30 ml/min
- Renal artery stenosis

Consider angiotensin receptor blockers (ARBs) in patients with intolerance to ACE inhibitor therapy, or who have either clinical or radiological signs of heart failure or LVEF of <40%.

**Refer to PHP Diabetic Clinical Practice Guideline.**
### Cholesterol-Lowering Agents

Start dietary therapy in all patients (<7% of total calories as saturated fat and < 200 mg/day cholesterol). Promote physical activity and weight management. Encourage increased consumption of omega-3 fatty acids. Add drug therapy according to the following guide:

- **LDL-C substantially less than 100 mg/dL (baseline or on-treatment):**
  - ♦ Statins should be used to lower LDL-C.

- **LDL-C ≥ 100 mg/dL (baseline or on-treatment):**
  - ♦ Intensify LDL-C lowering therapy with drug treatment, giving preference to statins.

**Primary goal LDL-C substantially less than 100 mg/dL.**

A therapeutic option is to set the goal for LDL less than 70 mg/dL for **very high-risk** patients, defined as a patient who:
- Had a recent heart attack, or
- Has cardiovascular disease combined with either diabetes or severe or poorly controlled risk factors (such as continued smoking), or metabolic syndrome.

Patients with normal plasma cholesterol levels who have a HDL cholesterol level of <35 mg/dL should begin therapeutic lifestyle therapy designed to elevate the HDL level, such as increased physical activity, weight loss, and smoking cessation.

**If TG is > 150 mg/dL or HDL-C is < 40 mg/dL:**
- ♦ Emphasize weight management and physical activity. Advise smoking cessation.

**If TG is 200 to 499 mg/dL:**
- ♦ After LDL-C lowering therapy, consider adding fibrate or niacin.

**If TG is > 500 mg/dL:**
- ♦ Consider fibrate or niacin before LDL-C lowering therapy.
- ♦ Consider omega-3 fatty acids as adjunct for high TG.

**Primary goal for Non-HDL-C substantially less than 130 mg/dL.**
### Cardiovascular Health Practice Guideline

**Outpatient Management of Coronary Artery Disease 2005-2006**

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>RECOMMENDATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ventricular Function</strong></td>
<td>Assess LVEF in acute coronary syndrome and coronary disease patients during hospital or outpatient evaluation, if appropriate.</td>
</tr>
<tr>
<td><strong>Stress Test With or Without Imaging</strong></td>
<td>Perform a stress test with or without imaging in appropriate patients (i.e., adult patients with an intermediate pretest probability of CAD based on gender, age, and symptoms, undergoing initial evaluation with known CAD, before discharge for prognostic assessment, activity prescription, or evaluation of medical therapy, before and after revascularization), timing to be determined by practitioner.</td>
</tr>
<tr>
<td><strong>Lipid Profile</strong></td>
<td>Perform lipid profile at 4-6 weeks following AMI and repeat 3 months following initiation of therapeutic lifestyle changes (TLC) and/or drug management to determine adherence and response to therapy.</td>
</tr>
</tbody>
</table>

**Test in fasting state and include:**
- Total Cholesterol
- Triglycerides
- LDL
- HDL

**Target Values:**
- Cholesterol <200 mg/dL
- Triglycerides <150 mg/dL
- LDL <100 mg/dL
- HDL >40 mg/dL

**Category of CAD risk based on lipoprotein levels in adults:**

<table>
<thead>
<tr>
<th>Risk</th>
<th>LDL</th>
<th>HDL</th>
<th>Triglycerides</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>&gt;130 mg/dL</td>
<td>&lt;40 mg/dL</td>
<td>&gt;200 mg/dL</td>
</tr>
<tr>
<td>Borderline</td>
<td>100-129 mg/dL</td>
<td>40-59 mg/dL</td>
<td>150-199 mg/dL</td>
</tr>
<tr>
<td>Low</td>
<td>&lt;100 mg/dL</td>
<td>&gt;60 mg/dL</td>
<td>&lt;150 mg/dL</td>
</tr>
</tbody>
</table>

Once cholesterol goal has been achieved, measure lipid profile at least every 4 to 6 months to monitor response and adherence to drug therapy for one year. Long-term monitoring entails annual lipoprotein analyses.

Consider more aggressive targets for HDL cholesterol and triglycerides in women.
<table>
<thead>
<tr>
<th><strong>PSYCHOLOGY ASSESSMENT</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Depression Screen</strong></td>
<td>The psychological status of patients should be evaluated, including inquiries regarding symptoms of depression, anxiety, or sleep disorders and the social support environment. Routine screening for adults. **</td>
</tr>
<tr>
<td><strong>Education and Self-Management Principles</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Smoking Cessation</strong></td>
<td>Assessment of smoking status at each visit.</td>
</tr>
<tr>
<td></td>
<td>All smokers should be counseled on tobacco cessation at each visit. Refer to stop smoking program and if necessary, recommend smoking cessation aids. Follow up on progress at each visit.</td>
</tr>
<tr>
<td><strong>Nutrition Counseling</strong></td>
<td>Advise all patients with CAD about symptoms of AMI and instruct how to seek help if symptoms occur.</td>
</tr>
<tr>
<td><strong>Weight Management</strong></td>
<td>Advise patient and family on lower sodium, lower fat, lower cholesterol and higher fiber diet.</td>
</tr>
<tr>
<td><strong>Exercise/Physical Activity</strong></td>
<td>Recommend AHA Step II diet, which is low in saturated fat and cholesterol (&lt;7% of total calories as saturated fat and &lt;200 mg/d cholesterol).</td>
</tr>
<tr>
<td></td>
<td>Advise patient to achieve or maintain healthy weight (BMI of 25.0-30.0 is considered overweight, BMI &gt;30.0 is considered obese).</td>
</tr>
<tr>
<td></td>
<td>Advise patients on the appropriate type, level of intensity, and frequency of a regular exercise/physical activity program (e.g., walking, housework, climbing stairs). For certain patients a referral to a monitored exercise program may be appropriate.</td>
</tr>
<tr>
<td></td>
<td>Advise patient when to return to previous levels of activity, sexual activity, driving, and employment.</td>
</tr>
</tbody>
</table>
**Cardiovascular Health Practice Guideline**  
*Outpatient Management of Coronary Artery Disease 2005-2006*

| **Blood Pressure Control** | Monitor BP every office visit.  
Target adults: goal is <140/90 mmHg.  
Preferred goal is < 130/85 mmHg. |
|----------------------------|--------------------------------------------------------------------------------|
| **Glycemic Control**       | For patients who have diabetes, quarterly testing is recommended if poorly controlled or if therapy has changed. **  
Target HbA1c <7.0%.  
** Refer to PHP Diabetes Clinical Practice Guideline. |
| **Cardiac Rehabilitation** | Consider cardiac rehabilitation** or a monitored exercise program for those patients who may be at higher risk for infarction or sudden death.  
**Refer to Medical Management Guideline: Cardiac Rehabilitation – Commercial or Secure Horizons |

As a guideline, this document is intended to provide information to aid health care providers and is not a substitute for clinical judgement in treating individual patients. It is subject to updates pending the release and review of additional data, based upon changes in scientific knowledge and technology.

**References:**


Cardiovascular Health Practice Guideline

Outpatient Management of Coronary Artery Disease 2005-2006


# Diabetes Management Guidelines for 2006

**Authorized By:** Medical Management Guideline Committee  
**Approval Date:** 02/13/98  
**Revision Date:** 04/13/00; 04/11/02; 03/16/04; 02/22/05; 2/22/06

## ROUTINE EXAMINATION

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>RECOMMENDATION</th>
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</thead>
<tbody>
<tr>
<td><strong>Routine Visits</strong></td>
<td>Individuals with diabetes should be seen at least quarterly until achievement of treatment goals. Thereafter, frequency may decrease as long as patient continues to meet goals. More frequent visits are required if not meeting glycemic target, or BP control, lipid control, or have evidence of microvascular or macrovascular complications, or/and undergoing intensive insulin therapy. Intensive insulin therapy defined as keeping blood glucose as close to normal as possible through frequent injections or use of an insulin pump; meal planning; adjustment of insulin; and exercise based on blood glucose test results and frequent contact with the health care team.</td>
</tr>
</tbody>
</table>
| **Blood Pressure Testing and Control** | Blood pressure should be measured at every routine diabetes visit. Patients found to have systolic blood pressure ≥130 mmHg or diastolic blood pressure ≥80 mmHg should have blood pressure confirmed on a separate day. (C)  
Blood Pressure Goals:  
- Patients with diabetes should be treated to a systolic blood pressure < 130 mmHg. (C)  
- Patients with diabetes should be treated to a diastolic blood pressure < 80 mmHg. (B)  
Patients with a systolic blood pressure of 130-139 mmHg or a diastolic blood pressure of 80-89 mmHg should be given lifestyle and behavioral therapy alone for a maximum of 3 months and then, if targets are not achieved, in addition, be treated with pharmacological agents that block the renin-angiotensin system. (E)  
Patients with hypertension (systolic ≥140 mmHg or diastolic ≥90 mmHg) should receive drug therapy in addition to lifestyle and behavioral therapy. (A)  
In elderly hypertensive patients, blood pressure should be lowered gradually to avoid complications. (E)  
For children: hypertension in childhood is defined as an average systolic or diastolic blood pressure ≥95th percentile for age, sex, and height percentile measured on at least three separate days. |
| **Weight**                      | Every routine diabetes visit.  
For children: target age-related normative values. |
<table>
<thead>
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</tr>
</thead>
<tbody>
<tr>
<td>Foot Examination</td>
<td>Perform a comprehensive foot examination and provide foot self-care education annually on patients with diabetes to identify risk factors predictive of ulcers and amputations. (B) The foot examination can be accomplished in a primary care setting and should include the use of a monofilament, tuning fork, palpation, and a visual examination. (B) Simple inspection of insensate feet should be performed at each office where diabetic condition is assessed. An abnormality should trigger referral for special footwear, preventive specialist, or podiatric care. (B) Initial screening for peripheral arterial disease (PAD) should include a history for claudication and an assessment of the pedal pulses. Consider obtaining an ankle-brachial index (ABI), as many patients with PAD are asymptomatic. (C)</td>
</tr>
</tbody>
</table>
| Retinal Eye Examination | Initial dilated and comprehensive eye testing by an ophthalmologist or optometrist is recommended:  
  - For adults and adolescents with type 1 diabetes, within 3-5 years after the onset of diabetes. (B)  
  - For type 2 diabetes, shortly after the time of diagnosis. (B)  
  - For children with type 1 diabetes, once patient is 10 years of age or older, within 3-5 years after diagnosis. (E)  
  - For women with diabetes who are planning pregnancy or who have become pregnant, they should have a comprehensive eye examination and should be counseled on the risk of development and/or progression of diabetic retinopathy. Eye examinations should occur in the 1st trimester of pregnancy, with close follow-up throughout pregnancy and for one year postpartum. (B)  
Annual testing is recommended for both type 1 and type 2 diabetic patients thereafter. Less frequent exams (every 2-3 years) may be considered with the advice of an eye care professional in the setting of a normal eye exam. Examinations will be required more frequently is retinopathy is progressing. (B) |
| Psychosocial Assessment and Care | Preliminary assessment of psychological and social status should be included as part of the medical management of diabetes. (E)  
Psychosocial screening should be include but is not limited to attitudes about the illness, expectations for medical management and outcomes, affect/mood, general and diabetes-related quality of life, resources (financial, social, and emotional), and psychiatric history. (E)  
Screening for psychosocial problems such as depression, eating disorders, and cognitive impairment is needed when adherence to the medical regimen is poor. (E)  
It is preferable to incorporate psychological treatment into routine care rather than to wait for identification of a specific problem or deterioration in psychological status. (E) |
Preconception Counseling

All women with diabetes and childbearing potential should be educated about the need for good glucose control before pregnancy. (E)

Women with diabetes who are contemplating pregnancy should be evaluated, and if indicated, treated for diabetes retinopathy, nephropathy, neuropathy, and CVD. (E)

Contraindications of medications during pregnancy: (E)

- Statins in pregnancy are category X and should be discontinued before conception if possible.
- ACE inhibitors and ARBs are category C in the first trimester (maternal benefit may outweigh fetal risk in certain situations) but category D in later pregnancy and should generally be discontinued before pregnancy.
- Among the oral antidiabetic agents, metformin and acarbose are classified as category B and all others as category C; potential risks and benefits of oral antidiabetic agents in the preconception period must be carefully weighed, recognizing that sufficient data are not available to establish the safety of these agents in pregnancy. They should generally be discontinued in pregnancy.

