New Approved Guidelines:

1. Orthognathic Surgery
2. Vision Impairment Rehabilitation

Revised Guidelines:

1. Cardiac Rehabilitation
2. Temporomandibular Joint Disorders
3. Transplants - Progenitor Cell
4. Transplants - Solid Organ
5. Wound Treatment

Retired Guidelines:

None
DISCLAIMER

Secure Horizons's medical management guidelines represent the recommendation of the Secure Horizons 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 Horizons'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.

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A. BACKGROUND

1. 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):
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- Patient assessment
- Nutritional counseling
- Lipid management
- 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 I, 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 2001, the American Heart Association (AHA) estimated a prevalence of coronary artery disease (CAD) of 13.2 million cases in the United States, including 7.8 million cases of myocardial infarction (MI) and 6.8 million cases of angina pectoris. According to the AHA, of 64.4 million Americans with one or more types of cardiovascular disease (CVD), 25.3 million are estimated to be age 65 and older (AHA 2003).
2. **Benefit**
   Secure Horizons covers cardiac rehabilitation programs when determined to be medically necessary and specific criteria are met.

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 Insurance (COI). If there is a discrepancy between this guideline and the member’s EOC/SOB/COI, the member’s EOC/SOB/COI provision will govern.

1. Outpatient cardiac rehabilitation services are recommended (CMS CIM):
   a. For those members who have been referred by their attending physician and have one or more of the following:
      1) A documented diagnosis of an acute myocardial infarction (MI) within the past 12 months
      2) Coronary artery bypass surgery (CABG)
      3) Stable angina pectoris
   b. When cardiac rehabilitation services meet all of the following criteria:
      1) 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:
         a) A physician must be on the premises and available to perform medical duties
         b) Services of non-physician personnel must be furnished under the direct supervision of a physician
      2) Services must be provided either by the outpatient department of a hospital or in a physician-directed clinic
      3) 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)

2. Cardiac rehabilitation services include, but are not limited to (CMS CIM):
   a. One baseline and one follow up stress test, using treadmill or bicycle ergometer with physician monitoring and written reports to:
      1) Evaluate chest pain, especially atypical chest pains
      2) Develop an exercise program for members with known cardiac disease
3) Evaluate the pre- and/or post-operative tolerance of the coronary artery bypass surgery
   a) Continuous ECG monitoring during exercise
   b) Limited examination for physician follow-up to adjust medication or other treatment changes
   c) 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
   d) 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)
   e) Member educational services regarding diet, nutrition and sexual activities

3. Services in connection with a cardiac rehabilitation program are recommended for up to 36 sessions, usually 3 sessions per week in a single 12-week period (CMS CIM)
   a. Continued participation in cardiac exercise programs beyond 12 weeks will be covered only on a case-by-case basis in accordance with discharge guidelines (not to exceed a maximum of 24 weeks).

4. Discharge guidelines from a cardiac rehabilitation program are as follows (CMS CIM):
   a. Member has achieved a stable level of exercise tolerance without ischemia or dysrhythmia
   b. Symptoms of angina or dyspnea are stable at the member’s maximum exercise level
   c. Member’s resting blood pressure and heart rate are within normal limits
   d. Member’s stress test is negative during exercise

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: Chronic Nonmalignant Pain Management

Authorized By: Medical Management Guideline Committee

Approval Date: 11/26/02     Revision Date: 03/16/04

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A. BACKGROUND

1. Description
Chronic pain has been defined as a pain state that is persistent and in which the cause of pain cannot be removed. Chronic pain may be associated with an incurable or intractable medical condition, disease, or injury. Pain that persists beyond the time when normal healing should have taken place may indicate that neuroplastic changes have occurred (College of Physicians and Surgeons of Nova Scotia, 1999). The prevalence of chronic pain among adults in the United States has been estimated to range from 2% to 40% of the general population (Glajchen 2001). Chronic pain represents a common problem among patients 65 years of age and older (American Geriatrics Society 2002).
The optimal medical management of pain is based upon current knowledge and research and includes the use of both pharmaceutical and nonpharmaceutical modalities. Pain should be assessed and treated promptly. The goals of pain management should be to treat the patient’s pain for its duration while effectively addressing related aspects of the patient’s functioning, including physical, psychosocial, social, and work-related factors (New Hampshire Medical Society 1998). Nonpharmaceutical modalities for chronic pain management may be utilized alone or in conjunction with pharmaceutical treatment (HAYES 2002).

2. **Benefit**

Secure Horizons covers treatments in the management of chronic nonmalignant pain when determined to be medically necessary and specific criteria are met. See the Secure Horizons Benefit Interpretation Policy (BIP) *Medications and Unlabeled Drug Use*.

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 Insurance (COI). If there is a discrepancy between this guideline and the member’s EOC/SOB/COI, the member’s EOC/SOB/COI provision will govern.

1. **Pharmaceutical management**

Unless pain is severe, it is recommended to progress from non-opioid analgesics, such as acetaminophen, to anti-inflammatory drugs, neurotransmitter-modulating and membrane-stabilizing drugs, and opioids, to balance medical risks and progressively more severe pain (American Geriatrics Society 2002).

a. **Opioid analgesics**

While opioids are considered an accepted mainstay for the management of moderate to severe cancer pain, controversy remains regarding their use for chronic nonmalignant pain (International Association for the Study of Pain 1995). Opioid analgesia is characterized by a dose-effect response with no predetermined ceiling dose. Initially, the dose titration should be designed to reduce pain from severe to easily tolerated. If minimal or no side effects are
present, dose increase will be pursued to achieve higher levels of relief and improvement in physical and social function. The opioid dose should be adjusted until satisfactory pain relief or unmanageable side effects occur. Close patient supervision is very important during the titration (Pappagallo and Heinberg, 1997). An assessment of the patient’s functional status should include the ability to perform household chores, work tasks, leisure interests, and sleep (Glajchen 2001).

A trial of long-term opioid therapy is considered legitimate medical practice when a reasonable trial of other standard modalities fails to improve comfort or function for the patient (Canadian Pain Society 1998). The quantity and frequency of medication doses should be adjusted according to the intensity and pattern of the pain (New Hampshire Medical Society 1998). The benefits of long-acting opioids for chronic pain include continuous pain relief, a reduction in the peak-and-through effect found with short-acting opioids, less sleep disturbance, fewer problems with patient compliance, and fewer reported side effects (Glajchen 2001). Long-acting agents given on a 24-hour basis are recommended to avoid daily “mini-withdrawals,” achieve a steady level of satisfactory analgesia throughout the day, and enhance the patient’s treatment compliance (Pappagallo and Heinberg, 1997).

Long-acting opioids are recommended for patients meeting the following criteria (Marcus 2000):
- Definitive pain diagnosis
- Constant pain or pain with significant disability
- Regular overuse of analgesics

Short-acting opioids are recommended for patients with intermittent pain flares (Marcus 2000).

Note: Prior to prescription of opioids, the patient’s records must document a complete pain history and physical examination, including the etiology of the patient’s pain; an assessment for coexistent behavioral diagnoses, including depression, sleep disorder, personality disorder, poorly developed coping skills, and social functioning level; and any relevant documentation concerning prior investigations and consultations to consider whether a new diagnosis may be present (College of Physicians and Surgeons of Alberta, 1993).
Note: Thorough and complete documentation is needed in the patient’s medical record of not only the patient’s evaluation and treatment plan but also any written protocol or contract signed by the physician and patient and any other appropriate healthcare providers. Opioid analgesic prescriptions that do not meet these criteria may not be approvable (HAYES 2002).

The following table presents opioids prescribed for chronic nonmalignant pain (HAYES 2002).

<table>
<thead>
<tr>
<th>Drug name</th>
<th>Trade name</th>
<th>Indication</th>
<th>Dosing information</th>
<th>Daily dose</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Narcotic (opioid agonists)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Codeine</td>
<td>Codeine</td>
<td>Mild to moderate pain</td>
<td>15-60mg q 4-6 hrs</td>
<td>360mg</td>
</tr>
<tr>
<td>Morphine</td>
<td>MS Contin</td>
<td>Moderate to severe pain</td>
<td>Q 12 hrs Initial dose determined by prior opiate use</td>
<td>Not determined</td>
</tr>
<tr>
<td></td>
<td>Kadian</td>
<td>Moderate to severe pain</td>
<td>Initial dose 20mg QD or BID</td>
<td>Not determined</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>Vicodin</td>
<td>Moderate to moderately severe pain</td>
<td>5-10mg q 4-6 hrs prn</td>
<td>8 tablets</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>Dilaudid</td>
<td>Moderate to severe pain</td>
<td>2-4mg q 4-6 hrs</td>
<td>Not determined</td>
</tr>
<tr>
<td>Levorphanol</td>
<td>Levo-Dromoran</td>
<td>Moderate to severe pain</td>
<td>2-3mg q 6-8 hrs</td>
<td>24mg</td>
</tr>
<tr>
<td>Methadone</td>
<td>Dolophine</td>
<td>Severe pain</td>
<td>5-20mg q 6-8 hrs</td>
<td>60mg</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>OxyContin</td>
<td>Moderate to severe pain; not intended as a prn analgesic</td>
<td>Q 12 hrs</td>
<td>Not determined</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>Actiq</td>
<td>Indicated only for the management of breakthrough cancer pain in patients with malignancies who are already receiving and are tolerant to opioid therapy for their underlying persistent cancer pain</td>
<td>Duragesic transdermal patch Chronic pain Initial dose in nonopioid user 25µg/hr</td>
<td>Not determined</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Narcotic-like</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tramadol</td>
<td>Ultram</td>
<td>Moderate to moderately severe pain</td>
<td>Initial dose 25mg QD</td>
<td>400mg</td>
</tr>
</tbody>
</table>
Note: Meperidine (Demerol), propoxyphene (Darvocet), and pentazocine (Talwin) are not recommended for long-term use due to potentially toxic effects on the central nervous system (CNS) (Pappagallo and Heinberg, 1997).

Note: Tramadol should not be used concurrently with pure opioid agonists because of the risk of inducing withdrawal symptoms (Pappagallo and Heinberg, 1997).

Prescription of opioid analgesics in excess of established maximum daily dosage may be certified as appropriate for patients meeting all of the following criteria (HAYES 2002):

- The prescribing physician maintains thorough and complete documentation in the medical record of the patient’s evaluation, including (HAYES 2002):
  - Appropriate medical history, physical examination, results of relevant diagnostic evaluations, relevant coexisting diseases and conditions (including current or past substance use disorder) (New Hampshire Medical Society 1998)
  - Description of the nature and intensity of the pain (New Hampshire Medical Society 1998)
  - Effect of the pain on physical and psychosocial function (New Hampshire Medical Society 1998)
- A comprehensive treatment plan is documented for the patient, including (HAYES 2002):
  - Objectives that will be used to determine treatment success, such as pain relief and/or improved physical and or psychosocial function (New Hampshire Medical Society 1998)
  - A discussion of the risks and benefits of the use of controlled substances with the patient, significant other(s), and/or guardian (New Hampshire Medical Society 1998)
  - A comprehensive written protocol-contract, signed by the prescribing physician, the patient, and other healthcare providers involved in the patient’s treatment, may be implemented to facilitate documentation of the opioid treatment plan and the informed consent (Kirkpatrick et al, 1998)

- Medications are prescribed by one physician and dispensed by one pharmacy where possible, and communication between these parties is authorized (New Hampshire Medical Society 1998)
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- An ongoing review of the course of opioid treatment is documented in the patient’s medical record, including (HAYES 2002):
  - Any new information about the etiology and impact of the pain and use of appropriate alternative modalities for pain management (New Hampshire Medical Society 1998)
  - Documentation of any changes to opioid therapy and the rationale for each change (Canadian Pain Society 1998)

- The physician refers the patient for additional evaluation and treatment as necessary and reasonable, such as a pain management specialist or a specialist in addictive medicine, if adequate control of pain and other treatment objectives is not achieved (New Hampshire Medical Society 1998)

- The prescribing physician holds the appropriate state licenses, has a valid controlled substances registration, and complies with federal and state regulation for issuing controlled substances prescriptions (New Hampshire Medical Society 1998)

Note: Opioid analgesic prescriptions that do not meet these criteria may not be approvable (HAYES 2002).

b. Alternative medications
   In addition to opioid analgesics, the following medication may be utilized, either alone or in conjunction with opioid treatment. These alternative medications include, but are not limited to, the following (HAYES 2002):
   - Nonsteroidal anti-inflammatory drugs (NSAIDS) (Khouzam 2000)
   - Antidepressant medications for patients with chronic pain, especially if they have comorbid psychiatric conditions such as depression, sleep disorders, anxiety, somatization disorder, or somatoform pain disorders. Antidepressants also have proved effective in treating painful conditions such as cancer, arthritis, headache, diabetic neuropathy, fibromyalgia, vasculitic neuropathy, and low back pain (Khouzam 2000). Tricyclic antidepressants have been proven effective for the treatment of neuropathic pain (Dworkin et al, 2003)
   - Anticonvulsants, including phenytoin, carbamazepine, valproate, and gabapentin, may be effective in decreasing neuropathic pain (Khouzam 2000; Dworkin et al, 2003)
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- Membrane-stabilizing agents, including tocainide and mexiletine, may be effective in decreasing chronic neuropathic pain (Khouzam 2000)
- 5% Lidocaine patch, a topical preparation, for pain in patients with postherpetic neuralgia (Dworkin et al, 2003)
- Capsaicin, a topical nonprescription medication, is most effective when used as an adjunct to systemic medications (Khouzam 2000)
- Muscle relaxants, including metocarbamol, baclofen, and cyclobenzaprine, may be used to decrease generalized muscle pain in fibromyalgia as well as chronic pain due to increased muscle spasm (Khouzam 2000)
- Clonidine may be useful in patients who have a tolerance to opiates (Khouzam 2000)

Note: Tricyclic antidepressants must be used with extreme caution in elderly patients because of the risk of toxic adverse effects to the heart and anticholinergic adverse effects. In addition, gabapentin, opioid analgesics, tramadol, and tricyclic antidepressants must all be used with caution in older patients because of the risk of falls and cognitive impairment (Dworkin et al, 2003).

2. Nonpharmaceutical management
Nonpharmaceutical treatment modalities include noninvasive treatment modalities and surgical interventions. Non pharmaceutical treatment modalities may be utilized either alone or in conjunction with opioid treatment (HAYES 2002).

a. Noninvasive treatment modalities
Noninvasive treatment modalities include, but are not limited to, the following (HAYES 2002):

- Psychological therapy, including relaxation, biofeedback, and coping strategies (Graziotti and Goucke, 1997; Milliman USA 2002)
- Transcutaneous electrical nerve stimulation (TENS) (Khouzam 2000; Milliman USA 2002)
- Physical therapy – focusing on reconditioning, stretching exercises, and pain reducing modalities (Marcus 2000; Milliman USA 2002)
- Occupational therapy – focusing on proper body mechanics, to help the patient return to more normal levels of activity in household chores, work, and leisure (Marcus 2000)
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Note: Noninvasive treatment regimens may involve a multidisciplinary approach, including physical therapy for reconditioning, stretching exercises, and occupational therapy, focusing on proper body mechanics (Marcus 2000).

b. Invasive treatment modalities
Invasive treatment modalities include, but are not limited to, the following (HAYES 2002; Khouzam 2000):

- Local anesthetic nerve blocks
- Sympathetic blockade
- Electrical stimulation of the spinal cord
- Delivery of narcotics into the epidural space or intrathecally into the spinal cord fluid

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


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
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overwhelmed by capillary filtrate such as in ascities, anasarca, congestive heart failure, or venous insufficiency (TrailBlazer 2001).

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) Physical, Occupational and Speech Therapy.

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 Insurance (COI). If there is a discrepancy between this guideline and the member’s EOC/SOB/COI, the member’s EOC/SOB/COI 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

Complex Decongestive Physiotherapy for Lymphedema – Secure Horizons
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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
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
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.
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When utilization management guidelines cannot be applied appropriately, individual case discussions shall ensue.
D. REFERENCES


Medical Management Guideline

TITLE: Diabetes and Renal Disease: Medical Nutrition Therapy

Authorized By: Medical Management Guideline Committee

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

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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 Insurance (COI). If there is a discrepancy between this
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guideline and the member’s EOC/SOB/COI, the member’s EOC/SOB/COI 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 CIM):

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 CIM).

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: 05/25/04

Diabetes and Renal Disease: Medical Nutrition Therapy – Secure Horizons
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 Insurance (COI). If there is a discrepancy between this guideline and the member’s EOC/SOB/COI, the member’s EOC/SOB/COI 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)

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 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

Available at http://www.cms.hhs.gov/manuals/11_hha/HH00.asp

Available at http://www.cms.hhs.gov/manuals/pm_trans/2001/memos/comm_date_dsc.asp

Available at http://www.access.gpo.gov/cgi-bin/cfissemble.cgi?title=200342
MEDICAL MANAGEMENT GUIDELINE

TITLE: Foot Care and Podiatry Services

Authorized By: Medical Management Guideline Committee

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

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 Decision is in place.

This medical management guideline is intended for use by PacifiCare employees, PacifiCare contracted providers, and practitioners only. The information contained in this medical management guideline is confidential and proprietary to PacifiCare.

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 28, 2004:

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)  
Buerger's Disease (Thromboangiitis obliterans)  
*Chronic thromboophlebitis  
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  
angiokeratoma 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
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Class B Findings:
- Absent posterior tibial pulse
- Absent dorsalis pedis pulse
- Advanced trophic changes, such as: (three required)
  - Hair growth decreased or absent
  - 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.
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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)

Texas: Trailblazer – Routine Foot Care/Mycotic Nail Debridement (Trailblazer 2003)
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).
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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 Insurance (COI). If there is a discrepancy between this guideline and the member’s EOC/SOB/COI, the member’s EOC/SOB/COI provision will govern.

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 CIM).

   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 CIM).

   The examination should include all of the following (CMS CIM):
   • 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 CIM):

- 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


A. BACKGROUND

1. Description
   a. 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.

      Genetic testing is undertaken for several purposes, including the following:
      - Carrier screening
Prenatal diagnostic testing
Newborn testing
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:

- 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 mucous 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:
• 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)

b. 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.

2. 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.

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 Insurance (COI). If there is a discrepancy between this guideline and the member’s EOC/SOB/COI, the member’s EOC/SOB/COI provision will govern.
1. General Recommendations for Genetic Testing

Genetic testing is recommended in the following instances:

- For members at direct risk of genetic disease
- For parent(s) and/or fetus after 3 consecutive spontaneous abortions to determine etiology
- 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
- 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
- To establish prenatal or clinical diagnoses
- To direct clinical management

2. Recommendations for Specific Genetic Tests

a. 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). 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).

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. 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.

Diagnostic testing for fragile X syndrome is recommended for:
- Individuals of either sex with mental retardation, developmental delay, or autism, particularly if they have any of the following:
  - Physical or behavioral characteristics of fragile X syndrome
  - Family history of fragile X syndrome
  - Male or female relatives with undiagnosed mental retardation
- Individuals seeking reproductive counseling who have either of the following:
  - Family history of fragile X syndrome
  - Family history of undiagnosed mental retardation
- Fetuses of known carrier mothers
- 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.

Factor V Leiden mutation testing is recommended for:
- Individuals under age 50 with any venous thrombosis
- Individuals with a venous thrombosis in unusual sites, such as the hepatic, mesenteric, or cerebral veins
- Individuals with recurrent venous thrombosis
- Individuals with venous thrombosis and a strong family history of thrombotic disease
- Women with venous thrombosis during pregnancy or while taking oral contraceptives
- 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).
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:

- Individuals at risk for Tay-Sachs disease due to ethnic background or family history
- Partners of Tay-Sachs disease carriers
- Prenatal testing when both parents are known to be Tay-Sachs disease carriers
- Individuals who have an ambiguous enzyme test in both serum and leukocytes
- 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
- 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.

b. 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 211,300 new cases of invasive breast cancer are expected to occur during 2003, with an estimate of 40,200 deaths (39,800 women, 400 men). Ovarian cancer is less common, with an estimated 25,400 new cases expected in 2003, accounting for an estimated 14,300 deaths. 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.
Genetic testing for breast and ovarian cancer susceptibility genes BRCA1 and BRCA2 is recommended when both of the following criteria are met:

a. An increased risk for a mutation is evident based on any of the following:
   1) There are 3 or more affected first or second degree relatives on the same side of the family, regardless of age at diagnosis, or
   2) There are fewer than 3 affected relatives, but
      a) The patient was diagnosed at 45 years of age or less, or
      b) A family member has been identified with a detectable mutation, or
      c) 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
      d) There are multiple primary or bilateral breast cancers in the patient or one family member, or
      e) There is breast cancer in a male patient, or in a male relative, or
      f) 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

b. 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:
   1) Clarification of the patient’s increased risk status
   2) Explanation of how genetics affect cancer susceptibility
   3) Potential benefits, risks, and limitations of testing
   4) Possible outcomes of testing (positive, negative, or uncertain test results)
   5) Limited data on efficacy methods for early detection and prevention
   6) Possible psychological and social impact of testing
   7) 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 105,500 new cases of colon cancer and 42,000 new cases of rectal cancer expected for the year 2003 in the United States. Colorectal cancer is expected to result in 57,100 deaths in 2003, accounting for about 10% of cancer deaths. 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).

Genetic Testing for Familial Adenomatous Polyposis (FAP)

Genetic testing for FAP is based on testing for mutation of the adenomatous polyposis coli (APC) gene.

Genetic testing for FAP is recommended to diagnose and establish a detectable mutation in the pedigree for:
- Individuals affected with FAP (≥100 colorectal adenomas)
- Individuals with first degree relatives diagnosed with FAP if a detectable mutation in the pedigree has been identified
- Individuals with ≥20 cumulative colorectal adenomas (suspected attenuated FAP)
- 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.

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

c. 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).

Prenatal genetic testing is recommended in any the following instances:
- Mother ≥35 years of age or older at estimated date of delivery
- Chromosome rearrangement in either parent
- 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)
- Previous child with a chromosomal abnormality
- Previous pregnancy with a fetal diagnosis of sex chromosome aneuploidy, autosomal trisomy, or other chromosomal abnormality
- Positive maternal serum-marker screening

3. Genetic counseling

Genetic counseling is recommended for individuals or families fulfilling any of the following criteria:

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

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

Adolescent/adult
- Mental retardation
- Personal or family history of possibly hereditary cancers
- Personal or family history of a known or suspected genetic condition or chromosome abnormality
- Severe visual or hearing impairment
- Development of a degenerative disease

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


Medical Management Guideline

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

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 Decision is in place.

This medical management guideline is intended for use by PacifiCare employees, PacifiCare contracted providers, and practitioners only. The information contained in this medical management guideline is confidential and proprietary to PacifiCare.

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 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:

a. May require pre-certification to be covered *(Note: The Market pre-certification process varies)*

b. 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

c. 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

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 Insurance (COI). If there is a discrepancy between this guideline and the member’s EOC/SOB/COI, the member’s EOC/SOB/COI 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

17. Ultraviolet Light Therapy System (Cabinet)

18. Ventilators (Respirators)

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

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
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- Maintenance of a clean, moist bed of granulation tissue with 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 all of the following criteria are met (CMS b):

a. General
   1) Diagnosis of bilateral severe-to-profound sensorineural hearing impairment that cannot be intensified with the appropriate hearing (or vibrotactile) aids
   2) Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation
   3) 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
   4) No contraindications to surgery
5) The device must be used in accordance with the FDA approved labeling

b. Adults
   1) Cochlear implants for prelinguistically, perilinguistically, and postlinguistically deafened adults (over age 18)
   2) Postlinguistically deafened adults must demonstrate test scores of 30% or less on sentence recognition from tape-recorded tests in the patient's best-aided listening condition (test should be conducted with the patient’s hearing aid in place [FDA 2001; FDA 2000; FDA 1997a and 1997b])

c. Children
   1) Cochlear implants for prelinguistically and postlinguistically deafened children aged 2 through 17
   2) Bilateral profound sensorineural deafness must be demonstrated by the inability to improve on age appropriate, closed-set word identification tasks with amplification

Note: Prelinguistically/Perilinguistically/Postlinguistically refers, respectively, to before, during, and after language and/or speaking skills develop in children, adolescents, and young adults.

3. High Frequency Chest Wall Oscillation Devices (ex. ThAIRapy Vest)
   Recommended for patients who meet either criterion a. or b. and criterion c. (DMERC 2003a):
   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 or spiral 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 2003b):
   - 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 2003b):
   - 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 2003b):
- 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 2002):
   a. Treatment of diabetes mellitus – continuous subcutaneous insulin infusion pump (CSII) and related drugs and supplies are medically necessary in the home setting only for diabetics with a fasting serum C-peptide level that is less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method, if either of the following criteria 1) or 2) are met:
      1) 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:
         - Glycosylated hemoglobin level (HbA1c) >7.0%
         - History of recurring hypoglycemia
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- Wide fluctuations in blood glucose before mealtime
- Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl
- History of severe glycemic excursions

2) 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

3) 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 acute iron poisoning and 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. Other uses – external infusion pumps are recommended if the patient’s physician verifies the appropriateness of the therapy and of the prescribed pump for the individual patient

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:
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- 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 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 2003c):
  a. Criterion 1 and 2 and 3, or
  b. Criterion 4, or
  c. 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
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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 trunk or pelvis (surgery within the past 60 days)
6) The patient has been on a Group 2 or 3 support surface immediately prior to a recent discharge from a hospital or nursing facility (discharge within the past 30 days)

If the patient is using a Pressure Reducing Mattress, there should be a care plan established by the physician or home care nurse, which includes the elements listed above. The support surface provided for the patient should be one in which the patient does not "bottom out.” Bottoming out is the finding that an outstretched hand can readily palpate the bony prominence (coccyx or lateral trochanter) when it is placed palm up beneath the undersurface of the mattress or overlay and in an area under the bony prominence. The bottoming out criterion should be tested with the patient in the supine position with their head flat, in the supine position with their head slightly elevated (no more than 30 degrees), and in the sidelying position.

When a Pressure Reducing Mattress is provided following a myocutaneous flap or skin graft, recommendation generally is limited to 60 days from the date of surgery.

Continued use of a Pressure Reducing Mattress is recommended until the ulcer is healed or, if healing does not continue, there is documentation in the medical record to show the following:

- Other aspects of the care plan are being modified to promote healing, or
- The use of the Pressure Reducing Mattress is medically necessary for wound management
7. **Negative Pressure Wound Therapy (NPWT) Pump**
   Please refer to the Medical Management Guideline (MMG) *Wound Treatment – Secure Horizons*.

8. **Neuromuscular Electrical Stimulation (NMES)**
   NMES is recommended for the following (DMERC 2003e):
   - 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
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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
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- 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 g; 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 2001a; CMS g; 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) Failed spinal fusion, if at least 9 months have passed since the last surgery
      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
      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 both of the following criteria apply (DMERC 2001a; CMS g; Benefit Interpretation Policy, Osteogenic/Bone Stimulation – 12/18/03):
   1) Patient's nonunion bone fractures has failed at least one 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

Note: Long bones include the following: Clavicle, humerus, 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 2003f):
   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 prosthettist 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 2003f).

Note: Lower limb prostheses are not recommended for patients with functional level 0 (DMERC 2003f).

**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 2003f).

- 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 is covered 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 2003f).

a. A fluid, pneumatic, or electronic prosthetic knee is recommended for patients whose functional level is 3 or above (DMERC 2003f)

b. 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)
   - 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 2003f)

Ankles:
An axial rotation unit is recommended for patients whose functional level is 2 or above (DMERC 2003f).

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 2003f).
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 2003g).

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 2004b):

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) Restricted 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 H2O 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
Medical Management Guideline

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). 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 2004b):
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 2003k):
   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 c).