A1C test levels should be normal or as close to normal as possible (<1% above the upper limits of normal) before conception is attempted. (B)

Women with diabetes and chronic hypertension, blood pressure target goals of 110-129/65-79 mmHg are suggested in the interest of long-term maternal health and minimizing impaired fetal growth. (E)

Hemoglobin A1C (A1C) Testing and Control

A1C testing is recommended at initial visit and at least two times per year thereafter in patients who are meeting treatment goals and who have stable glycemic control. (E)

Quarterly testing is recommended for patients who are not meeting glycemic goals or whose therapy has changed. (E)

A1C goals:

- Target goal < 7.0%

More stringent goals of an A1C as close to normal (< 6%) as possible without significant hypoglycemia can be considered in individual patients. (B)

Less stringent treatment goals may be appropriate for patients with a history of severe hypoglycemia, patients with limited life expectancies, very young children or older adults, and individuals with comorbid conditions. (E)
ROUTINE EXAMINATION

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<thead>
<tr>
<th>CATEGORY</th>
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</thead>
<tbody>
<tr>
<td>Diabetic Kidney Disease</td>
<td><strong>Diabetic Kidney Disease Screening:</strong></td>
</tr>
<tr>
<td></td>
<td>Perform an annual test for the presence of microalbuminuria in type 1 diabetic patients with diabetes duration of 5 or more years and in all type 2 diabetic patients, starting at diagnosis and at the initial obstetrical visit during pregnancy. (E)</td>
</tr>
<tr>
<td></td>
<td><strong>For children:</strong> Annual screening for microalbuminuria should be initiated once the child is 10 years of age and has had diabetes for 5 years. Screening may be done with a random spot urine sample analyzed for microalbuminuria-to-creatinine ratio. (E)</td>
</tr>
<tr>
<td></td>
<td>Serum creatinine should also be measured at least annually for the estimation of glomerular filtration rate (GFR) in all adults with diabetes regardless of the degree of urine albumin excretion. The serum creatinine alone should not be used as a measure of kidney function but instead used to estimate GFR and stage the level of chronic kidney disease. (E)</td>
</tr>
<tr>
<td></td>
<td><strong>Definitions of abnormalities in albumin excretion:</strong></td>
</tr>
<tr>
<td></td>
<td><em>Because of variability in urinary albumin excretion, two of three specimens collected within a 3- to 6-month period should be abnormal before considering a patient to have crossed one of these diagnostic thresholds.</em></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Category</th>
<th>24-h collection (mg/24 h)</th>
<th>Timed Collection (µg/min)</th>
<th>Spot Collection (µg/mg creatinine)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&lt;30</td>
<td>&lt;20</td>
<td>&lt;30</td>
</tr>
<tr>
<td>Microalbuminuria</td>
<td>30-299</td>
<td>20-199</td>
<td>30-299</td>
</tr>
<tr>
<td>Clinical albuminuria</td>
<td>≥ 300</td>
<td>≥ 200</td>
<td>≥ 300</td>
</tr>
</tbody>
</table>

**Diabetic Kidney Disease Treatment:**

For individuals after diagnosis of microalbuminuria and institution of an ACE inhibitor or ARB therapy and blood pressure control, continued surveillance is recommended to assess both response to dietary therapy and progression of disease is recommended. (E).

Individuals with clinical albuminuria should be referred to a dietitian skilled in advising on renal (protein restricted) diets. To reduce the risk of nephropathy, protein intake should be limited to the RDA (0.8 g/kg) in those with any degree of Chronic Kidney Disease. (B)

Consider referral to the physician experienced in the care of diabetic renal disease when the estimated GFR has fallen to <60 ml/min per 1.73 m² of if difficulties occur in the management of hypertension or hyperkalemia. (B) It is suggested that consultation with a nephrologist be obtained when the GFR is <30 ml/min per 1.73 m².
## ROUTINE TESTING

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>RECOMMENDATION</th>
</tr>
</thead>
</table>
| **Lipid Testing and Control**   | In adult patients, test for lipid disorders at least annually and more often if needed to achieve goals. However, in adults with low-risk lipid values (LDL < 100 mg/dl, HDL > 50 mg/dl, and triglycerides <150 mg/dl), it is acceptable to repeat lipid assessment every 2 years. (E)  

Target Values*:  
- Cholesterol <200 mg/dL  
- Triglyceride < 150 mg/dL  
- LDL < 100 mg/dL diabetes without overt CVD, < 70 mg/dL diabetes with overt CVD  
- HDL > 40 mg/dl men and > 50 mg/dl women  

For Children  
- For children > 2 years of age (prepubertal): a fasting lipid profile should be performed at the time of diagnosis (after glucose control has been established) if there is a family history of hypercholesterolemia, or a history of a cardiovascular event before age 55 years, or if family history is unknown. If family history is not of concern, then the first lipid screening should be performed at puberty (> 12 years). If values fall within the accepted risk levels (LDL < 100 mg/dl) the measurement should be repeated every 5 years. (E)  
- Pubertal children (> 12 years of age): a fasting lipid profile should be performed at the time of diagnosis (after glucose control has been established). If values fall within the accepted risk levels (LDL <100 mg/dl), the measurement should be repeated every 5 years.  

If lipids are abnormal, annual monitoring is recommended in both age groups. (E) |
| **Immunizations**                | Annually provide an influenza vaccine to all diabetic patients 6 months of age or older. (C)  

Provide at least one lifetime pneumococcal vaccine for adults with diabetes. A one-time revaccination is recommended for individuals >64 years of age previously immunized when they were <65 years of age if the vaccine was administered more than 5 years ago. Other indications for repeat vaccination include nephrotic syndrome, chronic renal disease, and other immunocompromised states, such as transplantation. (C)  

**Refer to PHP Preventive Health Recommendations.** |
## Coronary Heart Disease

Cardiovascular risk factors should be assessed at least annually. Risk factors include: dyslipidemia, hypertension, smoking, a positive family history of premature coronary disease, presence of micro/macronutrienta. Patients at increased CHD risk should receive aspirin and may warrant an ACE inhibitor.

Candidates for a diagnostic cardiac stress test include those with:
- Typical or atypical cardiac symptoms
- Abnormal Resting ECG

Candidates for a screening cardiac stress test include those with:
- History of peripheral or carotid occlusive arterial disease
- Sedentary lifestyle, age > 35 years and plans to begin vigorous exercise program

Patients with abnormal exercise ECG and patients unable to perform an exercise ECG require additional/alternative testing. A consultation with a cardiologist is recommended regarding further work-up.

In patients > 55 years of age, with or without hypertension but with another cardiovascular risk factor (history of CVD, dyslipidemia, microalbuminuria, or smoking), and ACE inhibitor (if not contraindicated) should be considered to reduce the risk of cardiovascular events. (A)

In patients with a prior myocardial infarction or in patients undergoing major surgery, beta-blockers, in addition, should be considered to reduce mortality. (A)
### MEDICATIONS

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>RECOMMENDATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetic Agents</td>
<td>Insulin and oral anti-diabetic agents therapy selection based on recommendations of PHP National Pharmacy and Therapeutics Committee.</td>
</tr>
</tbody>
</table>
| Anti-hypertensive Agents      | Initial drug therapy for those with a blood pressure of > 140/90 mmHG should be with a drug class demonstrated to reduced CVD events in patients with diabetes (ACE inhibitors, ARBs, beta-blockers, diuretics and calcium channel blockers). (A)  
  Multiple drug therapy is generally required to achieve blood pressure targets. (B)  
  All patients with diabetes and hypertension should be treated with a regimen that includes either an ACE inhibitor or if not tolerated an ARB. If one class is not tolerated, the other should be substituted. If needed to achieve blood pressure target, a thiazide diuretic should be added. (E)  
  If ACE inhibitors, ARBs, or diuretics are used, monitor renal function and serum potassium levels. (E)  
  **For children:** Pharmacologic treatment of hypertension (systolic or diastolic blood pressure consistently above the 95th percentile for age, sex, and height, or consistently > 130/80, if 95% exceeds the value) should be initiated as soon as the diagnosis is confirmed. (E) ACE inhibitors should be considered for the initial treatment of hypertension. (E) |
| ACE Inhibitor/ARBs Use for Proteinuria | In the treatment of micro- and macroalbuminuria, either ACE inhibitors or if not tolerated an ARBs should be used except during pregnancy. (A)  
  If ACE inhibitors, ARBs, or diuretics are used, monitor renal function and serum potassium levels. (E)  
  • In hypertensive type 1 diabetics with any degree of albuminuria, ACE inhibitors have been shown to delay the progression of nephropathy (A)  
  • In hypertensive type 2 diabetics with microalbuminuria, ACE inhibitors and ARBs have been shown to delay the progression to macroalbuminuria (A)  
  • In hypertensive type 2 diabetics with macroalbuminuria and renal insufficiency (serum creatinine >1.5 mg/dl), ARBs have been shown to delay the progression of nephropathy (A)  
  • If one class is not tolerated, the other should be substituted (E)  
  In the setting of albuminuria or nephropathy, in patients unable to tolerate ACE inhibitors and/or ARBs, consider the use of non-dihydropyridine calcium channel blockers (DCCBs), beta-blockers, or diuretics for the management of blood pressure. Use of non-DCCBs may reduce albuminuria in diabetic patients, including during pregnancy. (E)  
  **For children:** confirmed, persistently elevated microalbumin levels should be treated with an ACE inhibitor, titrated to normalization of microalbumin excretion (if possible). (E) |
**MEDICATIONS**

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>RECOMMENDATION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hyperlipidemia Agents</strong></td>
<td>For individuals without overt CVD:</td>
</tr>
<tr>
<td></td>
<td>• For those under the age of 40 years but at increased risk due to other cardiovascular risk factors who do not achieve lipid goals with lifestyle modifications alone, the addition of pharmacologic therapy is appropriate. (C)</td>
</tr>
<tr>
<td></td>
<td>• For those over the age of 40 years, statin therapy to achieve and LDL reduction of 30-40% regardless of baseline LDL levels is recommended. (A)</td>
</tr>
<tr>
<td></td>
<td>For individuals with overt CVD:</td>
</tr>
<tr>
<td></td>
<td>• All patients should be treated with a statin to achieve an LDL reduction of 30-40%. (A)</td>
</tr>
<tr>
<td></td>
<td>• A lower LDL cholesterol goal of &lt;70 mg/dl, using a high dose of a statin is an option. (B)</td>
</tr>
<tr>
<td></td>
<td>Lowering triglycerides and increasing HDL cholesterol with a fibrate is associated with a reduction in cardiovascular events in patients with clinical CVD, low HDL, and near-normal levels of LDL. (A)</td>
</tr>
<tr>
<td></td>
<td>For children: the addition of pharmacologic lipid-lowering agents is recommended for LDL &gt; 160 mg/dl and is also recommended in patients who have LDL cholesterol values 130-159 mg/dl based on the patient’s CVD risk profile, after failure of nutrition therapy and lifestyle changes. (E) The goal of therapy is an LDL value &lt; 100 mg/dl. (E)</td>
</tr>
<tr>
<td><strong>Antiplatelet Agents / Aspirin Use</strong></td>
<td>Use aspirin therapy (75-162 mg/day) as a secondary prevention strategy in those with diabetes with a history of CVD. (A)</td>
</tr>
<tr>
<td></td>
<td>Use aspirin therapy (75-162 mg/day) as a primary prevention strategy in those with:</td>
</tr>
<tr>
<td></td>
<td>• Type 2 diabetes at increased cardiovascular risk, including those who are over 40 years of age or who have additional risk factors (family history of CVD, hypertension, smoking, dyslipidemia, albuminuria). (A)</td>
</tr>
<tr>
<td></td>
<td>• Type 1 diabetes at increased cardiovascular risk, including those who are over 40 years of age or who have additional risk factors (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria). (C)</td>
</tr>
<tr>
<td></td>
<td>Consider aspirin therapy in people between the ages of 30 and 40 years, particularly in the presence of other cardiovascular risk factors. (E)</td>
</tr>
<tr>
<td></td>
<td>Aspirin therapy should not be recommended for patients under the age of 21 years because of the increased risk of Reye’s syndrome. (E)</td>
</tr>
<tr>
<td></td>
<td>Combination therapy using other antiplatelet agents such as clopidrogel in addition to aspirin should be used in patients with severe and progressive CVD. (C)</td>
</tr>
<tr>
<td></td>
<td>Other antiplatelet agents may be a reasonable alternative for high-risk patients who are not candidates for aspirin therapy. (E)</td>
</tr>
</tbody>
</table>
## EDUCATION and COUNSELING

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>RECOMMENDATION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Education and Self-management Principles</strong>&lt;br&gt;This includes&lt;br&gt;• diabetes disease process and treatment options&lt;br&gt;• nutritional management&lt;br&gt;• physical activity&lt;br&gt;• medications&lt;br&gt;• monitoring&lt;br&gt;• acute complications&lt;br&gt;• chronic complications&lt;br&gt;• goal setting and problem solving&lt;br&gt;• psychosocial adjustment&lt;br&gt;• preconception care, pregnancy and gestational diabetes management</td>
<td>Medical Nutrition Therapy (MNT): People with diabetes should receive individualized MNT as needed to achieve treatment goals, preferably provided by a registered dietitian familiar with the components of diabetes MNT. (B)&lt;br&gt;• Weight loss is recommended for all overweight (BMI 25.0-29.9 kg/m²) or obese (BMI ≥ 30.0 kg/m²) adults, who have, or who are at risk for developing type 2 diabetes. (E)&lt;br&gt;• The primary approach for achieving weight loss is therapeutic lifestyle change, which includes a reduction in energy intake and an increase in physical activity. A moderate decrease in caloric balance (500-1,000 kcal/day) will result in a slow but progressive weight loss (1-2 lb/week). For most patients, weight loss diets should supply at least 1,000-1,200 kcal/day for women and 1,200-1,600 kcal/day for men. (E)&lt;br&gt;<strong>Physical Activity:</strong> To improve glycemic control, assist with weight maintenance, and reduce risk of CVD, at least 150 min/week of moderate-intensity aerobic physical activity (50-70% of maximum heart rate) is recommended and/or at least 90 min/week of vigorous aerobic exercise (&gt;70% of maximum heart rate). The physical activity should be distributed over at least 3 days/week and with no more than 2 consecutive days without physical activity. (A)&lt;br&gt;• In the absence of contraindications, people with type 2 diabetes should be encouraged to perform resistance exercise three times a week, targeting all major muscle groups, progressing to three sets of 8-10 repetitions at a weight that cannot be lifted more than 8-10 times. (A)&lt;br&gt;<strong>Self-Monitoring Blood Glucose (SMBG):</strong> Instruct the patient in SMBG and routinely evaluate the patient’s technique and ability to use data to adjust therapy. (E)&lt;br&gt;• For patients using multiple insulin injections, SMBG should be carried out three or more times daily. (A)&lt;br&gt;• For patients using less frequent insulin injections or oral agents or MNT alone, SMBG is useful in achieving glycemic goals. (E)&lt;br&gt;• Instruct the patient in SMBG and routinely evaluate the patient’s technique and ability to use the data to adjust therapy. (E) Health professionals should evaluate at regular intervals the patient’s ability to use SMBG data to guide treatment.&lt;br&gt;<strong>Foot Care:</strong> Patients with diabetes and high-risk foot conditions should be educated regarding their risk factors and appropriate management. Education about self-care of feet is a vital component of patient management. (B)&lt;br&gt;<strong>Preconception Care:</strong> Women with diabetes who are contemplating pregnancy should be evaluated and, if indicated, treated for diabetic retinopathy, nephropathy, neuropathy and cardiovascular disease. (E)&lt;br&gt;<strong>Smoking Cessation Counseling</strong></td>
</tr>
</tbody>
</table>

**ADA Evidence Grading System**

**Clinical Practice Guidelines – Diabetes Management**<br>Authorized by: Medical Management Guideline Committee. Approved: 02/13/98. Revised: 04/13/00; 04/11/02; 03/16/04; 02/22/05; 2/22/06
## Diabetes Management Guidelines for 2006

<table>
<thead>
<tr>
<th></th>
<th>Evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:● Evidence from a well-conducted multicenter trial● Evidence from a meta-analysis that incorporated quality ratings in the analysis● Compelling nonexperimental evidence, i.e., “all or none” rule developed by the Center for Evidence Based Medicine at Oxford. Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including:● Evidence from a well-conducted trial at one or more institutions● Evidence from a meta-analysis that incorporated quality ratings in the analysis.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A</strong></td>
<td>Supportive evidence from well-conducted cohort studies, including:● Evidence from a well-conducted prospective cohort study or registry● Evidence from a well-conducted meta-analysis of cohort studies. Supportive evidence from a well-conducted case-control study.</td>
</tr>
<tr>
<td><strong>B</strong></td>
<td>Supportive evidence from poorly controlled or uncontrolled studies, including:● Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results● Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)● Evidence from case series or case reports. Conflicting evidence with the weight of evidence supporting the recommendation.</td>
</tr>
<tr>
<td><strong>C</strong></td>
<td>Expert consensus or clinical experience.</td>
</tr>
</tbody>
</table>

This guideline is intended to provide information to aid health care providers, it is not a substitute for clinical judgment in treating individual patients. It is subject to updating pending the release and review of additional data, based upon changes in scientific knowledge and technology.
Diabetes Management Guidelines for 2006

References


### INTERVENTION

**Stage I. Acute Phase**

**Duration:** Up to 3 months  
**Goal:** Induce Remission

<table>
<thead>
<tr>
<th>RECOMMENDATION</th>
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</thead>
<tbody>
<tr>
<td><strong>Assessment and Treatment Planning (1-2 visits)</strong></td>
</tr>
<tr>
<td>• Diagnosis of Major Depressive Disorder (MDD) made using DSM-IV criteria</td>
</tr>
<tr>
<td>• Possible alternative psychiatric diagnoses (e.g., anxiety, bipolar disorder, chemical dependency) or medical diagnoses had been ruled out</td>
</tr>
<tr>
<td>• Medical disorder or medications which may contribute to depressive symptoms:</td>
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<tr>
<td>• Assess complaint severity, psychosis, suicide / homicide risk</td>
</tr>
<tr>
<td>• Assess initially and over the course of treatment: Presence of suicidal or homicidal ideation, intent or plans; Access to means/lethality; psychotic symptoms, command hallucinations, severe anxiety; alcohol/substance abuse; history of attempts, family history or recent exposure</td>
</tr>
<tr>
<td>• Obtain history (previous episodes, family history, precipitating factors)</td>
</tr>
<tr>
<td>• Assess current and previous history of substance use disorders</td>
</tr>
<tr>
<td>• Evaluate and address functional impairments</td>
</tr>
<tr>
<td>• Education: Emphasize that condition is medical; progress is good with treatment; take medications as prescribed</td>
</tr>
<tr>
<td>• Mild MDD: use either medication or psychotherapy as initial treatment</td>
</tr>
<tr>
<td>• Moderate to Severe MDD: requires medication. Psychotherapy may also be indicated. [I. vs AJP 2002 p 1354]</td>
</tr>
<tr>
<td>• Referral to psychiatrist - Consider if: psychotic or bipolar depression, comorbid substance abuse, severe psychosocial problems, suicidal, specialized treatment required (e.g., MAOIs, ECT), additional non-mood mental disorder, clinical need for immediate response, rapid deterioration, female patient considering pregnancy</td>
</tr>
</tbody>
</table>
**Guidelines for the Treatment of Major Depressive Disorder in Adults – 2005**