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 d).

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

a. Standard Wheelchairs (DMERC 2003h; Benefit Interpretation Policy, Wheelchairs and Accessories – 03/21/02)
   - Recommended if patient’s condition is such that without the use of a wheelchair the patient would otherwise be bed or chair confined
   Note: An individual may qualify for a wheelchair and still be considered bed-bound

b. Lightweight wheelchair (DMERC 2003h; Benefit Interpretation Policy, Wheelchairs and Accessories – 03/21/02)
   - Recommended only when the patient cannot self-propel in a standard wheelchair, but can self-propel in the lightweight wheelchair

c. High Strength, Lightweight Wheelchair (DMERC 2003h; Benefit Interpretation Policy, Wheelchairs and Accessories – 03/21/02)
   - Recommended only when the expected duration of need is more than 3
months and either of the following criteria are met:

- The patient engages in frequent activities (not recreational or leisure) that cannot be performed in a standard or lightweight wheelchair
- The patient requires a seat width, depth, or height that cannot be accommodated in a standard, lightweight, or hemi-wheelchair, and spends at least 2 hours per day in the wheelchair

d. Specially Sized Wheelchairs (CMS e; Benefit Interpretation Policy, Wheelchairs and Accessories – 03/21/02)
   - Recommended when needed to accommodate one of the following:
     - Place of use (e.g., home has narrow doorways and therefore the patient needs a narrow wheelchair)
     - Physical size of the patient

e. Electric wheelchair (DMERC 2003i; Benefit Interpretation Policy, Wheelchairs and Accessories – 03/21/02)
   - Recommended when both of the following criteria are met:
     - The patient’s condition is such that a wheelchair is medically necessary
     - The patient is unable to operate the wheelchair manually

f. Power operated vehicles (POV) (DMERC 2003j; Benefit Interpretation Policy, Wheelchairs and Accessories – 03/21/02)
   - Recommended when all of the following criteria are met:
     1) The patient's condition is such that a wheelchair is required for the patient to get around in the home and not for community ambulation (POV is limited to home use only)
     2) The patient is unable to operate a manual wheelchair
     3) The patient is capable of safely operating the controls for the POV
     4) The patient can transfer safely in and out of the POV, and has adequate trunk stability to be able to ride safely in the POV
     5) A physician specializing in physical medicine, orthopedic surgery, neurology, or rheumatology orders the POV. When such a specialist is not reasonably accessible (e.g., more than one day round trip from the patient’s home or patient’s condition precludes travel), a prescription from the beneficiary’s physician may be accepted
20. **Whirlpool (Non-Portable)**
   Medical necessity is determined by the following (CMS f):
   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

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


Medical Management Guideline


Medical Management Guideline


Appendix I

Staging of Pressure Ulcers (DMERC 2003c)

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:
CO, OK & TX:
http://www.palmettogba.com/palmetto/LMRPs_DMERC.nsf/$$ViewTemplate+for+Final?ReadForm

Approved by: Medical Management Guideline Committee  Date Approved: 05/25/04

High-End Durable Medical Equipment (DME) – Secure Horizons
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 urethrovessical 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 Insurance (COI). If there is a discrepancy between this guideline and the member’s EOC/SOB/COI, the member’s EOC/SOB/COI provision will govern.

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. Collagen implants are recommended for patients meeting the following criteria (CMS a):
   a) Stress urinary incontinence due to intrinsic sphincter deficiency (ISD)
   b) Congenital sphincter weakness secondary to myelomeningocele or epispadias
   c) Acquired sphincter weakness as a result of spinal cord tumors or lesions
   d) Men subsequent to trauma
   e) Men subsequent to prostate surgery (prostatectomy) and/or radiation treatment
   f) Women without urethral hypermobility and an abdominal leak point pressure (ALLP) of 100cm H2O or less (ALLP is the intra-abdominal pressure at which leakage occurs from a woman's bladder (around the catheter) when the bladder is filled with a minimum of 150cc of fluid. It is stated in centimeters of water (cm H2O))

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
Medical Management Guideline

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).

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).

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


Approved by: Medical Management Guideline Committee Date Approved: 05/25/04
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 (AAOMS 2004). Such skeletal abnormalities may cause difficulties with eating or chewing, abnormal speech patterns, or dysfunction of the temporomandibular joint (TMJ) (ASPS 1997).
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 (ASPS 1997).

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, 2001).

The following terms describe the relationship between the dentition of the upper and lower arches (Patel et al, 2001):

- **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 Insurance (COI). If there is a discrepancy between this guideline and the member’s EOC/SOB/COI, the member’s EOC/SOB/COI 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, 2002; 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)
A. BACKGROUND

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. 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. 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. Over the past decade, treatment costs associated with osteoporosis have increased in the United States to $12–15 billion a year.
1. 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.

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.

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).

Women in this group who have already experienced one or more fractures are deemed to have severe or “established” osteoporosis (see Table 1).

<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>One or more fractures</td>
</tr>
</tbody>
</table>
Screening:
Screening individuals for risk factors aids physicians in identifying those who require further assessment and investigation to determine whether medical intervention is needed to reduce their risk of osteoporotic (fragility) fracture.

Predictors of low BMD:
- 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.
- Central sites are more likely to demonstrate response than peripheral sites and are preferred for baseline and serial measurements
- Peripheral site measurements should be limited to risk assessment
- 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

Treatment:
The goal of prevention and management of osteoporosis is to retain bone mass and preserve structural integrity of the skeleton. Treatment options include pharmacotherapy (see Table 2) and lifestyle changes to include exercise and modify diet. Adequate intake of calcium and vitamin D in addition to exercise will benefit skeletal structure.

<table>
<thead>
<tr>
<th>Indication</th>
<th>Estrogens</th>
<th>Bisphosphonates</th>
<th>SERMs</th>
<th>Miacalcin</th>
<th>Parathyroid hormones</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ERT/HRT</td>
<td>Actonel® (Risedronate)</td>
<td>Fosamax® (Alendronate)</td>
<td>Evista® (Raloxifene)</td>
<td>Miacalcin® (Calcitonin, salmon)</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.
## Table 3. Pharmacotherapy: Summary of clinical efficacy

<table>
<thead>
<tr>
<th>Therapeutic Class</th>
<th>Effect on BMD</th>
<th>Effect on Fractures*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estrogens</td>
<td>Decrease rate of bone loss; increase bone density of the spine and hip</td>
<td>The Women’s Health Initiative study showed a 36% reduction in hip fractures and a 24% reduction for all fractures with an average of 5.2 years of use.</td>
</tr>
<tr>
<td>Bisphosphonates (Actonel®, Fosamax®)</td>
<td>Increase bone density of the spine, trochanter, and femoral neck</td>
<td>Decrease the risk of vertebral and non-vertebral fractures (including hip fractures) by 40% to 50%</td>
</tr>
<tr>
<td>SERMs (Evista®)</td>
<td>Increase bone density of the spine and femoral neck</td>
<td>Decrease the risk of vertebral fracture by 30% to 50%; no significant reduction in nonvertebral fractures was seen</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 cortical sites, especially the hip</td>
<td>In the PROOF trial, a 30% decrease in vertebral fractures and no significant reduction in nonvertebral fractures was observed. Calcitonin has analgesic effect and is often used in patients with acute symptomatic vertebral fractures.</td>
</tr>
<tr>
<td>Parathyroid hormone (Forteo™)</td>
<td>Increases vertebral, femoral, and total-body bone mineral density</td>
<td>Decreases the risk of vertebral and nonvertebral fractures by 65% and 53%, respectively.</td>
</tr>
</tbody>
</table>

These are not head to head comparisons

### 2. 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*. 

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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 Insurance (COI). If there is a discrepancy between this guideline and the member’s EOC/SOB/COI, the member’s EOC/SOB/COI provision will govern.

Screening:
Routine osteoporosis screening is covered when one of the following criteria are met:
- Age ≥ 65
- Beginning at age 60 for women at increased risk for osteoporotic fracture - Increased risk: individuals with at least 1 major or 2 minor risk factors (Table 5).

Diagnosis:
Bone mass measurement is covered when all of the following criteria and requirements are met:
1. Bone mass measurement is a radiologic, radioisotopic or other procedure (e.g., DEXA 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 (e.g., ultrasound) device approved or cleared for marketing by the Food and Drug Administration
   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, based on her medical history and other findings
   b. A member with vertebral abnormalities as demonstrated by an X-ray to be indicative of osteoporosis, osteopenia (low bone mass), or vertebral fracture
   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
   d. A member with primary hyperparathyroidism
   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
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f. A member being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy

3. The measurements are 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.

4. The measurements are furnished by a qualified supplier or provider of such services under the appropriate level of supervision of a physician.

5. Frequency Standard: Bone mass measurements are covered 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:

- 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.

- Examples include, but are not limited to:
  - Coverage of a baseline measurement using bone densitometry if the initial test was performed using bone sonometry and monitoring is anticipated using bone densitometry

Bone biopsy is covered when used for the qualitative evaluation of bone, not to exceed 4 bone biopsies for a member, unless there is special justification provided.
Table 4. Bone mineral density (BMD) measurement techniques

<table>
<thead>
<tr>
<th>Technique*</th>
<th>Site Measured</th>
<th>Unit of Measure</th>
<th>Utility</th>
</tr>
</thead>
<tbody>
<tr>
<td>DXA</td>
<td>Postanterior spine, proximal femur</td>
<td>Areal density (g/cm²)</td>
<td>Diagnosis and monitoring</td>
</tr>
<tr>
<td>DXA</td>
<td>Lateral spine, total body, forearm, heel, phalanges</td>
<td>Areal density (g/cm²)</td>
<td>Risk assessment</td>
</tr>
<tr>
<td>QCT</td>
<td>Spine</td>
<td>Volumetric density (g/cm³)</td>
<td>Diagnosis and monitoring</td>
</tr>
<tr>
<td>pQCT</td>
<td>Forearm, hip</td>
<td>Volumetric density (g/cm³)</td>
<td>Risk assessment</td>
</tr>
<tr>
<td>QUS</td>
<td>Heel, forearm, tibia, phalanges, metatarsals</td>
<td>SOS, BUA</td>
<td>Risk assessment</td>
</tr>
<tr>
<td>RA</td>
<td>Phalanges</td>
<td>Volumetric density (arbitrary units)</td>
<td>Risk assessment</td>
</tr>
</tbody>
</table>

*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.

Table 5. Factors that identify people who should be assessed for osteoporosis

<table>
<thead>
<tr>
<th>Major Risk Factors</th>
<th>Additional Risk Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personal history of fracture as an adult</td>
<td>Impaired vision</td>
</tr>
<tr>
<td>History of fragility fracture in a first-degree relative</td>
<td>Estrogen deficiency at an early age (&lt;45 yrs)</td>
</tr>
<tr>
<td>Low body weight (&lt;127lbs)</td>
<td>Dementia</td>
</tr>
<tr>
<td>Current smoking</td>
<td>Poor health/frailty</td>
</tr>
<tr>
<td>Use of oral corticosteroid therapy for more than 3 months</td>
<td>Recent falls</td>
</tr>
<tr>
<td></td>
<td>Low calcium intake (lifelong)</td>
</tr>
<tr>
<td></td>
<td>Low physical activity</td>
</tr>
<tr>
<td></td>
<td>Alcohol in amounts &gt; 2 drinks per day</td>
</tr>
</tbody>
</table>

Risk factors have an additive effect. An individual with a low BMD in addition to a fragility fracture or is over 65 and has a BMD in the range associated with osteoporosis should be considered to be at high risk for fracture and a candidate for therapy.

Pharmacotherapy:

Prevention For High Risk Individuals (individuals with reduced BMD i.e. osteopenia):
- Bisphosphonates are first-line therapies in the prevention of postmenopausal osteoporosis

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- 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
- Bisphosphonates are the first-line therapy for the prevention of osteoporosis in patients requiring prolonged glucocorticoid therapy
- Estrogen (alone for a woman without a uterus) and estrogen and progestin/progesterone is a first-line therapy in the prevention of postmenopausal osteoporosis. However, when used only for the prevention of post menopausal osteoporosis the risks of HRT may outweigh the benefits. The risk of estrogen alone is to be determined.
- Age-appropriate calcium and vitamin D intake are recommended for the prevention of osteoporosis

Treatment:
- Bisphosphonates are first-line therapies in the treatment of postmenopausal osteoporosis
- 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
- Bisphosphonates are first line therapy for patients with glucocorticoid induced osteoporosis
- Estrogen without progestin/progesterone may be considered first line therapy for women who have had their uterus removed surgically.
- Estrogen and progestin/progesterone is a second-line therapy in the treatment of postmenopausal osteoporosis. Prolonged use is associated with risks
- Nasal calcitonin is a second-line therapy in the treatment of postmenopausal osteoporosis
- Forteo is a second line therapy for individuals unable to tolerate anti resorptive therapy

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.

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

D. REFERENCES


Medical Management Guideline

TITLE: Oxygen for Home Use

Authorized By: Medical Management Guideline Committee

Approval Date: 04/22/03 Revision Date: 10/28/03

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 Decision is in place.

This medical management guideline is intended for use by PacifiCare employees, PacifiCare contracted providers, and practitioners only. The information contained in this medical management guideline is confidential and proprietary to PacifiCare.

A. BACKGROUND

1. Description

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

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.

Some examples of new ambulatory lightweight portable oxygen systems include the following:
- 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.

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.

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.

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%.
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Table 1 compares some portable/ambulatory lightweight oxygen systems (Lewarski 2001).

<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</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</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.

2. **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.*
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 Insurance (COI). If there is a discrepancy between this guideline and the member’s EOC/SOB/COI, the member’s EOC/SOB/COI provision will govern.

1. Oxygen for home use and accompanying necessary accessories are recommended when the following criteria are met (see section 4 below for covered delivery systems):
   a. The physician provides acceptable medical documentation of each of the following:
      1) Member’s diagnosis
      2) Oxygen flow rate
      3) Anticipated duration of use and need
      4) Type of oxygen system
      5) Failure of other appropriate forms of treatment
   b. Member meets the criteria of one of the following three categories:
      1) Members with any of the following:
         a) Arterial PO2 at or below 55 mm Hg or arterial oxygen saturation at or below 88%, taken at rest, breathing room air
         b) Arterial PO2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88% 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
         c) A decrease in arterial PO2 more than 10 mm Hg or a decrease in arterial oxygen saturation more than 5% during sleep
         d) 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

Notes:
- In cases a) b) c) and d) above, coverage is limited to 12 months or the physician specified length of need, whichever is shorter
- In cases b) and c) above, coverage is provided only for use of oxygen during sleep and only for one type of unit (e.g. portable oxygen is not covered in these cases)
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- In d) 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

2) Members with arterial PO2 at 56-59 mm Hg or with a blood oxygen saturation of 89%, if there is evidence of any of the following:
   a) Dependent edema suggesting congestive heart failure (CHF)
   b) Cor Pulmonale (pulmonary hypertension)
   c) Erythrocythemia with a hematocrit greater than 56%

Notes:
In cases a) b) and c) above, coverage is limited to 3 months or the physician specified length of need, whichever is shorter

2. Liter flow greater than 4 LPM is covered for home use when the criteria for oxygen are met and the blood gas study is performed while the patient is on 4 LPM

3. Home oxygen is not appropriate for members with the following:
   a. An arterial PO2 at or above 60mm Hg or on ABG O2 saturation at or above 90%
   b. Angina pectoris in the absence of hypoxemia
   c. Breathlessness without cor pulmonale or evidence of hypoxemia
   d. Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities
   e. Terminal illness that does not affect the lungs

4. Delivery Systems: stationary, portable (i.e., ≥10 pounds), and lightweight ambulatory (i.e.,< 10 pounds)
   a. Stationary compressed gaseous oxygen cylinders and oxygen concentrators, in addition to necessary accessories, are covered as follows:
      1) The member does not routinely travel 50 feet beyond the delivery system or
      2) The member only uses oxygen at night
   b. Portable oxygen concentrators and portable gaseous oxygen cylinders with standard regulators are systems that weigh 10 pounds or more and can be transported on wheels. These systems including necessary accessories are covered when the following criteria are met:
      1) 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.
      2) Blood gas study was performed at rest (awake) or during exercise
   c. Stationary or portable liquid oxygen systems in addition to necessary accessories, are covered when substituted in section 4.a. or 4.b. above, when both of the following additional criteria are met:
      1) Patient requires continuous high flow oxygen ≥ 3L/min
2) Patient cannot tolerate a conserving device
d. Ambulatory lightweight (< 10 pounds) gaseous oxygen systems (e.g., Oxylite) are designed to be carried by the patient. These systems, including necessary accessories, are covered alone or combined with stationary systems when the following are clearly documented:
   1) 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
   2) Blood gas study performed at rest (awake) or during exercise AND
   3) Patient has upper body weakness and walks with an assistive device in the home OR
   4) Patient cannot maneuver within the home with standard portable oxygen or extension tubing on stationary oxygen equipment
e. Ambulatory lightweight (< 10 pounds) liquid oxygen systems (e.g., Helios) are designed to be carried by the patient. These systems, including necessary accessories, are not recommended unless all of the following are clearly documented:
   1) Patient cannot tolerate ambulatory lightweight gaseous oxygen systems (e.g., Oxylite)
   2) Patient requires continuous high flow oxygen ≥ 3L/min
   3) Patient meets criteria for ambulatory lightweight gaseous oxygen (see d. above)
f. Oxygen and water vapor enriching systems are not covered. Emergency or stand-by oxygen systems are not covered (e.g., preset portable oxygen units)
g. Necessary accessories such as conservers are not separately payable unless used with a patient-owned system that was purchased prior to June 1, 1989

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


Durable Medical Equipment Regional Carriers DMERC-D IX Region Wide Medical Review Policies.


Medicare Carrier Manual CAR3 § 4105.


A. BACKGROUND

1. 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 to a silica matrix. The device is used in conjunction with a plasmapheresis machine. In this ex vivo treatment, blood is withdrawn from the patient, cells are separated from plasma in the machine, and the plasma is passed through the protein A immunoadsorption column. The plasma is then recombined with the cells and returned to the patient (Prosorba® prescribing information).

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 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.

Settings
Plasmapheresis/plasma exchange are conducted in outpatient settings, including blood banks, dialysis centers, hospitals, and physicians’ offices (Hayes 2001).

Centers for Medicare and Medicaid Services (CMS)
Apheresis is covered by CMS only when performed in the following settings:
In a hospital setting (either inpatient or outpatient), nonphysician 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.

In a nonhospital setting, e.g., a physician-directed clinic (see CMS Pub. 14-3, §2050.4), apheresis is covered when the following conditions are met:
- 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
- Each patient is under the care of a physician
- All nonphysician services are furnished under the direct, personal supervision of a physician

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 Insurance (COI). If there is a discrepancy between this guideline and the member’s EOC/SOB/COI, the member’s EOC/SOB/COI provision will govern.

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

Plasmapheresis/plasma exchange is recommended for patients who meet the CMS coverage criteria (see above). Treatment may be delivered in a hospital or nonhospital 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 (see above).

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


Plasmapheresis/Plasma Exchange – Secure Horizons


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Approved by: Medical Management Guideline Committee  
Date Approved: 12/11/03

*Plasmapheresis/Plasma Exchange – Secure Horizons*
Medical Management Guideline

TITLE: Positron Emission Tomography (PET)

Authorized By: Medical Management Guideline Committee

Approval Date: 04/22/03   Revision Date: 07/22/03
10/28/03

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 Decision is in place.

This medical management guideline is intended for use by PacifiCare employees, PacifiCare contracted providers, and practitioners only. The information contained in this medical management guideline is confidential and proprietary to PacifiCare.

A. BACKGROUND

1. Description
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.

2. **Benefit**
Secure Horizons covers FDG PET when determined to be medically necessary and specific criteria are met. See the Secure Horizons Benefit Interpretation Policy (BIP) *Diagnostic and Therapeutic Radiology 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 Insurance (COI). If there is a discrepancy between this guideline and the member’s EOC/SOB/COI, the member’s EOC/SOB/COI provision will govern.

1. **General Recommendations**

For all uses of PET relating to malignancies, the following conditions apply:

**Diagnosis**
PET is recommended only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure.

Note: PET is not recommended for screening (testing of patients without specific signs and symptoms of disease).

**Staging and/or Restaging**
PET is recommended in clinical situations in which

- the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound)
- or
- the use of PET could potentially replace one or more conventional imaging...
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studies when it is expected that conventional study information is insufficient for the clinical management of the patient and

• clinical management of the patient would differ depending on the stage of the cancer identified.

PET is recommended for restaging only after the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence, or to determine the extent of a known recurrence.

Monitoring
The use of PET to monitor tumor response during the planned course of therapy (i.e., when no change in therapy is being contemplated) is not recommended except for breast cancer.

Unless otherwise noted, the recommendations apply when FDG is used as a radiotracer.

Allowable FDG PET Systems
The following definitions apply:

“FDA approved” indicates that the system has been approved or cleared for marketing by the FDA to image radionuclides in the body

“Certain coincidence systems” refers to the systems that have all the following features:

• Crystal at least 5/8-inch thick
• Techniques to minimize or correct for scatter or random or both
• Digital detectors and iterative reconstruction

Note: Gamma camera PET systems with crystals thinner than 5/8-inch are not recommended. In addition, systems using crystals greater than or equal to 5/8-inch in thickness but not meeting the other listed design characteristics are not recommended.
2. Specific Recommendations

This guideline addresses the use of PET for the following indications when criteria are met:

- Breast cancer
- Esophageal cancer
- Head and neck cancer
- Lung cancer: single pulmonary nodules, non-small cell lung cancer
- Colorectal cancer
- Lymphoma
- Melanoma
- Thyroid cancer
- Refractory seizures
- Cardiac diagnostics

For other indications, PET is not considered to be medically necessary.

**Breast cancer**

PET is recommended as an adjunct to other imaging modalities for:

- Staging patients with distant metastasis
- Restaging patients with locoregional recurrence or metastasis
- Monitoring tumor response to treatment for patients with locally advanced and metastatic breast cancer when a change in therapy is anticipated

Note: PET is not recommended for the initial diagnosis of breast cancer and for staging of axillary lymph nodes.

Allowable FDG PET systems are FDA approved full ring or partial ring systems.

Conditions as listed under General Recommendations apply.

**Esophageal cancer**

PET is recommended for the diagnosis, staging, and restaging of esophageal cancer.

Allowable FDG PET systems are FDA approved full ring or partial ring systems.

Conditions as listed under General Recommendations apply.
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Head and neck cancer
PET is recommended for the diagnosis, staging, and restaging of head and neck cancer.

Note: PET is not recommended for cancers of the central nervous system (CNS) or thyroid.

Allowable FDG PET systems are FDA approved full ring or partial ring systems.

Conditions as listed under General Recommendations apply.

Lung cancer
a. Solitary pulmonary nodules
   PET is recommended for the characterization of single pulmonary nodules (SPNs). The primary purpose of such characterization should be to determine the likelihood of malignancy in order to plan future management and treatment.

   Requirements:
   • Computed tomography (CT) or other detection method suggests an indeterminate or possibly malignant lesion not exceeding 4cm in diameter
   • A concurrent thoracic CT has been performed, ensuring the proper coordination of PET with other diagnostic modalities

   Note: In cases of serial evaluations of SPNs using both CT and PET chest scanning, PET is not recommended within 90 days of a negative PET scan.

   Note: A tissue sampling procedure is not recommended for routine performance in the case of a negative PET scan for characterization of SPNs.

   Allowable FDG PET systems are FDA approved full-ring or partial ring systems and certain coincidence systems.

b. Non-small cell lung cancer
   PET is recommended for the diagnosis, staging, and restaging of non-small cell lung cancer.
Allowable FDG PET systems are FDA approved full ring or partial ring systems and certain coincidence systems.

Conditions as listed under General Recommendations apply.

**Colorectal cancer**
PET is recommended for the diagnosis, staging, and restaging of colorectal cancer.

Allowable FDG PET systems are FDA approved full ring or partial ring systems.

Conditions as listed under General Recommendations apply.

**Lymphoma**
PET is recommended for the diagnosis, staging, and restaging of lymphoma.

Allowable FDG PET systems are FDA approved full ring or partial ring systems.

Conditions as listed under General Recommendations apply.

**Melanoma**
PET is recommended for the diagnosis, staging, and restaging of melanoma.

Note: PET is not recommended for the evaluation of regional nodes.

Allowable FDG PET systems are FDA approved full-ring or partial ring systems.

Conditions as listed under General Recommendations apply.

**Thyroid cancer**
PET is recommended for restaging of recurrent or residual thyroid cancers of follicular cell origin that have been previously treated by thyroidectomy and radioiodine ablation and have a serum thyroglobulin >10µg/ml and negative I-131 whole body scan performed.

Note: PET is not recommended for any other uses in the diagnosis and treatment of thyroid cancer.
Allowable FDG PET systems are FDA approved full ring or partial ring systems.

Conditions as listed under General Recommendations apply.

**Refractory seizures**
PET is recommended for the pre-surgical evaluation of patients for the purpose of localization of a focus of refractory seizure activity.

Allowable FDG PET systems are FDA approved full ring or partial ring systems.

**Cardiac diagnostics**

a. **Perfusion of the heart using rubidium-82**
PET using the radiotracer rubidium-82 is recommended for noninvasive imaging of the perfusion of the heart for the diagnosis and management of patients with known or suspected coronary artery disease.

Requirements:
- PET is performed in place of, but not in addition to, single photon emission computed tomography (SPECT)
- or
- PET is used following an inconclusive SPECT scan (i.e., equivocal, technically uninterpretable, or discordant with a patient’s other clinical data) when PET is considered necessary to determine what medical or surgical intervention is required to treat the patient

b. **Perfusion of the heart using ammonia N-13**
PET using the radiotracer ammonia N-13 is recommended for noninvasive imaging of the perfusion of the heart for the diagnosis and management of patients with known or suspected coronary artery disease.

Requirements:
- PET is performed in place of, but not in addition to, single photon emission computed tomography (SPECT)
- or
- PET is used following an inconclusive SPECT scan (i.e., equivocal, technically uninterpretable, or discordant with a patient’s other clinical data) when PET is considered necessary to determine what medical or surgical intervention is required to treat the patient
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c. Myocardial viability
   PET is recommended for the determination of myocardial viability as a primary or initial diagnostic study prior to revascularization, or following an inconclusive SPECT scan.

   Note: If a patient received an inconclusive PET scan, a follow-up SPECT is not recommended.

   Allowable FDG PET systems are FDA approved full ring or partial ring systems.

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: 10/28/03

Positron Emission Tomography (PET) – Secure Horizons
A. BACKGROUND

1. 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
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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 of Omaha 2003).

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.
2. 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*.

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 Insurance (COI). If there is a discrepancy between this guideline and the member’s EOC/SOB/COI, the member’s EOC/SOB/COI provision will govern.

**Indications for referral**
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:
- Reduced exercise tolerance or a decline in the patient's ability to perform activities of daily living
- Unexpected deterioration or worsening of symptoms against a background of long-standing dyspnea and a reduced but stable exercise tolerance level
- Need for surgical intervention (pre- and postoperative lung resection, transplantation)
- 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
Medical Necessity Criteria
Candidates for PR should meet all of the following:

• Prior to participation in the PR program, the patient should be receiving maximal medical treatment from a physician who has training and/or experience in the treatment of pulmonary diseases.
• Patient should be medically stable and not limited by another serious or unstable medical and/or mental condition.
• Patient is not a smoker for at least 2 months.
• Pulmonary Function Tests (PFTs) revealing Forced Vital Capacity (FVC) or Forced Expiratory Volume in one second (FEV₁) <60% of normal or Diffusing Lung Capacity for Carbon Monoxide (DCCO) <60%, uncorrected for volume, within 90 days of initiating PR (Mutual of Omaha, 2003).
• 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.
• The initial PR assessment should indicate patient is an appropriate candidate for PR by documenting the following:
  a) Effect of disease on the patient’s ADLs (in objective terms)
  b) Physical activity reduction including
     1) Changes in occupational performance
     2) Dependence versus independence in ADLs
  c) Motivation and commitment to active participation.