<table>
<thead>
<tr>
<th>INTERVENTION</th>
<th>RECOMMENDATION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medication Treatment</strong></td>
<td>• Patients with moderate to severe symptoms, psychosis, elevated suicide or homicide risk need medication. Consider medication as initial therapy for mild MDD</td>
</tr>
<tr>
<td></td>
<td>• 65-70% of patients respond to the 1st antidepressant [A].</td>
</tr>
<tr>
<td></td>
<td>• Antidepressant effectiveness is generally comparable between and within classes [A].</td>
</tr>
<tr>
<td></td>
<td>• Selection of antidepressant depends on: [I, B]</td>
</tr>
<tr>
<td></td>
<td>• Short/long term side effects</td>
</tr>
<tr>
<td></td>
<td>• Safety, tolerability</td>
</tr>
<tr>
<td></td>
<td>• Patient age, preference, convenience, concerns</td>
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<tr>
<td></td>
<td>• History of prior response of patient or family member to medication</td>
</tr>
<tr>
<td></td>
<td>• Concurrent medical illness</td>
</tr>
<tr>
<td></td>
<td>• Concomitant non-psychotropic medications (potential drug interactions)</td>
</tr>
<tr>
<td></td>
<td>• Likelihood of adherence based on history</td>
</tr>
<tr>
<td></td>
<td>• Cost of medication</td>
</tr>
<tr>
<td></td>
<td>• Education (i.e., expected duration, side effects) reduces premature discontinuation</td>
</tr>
<tr>
<td></td>
<td>• In patients &gt; 65 years old, use lower doses of antidepressants and avoid TCAs</td>
</tr>
<tr>
<td></td>
<td>• Caution: Screen for bipolar disorder/ family history, as 30-50% of patients with bipolar disorder will develop acute mania particularly when started on monotherapy with an antidepressant medication.</td>
</tr>
<tr>
<td></td>
<td>• MAOIs: reserve for patients who do not respond to other drugs</td>
</tr>
<tr>
<td><strong>Consideration for Psychotherapy</strong></td>
<td>• Consider psychotherapy as alternative to medication for patients with mild depression [I, A], or with preference for non-pharmacological therapy</td>
</tr>
<tr>
<td></td>
<td>• If no response in 6 weeks, or partial response within 12 weeks, consider medications</td>
</tr>
<tr>
<td></td>
<td>• Consider psychotherapy, in addition to medication, for persons with:</td>
</tr>
<tr>
<td></td>
<td>• Depressive episode of 2+ years</td>
</tr>
<tr>
<td></td>
<td>• Hx of 2+ episodes of MDD with poor inter-episode recovery</td>
</tr>
<tr>
<td></td>
<td>• History of partial response to previous trials of drugs or psychotherapy</td>
</tr>
<tr>
<td></td>
<td>• Prominent psychosocial issues</td>
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<td></td>
<td>• History of treatment adherence problems</td>
</tr>
<tr>
<td></td>
<td>• Personality disorder</td>
</tr>
<tr>
<td><strong>Repeat Evaluations During Months 1-3</strong></td>
<td>• Monitor initial acute treatment every 1-2 weeks (e.g., response, side effects, psychosocial supports, suicidal tendencies) [D]</td>
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<tr>
<td></td>
<td>• By 6 weeks (or 4 weeks if severely ill):</td>
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<tr>
<td></td>
<td>• If positive response – continue treatment at same dose</td>
</tr>
<tr>
<td></td>
<td>• If partial or no symptomatic relief, reassess: diagnosis; adequacy of treatment; adequacy of medication dosage and compliance [I]</td>
</tr>
<tr>
<td></td>
<td>• Recommended options:</td>
</tr>
<tr>
<td></td>
<td>• For partial or no response: Increase medication. Monitor response every 2 weeks</td>
</tr>
<tr>
<td></td>
<td>• Switching antidepressant medication is preferred to adding a 2nd drug to 1st and should not be attempted until there has been an adequate trial of 1st drug</td>
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<tr>
<td></td>
<td>• Augment with agents such as lithium, thyroid hormone (particularly in women) stimulants or anticonvulsants</td>
</tr>
<tr>
<td>INTERVENTION</td>
<td>RECOMMENDATION</td>
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</tbody>
</table>
| • Addition of psychotherapy  
• If some symptoms persist, do not change medication - re-evaluate at week 12  
• Referral to Psychiatrist – consider if: fails 2 or more medication trials (treatment refractory depression); symptoms are intense, prolonged, or severely melancholic; marked functional impairment; psychotic symptoms present; suicide/homicide risk persists or emerges. (Elderly - highest risk for suicide of all age groups) |  
| **Stage II. Continuation Phase**  
**Duration:** 4-9 months, after remission achieved.  
**Goal:** Preserve Remission; Prevent Relapse |  
• Evaluate every 1-3 months  
• Dosage remains the same for 4-9 months after achieving full remission [A]  
• For those with previous episode(s), continue treatment for at least 9 months  
• Consider psychotherapy to help prevent relapse  
• Educate patient and support system that symptoms can recur  
• Patients at low risk of relapse (MDD with 1 episode) should be considered for discontinuation with tapering and with careful monitoring for relapse |  
| **Stage III. Maintenance Phase**  
**Duration:** Indefinite. Depends on frequency and severity of prior episodes.  
**Goal:** Prevent new episode. Protect susceptible patients against recurrence |  
• Consider maintenance therapy to prevent relapse. 50-85% of patients with single episode of MDD will have at least one more episode, usually within 2-3 years  
• Recommended for patients at high risk (2+episodes of MDD, psychotic depression, 1st onset at age <20 or age >65, persistent residual symptoms, suicidality) [B]  
• Evaluate every 2-3 months, or more frequently as required  
• In general, continue same treatment that was effective in prior phases [II]  
• Although further trials needed to establish optimum length of therapy, consider:  
  • After 2nd episode (80% risk of recurrence), up to 3 years of therapy  
  • After 3rd episode (90% risk of recurrence), continue therapy indefinitely  
• Educate patient that symptoms can recur  
• Consultation with a psychiatrist – Consider for patients needing maintenance therapy  
• When discontinuing active therapy, base decision on: probability of recurrence; frequency/ severity of past episodes, persistence of dysthymic symptoms, presence of comorbid conditions, patient preference [I]  
• When discontinuing, taper drug over several weeks |  

This guideline is intended to provide information to aid health care providers and it is not a substitute for clinical judgment in treating individual patients. It is subject to updating, pending the release and review of additional data, based upon changes in scientific knowledge and technology.

**Level of Evidence**

*Clinical Practice Guidelines – Depression Management*

Authorized by: Medical Management Guideline Committee. Approved: 04/08/99. Revised: 04/12/01; 04/10/03; 05/25/04; 05/24/05
Guidelines for the Treatment of Major Depressive Disorder in Adults – 2005

<table>
<thead>
<tr>
<th>APA 2000</th>
<th>UMHS 1998</th>
</tr>
</thead>
<tbody>
<tr>
<td>I = Recommended with substantial clinical confidence</td>
<td>A = randomized controlled trials</td>
</tr>
<tr>
<td>II = Recommended with moderate clinical confidence</td>
<td>B = controlled trials, no randomization</td>
</tr>
<tr>
<td>III = May be recommended on the basis of individual circumstances</td>
<td>C = observational trials</td>
</tr>
<tr>
<td></td>
<td>D = opinion of expert panel</td>
</tr>
</tbody>
</table>

References

Brigham and Women’s Hospital. Depression. A guide to Diagnosis and Treatment. Boston, Mass. 2001


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Clinical Practice Guidelines – Depression Management
Authorized by: Medical Management Guideline Committee. Approved: 04/08/99. Revised: 04/12/01; 04/10/03; 05/25/04; 05/24/05
Preventive Health Recommendations for 2006 – Final

DEVELOPED BASED ON SCIENTIFIC EVIDENCE

These recommendations are not to be confused with the benefits covered by PacifiCare/Secure Horizons as defined in the member’s Evidence of Coverage/Disclosure Form.

Authorized By: Medical Management Guideline Committee

Approval Date: 02/11/99  Revision Date: 04/08/99; 02/10/00; 02/08/01; 02/14/02; 04/11/02; 02/13/03; 03/16/04; 2/22/05; 9/1/05; 11/22/05; 2/22/06

<table>
<thead>
<tr>
<th>ASSESSMENT</th>
<th>0–10 years</th>
<th>11–24 years</th>
<th>25–64 years</th>
<th>65+ years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal Aortic Aneurysm(^1)</td>
<td></td>
<td></td>
<td></td>
<td>One-time screening for abdominal aortic aneurysm by ultrasonography in men aged 65-75 who have ever smoked</td>
</tr>
<tr>
<td>Breast Cancer Screening(^2,3)</td>
<td></td>
<td></td>
<td></td>
<td>One-time screening for abdominal aortic aneurysm by ultrasonography in men aged 65-75 who have ever smoked</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Screening mammography, with or without clinical breast exam, every 1 to 2 years for women age 40 and older</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Inform of potential benefits, limitations, and possible harms of mammography in making decisions about when to begin screening</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Women whose family history is associated with an increased risk for deleterious mutations in BRCA1 or BRCA2 genes be referred for genetic counseling and evaluation for BRCA testing.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Screening mammography, with or without clinical breast exam, every 1 to 2 years for women age 40 and older</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Inform of potential benefits, limitations, and possible harms of mammography in making decisions about when to begin screening</td>
</tr>
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Preventive Health Rec-CPG-SH-Provider
Preventive Health Recommendations for 2006 – Final