Duration
The duration of outpatient PR program for SH members should not exceed 8 weeks and may be accomplished in less time. Home self-monitored exercises should continue after the formal program, but do not require skilled supervision or monitoring.

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

**Exclusion Criteria**
PR is not recommended for the following (ATS 1999):
- Conditions that might interfere with the patient’s undergoing the rehabilitative process such as advanced arthritis, the inability to learn, or disruptive behavior
- Conditions that might place the patient at undue risk during exercise training such as severe pulmonary hypertension, unstable angina, or recent myocardial infarction
- Smoking or substance abuse without desire to cease use
- 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

**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: 10/28/03

Outpatient Pulmonary Rehabilitation – Secure Horizons
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

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 Decision is in place.

This medical management guideline is intended for use by PacifiCare employees, PacifiCare contracted providers, and practitioners only. The information contained in this medical management guideline is confidential and proprietary to PacifiCare.

A. BACKGROUND

1. 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 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 2002):

- **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 multi-disciplinary program, occupational therapy as a sole therapy never requires an inpatient rehabilitation unit. The service is intended to improve upper extremity strength, activities of daily living, functional or vocational training, and can be provided in an outpatient setting.

- **Speech Therapy**, though often needed and provided in the multi-disciplinary program, speech therapy as a sole therapy never requires 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.

2. **Benefit**
Secure Horizons covers SNF care when determined to be medically necessary and specific criteria are met. See the Secure Horizons Benefit Interpretation Policies (BIPs) *Skilled Nursing Facility (SNF) Care* and *Exhaustion of Skilled Nursing Facility (SNF) Benefits*.

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 Insurance (COI). If there is a discrepancy between this guideline and the member’s EOC/SOB/COI, the member’s EOC/SOB/COI provision will govern.
Patient Selection Criteria
Care in a SNF is recommended if all of the following 3 factors are met (CMS 2003):

- 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)
- The patient requires these skilled services on a daily basis; the service must also be reasonable in terms of duration and quantity
- 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)

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 2002). 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.

- **Level 1 – Skilled Nursing Care**
  Patients who meet all the above patient selection criteria for SNF care and require the following:
  - Injectable drug administration: Intravenous, subcutaneous, intramuscular up to four times daily
  - Post-surgical patient training/education
  - Bowel and bladder training
  - Administration of insulin and training of newly diagnosed insulin dependent diabetic; administration of sliding scale insulin
  - Nasogastric tube, gastrostomy or jejunostomy care including feedings
  - Colostomy/ileostomy care during early postoperative period
  - Foley catheter care with daily irrigation

  Patients must meet coverage criteria for SNF care and have Level 1 skilled needs for coverage of the following services:
  - Stable tracheostomy care (chronic tracheostomy not as a result of current acute episode and/or admission) and only requiring suction and/or dressing change once per day
  - Post-surgical wound or dressing care at least twice per day per wound
Level 2 – Rehabilitation Skilled Nursing Care
Patients who meet the patient selection criteria for SNF care, possibly require service in Level 1 and any of the following:
- New tracheostomy care requiring suctioning and mist treatment twice per day
- Continuous oxygen (3 liters/minute or more)
- Pulse oximetry
- Postural drainage and percussion
- New colostomy/ileostomy care
- Intravenous hydration
- Administration of 1 intravenous antibiotic up to 4 times daily
- Physical, occupational and/or speech therapy services up to a maximum of 2 hours per day, 6 days per week
- Post-surgical wound or dressing care at least 3 times per day per wound

Level 3 – Extensive Skilled Nursing Care
Patients who meet the coverage criteria for SNF care, possibly require service in Level 1 and Level 2 and any of the following:
- Continuous intravenous medication administration
- Total parenteral nutrition and lipid administration
- Administration of 2 intravenous antibiotics up to four times daily
- Continuous subcutaneous, intravenous or intrathecal infusion for pain control or use of a patient controlled analgesic (PCA) pump
- Physical, occupational and/or speech therapy services up to a maximum of 3 hours per day, 6 days per week
- Isolation care (excluding universal precautions)
- Wound Care of a Stage III-IV decubitus ulcer(s)
- New tracheostomy care requiring suctioning and mist treatment more than twice per day

Level 4 – Ventilator/Sub-Acute Care
- Ventilator care
- Continuous oxygen/humidification over the tracheostomy site
- Physical, occupational and/or speech therapy services 4 or more hours per day, 6 days per week
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 2002). Covered services include, but are not limited to:

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

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


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*.

**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 Insurance (COI). If there is a discrepancy between this guideline and the member’s EOC/SOB/COI, the member’s EOC/SOB/COI 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)
Medical Management Guideline

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.

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 (Kryshalskyj 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).
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


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

*refers to disc position in relation to condyle when the mouth is open
# Patient Selection Criteria

## Autologous Hematopoietic Progenitor Cell Transplantation

### Hodgkin’s Disease and Non-Hodgkin’s Lymphoma

<table>
<thead>
<tr>
<th>Indications</th>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td>One of the following</td>
<td></td>
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<tr>
<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>
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<tr>
<td>▪ Individuals with relapsed or primary refractory intermediate or high grade (stage III or IV) Non-Hodgkin’s Lymphoma</td>
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<tr>
<td>▪ Individuals with Non-Hodgkin’s Disease in first remission with extensive stage IV disease and elevated LDH.</td>
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</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>▪ Sepsis or systemic infection unresponsive to treatment</td>
<td></td>
</tr>
<tr>
<td>▪ Malignant disease considered likely to limit successful clinical outcome or interfere with compliance with a disciplined medical regimen or rehabilitation after transplantation</td>
<td></td>
</tr>
<tr>
<td>▪ Malignancy: see ASTS guideline in appendix 1</td>
<td></td>
</tr>
<tr>
<td>▪ Seropositive for HIV antibody</td>
<td></td>
</tr>
<tr>
<td>▪ Neuropsychiatric disorders which are likely to lead to non-compliance or will inhibit rehabilitation of the patient</td>
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<tr>
<td>▪ Inadequate pulmonary, hepatic, cardiac, or renal function</td>
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<tr>
<td>▪ Patients with:</td>
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<tr>
<td>  ▪ NYHA Class III or IV cardiac insufficiency or</td>
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<tr>
<td>  ▪ LVEF &lt; 45%</td>
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<tr>
<td>  ▪ PFT with DLCO &lt; 50</td>
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<tr>
<td>  ▪ Substantial liver damage (SGOT or SGPT &gt; 300 IU or</td>
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<td>  ▪ Total bilirubin &gt; 2mg/dl</td>
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<td>  ▪ Serum creatinine &gt; 2.0 mg/dl and/or</td>
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<tr>
<td>  ▪ creatinine clearance &lt; 50ml/minute</td>
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<tr>
<td>▪ Substance abuse (drug and alcohol free)</td>
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</table>
### Patient Selection Criteria
Autologous Hematopoietic Progenitor Cell Transplantation

<table>
<thead>
<tr>
<th>Multiple Myeloma</th>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
<td>Durie-Salmon stage II (intermediate tumor burden) or III (high tumor burden) disease that meets the following requirements</td>
</tr>
<tr>
<td></td>
<td>• 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</td>
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<tr>
<td></td>
<td>• Adequate cardiac, renal, pulmonary and hepatic function</td>
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<tr>
<td><strong>Exclusions/ Contraindications</strong></td>
<td>Any single contraindication listed below shall preclude approval for transplantation</td>
</tr>
<tr>
<td></td>
<td>• Refractory multiple myeloma</td>
</tr>
<tr>
<td></td>
<td>• Sepsis or systemic infection unresponsive to treatment</td>
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<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>
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<tr>
<td></td>
<td>• Malignancy: see ASTS guideline in appendix 1</td>
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<tr>
<td></td>
<td>• Seropositive for HIV antibody</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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<tr>
<td></td>
<td>• Inadequate pulmonary, hepatic, cardiac, or renal function</td>
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<tr>
<td></td>
<td>• Severe hepatic disease as evidenced:</td>
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<tr>
<td></td>
<td>• SGOT or SGPT, total bilirubin or alkaline</td>
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<tr>
<td></td>
<td>• 2.5 times normal</td>
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<td></td>
<td>• Compromised renal function as evidenced by:</td>
</tr>
<tr>
<td></td>
<td>• Serum creatinine &gt; or = 2.0 mg/dl</td>
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<tr>
<td></td>
<td>• Creatinine clearance &lt; 55ml/min</td>
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<tr>
<td></td>
<td>• LVEF (MUGA or ECHO) &lt; or = 45%</td>
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<tr>
<td></td>
<td>• PFT with DLCO &lt; 50</td>
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<td></td>
<td>• Substance abuse (drug and alcohol free)</td>
</tr>
</tbody>
</table>
## Patient Selection Criteria

### Autologous Hematopoietic Progenitor Cell Transplantation

### Indications

- One of the following
  - 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 (AllSCT) due to age or lack of an HLA-matched related donor
  - Acute Lymphocytic or Myeloid Leukemia in first or second remission
  - Individuals with Acute Myelocytic Leukemia who fail to achieve a complete response after 4 weeks of induction therapy

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.

**OR**

- Adults at high risk of mortality from AllSCT

### Exclusions/Contraindications

Any single contraindication listed below shall preclude approval for transplantation.

- Failure to harvest adequate stem cells
- Substance abuse (drug and alcohol free)
- Chronic Myeloid leukemia (CML)
- Chronic lymphoid Leukemia (CLL)
- 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
- Seropositive for HIV antibody
- 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 Association class III or IV cardiac insufficiency or LVEF < 45%
  - PFT with DLCO < 50
  - SGOT or SGPT > 200 IU
  - Total bilirubin > 2mg/dl
  - Serum creatinine > 2.0 mg/dl and/or Creatinine clearance < 50ml/min
Progenitor Cell Transplantation Criteria – August 2004

### Patient Selection Criteria
Autologous Hematopoietic Progenitor Cell Transplantation

<table>
<thead>
<tr>
<th>Breast Cancer</th>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></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>

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

<table>
<thead>
<tr>
<th>Neuroblastoma</th>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></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>
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<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><strong>Exclusions/ Contraindications</strong></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>
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<td></td>
<td>- Malignancy: see ASTS guideline in appendix 1</td>
</tr>
<tr>
<td></td>
<td>- Seropositive for HIV antibody</td>
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<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>
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<td>- Inadequate social support system</td>
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<td>- Inadequate pulmonary, hepatic, cardiac, or renal function</td>
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<td></td>
<td>- New York Heart Association Class 3 or 4 cardiac insufficiency or</td>
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<td></td>
<td>- LVEF &lt; 45%</td>
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<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>
</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>

Note: CMS Coverage issues manual section 35-31.1 states: Insufficient data exist to establish definite conclusions regarding the efficacy of autologous stem cell transplantation for the following condition: Solid tumors (other than neuroblastoma)
Patient Selection Criteria
Allogeneic Hematopoietic Progenitor Cell Transplantation

<table>
<thead>
<tr>
<th>Leukemia</th>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications</td>
<td>One of the following:</td>
</tr>
<tr>
<td></td>
<td>Acute Leukemia (ALL, AML /ANLL) with one of the following:</td>
</tr>
<tr>
<td></td>
<td>• Failure to achieve complete remission after 4 weeks of induction therapy</td>
</tr>
<tr>
<td></td>
<td>• First complete remission: high risk disease</td>
</tr>
<tr>
<td></td>
<td>• Second or third complete remission or relapse</td>
</tr>
<tr>
<td></td>
<td>OR</td>
</tr>
<tr>
<td></td>
<td>• Chronic Myeloid Leukemia (CML): Patients in their first or second chronic phase</td>
</tr>
<tr>
<td></td>
<td>All of the following</td>
</tr>
<tr>
<td></td>
<td>• Relatively normal performance status as judged by medical history, physical examination, and evaluation of pulmonary, hepatic, cardiac, and renal function</td>
</tr>
<tr>
<td></td>
<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>
</tr>
<tr>
<td></td>
<td>• Patient's disease should be responsive to chemotherapy with a dose-limiting toxicity of bone marrow suppression</td>
</tr>
<tr>
<td></td>
<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>
</tr>
<tr>
<td></td>
<td>• Adults should be &lt;55 years old (graft vs. host disease is more common among older recipients)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exclusions/Contraindications</th>
<th>Contraindications—Any single contraindication listed below shall preclude approval for transplantation.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chronic Myeloid Leukemia (CML) in blast crisis</td>
</tr>
<tr>
<td></td>
<td>Sepsis or systemic infection unresponsive to treatment</td>
</tr>
<tr>
<td></td>
<td>Seropositive for HIV antibody</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>
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<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>Hodgkin’s Disease, Non-Hodgkin’s Lymphoma</th>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
<td><strong>Hodgkin’s Disease (HD)</strong> with one of the following:</td>
</tr>
<tr>
<td></td>
<td>- Patients with stage III or IV disease who fail to achieve a complete response to standard chemotherapy</td>
</tr>
<tr>
<td></td>
<td>- Patients with stage III or IV disease who relapse after remission</td>
</tr>
<tr>
<td></td>
<td><strong>OR</strong></td>
</tr>
<tr>
<td></td>
<td>Non Hodgkin’s Lymphoma (NHL)**</td>
</tr>
<tr>
<td></td>
<td>- Patients who are responsive to chemotherapy but relapse after a remission</td>
</tr>
<tr>
<td></td>
<td>- Patients with refractory disease</td>
</tr>
<tr>
<td></td>
<td>- All of the following</td>
</tr>
<tr>
<td></td>
<td>- Relatively normal performance status as judged by medical history, physical examination, and evaluation of pulmonary, hepatic, cardiac, and renal function</td>
</tr>
<tr>
<td></td>
<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>
</tr>
<tr>
<td></td>
<td>- Patient's disease should be responsive to chemotherapy with a dose-limiting toxicity of bone marrow suppression</td>
</tr>
<tr>
<td></td>
<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>
</tr>
<tr>
<td></td>
<td>- Adults should be &lt;55 years old (graft vs. host disease is more common among older recipients)</td>
</tr>
<tr>
<td></td>
<td><em>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 allogeic BMT.</em></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exclusion/Contraindications</th>
<th><strong>Contraindications</strong> — 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>- Seropositive for HIV antibody</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>
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<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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<tr>
<td></td>
<td>- Inadequate pulmonary, hepatic, cardiac, or renal function</td>
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<tr>
<td></td>
<td>- New York Hear Association Class 3 or 4 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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<tr>
<td></td>
<td>- Substantial liver damage (SGOT or SGPT &gt; 300 IU or</td>
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<td></td>
<td>- Total bilirubin &gt; 2mg/dl</td>
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<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>Non-Myeloablative</th>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications</td>
<td>Non-myeloablative allogeneic HSCT is recommended for the treatment of patients with hematological malignancies who are ineligible for conventional allogeneic 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>
</tr>
<tr>
<td></td>
<td>Patient Selection Criteria</td>
</tr>
<tr>
<td></td>
<td>The patient must have one of the following:</td>
</tr>
<tr>
<td></td>
<td>Age &gt;45 years</td>
</tr>
<tr>
<td></td>
<td>Significant comorbidity, poor performance status, or pretreatment precluding conventional myeloablative conditioning regimens</td>
</tr>
<tr>
<td></td>
<td>Failure of previous conventional autologous or allogeneic HSCT due to relapse, rejection, or secondary malignancy</td>
</tr>
<tr>
<td></td>
<td>Exclusion</td>
</tr>
<tr>
<td></td>
<td>Patients with chemorefractory disease</td>
</tr>
<tr>
<td></td>
<td>Non-myeloablative allogeneic HSCT for solid tumors</td>
</tr>
<tr>
<td></td>
<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>
</tr>
</tbody>
</table>
### Donor Lymphocyte Infusion for Relapsed Leukemia or Multiple Myeloma after Allogeneic Bone Marrow/Stem Cell Transplantation

**Indications**
- Chronic myeloid leukemia (CML) in chronic phase
- Relapse after allogeneic bone marrow/stem cell transplantation

### Aplastic Anemia

**Indications**
- Individuals with severe aplastic anemia who have a HLA-identical sibling donor
- Individuals with severe aplastic anemia who have failed immunosuppressive therapy and have a HLA-nonidentical related donor or HLA-matched unrelated donor

### Wiskott-Aldrich Syndrome

**Indications**
- Individuals with a HLA-identical sibling donor
- Individuals with a HLA-nonidentical related and HLA-identical unrelated donor
Organ Toxicity Criteria

<table>
<thead>
<tr>
<th>Patient must have adequate organ function as defined by:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renal Function</td>
</tr>
<tr>
<td>a) Serum creatinine $\leq$ 2mg/dl or</td>
</tr>
<tr>
<td>b) Creatinine clearance $&gt; 50$-55 ml/min</td>
</tr>
<tr>
<td>Liver Function</td>
</tr>
<tr>
<td>a) Total bilirubin $\leq$ 2mg/dl and</td>
</tr>
<tr>
<td>b) SGOT/SGPT $&lt; 2.5 \times$ normal</td>
</tr>
<tr>
<td>Cardiac Function</td>
</tr>
<tr>
<td>a) Ejection fraction $&gt; 45%$ by ECHO</td>
</tr>
<tr>
<td>Pulmonary Function</td>
</tr>
<tr>
<td>a) PFT with DLCO $&gt; 50$</td>
</tr>
</tbody>
</table>
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>Karposi’s and other Sarcomas</td>
<td>2 years</td>
</tr>
<tr>
<td>Breast</td>
<td></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>
### Solid Organ Transplantation Criteria – Updated 08/24/04

**Authorized By:** Medical Management Guideline Committee  
**Approval Date:** 07/22/03  
**Revision Date:** 03/16/04  
**Revision Date:** 08/24/04

**Adult Patient Selection Criteria**

<table>
<thead>
<tr>
<th>Kidney</th>
<th>PaciFiCare</th>
</tr>
</thead>
</table>
| **Indications** | All of the following:  
  - Irreversible, progressive, end-stage renal disease: creatinine clearance ≤ 20ml/min or on dialysis  
  - Stable psychosocial status  
  - Willingness to comply (patient and/or caregiver) with medical advice |
| **Absolute Contraindications** |  
  - Active infection  
  - Seropositive for HIV antibody, unless viral load undetectable by RNA testing  
  - Insufficient cardiac reserve:  
    - Non-correctable CAD  
    - Recent MI  
    - Ejection fraction < 35%  
  - Severe hepatic dysfunction:  
    - Bilirubin > 2.5mg/dl  
    - SGOT > 2x  
    - INR ≥ 1.5  
  - 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** |  
  - Life threatening co-existing systemic disease  
  - BMI ≥ 35  
  - Substance abuse (drug, alcohol and nicotine free for 6 months prior to transplantation)  
  - Age ≥ 65 years of age  
  - Insufficient cardiac reserve:  
    - Insufficient cardiac reserve  
    - Ejection fraction 35% - 50% |
| **Diseases associated with diminishing kidney function:** |  
  - Irreversible Chronic Renal Failure:  
    - Chronic pyelonephritis  
    - Chronic glomerulonephritis  
    - Diabetic nephropathy  
    - Goodpasture’s disease  
    - Hypocomplementemic nephritis |
<table>
<thead>
<tr>
<th>Kidney</th>
<th>PacifiCare</th>
</tr>
</thead>
</table>
|        | - 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  
| | - 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 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)  

## Pediatric Patient Selection Criteria

<table>
<thead>
<tr>
<th>Kidney</th>
<th>PacifiCare</th>
</tr>
</thead>
</table>
| **Indications** | All of the following:  
  - Irreversible, progressive, end-stage renal disease  
  - Age \(\leq 18\) years  
  - Stable psychosocial status  
  - Willingness to comply (patient and/or caregiver) with medical advice |
| **Absolute Contraindications** |  
  - Active infection  
  - Seropositive for HIV antibody, unless viral load undetectable by RNA testing  
  - 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** |  
  - Life threatening co-existing systemic disease  
  - Substance abuse (caregiver and/or patient drug, alcohol and nicotine free for 6 months prior to transplantation)  
  - BMI > 35 |
| **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 |
<table>
<thead>
<tr>
<th>Kidney</th>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Oxalosis</td>
</tr>
<tr>
<td></td>
<td>Amyloidosis</td>
</tr>
<tr>
<td></td>
<td>Cystinosis</td>
</tr>
<tr>
<td>Irreversible Acute Failure:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cortical necrosis</td>
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<td></td>
<td>Hemolytic uremic syndrome</td>
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<td></td>
<td>Acute and subacute glomerulonephritis</td>
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<td>Acute tubular necrosis</td>
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<tr>
<td>Trauma Requiring Nephrectomy</td>
<td></td>
</tr>
<tr>
<td>Renal Vascular Diseases:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Renal artery occlusion</td>
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<td>Renal vein thrombosis</td>
</tr>
<tr>
<td>Tumors Requiring Nephrectomy:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Renal carcinoma</td>
</tr>
<tr>
<td></td>
<td>Wilms' tumor</td>
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<td>Tuberous sclerosis</td>
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<td>Other:</td>
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</tr>
<tr>
<td></td>
<td>Multiple myeloma in CR, and cleared by Oncology</td>
</tr>
<tr>
<td></td>
<td>Macroglobulinemia</td>
</tr>
<tr>
<td></td>
<td>Wegener's disease</td>
</tr>
<tr>
<td></td>
<td>Scleroderma</td>
</tr>
<tr>
<td></td>
<td>Lupus erythematosus</td>
</tr>
<tr>
<td></td>
<td>Polyarteritis (periarteritis nodosa)</td>
</tr>
</tbody>
</table>
## Adult Patient Selection Criteria

<table>
<thead>
<tr>
<th>Kidney-Pancreas</th>
<th>PacifiCare</th>
</tr>
</thead>
</table>
| **Indications** | All of the following:  
| | • 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. |

<table>
<thead>
<tr>
<th>Absolute Contraindications</th>
</tr>
</thead>
</table>
| • Active infection  
| • Seropositive for HIV antibody  
| • 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 |

<table>
<thead>
<tr>
<th>Relative Contraindications</th>
</tr>
</thead>
</table>
| • 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) |
## Adult Patient Selection Criteria

<table>
<thead>
<tr>
<th>Liver (Living or Cadaver)</th>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></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>
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<td>- Decompensation of previously stable liver disease</td>
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<td>- Severe impairment of quality of life directly related to the liver disease</td>
</tr>
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<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>

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

<table>
<thead>
<tr>
<th><strong>Relative Contraindications</strong></th>
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</tr>
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<tbody>
<tr>
<td></td>
<td>Intrahepatic or biliary sepsis</td>
</tr>
<tr>
<td></td>
<td>Portal vein thrombosis</td>
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<tr>
<td></td>
<td>Previous upper quadrant surgery – because of scarring and possible alterations to portal vein architecture</td>
</tr>
<tr>
<td></td>
<td>Stage IV hepatic coma</td>
</tr>
<tr>
<td></td>
<td>Substance abuse (drug, alcohol and nicotine free for 6 months prior to transplantation)</td>
</tr>
</tbody>
</table>
### Liver (Living or Cadaver) Criteria

<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 disease</td>
</tr>
<tr>
<td>• Budd-Chiari syndrome</td>
</tr>
</tbody>
</table>

### Living Donor Selection Criteria

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

#### Liver

<table>
<thead>
<tr>
<th>Indications</th>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td>All of the following:</td>
<td>- End-stage liver disease, which may be characterized by the following:</td>
</tr>
<tr>
<td></td>
<td>- Age ≤ 18</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>
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<td></td>
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</tbody>
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<table>
<thead>
<tr>
<th>Absolute Contraindications</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Active infection</td>
<td></td>
</tr>
<tr>
<td>Seropositive for HIV antibody, unless viral load undetectable by RNA testing</td>
<td></td>
</tr>
<tr>
<td>Active malignancy extending beyond the margins of the liver</td>
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<td>Encephalopathy with evidence of irreversible brain damage</td>
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<td>Congenital anomalies that prevent surgery</td>
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<td>Severe hypoxemia</td>
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<tr>
<td>Severe renal, neurological or cardiopulmonary disease</td>
<td></td>
</tr>
<tr>
<td>Malignancy: see ASTS guideline in appendix 1</td>
<td></td>
</tr>
<tr>
<td>Psychiatric illness that would make compliance with a disciplined 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>
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<td>Stage IV hepatic coma</td>
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<tr>
<td>Substance abuse (patient and/or care giver drug, alcohol and nicotine free for 6 months prior to transplantation)</td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Diseases associated with diminishing liver function</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Extrahepatic biliary atresia</td>
<td></td>
</tr>
<tr>
<td>Biliary atresia</td>
<td></td>
</tr>
<tr>
<td>Primary biliary cirrhosis</td>
<td></td>
</tr>
<tr>
<td>Primary sclerosing cholangitis</td>
<td></td>
</tr>
<tr>
<td>Alpha-1 antitrypsin deficiency disease</td>
<td></td>
</tr>
<tr>
<td>Metabolic disease (Crigler-Najjar Syndrome)</td>
<td></td>
</tr>
</tbody>
</table>
### Adult Patient Selection Criteria

<table>
<thead>
<tr>
<th>Heart</th>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
<td>All of the following:</td>
</tr>
<tr>
<td></td>
<td>• End stage heart disease (NYHA Class III or IV) and a likelihood of a 1-year survival of ≤50%</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>

| **Absolute Contraindications** | |
|-------------------------------| |
| • Active infection            | |
| • Seropositive for HIV antibody| |
| • Irreversible pulmonary hypertension | |
| • Transpulmonary gradient > 16mmHg with use of vasodilators | |
| • Pulmonary artery systolic pressure > 60 mmHg with use of vasodilators | |
| • Diabetes mellitus with end-organ dysfunction | |
| • Irreversible hypertension | |
| • 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** | |
|-------------------------------| |
| • Age ≥ 65 years of age | |
| • Severe hypertension (not of cardiac origin) requiring multiple drug therapy | |
| • Significant peripheral vascular disease | |
| • Cerebroembolic disease | |
| • Pulmonary hypertension | |
| • Chronic obstructive pulmonary disease | |
| • Mean transpulmonary gradient between 13-15 mmHg with use of vasodilators | |
| • 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 | |
| • BMI ≥ 35 | |
| • Cachexia | |
### Heart

<table>
<thead>
<tr>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Severe osteoporosis</td>
</tr>
<tr>
<td>- Any co-existing systemic illness likely to limit or preclude survival and rehabilitation after transplantation</td>
</tr>
<tr>
<td>- Substance abuse (drug, alcohol and nicotine free for 6 months prior to transplantation)</td>
</tr>
</tbody>
</table>

### Diseases associated with diminishing heart function

<table>
<thead>
<tr>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Cardiomyopathy</td>
</tr>
<tr>
<td>- Acute Massive Myocardial Infarction</td>
</tr>
<tr>
<td>- Life-threatening arrhythmias uncontrolled by conventional methods</td>
</tr>
<tr>
<td>- Valvular heart disease</td>
</tr>
<tr>
<td>- Severe limiting angina with diffuse coronary artery disease</td>
</tr>
<tr>
<td>- Severely impaired ventricular function</td>
</tr>
<tr>
<td>- Ischemic heart disease</td>
</tr>
</tbody>
</table>