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<table>
<thead>
<tr>
<th>ASSESSMENT</th>
<th>0–10 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervical Cancer Screening⁴</td>
<td>• At least every 3 years beginning at age 21 or for women who are or have</td>
</tr>
<tr>
<td></td>
<td>been sexually active, whichever comes first; interval as recommended by</td>
</tr>
<tr>
<td></td>
<td>physician based on risk factors</td>
</tr>
<tr>
<td></td>
<td>• At least every 3 years for women who have a cervix; interval as</td>
</tr>
<tr>
<td></td>
<td>recommended by physician based on risk factors</td>
</tr>
<tr>
<td></td>
<td>• May discontinue regular testing after age 65 in women who have</td>
</tr>
<tr>
<td></td>
<td>had adequate recent screenings in which test results have been normal</td>
</tr>
<tr>
<td></td>
<td>and who are otherwise not at risk</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ASSESSMENT</th>
<th>11–24 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlamydia Infection Screening⁵</td>
<td>• Routine for sexually active females</td>
</tr>
<tr>
<td></td>
<td>• Routine for sexually active females age 25 and younger</td>
</tr>
<tr>
<td></td>
<td>• Routine for other asymptomatic females at increased risk for infection</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ASSESSMENT</th>
<th>25–64 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorectal Cancer Screening⁶</td>
<td>• Routine screening beginning at age 50 for men and women at average risk</td>
</tr>
<tr>
<td></td>
<td>with interval determined by method. Potential screening options include</td>
</tr>
<tr>
<td></td>
<td>home Fecal Occult Blood Test (FOBT), flexible sigmoidoscopy, the</td>
</tr>
<tr>
<td></td>
<td>combination of home FOBT and flexible sigmoidoscopy, colonoscopy, and</td>
</tr>
<tr>
<td></td>
<td>double-contrast barium enema</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>ASSESSMENT</th>
<th>65+ years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Routine screening with interval determined by method. Potential</td>
</tr>
<tr>
<td></td>
<td>screening options include home Fecal Occult Blood Test (FOBT), flexible</td>
</tr>
<tr>
<td></td>
<td>sigmoidoscopy, the combination of home FOBT and flexible sigmoidoscopy,</td>
</tr>
<tr>
<td></td>
<td>colonoscopy, and double-contrast barium enema</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ASSESSMENT</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression Screening⁷</td>
<td>• Remain alert for possible signs and symptoms of depression</td>
</tr>
<tr>
<td></td>
<td>• Routine screening for adults</td>
</tr>
<tr>
<td></td>
<td>• Remain alert for possible signs and symptoms of depression in</td>
</tr>
<tr>
<td></td>
<td>younger patients</td>
</tr>
<tr>
<td></td>
<td>• Routine screening for adults</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ASSESSMENT</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes-Type 2⁸</td>
<td>• Screening of adults with hypertension or hyperlipidemia</td>
</tr>
<tr>
<td></td>
<td>• Screening of adults with hypertension or hyperlipidemia</td>
</tr>
</tbody>
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</tr>
</thead>
<tbody>
<tr>
<td>Hearing$^9$</td>
<td></td>
<td></td>
<td></td>
<td>• At physician discretion</td>
</tr>
<tr>
<td>Height and Weight$^{10}$</td>
<td>• Growth chart plotted during office visit from birth on</td>
<td>• Periodically</td>
<td>• Periodically</td>
<td>• Periodically</td>
</tr>
<tr>
<td>High Blood Pressure$^{11}$ (Hypertension)</td>
<td>• Periodic screening beginning at age 18 years</td>
<td>• Periodic screening</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human Immunodeficiency virus (HIV)$^{12}$</td>
<td>• Screen all adolescents and adults at increased risk for HIV infection</td>
<td>• Screen all adolescents and adults at increased risk for HIV infection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lead Testing$^{13}$</td>
<td>• Screening for elevated levels of lead in the blood at age 12 months for all children at increased risk of lead exposure</td>
<td></td>
<td></td>
<td></td>
</tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Lipid Disorder Screening¹⁴</td>
<td>• Routine screening beginning at age 20 if other risk factors for coronary heart disease exist</td>
<td>• Routine screening for males age 35 and older and females age 45 and older</td>
<td>• Routine screening for younger adults if other risk factors for coronary heart disease exist</td>
<td>• Routine screening for adults – offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults</td>
</tr>
<tr>
<td>Obesity¹⁵</td>
<td>• Routine screening for adults – offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults</td>
<td>• Routine screening for adults – offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults</td>
<td>• Routine screening for adults – offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults</td>
<td>• Routine screening for adults – offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults</td>
</tr>
<tr>
<td>Osteoporosis Screening¹⁶</td>
<td>• Routine screening beginning at age 60 for women at increased risk of osteoporotic fracture</td>
<td>• Routine screening beginning at age 60 for women at increased risk of osteoporotic fracture</td>
<td>• Routine screening for women at age 60 for women at increased risk of osteoporotic fracture</td>
<td>• Routine screening for women at age 60 for women at increased risk of osteoporotic fracture</td>
</tr>
<tr>
<td>Prostate Cancer Screening¹⁷</td>
<td>• Discuss risks and benefits of screening with medical professional</td>
<td>• Discuss risks and benefits of screening with medical professional</td>
<td>• Discuss risks and benefits of screening with medical professional</td>
<td>• Discuss risks and benefits of screening with medical professional</td>
</tr>
<tr>
<td>Syphilis Screening¹⁸</td>
<td>• Screening for persons at increased risk for syphilis infection</td>
<td>• Screening for persons at increased risk for syphilis infection</td>
<td>• Screening for persons at increased risk for syphilis infection</td>
<td>• Screening for persons at increased risk for syphilis infection</td>
</tr>
<tr>
<td>Tuberculosis Screening¹⁹</td>
<td>• All persons at increased risk of developing tuberculosis</td>
<td>• All persons at increased risk of developing tuberculosis</td>
<td>• All persons at increased risk of developing tuberculosis</td>
<td>• All persons at increased risk of developing tuberculosis</td>
</tr>
<tr>
<td>Vision Screening²⁰</td>
<td>• Screening for amblyopia, strabismus and defects in visual acuity in children younger than age 5 years</td>
<td>• Refer high risk individuals for evaluation by eye specialist; frequency at physician discretion</td>
<td>• Refer high risk individuals for evaluation by eye specialist; frequency at physician discretion</td>
<td>• Refer high risk individuals for evaluation by eye specialist; frequency at physician discretion</td>
</tr>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Cardiovascular Disease Prevention</strong></td>
<td>• Regular dental care</td>
<td>• Regular dental care</td>
<td>• Discuss aspirin chemoprevention, including potential benefits and harms, with adults who are at increased risk for coronary heart disease</td>
<td>• Discuss aspirin chemoprevention, including potential benefits and harms, with adults who are at increased risk for coronary heart disease</td>
</tr>
<tr>
<td></td>
<td>• Floss, brush with fluoride toothpaste daily</td>
<td>• Floss, brush with fluoride toothpaste daily</td>
<td>• Regular dental care</td>
<td>• Regular dental care</td>
</tr>
<tr>
<td></td>
<td>• Prescribe oral fluoride supplementation for preschoolers with fluoride-deficient water supplies</td>
<td>• Prescribe oral fluoride supplementation for preschoolers with fluoride-deficient water supplies</td>
<td>• Floss, brush with fluoride toothpaste daily</td>
<td>• Floss, brush with fluoride toothpaste daily</td>
</tr>
<tr>
<td><strong>Dental Health</strong></td>
<td>• Encourage breastfeeding of infants; diet of iron-enriched formula and foods</td>
<td>• Limit fat and cholesterol, maintain caloric balance and emphasize fruits, vegetables, and grain products containing fiber</td>
<td>• Limit fat and cholesterol, maintain caloric balance and emphasize fruits, vegetables, and grain products containing fiber</td>
<td>• Limit fat and cholesterol, maintain caloric balance and emphasize fruits, vegetables, and grain products containing fiber</td>
</tr>
<tr>
<td></td>
<td>• Over age 2, limit fat and cholesterol, maintain caloric balance and emphasize fruits, vegetables, and grain products containing fiber</td>
<td>• Adequate calcium intake (women)</td>
<td>• Adequate calcium intake (women)</td>
<td>• Adequate calcium intake (women)</td>
</tr>
<tr>
<td></td>
<td>• Regular physical activity</td>
<td>• Regular physical activity</td>
<td>• Regular physical activity</td>
<td>• Regular physical activity</td>
</tr>
<tr>
<td><strong>Hormone Replacement Therapy</strong></td>
<td>• Counsel women approaching menopause regarding alternatives to prevent chronic disease</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
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Preventive Health Rec-CPG-SH-Provider
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<tbody>
<tr>
<td></td>
<td>Recommended Topic:</td>
<td>Recommended Topic:</td>
<td>Recommended Topic:</td>
<td>Recommended Topic:</td>
</tr>
</tbody>
</table>
| Injury Prevention/Patient Safety<sup>25</sup> | - Federally approved child safety seats appropriate for the child’s age and size  
- Safety belts when not covered by state child safety seat laws<sup>26</sup>  
- Safety helmet for high speed activities  
- Smoke detectors  
- Flame retardant sleepwear  
- Place infants on their backs to sleep  
- Hot water heater temperature <120° F  
- Window/stair guards, pool fence  
- Restrict access to drugs, toxic substances, firearms and matches  
- Poison control phone number  
- CPR training for caretakers of high-risk individuals  
- Water Safety | - Safety belts<sup>26</sup>  
- Safety helmet for high speed activities  
- Smoke detectors  
- Restrict unauthorized access to firearms  
- CPR training for caretakers of high-risk individuals  
- Water safety | - Safety belts<sup>26</sup>  
- Safety helmet for high speed activities  
- Smoke detectors  
- Restrict unauthorized access to firearms  
- CPR training for caretakers of high-risk individuals  
- Water safety | - Safety belts<sup>26</sup>  
- Safety helmet for high speed activities  
- Smoke detectors  
- Restrict unauthorized access to firearms  
- CPR training for caretakers of high-risk individuals  
- Water safety  
- Hot water heater <120°F  
- CPR training for caretakers of high risk individuals  
- Measures to reduce risk of falling  
- Water safety |
Preventive Health Recommendations for 2006 – Final

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</thead>
<tbody>
<tr>
<td>Prenatal Care</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recommended Topic:</td>
<td>To reduce the risk of neural tube defects in newborns, all women not planning but still capable of pregnancy should take a multivitamin containing 0.4mg of folic acid daily.</td>
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</tr>
<tr>
<td></td>
<td>Pregnant women should be advised to seek their first prenatal visit in the first trimester or as soon as pregnancy is known.</td>
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</tr>
<tr>
<td></td>
<td>During the first prenatal visit, perform Rh (D) blood typing and antibody testing and screen for hepatitis B virus and syphilis infection; at 12-16 weeks’ gestation, screen for asymptomatic bacteriuria.</td>
<td>During the first prenatal visit, perform Rh (D) blood typing and antibody testing and screen for hepatitis B virus and syphilis infection; at 12-16 weeks’ gestation, screen for asymptomatic bacteriuria.</td>
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</tr>
<tr>
<td></td>
<td>Screen all pregnant women for HIV.</td>
<td>Screen all pregnant women for HIV.</td>
<td>Screen all pregnant women for HIV.</td>
<td>Screen all pregnant women for HIV.</td>
</tr>
<tr>
<td></td>
<td>Screen all pregnant women for tobacco use and provide augmented pregnancy-tailored counseling to those who smoke.</td>
<td>Screen all pregnant women for tobacco use and provide augmented pregnancy-tailored counseling to those who smoke.</td>
<td>Screen all pregnant women for tobacco use and provide augmented pregnancy-tailored counseling to those who smoke.</td>
<td>Screen all pregnant women for tobacco use and provide augmented pregnancy-tailored counseling to those who smoke.</td>
</tr>
<tr>
<td></td>
<td>Advise all pregnant women of the potential adverse effects of drug use on the development of the fetus.</td>
<td>Advise all pregnant women of the potential adverse effects of drug use on the development of the fetus.</td>
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<td>Advise all pregnant women of the potential adverse effects of drug use on the development of the fetus.</td>
</tr>
<tr>
<td>Sexual Behavior</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recommended Topic:</td>
<td>Sexually Transmitted Disease: All adolescent and adults advised of risk factors and counseled about effective measures to prevent infection</td>
<td>Sexually Transmitted Disease: All adult advised of risk factors and counseled about effective measures to prevent infection</td>
<td>Sexually Transmitted Disease: All adult advised of risk factors and counseled about effective measures to prevent infection</td>
<td>Sexually Transmitted Disease: All adult advised of risk factors and counseled about effective measures to prevent infection</td>
</tr>
<tr>
<td></td>
<td>Unintended pregnancy: Contraception</td>
<td>Unintended pregnancy: Contraception</td>
<td>Unintended pregnancy: Contraception</td>
<td>Unintended pregnancy: Contraception</td>
</tr>
</tbody>
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</tr>
</thead>
</table>
| Substance Use and Substance Abuse\(^{34}\) | • Effects of passive smoking  
• Anti-tobacco message | • Regular screening for tobacco-use status and provide tobacco cessation interventions for those who use tobacco products  
• Screening and behavioral counseling interventions to reduce alcohol misuse by adults  
• Avoid underage drinking and illicit drug use  
• Avoid alcohol/drug use while driving\(^{26}\), swimming, boating, etc. | • Regular screening for tobacco-use status and provide tobacco cessation interventions for those who use tobacco products  
• Screening and behavioral counseling interventions to reduce alcohol misuse by adults  
• Avoid alcohol/drug use while driving\(^{26}\), swimming, boating, etc. | • Regular screening for tobacco-use status and provide tobacco cessation interventions for those who use tobacco products  
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### IMMUNIZATIONS