### Cardiac failure can be defined as

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

<table>
<thead>
<tr>
<th>LVADs</th>
<th>PacifiCare</th>
<th>Absolute Contraindications</th>
<th>Relative Contraindications</th>
</tr>
</thead>
</table>
| **Indications**               | • 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:**  
  • As destination therapy for members with end-stage heart failure, this procedure meets significant cost criteria. Therefore, M+C organization will not be required to assume risk for the costs of service until payments are appropriately adjusted. | • PHP does not specify, since must meet cardiac transplant candidate criteria | • PHP does not specify, since must meet cardiac transplant candidate criteria |

---

**Ventricular Assist Device (LVAD)**

**Indications**

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:**
- As destination therapy for members with end-stage heart failure, this procedure meets significant cost criteria. Therefore, M+C organization will not be required to assume risk for the costs of service until payments are appropriately adjusted.
# Pediatric Patient Selection Criteria

<table>
<thead>
<tr>
<th>Heart Patient Selection Criteria</th>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
<td>All of the following:</td>
</tr>
<tr>
<td></td>
<td>- End stage heart disease</td>
</tr>
<tr>
<td></td>
<td>- Age ( \leq ) 18 years of age</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>

| **Absolute Contraindications**  | - Active infection |
|                                 | - Seropositive for HIV antibody |
|                                 | - 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 \( \geq \) 1.5 |
|                                 | - Insulin dependent diabetes mellitus |
|                                 | - Diverticulitis (recent history) or active peptic ulcer disease |
|                                 | - Severe chromosomal abnormalities and associated developmental delay |
|                                 | - BMI \( \geq \) 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) |
Diseases/processes associated with diminishing heart function:
- Cardiomyopathy (dilated, hypertrophic, restrictive)
- Congenital Heart disease
- Retransplantation

The following may be helpful in identifying the child or adolescent with end-stage cardiac disease who should benefit from a heart transplant:
- Progressive deterioration of ventricular function or functional status despite optimal medical therapy, including digitalis, diuretics and ACE inhibitors
- Growth failure secondary to CHF unresponsive to conventional medical therapy
- Malignant arrhythmias or survival of cardiac arrest, unresponsive to conventional medical therapy and not likely to be successfully treated with implantable cardioverter defibrillator
- Need for ongoing intravenous inotropic support
- Unacceptable poor quality of life
- Progressive pulmonary HTN that would predictably preclude heart transplantation at a later date
### Adult Patient Selection Criteria

<table>
<thead>
<tr>
<th>Lung</th>
<th>PacifiCare</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
<td><strong>All of the following:</strong></td>
</tr>
<tr>
<td></td>
<td>- Presence of end-stage lung disease refractory to other available medical and surgical approaches</td>
</tr>
<tr>
<td></td>
<td>- Projected life expectancy of &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><strong>Diseases associated with need for single lung transplant:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Idiopathic pulmonary fibrosis</td>
</tr>
<tr>
<td></td>
<td>- COPD due to emphysema</td>
</tr>
<tr>
<td></td>
<td>- Alpha 1 Antitrypsin Deficiency</td>
</tr>
<tr>
<td></td>
<td>- Primary pulmonary HTN</td>
</tr>
<tr>
<td></td>
<td>- Sarcoidosis without systemic disease</td>
</tr>
<tr>
<td></td>
<td>- Radiation fibrosis</td>
</tr>
<tr>
<td></td>
<td>- Bronchiectasis</td>
</tr>
<tr>
<td></td>
<td>- Bronchiolitis obliterans</td>
</tr>
<tr>
<td></td>
<td>- Secondary pulmonary HTN due to correctable congenital heart defects</td>
</tr>
<tr>
<td><strong>Disease associated with need for double Lung transplant</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Cystic fibrosis</td>
</tr>
<tr>
<td></td>
<td>- Bronchiectasis</td>
</tr>
<tr>
<td></td>
<td>- COPD due to emphysema</td>
</tr>
<tr>
<td></td>
<td>- Alpha 1 Antitrypsin Deficiency &lt; 50 years</td>
</tr>
<tr>
<td></td>
<td>- Primary pulmonary HTN</td>
</tr>
<tr>
<td></td>
<td>- Secondary pulmonary HTN due to correctable congenital heart defects</td>
</tr>
<tr>
<td><strong>Absolute Contraindication</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Irreversible co-existing end-stage organ failure</td>
</tr>
<tr>
<td></td>
<td>- Active malignant disease</td>
</tr>
<tr>
<td></td>
<td>- Uncontrolled hypertension that requires more than two drugs for adequate control</td>
</tr>
<tr>
<td></td>
<td>- Malignancy: see ASTS guideline in appendix 1</td>
</tr>
<tr>
<td></td>
<td>- Cerebroembolic disease</td>
</tr>
<tr>
<td></td>
<td>- Severe cardiac, renal or hepatic disease</td>
</tr>
<tr>
<td></td>
<td>- Insufficient cardiac reserve:</td>
</tr>
<tr>
<td></td>
<td>- Non-correctable CAD</td>
</tr>
<tr>
<td></td>
<td>- Recent MI</td>
</tr>
<tr>
<td></td>
<td>- Ejection fraction &lt; 50%</td>
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<td></td>
<td>- Severe renal impairment</td>
</tr>
<tr>
<td></td>
<td>- Creatinine &gt; 2mg/dl</td>
</tr>
<tr>
<td></td>
<td>- Creatinine clearance &lt; 50ml/min</td>
</tr>
<tr>
<td></td>
<td>- Severe hepatic dysfunction</td>
</tr>
</tbody>
</table>
## Solid Organ Transplantation Criteria – Updated 08/24/04

### Lung

<table>
<thead>
<tr>
<th>PacifiCare</th>
<th></th>
</tr>
</thead>
<tbody>
<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>• Active peptic ulcer disease</td>
<td></td>
</tr>
<tr>
<td>• Active infection</td>
<td></td>
</tr>
<tr>
<td>• Seropositive for HIV antibody</td>
<td></td>
</tr>
<tr>
<td>• Irreversible coagulopathies</td>
<td></td>
</tr>
<tr>
<td>• Neuromuscular and musculoskeletal disorders that prohibit ambulation</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>

### 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><strong>Indications</strong></td>
<td>All of the following</td>
</tr>
<tr>
<td>• End-stage lung disease refractory to other available medical and surgical approaches</td>
<td></td>
</tr>
<tr>
<td>• Declining functional status</td>
<td></td>
</tr>
<tr>
<td>• Age ≤ 18 years of age</td>
<td></td>
</tr>
<tr>
<td>• Pulmonary capacity suggestive of a short life expectancy, &lt; 2 years</td>
<td></td>
</tr>
<tr>
<td>• Stable psychosocial status</td>
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<tr>
<td>• Willingness to comply (patient and/or caregiver) with medical advice</td>
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<table>
<thead>
<tr>
<th>Absolute Contraindication</th>
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<tbody>
<tr>
<td>• Irreversible co-existing end-stage organ failure</td>
<td></td>
</tr>
<tr>
<td>• Malignancy: see ASTS guideline in appendix 1</td>
<td></td>
</tr>
<tr>
<td>• Active infection</td>
<td></td>
</tr>
<tr>
<td>• Seropositive for HIV antibody</td>
<td></td>
</tr>
<tr>
<td>• Severe thoracic scoliosis that affects chest mechanics</td>
<td></td>
</tr>
<tr>
<td>• Portal hypertension</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>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Relative Contraindications</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• High dose steroid therapy</td>
<td></td>
</tr>
<tr>
<td>• BMI ≥ 35</td>
<td></td>
</tr>
<tr>
<td>• Cachexia</td>
<td></td>
</tr>
</tbody>
</table>
### Lung

**PacifiCare**

- Diabetes mellitus
- Current significant acute illness that is likely to contribute to a poor outcome
- Co-existing end-stage organ disease
- Left ventricular dysfunction
- Congestive cardiomyopathy
- Substance abuse (caregiver and/or patient drug, alcohol and nicotine free for 6 months prior to evaluation)

### Diseases associated with diminishing lung function:

- Pulmonary fibrosis
- Interstitial lung disease
- Idiopathic pulmonary alveolar microlithiasis
- Pulmonary alveolar proteinosis
- Cystic fibrosis
- Obliterative bronchiolitis
- Bronchopulmonary deficiencies
- Congenital surfactant deficiencies
- Collagen vascular disease
- Pulmonary vascular disease
- Primary pulmonary HTN
- Eisenmenger’s syndrome
- Inadequate pulmonary vascular bed
- Congenital diaphragmatic hernia

---

### Adult Patient Selection Criteria

#### Heart - Lung

**Indications**

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

#### 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
### Heart - Lung

- 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
- Seropositive for HIV antibody
- 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 ≥ 50 mg of prednisone per day due to high likelihood of tracheal and bronchial dehiscence

### Relative Contraindications

- Age ≥ 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
- BMI ≥ 35
- 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>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>
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</tr>
<tr>
<td>Large, infiltrating (≥ 5 cm)</td>
<td>2-5 years</td>
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<tr>
<td>Wilm’s tumor</td>
<td>2 years</td>
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<tr>
<td>Anogenital</td>
<td></td>
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<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>Karporsi’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>
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<tr>
<td>Dukes A or B1</td>
<td>2 years</td>
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<tr>
<td>Higher stages</td>
<td>5 years</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>
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<tr>
<td>Leukemia</td>
<td>2 years</td>
</tr>
<tr>
<td>Skin</td>
<td></td>
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<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>
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</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

Disclaimer
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A. BACKGROUND

1. 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 includes 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.

Out-of-Area Emergency/Urgently Needed Services and Transportation – Secure Horizons
2. 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.

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 Insurance (COI). If there is a discrepancy between this guideline and the member’s EOC/SOB/COI, the member’s EOC/SOB/COI provision will govern.

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

1. Emergency/urgently needed services
   a. Requested services are medically necessary
   b. Requested services are considered covered benefits by Secure Horizons
   c. Requested services are necessary to enable the member to return to the service area, or to prevent serious deterioration of the member’s condition
   d. Determine treatment plan. The treating physician must be in agreement with the Plan’s proposed treatment plan. If not, a plan physician, ideally with privileges at the facility, who will assume care of that member and authorize transfer of the member back to the service area must be sought. If not, the Plan must again 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.
2. Transportation  
   a. 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

   Note: Ambulance services are not covered for any of the following:

   • Member initiated for social or convenience reasons that are not primarily medical (e.g., moving to be closer to family)
   • Moving from one contracting facility to another contracting facility unless the transfer is necessary to deliver medical services

Management of the patient should be based on the following:

1. Post-stabilization care cannot be limited except when there is a Plan 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
Medical Management Guideline

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

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
   Evidence of Coverage 2003 for AZ, CA, CO, NV, OK, OR, TX, WA.
   Konowiecki & Rank LLP Memorandum Out of Area Benefit Determinations

Approved by: Medical Management Guideline Committee
Date Approved: 03/16/04

Out-of-Area Emergency/Urgently Needed Services and Transportation – Secure Horizons
Medical Management Guideline

TITLE: Verteporfin (Visudyne™) for Ocular Photodynamic Therapy (OPT)

Authorized By: Medical Management Guideline Committee

Approval Date: 01/28/03       Revision Date: 05/25/04

Disclaimer
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A. BACKGROUND

1. Description
Ocular Photodynamic Therapy (OPT) is a treatment for wet form age-related macular degeneration (AMD). OPT combines a light-sensitive medication, verteporfin (Visudyne™), and laser to destroy diseased tissue and abnormal blood vessels in the eye. Verteporfin, a benzoporphyrin derivative, is an intravenous lipophilic photosensitive drug. Verteporfin was first approved by the Food and Drug Administration on April 12, 2000, for use in photodynamic therapy for the treatment of age-related macular degeneration (wet form) in patients with predominantly classic subfoveal choroidal neovascularization. Verteporfin is the first drug approved for OPT. Effective July 1, 2001, verteporfin was approved for inclusion in the United States Pharmacopeia (USP) (CMS a; CMS b).
2. **Benefit**

Secure Horizons covers verteporfin for OPT when determined to be medically necessary and specific criteria are met. See the Secure Horizons Benefit Interpretation Policy (BIP) Vision Care 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 Insurance (COI). If there is a discrepancy between this guideline and the member’s EOC/SOB/COI, the member’s EOC/SOB/COI provision will govern.

**Setting:** Outpatient

**Criteria:**

1. Verteporfin for ocular photodynamic therapy (OPT) is indicated when furnished intravenously incident to a physician’s service when all of the following is present (CMS a):
   - Fluorescein angiographic evidence of predominantly classic choroidal neovascularization (CNV) secondary to age-related macular degeneration (wet form), pathologic myopia, or presumed ocular histoplasmosis
   - CNV extends below the geometric center of the foveal avascular zone
   - Area of CNV is at least 50% of the area of the total lesion

2. Verteporfin for ocular photodynamic therapy (OPT) is indicated when furnished intravenously incident to a physician's service when either of the following is present (CMS c):
   a. Subfoveal occult with no classic choroidal neovascularization (CNV) associated with age-related macular degeneration (wet form)
   b. Subfoveal minimally classic choroidal neovascularization (CNV) associated with age-related macular degeneration (wet form)

For indications 2a and 2b, all of the following criteria have to be met (CMS c):
- The lesions are small (4 disk areas or less in size) at the time of initial treatment or within the 3 months prior to initial treatment
- The lesions have shown evidence of progression within the 3 months prior to
Medical Management Guideline

initial treatment. Evidence of progression must be documented by deterioration of visual acuity (at least 5 letters on a standard examination), lesion growth (an increase in one disk area), or the new appearance of blood in the lesion

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://cms.hhs.gov/manuals/06_cim/ci35.asp#_35_100

Available at http://cms.hhs.gov/manuals/06_cim/ci45.asp#sect_45_30

Centers for Medicare and Medicaid Services (CMS c). Medicare Coverage Database. Decision Memo for Ocular Photodynamic Therapy with Verteporfin for Macular Degeneration (CAG-00066R3).
Available at http://cms.hhs.gov/mcd/viewdecisionmemo.asp?id=101

Approved by: Medical Management Guideline Committee
Date Approved: 05/25/04

Verteporfin (Visudyne™) for Ocular Photodynamic Therapy (OPT) – Secure Horizons
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 2004).
Vision rehabilitation services are provided by a multi-disciplinary team, usually consisting of an optometrist or ophthalmologist and other trained individuals, such 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 9, 2004:

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 Insurance (COI). If there is a discrepancy between this guideline and the member’s EOC/SOB/COI, the member’s EOC/SOB/COI 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 2004).