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<th>65+ years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphtheria, Tetanus, acellular Pertussis</td>
<td>• 2, 4, 6, 15–18 months and 4–6 years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tetanus Diphtheria</td>
<td>• Once at 11–12 years; then every 10 years</td>
<td>• If already immunized with Tetanus and Diphtheria (Td), a single dose with a 5-year interval between Td and Tetanus, Diphtheria and acellular Pertussis.</td>
<td>• Every 10 years instead of Td</td>
<td>• Booster every 10 years</td>
</tr>
<tr>
<td>Tetanus, Diphtheria and acellular Pertussis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haemophilus Influenza type B</td>
<td>• 2, 4, 6 and 12–15 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis A</td>
<td>• 1st dose between 1-2 yrs; 2nd dose 6-18 months after 1st dose - consult your physician.</td>
<td>• If not previously immunized, all children and adolescents through age 18 living in areas with rates that are at least twice the national average, 2 doses: 2nd dose 6–18 months after 1st dose – consult your physician</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: The 2006 ACIP recommendations include a catch-up schedule for children and adolescents who start late or who are >1 month behind. Refer to [www.cdc.gov/nip](http://www.cdc.gov/nip) for additional information. The PacifiCare/Secure Horizons member’s Evidence of Coverage/Disclosure Form should be consulted for the specific coverage and limitations of benefits for vaccines recommended for travel and occupational risk.
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<tr>
<td><strong>Hepatitis B</strong></td>
<td>• 1st dose soon after birth and before discharge; 2nd dose 1 month after 1st dose; 3rd dose 4 months after 1st dose and at least 2 months after the 2nd dose, but not before 6 months of age</td>
<td>• 11–12 years if not previously immunized</td>
<td>• All adults with medical, behavioral, occupational or other high risk indications</td>
<td>• All adults with medical, behavioral, occupational or other high risk indications</td>
</tr>
<tr>
<td></td>
<td>• 11–12 years if not previously immunized</td>
<td>• All adults with medical, behavioral, occupational or other high risk indications</td>
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<td></td>
<td>• All adults with medical, behavioral, occupational or other high risk indications</td>
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<td>• All adults with medical, behavioral, occupational or other high risk indications</td>
</tr>
<tr>
<td><strong>Influenza</strong></td>
<td>• For children ≥ 6 months with increased risk of complication or transmission to high risk persons, annually in fall or winter</td>
<td>• All children and adults at increased risk for complications or transmission to high risk persons, annually in fall or winter</td>
<td>• All adults beginning at age 50 and others at increased risk for complications or transmission to high risk persons, annually in fall or winter</td>
<td>• Annually, in fall or winter</td>
</tr>
<tr>
<td><strong>Measles, Mumps, Rubella</strong></td>
<td>• 12–15 months and 4–6 years</td>
<td>• If second dose not completed: then 2nd dose at 11–12 years old</td>
<td>• Based on vaccine history</td>
<td>• Based on vaccine history</td>
</tr>
<tr>
<td><strong>Meningococcal Conjugate</strong></td>
<td>• 11-12 years old</td>
<td>• Teens entering high school (interim recommendation)</td>
<td>• College freshman living in dormitories (interim recommendation)</td>
<td>• Adolescents and college students who do not live in dormitories who want to reduce their risk of infection (interim recommendation)</td>
</tr>
<tr>
<td><strong>Inactivated Polio Vaccine</strong></td>
<td>• 2, 4, 6–18 months and 4–6 years</td>
<td>•</td>
<td>•</td>
<td>•</td>
</tr>
</tbody>
</table>
## Preventive Health Recommendations for 2006 – Final

**DEVELOPED BASED ON SCIENTIFIC EVIDENCE**

*These recommendations are not to be confused with the benefits covered by PacifiCare/Secure Horizons as defined in the member’s Evidence of Coverage/ Disclosure Form.*

<table>
<thead>
<tr>
<th>IMMUNIZATIONS</th>
<th>0–10 years</th>
<th>11–24 years</th>
<th>25–64 years</th>
<th>65+ years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pneumococcal</td>
<td>All children ≥ 2 years at increased risk for pneumococcal disease</td>
<td>All children and adults at increased risk for pneumococcal disease</td>
<td>All adults at increased risk for pneumococcal disease</td>
<td>All persons ≥ 65 years; second dose if initial vaccination was ≥ 5 years previously and &lt;65 years</td>
</tr>
<tr>
<td>Rubella</td>
<td></td>
<td>All women of childbearing age should be screened for rubella susceptibility or, if nonpregnant, may be offered vaccination without screening</td>
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<td></td>
</tr>
<tr>
<td>Varicella</td>
<td>12–18 months</td>
<td>Susceptible persons ≥13 years at risk for exposure or transmission: 2 doses 4 weeks apart</td>
<td>Susceptible persons at risk for exposure or transmission: 2 doses 4 weeks apart</td>
<td>Susceptible persons at risk for exposure or transmission: 2 doses 4 weeks apart</td>
</tr>
<tr>
<td>Pneumococcal conjugate vaccine (PCV7)</td>
<td>≤6 months – 3 doses, 2 months apart beginning at age 2 months; 1 dose at 12–15 months; For unvaccinated children: 2–6 months – 3 doses, 2 months apart beginning at age 2 months and 1 dose at 12–15 months; 7–11 months – 2 doses, 2 months apart; 1 dose at 12–15 months; 12–23 months – 2 doses, 2 months apart; 24–59 months with SCD, asplenia, HIV infection, chronic illness or immunocompromising condition – 2 doses, 2 months apart</td>
<td></td>
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</tbody>
</table>
Nothing in these guidelines should be construed to establish a new benefit under PacifiCare or indicate a change in federal or state required benefits. The PacifiCare/Secure Horizons member’s Evidence of Coverage/Disclosure Form should be consulted for the specific coverage and limitations of benefits.

References: American Academy of Pediatrics (AAP), Centers for Disease Control and Prevention (CDC) and US Preventive Services Task Force (USPSTF). Unless otherwise specified, please note that the designations for each recommendation reflect the evidence rating assigned by the USPSTF. Designations: (A) strongly recommends the service based on good evidence; (B) recommends the service based on fair evidence; (C) makes no recommendation for or against the service based on fair evidence but concludes the balance of benefits and harms is too close to justify a general recommendation; (D) recommends against the service in asymptomatic patients based on at least fair evidence that the service is ineffective or that harms outweigh benefits; (I) insufficient evidence for or against the service based on evidence that the service is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined.

1The USPSTF found good evidence that screening for abdominal aortic aneurysm (AAA) and surgical repair of large AAAs (5.5 cm or more) in men age 65-75 who have ever smoked (current and former smokers) leads to decreased AAA-specific mortality (B). There is good evidence that abdominal ultrasonography, performed in a setting with adequate quality assurance (i.e., in an accredited facility with credentialed technologists), is an accurate screening test for AAA. There is also good evidence of important harms of screening and early treatment, including an increased number of surgeries with associated clinically-significant morbidity and mortality, and short-term psychological harms. Based on moderate magnitude of net benefit, the USPSTF concluded that the benefits of screening for AAA in men aged 65 to 75 who have ever smoked outweigh the harms.

2The USPSTF recommends screening mammography, with or without clinical breast examination, every 1 to 2 years for women age 40 and older (B). The USPSTF further recommends women be informed of potential benefits, limitations, and possible harms of mammography in making decisions about when to begin screening. The most frequently discussed harms of mammography are the anxiety, discomfort, and cost associated with positive results, many of which are false positive, and the diagnostic procedures they generate. Radiation exposure is also a potential risk.

3The USPSTF recommends that women whose family history is associated with an increased risk for deleterious mutations in BRCA1 or BRCA2 genes be referred for genetic counseling and evaluations for BRCA testing (B). Counseling, that allows for informed decision making, should be carried out by a suitably trained health care provider. There is insufficient evidence to determine the benefits of chemoprevention or intensive screening in improving health outcomes in these women if they test positive for deleterious BRCA1 or BRCA2 mutations. However, there is fair evidence that prophylactic surgery for these women significantly decreases breast and ovarian cancer incidence. Thus, the potential benefits of referral and discussion of testing and prophylactic treatment for these women may be substantial.

4The USPSTF strongly recommends cervical cancer screening for all women whom are or have been sexually active and who have a cervix (A). Direct evidence to determine the optimal starting and stopping age and interval for screening is limited. Indirect evidence suggests most of the benefit can be obtained by screening within 3 years of onset of sexual activity or age 21 (which ever comes first) and screening at least every 3 years. The USPSTF recommends against routinely screening women older than age 65 for cervical cancer if they have had adequate recent screening with normal Pap smears and are not otherwise at high risk for
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cervical cancer. (D) The USPSTF recommends against routine Pap smear screening in women who have had a total hysterectomy for benign disease. (D)
The USPSTF concluded that the evidence is insufficient to recommend for or against the routine use of new technologies to screen for cervical cancer. (I)
5The USPSTF strongly recommends routinely screening all sexually active women age 25 and younger and other asymptomatic women at increased risk for infection, for chlamydial infection (A).
6The USPSTF strongly recommends that clinicians screen men and women 50 years of age and older for colorectal cancer (A). Potential screening options include home FOBT, flexible sigmoidoscopy, the combination of home FOBT and flexible sigmoidoscopy, colonoscopy, and double-contrast barium enema. Each option has advantages and disadvantages that may vary for individual patients and practice settings. The choice of specific screening strategy should be based on patient preferences, medical contraindications, patient adherence, and available resources for testing and follow-up. Clinicians should talk to patients about the benefits and potential harms associated with each option before selecting a screening strategy. The optimal interval for screening depends on the test. Annual FOBT offers greater reductions in mortality rates than biennial screening but produces more false-positive results. A 10-year interval has been recommended for colonoscopy on the basis of evidence regarding the natural history of adenomatous polyps. Shorter intervals (5 years) have been recommended for flexible sigmoidoscopy and double-contrast barium enema because of their lower sensitivity, but there is no direct evidence with which to determine the optimal interval for tests other than FOBT.
7The USPSTF recommends screening adults for depression in clinical practices that have systems in place to assure accurate diagnosis, effective treatment and follow-up (B). Many formal screening tools are available. Asking two simple questions about mood and anhedonia (“Over the past 2 weeks, have you felt down, depressed or hopeless?” and “Over the past 2 weeks, have you felt little interest or pleasure in doing things?”) may be as effective as using longer instruments. All positive tests should trigger full diagnostic interviews that use standard diagnostic criteria to determine the presence or absence of specific depressive disorders. The optimal interval for screening is unknown. The USPSTF concluded evidence is insufficient to recommend for or against routine screening of children or adolescents for depression (I)
8The USPTF recommends screening for type 2 diabetes in adults with hypertension or hyperlipidemia. (B)
9The USPSTF concluded there is insufficient evidence to recommend for or against routine screening of newborns for hearing loss during the postpartum hospitalization (I). The USPSTF recommends screening older adults for hearing impairment by periodically questioning them about their hearing, counseling them about the availability of hearing aid devices and making referrals for abnormalities when appropriate. The optimal frequency of such screening has not been determined and is left for clinical discretion. (B).
10The AAP and USPSTF recommend periodic height and weight measurements plotted on growth chart (B).
11The USPSTF strongly recommends screening adults aged 18 and older for high blood pressure (A). Evidence is lacking to recommend an optimal interval for screening adults for high blood pressure. The sixth report of the Joint National Committee of Prevention, Detection, Evaluation, and Treatment of High Blood Pressure recommends screening every two years for persons with SBP and DBP <130 mm Hg and 85 mm Hg, respectively, and more frequent intervals for screening those with blood pressure at higher levels. The USPSTF concluded that the evidence is insufficient to recommend for or against routine screening for high blood pressure in children and adolescents to reduce the risk of cardiovascular disease (I). The decision to screen children and adolescents for hypertension remains a matter of clinical judgment.
The USPSTF strongly recommends that clinicians screen for human immunodeficiency virus (HIV) all adolescents and adults at increased risk for HIV infection (A). A person is considered at increased risk for HIV infection if he or she reports one or more individual risk factors or receives health care in a high-prevalence or high-risk clinical setting. Those at individual risk include: men who have had sex with men after 1975; men and women having unprotected sex with multiple partners; past or present injection drug users; men and women who exchange sex for money or drugs or have sex partners who do; individuals whose past or present sex partners were HIV-infected, bisexual, or injection drug users; persons being treated for sexually transmitted diseases; and persons with a history of blood transfusion between 1975 and 1985. Persons who request an HIV test despite reporting no individual risk factors may also be considered at increased risk, since this group is likely to include individuals not willing to disclose high risk behaviors. The USPSTF recommends that clinicians screen all pregnant women for HIV (A). Early detection of maternal HIV infection allows for discussion of elective cesarean section and avoidance of breast feeding, both of which are associated with lower HIV transmission rates.

The USPSTF recommends screening for elevated lead levels by measuring blood lead at least once age 12 months for all children at increased risk for lead exposure (B).

The USPSTF strongly recommends routinely screening men age 35 and older and women age 45 and older for lipid disorders and treating abnormal lipids in people who are at increased risk of coronary heart disease (A). The USPSTF recommends routinely screening younger adults for lipid disorders if they have other risk factors for coronary heart disease (B).

The USPSTF recommends that clinicians screen all adult patients for obesity and offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults (B). The USPSTF found good evidence that Body Mass Index (BMI), calculated as weight in kilograms divided by height in meters squared, is reliable and valid for identifying adults at increased risk for mortality and morbidity due to overweight and obesity. There is fair to good evidence that high-intensity counseling-about diet, exercise, or both– together with behavioral interventions aimed at skill development, motivation, and support strategies produces modest, sustained weight loss in adults who are obese. Although the USPSTF did not find direct evidence that behavioral interventions lower mortality or morbidity from obesity, the USPSTF concluded that changes in intermediate outcomes, such as improved glucose metabolism, lipid levels, and blood pressure, from modest weight loss provide indirect evidence of health benefits. No evidence was found that addressed the harms of counseling and behavioral interventions. The USPSTF concluded that the benefits of screening and behavioral interventions outweigh potential harms.

The USPSTF recommends that women aged 65 and older be screened routinely for osteoporosis. The USPSTF recommends that routine screening begin at age 60 for women at increased risk of osteoporotic fractures (B). The exact risk factors that should trigger screening in this age group are difficult to specify based on evidence. Lower body weight (weight <70kg) is the single best predictor of low bone mineral density. There is less evidence to support the use of other individual risk factors (for example, smoking, weight loss, family history, decreased physical activity, alcohol or caffeine use, or low calcium and vitamin D intake) as a basis for identifying high-risk women younger than 65. At any given age, African-American women on average have higher bone mineral density (BMD) than white women and are thus less likely to benefit from screening. Among different bone measurement tests performed at various anatomical sites, bone density measured at the femoral neck by dual-energy x-ray absorptiometry (DXA) is the best predictor of hip fracture and is comparable to forearm measurements for predicting fractures at other sites. Other technologies for measuring peripheral sites include quantitative ultrasonography (QUS), radiographic absorptiometry, single energy x-ray absorptiometry, peripheral dual energy x-ray absorptiometry, and peripheral quantitative computed tomography. Recent data suggest that peripheral bone density
testing in the primary care setting can also identify postmenopausal women who have a higher risk of fracture over the short term (1-year). Further research is needed to determine the accuracy of peripheral bone density testing in comparison with DXA. The optimal interval for repeated screening is unknown. Because of limitations in the precision of testing, a minimum of 2 years may be needed to reliably measure a change in BMD; however, longer intervals may be adequate. 

17The USPSTF does not recommend routine screening for prostate cancer. Patients who request screening should be given objective information about the potential benefits and harms of early detection and treatment. Despite the absence of firm evidence of effectiveness, some clinicians may opt to perform prostate screening for other reasons. Clinicians should not order the PSA test without first discussing the potential, but uncertain, benefits and possible harms.

18The USPSTF strongly recommends that clinicians screen persons at increased risk for syphilis infection (A). Persons at increased risk (based on incident rates) include men who have sex with men and engage in high-risk sexual behavior, commercial sex workers, persons who exchange sex for drugs, and those adults in adult correctional facilities. There is no evidence to support an optimal screening frequency in this population. All pregnant women should also be tested at their first prenatal visit (A). For women in high-risk groups, repeat serologic testing may be necessary in the third trimester and at delivery.

19The USPSTF recommends screening by tuberculin skin testing for all persons at increased risk of developing tuberculosis (A).

20The USPSTF recommends screening to detect amblyopia, strabismus, and defects in visual acuity in children younger than age 5 years (B). There is insufficient evidence to recommend for or against routine screening by primary care practitioners for elevated intraocular pressure or early glaucoma (C). Recommendations to refer high-risk patients for evaluation by eye specialist may be based on the substantial prevalence of unrecognized glaucoma in these populations, the progressive nature of untreated disease, and expert consensus that reducing intraocular pressure may slow the rate of visual loss in patients with early glaucoma or severe intraocular hypertension. Populations in whom the prevalence is >1% include blacks over age 40 and whites over age 65. Patients with family history of glaucoma, patients with diabetes, and patients with severe myopia are also at increased risk. The optimal frequency for glaucoma screening has not been determined and is left to clinical discretion.

21The USPSTF strongly recommends that clinicians discuss aspirin chemoprevention with adults who are at increased risk for coronary heart disease. Discussions should address both the potential benefits and harms of aspirin therapy. The USPSTF found good evidence that aspirin decreases the incidence of coronary heart disease in adults who are at increased risk for heart disease. They also found good evidence that aspirin increases the incidence of gastrointestinal bleeding and fair evidence that aspirin increases the incidence of hemorrhagic strokes. The USPSTF concluded that the balance of benefits and harms is most favorable in patients with high risk of coronary heart disease (5-year risk of greater than or equal to 3 percent) but is also influenced by patient preferences. Decisions about aspirin therapy should take into account overall risk for coronary heart disease. Risk assessment should include asking about the presence and severity of the following risk factors: age, sex, diabetes, elevated total cholesterol levels, low levels of high-density lipoprotein, cholesterol, elevated blood pressure, family history (in younger adults), and smoking. Tools that incorporate specific information on multiple risk factors provide more accurate estimation of cardiovascular risk than categorizations based simply on counting the numbers of risk factors (http://www.intmed.mcw.edu/clincalc/heartrisk.html).

22The USPSTF recommends that primary care clinicians prescribe oral fluoride supplements at currently recommended doses to preschool children older than 6 months of age whose primary water source is deficient in fluoride (B). The USPSTF concludes that the evidence is insufficient to recommend for or against routine risk assessment of preschool children by primary care clinicians for the prevention of dental disease (I).
The USPSTF recommends counseling to promote regular physical activity for all children and adults to prevent coronary heart disease, hypertension, obesity, and diabetes (A). Adults and children over age 2 should limit dietary intake of fat (A) and cholesterol (B), maintain caloric balance in their diet (B), and emphasize fruits, vegetables, and grain products containing fiber (B). Clinicians who lack the time or skill to perform a complete dietary history, to address potential barriers to changes in eating habits, and to offer specific guidance on meal planning and food selection and preparation, should either have patients seen by other trained providers in the office or clinic or should refer patients to a registered dietician or qualified nutritionist for further counseling. Parents should be encouraged to offer breastfeeding to their infants (A) and to include iron-enriched foods in their diet (B). The USPSTF recommends structured breastfeeding education and behavioral counseling programs to promote breastfeeding (B).

The USPSTF recommends against the routine use of estrogen and progestin for the prevention of chronic conditions in postmenopausal women (D). The USPSTF concludes that the evidence is insufficient to recommend for or against the use of unopposed estrogen for the prevention of chronic conditions in postmenopausal women who have had a hysterectomy (D). Clinicians should develop a shared decision-making approach to preventing chronic diseases in perimenopausal and postmenopausal women. This approach should consider individual risk factors and preferences in selecting effective interventions for reducing the risks of fracture, heart disease, and cancer. Clinicians should discuss with patients other effective strategies for preventing osteoporosis and fractures.

Injury prevention is addressed under USPSTF recommendation for periodic counseling (B).

The CDC Task Force on Community Preventive Services strongly recommends interventions to increase use of child safety seats, increase safety belt use and reduce alcohol-impaired driving.

The USPSTF recommends that to reduce the risk of neural tube defects in newborns, all women not planning but still capable of pregnancy should take a multivitamin containing 0.4mg of folic acid daily (B).

The American College of Obstetricians and Gynecologists (ACOG) recommends prenatal care beginning early in pregnancy and continuing through the postpartum period.

The USPSTF strongly recommends Rh (D) blood typing and antibody testing for all pregnant women during their first visit for pregnancy-related care (A). The USPSTF recommends repeated Rh (D) antibody testing for all unsensitized Rh (D)-negative women at 24-28 weeks’ gestation, unless the biological father is known to be Rh (D)-negative (B).

The USPSTF strongly recommends screening for hepatitis B virus (HBV) infection in women at their first trimester prenatal visit (A).

The USPSTF strongly recommends that all pregnant women be screened for asymptomatic bacteriuria using urine culture at 12-16 weeks’ gestation (A).

The USPSTF strongly recommends that clinicians screen all pregnant women for tobacco use and provide augmented pregnancy-tailored counseling to those who smoke. The USPSTF found good evidence that extended or augmented smoking cessation counseling (5-15 minutes) using messages and self-help materials tailored for pregnant smokers, compared with brief generic counseling interventions alone, substantially increases abstinence rates during pregnancy, and leads to increased birth weight. Although relapse rates are high in the post-partum period, the USPSTF concluded that reducing smoking during pregnancy is likely to have substantial health benefits for both the baby and the expectant mother. The USPSTF concluded that the benefits of smoking cessation counseling outweigh any potential harms.
The USPSTF recommends that all adolescent and adult patients be advised about risk factors for sexually transmitted disease and counseled appropriately about effective measures to reduce risk of infection (B). Periodic counseling about effective contraceptive methods is recommended for all women and men at risk for unintended pregnancy (B).

The USPSTF recommends pregnant women and parents with children living at home also should be counseled on the potentially harmful effects of smoking on fetal and child health (A). The USPSTF strongly recommends that clinicians screen all adults for tobacco use and provide tobacco cessation interventions for those who use tobacco products (A). Brief tobacco cessation counseling interventions, including screening, brief counseling (3 minutes or less), and/or pharmacotherapy, have proven to increase tobacco abstinence rates, although there is a dose-response relationship between quit rates and the intensity of counseling. Effective interventions may be delivered by a variety of primary care clinicians. The USPSTF recommends screening and behavioral health counseling interventions to reduce alcohol misuse by adults, including pregnant women, in primary care settings (B). Clinicians can choose screening strategies that are appropriate for their clinical population and setting. Assessing Alcohol Problems: A Guide for Clinicians and Researchers is available at http://www.niaaa.nih.gov/publications/Assesing%20Alcohol/index.htm

Effective interventions to reduce alcohol consumption can be delivered wholly or in part in the primary care setting. The USPSTF concluded that the evidence is insufficient to recommend for or against screening and behavioral counseling interventions to prevent or reduce alcohol misuse by adolescents in primary care setting (I).

The ACIP Schedule (2006), updated by the CDC’s Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians (AAFP), and the AAP, is recommended. The schedule indicates the recommended ages for routine administration of currently licensed childhood vaccines. Combination vaccines may be used whenever the combination is licensed for use for any components of the combination that are indicated and its other components are not contraindicated. Providers should consult the manufacturers’ package inserts for detailed recommendations. Information on vaccine supply and statements on specific vaccines can be found at www.cdc.gov/nip. The PacifiCare/Secure Horizons member’s Evidence of Coverage/Disclosure Form should be consulted for the specific coverage and limitations of benefits for vaccines recommended for travel and occupational risk.

DTaP is the preferred vaccine for all doses, including completion of a series begun with whole cell DTP according to ACIP guidelines. The fourth dose may be administered as early as 12 months, provided 6 months have elapsed since the 3rd dose and if the child is unlikely to return at age 15–18 months. The final dose in the series should be given ≥ 4 years. The ACIP recommends that, whenever feasible, the same brand of DTaP vaccine be used for all doses in the vaccine series. When unknown or not available, any of the licensed vaccines can be used.

For persons over aged 64 years, Td boosters are recommended every 10 years. Tetanus prophylaxis in routine wound management if other than clean or minor wound and >5 years since last dose.

As of June 2005, the ACIP recommends adolescents age 11-12 years receive a single dose of Tetanus, diphtheria and acellular Pertussis (Tdap). Adolescents that have already received Tetanus-Diphtheria (Td) but not Tdap should receive a single dose. A five-year interval between Td and Tdap is recommended. As of Nov 2005, the ACIP recommends that adults aged 19-64 be vaccinated with a newly licensed adult booster Tdap. A booster of Tdap vaccine is recommended for persons that have not received a Td booster in ten or more years. Tdap should also be given to adults who will have close contact with an infant less than 12 months of age, ideally at least one month before beginning close contact with infants. In situations where it is important to protect against Pertussis, intervals shorter than 10 years since the last Td vaccination may be used. A 2-year interval between Td and Tdap is suggested to reduce the risk of reactions following vaccination.
The ACIP recommends that DtaP/Hib combination products not be used for primary immunization in infants at ages 2, 4 or 6 months but can be used as boosters following any Hib vaccine. The final dose in the series should be given at ≥ 12 months.

As of Oct 2005, the ACIP recommends children receive the first dose of a two dose series of Hepatitis A vaccine between 1 and 2 years of age and that the vaccine be integrated into the routine childhood schedule. The original ACIP recommendation includes Hepatitis A vaccination for persons, ≥ 2 years, who are at increased risk for infection (travelers, men who have sex with men, illegal-drug users, occupational risk, clotting-factor disorder, chronic liver disease – consult ACIP) and any person wishing to obtain immunity. Children, ≥ 2 years, living in areas where rates of hepatitis A are at least twice (≥20 cases per 100,000 population) the national average, should be routinely vaccinated. Vaccination should be considered for children living in areas where rates of hepatitis A are at (≥10 <20 cases per 100,000 population) the national average. The schedule is determined based on vaccine formulation and age. Contact local public health authority for current recommendations.

The ACIP recommends all infants receive the 1st dose of hepatitis B vaccine soon after birth and before hospital discharge; the 1st dose may also be given by age 2 months if the infant is born to a hepatitis B surface antigen (HbsAg)-negative mother. Only monovalent HepB can be used for the birth dose. Monovalent or combination vaccine containing HepB may be used to complete the series. Four doses of vaccine may be administered when a birth dose is given. The 2nd dose should be at least 4 weeks after the 1st dose, except for combination vaccines that cannot be administered before age 6 weeks. The 3rd dose should be administered at least 16 weeks after the 1st dose and at least 8 weeks after the 2nd dose, but not before 6 months of age. The last dose in the vaccine series (3rd or 4th) should not be administered before age 24 weeks. Infants born to HBS-Ag-positive mothers should receive hepatitis B vaccine and 0.5 ml hepatitis B immune globulin (HBIG) within 12 hours of birth at separate sites. The 2nd dose is recommended at 1 to 2 months of age. The last dose in the immunization series should not be administered before age 24 weeks. Infants born to mothers whose HbsAG status is unknown should receive hepatitis B vaccine within 12 hours of birth. Maternal blood should be drawn at the time of delivery to determine the mother’s Hasbro status; if the Hasbro test is positive, the infant should receive HBIG as soon as possible (no later than 1 week of age). The 2nd dose is recommended at 1 to 2 months of age. The last dose in the immunization series should not be administered before age 24 weeks.

The ACIP recommends all children and adolescents who have not been immunized against Hepatitis B should begin the Hepatitis B vaccination series during any visit (refer to Catch-up Schedule). Immunization status should be routinely evaluated during preadolescents (age 11-12 years).

The ACIP recommends administering 3 doses of Hepatitis B for persons with medical (hemodialysis patients and patients who receive clotting-factor concentrates), behavioral (injecting drug users, persons with more than 1 sex partner in 6 months, persons with a recently acquired STD, clients in STD clinics and men who have sex with men), occupational (health-care and public-safety workers who have exposure to blood), or other indications (household contacts and sex partners of persons with chronic Hepatitis B infection, clients and staff of institutions for the developmentally disabled, international travelers who will be in countries with high or intermediate prevalence of chronic Hepatitis B infection for more than 6 months, inmates of correctional facilities). The 2nd dose should be administered 1-2 months after the 1st dose and the 3rd dose should be administered 4-6 months after the 1st dose.

The ACIP recommends inactivated influenza vaccination for the following persons who are at increased risk for complications from influenza: persons 65 yrs and older; residents of nursing homes and other chronic-care facilities that house persons of any age who have chronic medical conditions; adults and children who have chronic disorders of the pulmonary or cardiovascular systems, including asthma (hypertension is not considered a high risk condition); adults and children who have required regular medical follow-up or hospitalization during the preceding year because of chronic metabolic diseases (including diabetes mellitus), renal
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dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus; adults and children who have any condition (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders, or other neuromuscular disorders) that can compromise respiratory function or the handling of secretions or that can increase the risk of aspiration; children and adolescents (age 6 months to 18 years) who are receiving long-term aspirin therapy and, therefore, might be at risk for experiencing Reye syndrome after influenza infection; women who will be pregnant during the influenza season; and children aged 6-23 months. Vaccination is also recommended for persons aged 50-64 years, persons who can transmit influenza to those at high risk and health care workers. Depending on vaccine supply, in addition to the groups for which vaccination is recommended, persons who wish to reduce the likelihood of becoming ill with influenza or transmitting influenza to others should they become infected may be vaccinated.

The ACIP recommends the 2nd MMR vaccination at 4–6 years of age but vaccine may be administered during any visit provided at least 4 weeks have elapsed since receipt of the 1st dose and that both doses are administered beginning at or after 12 months of age. Those who have not previously received the 2nd dose should complete the schedule by the 11–12 years old visit.

The ACIP recommends, for the measles component, 2 doses of MMR for adults with one or more of the following conditions and without vaccination history: adults born after 1956, persons vaccinated with killed measles virus vaccine 1963-1969, students in post-secondary education institutions, health care workers, susceptible international travelers to measles endemic countries. For the mumps component, 1 dose of MMR should be adequate protection. See Rubella recommendations.

The ACIP recommends that children, age 11-12 years old, teens entering high school, as well as college freshman living in dormitories receive Meningococcal Conjugate Vaccine. To foster the most rapid reduction of meningococcal disease, the ACIP also recommended that for the next 2-3 years (as of 2/10/05), teens entering high school and college freshman who live in dormitories also be vaccinated. Meningococcal conjugate vaccine may also be provided to college students who do not live in dormitories and adolescents who want to reduce their risk of meningococcal disease.

The ACIP recommends an all-inactivated poliovirus (IPV) vaccination at 2, 4, 6–18 months and at 4–6 years. For children who have already received oral polio vaccine (OPV) but have not completed the series, the additional doses should be IPV. If accelerated protection is needed, the minimum interval between doses is 4 weeks, although the preferred interval between the 2nd and 3rd doses is 2 months. All children who received three doses of IPV before age 4 years should receive a 4th dose before or at school entry. The 4th dose is not needed if the 3rd dose is administered on or after the 4th birthday. If both OPV and IPV were given as part of the series, a total of 4 doses should be given, regardless of the child’s current age.

The ACIP recommends pneumococcal vaccine for all immunocompetent persons whom are 65 years and older with 2nd dose if vaccine was administered under age 65 years and more than 5 years previously (A). Additionally vaccination is recommended, for persons age 2–64 years with chronic cardiovascular disease, chronic pulmonary disease, diabetes, or functional/anatomic asplenia (A). For persons > 10 years with asplenia, single revaccination ≥ 5 years after previous dose. For persons ≤ 10 years with asplenia, consider revaccination 3 years after previous dose (A).

The USPSTF recommends screening for rubella susceptibility by history of vaccination or by serology for all women of childbearing age (B). Alternatively, all susceptible nonpregnant women of childbearing age should be offered vaccination against rubella without screening (B).
51 The ACIP recommends vaccination at any visit on or after the first birthday for susceptible children, i.e. those who lack a reliable history of chickenpox (as judged by a health care provider) and have who have not been immunized. Susceptible persons age ≥13 years at high risk for exposure or transmission should receive 2 doses, given at least 4 weeks apart.

52 The ACIP recommends all children age 2 to 23 months should be vaccinated with PCV7. Infant vaccination provides the earliest possible protection, age 2–6 months and age 7–23 months (B). Children age 24–59 months should receive PCV7 vaccination if they are at high risk for pneumococcal infection caused by an underlying medical condition. This recommendation applies to the following groups: children with sickle cell disease and other sickle cell hemoglobinopathies, including hemoglobin SS, hemoglobin S-C, or hemoglobin s-β-thalassemia, or children who are functionally or anatomically asplenic (B); children with HIV infection (B); children who have chronic disease, including chronic cardiac and pulmonary disease (excluding asthma), diabetes mellitus, or CSF leak; and children with immunocompromising conditions including a) malignancies, b) chronic renal failure or nephrotic syndrome; c) those children receiving immunosuppressive chemotherapy, including long-term systemic corticosteroids; and d) those children who have received a solid organ transplant (C). The final dose in the series should be given at age ≥12 months. The ACIP further recommends that PCV7 vaccination (1 dose) be considered for all other unvaccinated children age 24–59 months with priority given to children age 24–35 months, children of Alaska Native, American Indian or African-American descent, and children who attend group day care centers (B). Modified recommendations apply during periods of shortage. See MMWR 12/21/02.