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.

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D. REFERENCES


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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), Orthotics, Prosthetics, 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 Insurance (COI). If there is a discrepancy between this guideline and the member’s EOC/SOB/COI, the member’s EOC/SOB/COI 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
- 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

b. Dermagraft

Dermagraft is a cryopreserved dermal substitute composed of fibroblasts, extracellular matrix, and a bioabsorbable scaffold. The manufacturing process involves the seeding of human fibroblasts derived from human male neonatal foreskin into a polyglactin mesh scaffold. The fibroblasts secrete human dermal collagen, matrix proteins, growth factors, and cytokines to create a 3-dimensional human dermal substitute containing metabolically active, living cells. Dermagraft is designed to facilitate healing by stimulating the ingrowth of fibrovascular tissue from the wound bed and reepithelization from the wound edges. As it does not close the wound, Dermagraft is marketed for stimulating the healing of chronic lesions, such as diabetic foot ulcers, rather than for the closing of burn wounds (HAYES 2004).

Dermagraft 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):

- Full-thickness, diabetic ulcer(s) of more than 6 weeks duration (CMS 2002)
Medical Management Guideline

- No tendon, muscle, capsule, or bone exposure (HAYES 2004; CMS 2002)
- Adequate blood supply to the involved foot (CMS 2002)
- Ulcer(s) have not adequately responded to standard therapy (HAYES 2004; CMS 2002)

4. Negative Pressure Wound Therapy (NPWT) Pump

An NPWT pump and supplies are recommended for treating ulcers and wounds in the home setting when the following criterion is met (DMERC 2003):

- 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

Treatment of Wounds – Secure Horizons
Medical Management Guideline

4) For venous insufficiency ulcers:
   • Compression bandages and/or garments have been consistently applied
   • Leg elevation and ambulation have been encouraged

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 I

Staging of Pressure Ulcers (DMERC 2003)

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:

CO, OK & TX:
http://www.palmettogba.com/palmetto/LMRPs_DMERC.nsf/$$ViewTemplate+for+Final?ReadForm
### Assessment

<table>
<thead>
<tr>
<th>Frequency of visits</th>
<th>Schedule regular visits, every 1-6 months.</th>
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<tbody>
<tr>
<td><strong>At each regular or unplanned visit, assess:</strong></td>
<td></td>
</tr>
<tr>
<td>Signs &amp; Symptoms</td>
<td>Signs and symptoms of asthma</td>
</tr>
<tr>
<td>Pulmonary Function</td>
<td>Lung sounds, respiratory status and peak flow</td>
</tr>
<tr>
<td></td>
<td>Use appropriate reference populations for adolescents</td>
</tr>
<tr>
<td>Functional Status</td>
<td>Quality of life/ functional status (missed school/ work, reduced activity, sleep disturbances)</td>
</tr>
<tr>
<td>Medications</td>
<td>Usage, understanding, compliance and technique</td>
</tr>
<tr>
<td>Exacerbation History</td>
<td>History of exacerbations since last visit</td>
</tr>
<tr>
<td>Severity</td>
<td>Classify Asthma Severity (See attachments A, B)</td>
</tr>
<tr>
<td>Referral to Specialist (Pulmonologist, Allergist)</td>
<td>Recommended for patients &gt; 3 yrs of age if there are difficulties achieving or maintaining control of asthma or if the patient requires step 4 care. Consider for patients who require step 3 care. Recommended for patients &lt; 3 yrs of age if the child requires step 3 or 4 care. Consider if the child requires step 2 care</td>
</tr>
<tr>
<td>Psychosocial</td>
<td>For patients with significant psychiatric, psychosocial, or family problems that interfere with therapy, consider a Mental Health referral</td>
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</table>

### Testing

<table>
<thead>
<tr>
<th>Spirometry</th>
<th>Spirometry is recommended</th>
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<tbody>
<tr>
<td></td>
<td>(1) at the time of initial assessment,</td>
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<td></td>
<td>(2) after treatment is initiated and symptoms and PEF have stabilized,</td>
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<td></td>
<td>(3) at least every 1 to 2 years,</td>
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<td></td>
<td>(4) to evaluate the response to change in therapy</td>
</tr>
<tr>
<td>Peak Flow Monitoring</td>
<td>Monitor Peak Expiratory Flow (PEF) at each routine visit. Useful for patients generally &gt; 5 yrs old</td>
</tr>
<tr>
<td></td>
<td>• Instruct patients how to establish their personal best PEF and use as the basis for their action plan.</td>
</tr>
<tr>
<td></td>
<td>• Check technique every visit.</td>
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<tr>
<td></td>
<td><strong>Short-term</strong> monitoring (twice daily for 2-3 weeks):</td>
</tr>
<tr>
<td></td>
<td>• to establish the patient’s personal best PEF;</td>
</tr>
<tr>
<td></td>
<td>• evaluate response to therapy changes;</td>
</tr>
<tr>
<td></td>
<td>• identify relationship between changes in PEF and exposure to irritants or allergens;</td>
</tr>
<tr>
<td></td>
<td>• during exacerbations</td>
</tr>
</tbody>
</table>
### Clinical Practice Guidelines – Outpatient Management of Asthma

**Long-term** daily monitoring is recommended for patients with:
- moderate-to-severe persistent asthma,
- poor symptom perception,
- a history of severe exacerbations

For patients with asthma symptoms but normal spirometry, assessment of diurnal variation in PEF over 1-2 weeks is recommended

### Allergens

For patients with persistent asthma, consider skin testing or in vitro testing to assess sensitivity to perennial indoor allergens. Immunotherapy may be appropriate for some patients.

### Medications

Severity determines treatment. See: Stepwise Approach to Managing Asthma -Attachment A (Adults and Ages > 5 yrs), Attachment B (Infants & children ≤ 5 yrs)

#### Stepwise Approach

Use a Stepwise Approach to gain and maintain control
- To gain control, either
  1) start with high-dose therapy and step down *(preferred)* or
  2) start at appropriate step and gradually step-up therapy

Gain control as quickly as possible, then step down treatment to the least medication necessary to maintain control
- Monitor to ensure that control is achieved

#### All Asthmatics

Need an inhaled short-acting beta₂-agonist for exacerbations.

#### Persistent Asthma

Requires both long-term control and quick relief medications

#### Intermittent Asthma

No daily long-term control medications
- Quick relief medications: Short acting inhaled beta₂- agonists as needed to treat symptoms
- Inhaled beta₂- agonists, cromolyn or nedocromil shortly before exercise (5-15 mins) for Exercise Induced Bronchospasm (EIB)

### Medication Class: Long-term Control Medications

#### Steroids

**Inhaled corticosteroids (ICS)** are the most potent inhaled anti-inflammatory agent; most effective long-term therapy for persistent asthma.
- ICS are well tolerated and safe at the recommended dosages.
- Before increasing ICS dose, add-on therapy with another class of controller is preferred
- Higher doses of ICS may be associated with possible, but not predictable, growth retardation (children) and systemic effects
  - Local adverse effects: Oral candidiasis, dysphonia, reflex cough and bronchospasm
  - Use Spacer/holding chamber, and mouth washing after use, to decrease local side effects and systemic absorption
**Non Steroid**

Long-acting inhaled beta\(_2\)-agonists:
- Adjunctive therapy to ICS for maintaining control
- Also prevents exercise-induced bronchospasm (EIB)
- Does not replace anti-inflammatory therapy
- Do not use to treat acute symptoms or exacerbations
- Inhaled are longer acting and have fewer side effects than oral sustained release beta\(_2\)-agonists

Cromolyn Sodium and Nedocromil:
- Anti-inflammatory agents with sound safety profiles
- Can be used as preventive treatment prior to exercise or unavoidable exposure to known allergens
- Clinical response is less predictable than response to ICS

Leukotriene modifiers
- Although further clinical study is needed to establish role in therapy, may be considered as an alternative to low-dose ICS for long-term control of mild persistent asthma; alternative adjunctive therapy for moderate:
  - Montelukast: adults and children ≥2yrs
  - Zafirlukast: adults and children ≥5 yrs
    - Monitor prothrombin times closely for patients receiving zafirlukast and warfarin
  - Zileuton: adults and children ≥12yrs
    - Liver enzyme monitoring is recommended with Zileuton; monitor warfarin, propanolol and theophylline dosing

Methylxanthines: (Theophylline)
- Sustained release theophylline as adjuvant to ICS for long-term control and prevention of symptoms, especially nocturnal symptoms
- Monitor serum concentration routinely due to significant toxicities

**Medication Class: Initial Relief Medications**

Short-acting inhaled beta\(_2\)-agonists
- Short-acting inhaled beta\(_2\)-agonists (IBA) are the most effective medication for relieving acute bronchospasm; drug of choice for acute symptoms and exacerbations, and preventing EIB
  - Increasing use or the use of >1.2 beta\(_2\)-agonist canisters/month may indicate inadequate control
  - Regularly scheduled, daily use of short-acting beta\(_2\)-agonists is generally not recommended
### Systemic Corticosteroids

**Systemic corticosteroid**, for moderate to severe exacerbations. Use at lowest effective dose. Continue short-term therapy until patient achieves 80% PEF personal best or symptoms resolve (usually 3-10 days). Potential adverse side-effects are generally not observed during short course of therapy. Time to action: 2-3 hours.

### Other:

**Anticholinergic**

Ipratropium bromide may provide some additive benefit to inhaled beta₂-agonists in severe asthma exacerbations. Alternative bronchodilator for patients who do not tolerate inhaled beta₂-agonists. Time to action: 45 minutes.

**Influenza Vaccine**

Recommended annually for patients with persistent asthma

**Varicella Vaccine**

Recommended for:
- children ≥12months (See Preventive Health Guidelines)
- children requiring episodic systemic corticosteroid therapy and who have not had clinical varicella

Do not administer to patients on immunosuppressive doses, unless the dosage is discontinued for >1 month

**Aerosol Delivery Devices**

**MDI**: For > 5yrs old. (< 5 yrs old with spacer/ holding chamber and face mask for some children)

**Breath-actuated MDI**: For > 5yrs old

**DPI**: Most consistent effects with > 5yrs. May use for 4 yr olds

**Spacer/Holding Chamber**: For > 4yrs old; ≤ 4yrs, with a spacer/ face mask.

Recommend use with ICS by MDI

**Nebulizer with face mask**: For ≤ 2yrs and patients who cannot use other devices. Delivery method of choice for Cromolyn

- Optimal inhaler technique > 5 yrs old: Either open mouth with inhaler 1-2” away or with spacer/holding chamber
- Children’s ability to use different devices may vary considerably. Tailor the delivery device to the child.
### Exacerbations

| Acute Exacerbations | Severity determines the treatment. Primary therapies include:  
|---------------------|---------------------------------------------------------------|
|                     | • Repetitive administration of short-acting beta₂-agonist  
|                     | • Early introduction of systemic corticosteroids  
|                     | • Oxygen supplementation  
|                     | 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  
|                     | Early treatment, according to a written action plan to guide self-management, is especially important for patients with moderate to severe persistent asthma |

| Exacerbations due to Viral Illness | Mild symptoms: Consider Inhaled Beta₂-agonist q4-6 hrs x24hrs, or longer as needed.  
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<td></td>
<td>• If therapy needs to be repeated more than q6 weeks, a step-up in long-term care is recommended</td>
</tr>
</tbody>
</table>

### Education and Counseling

| Education & Self-management | Teach self-management, and reinforce at every opportunity:  
|-----------------------------|--------------------------------------------------------------------------|
|                             | • Basic facts about asthma  
|                             | • Roles of medications  
|                             | • Skills: inhaler/spacer/holding chamber use, self-monitoring  
|                             | • Environmental and control measures  
|                             | • When and how to take rescue actions  
|                             | Children ≥ 2 yrs old can begin learning about their asthma |

| Allergens and Irritants | Counsel all patients with asthma to avoid:  
|-------------------------|--------------------------------------------------------------------------|
|                         | • Exposure to allergens to which they are sensitive.  
|                         | • Exposure to environmental tobacco smoke.  
|                         | • Exertion when levels of air pollution are high.  
|                         | • Use of beta-blockers.  
|                         | • Sulfite-containing and other foods to which they are sensitive  
|                         | Other factors that can contribute to asthma severity: rhinitis, sinusitis, GERD, some medications, viral respiratory infections.  
|                         | Counsel adult patients with severe persistent asthma, nasal polyps, or a history of sensitivity to aspirin or nonsteroidal anti-inflammatories regarding the risk of severe and even fatal exacerbations from using these drugs. |

| Action Plan | The use of written self-management (action) plans has been shown to reduce morbidity with both adults and children.  
|-------------|--------------------------------------------------------------------------|
|             | Develop a written Action Plan with all asthmatic patients to guide:  
|             | • Self-management,  
|             | • Recognition of early signs, |
### PacifiCare Health Plans

**Asthma Practice Guidelines: Outpatient Management of Asthma 2002**

- Appropriate intensification of therapy,
- Removal or allergic or irritant precipitants, and
- Prompt communication between patient and clinician

Base the written action plan on signs and symptoms and/or PEF. Instruct patient how to use their plan.

For patient education, using the “traffic signal” Peak Flow Zone system for Action Plans, with specific instructions for action in each zone, may facilitate the patient’s self-management:

- **Green Zone** (80-100% of personal best) = Good control
- **Yellow Zone** (e.g. 60-<80%) = Caution
- **Red Zone** (e.g. <60%) = Danger. Medical Alert

Caretakers of children with asthma (teachers, coaches, sitters, etc.) should have a copy and understand the action plan.

Provide appropriate patients with a daily asthma diary

### Smoking

Advise patients not to smoke, and to avoid smoke exposure. Tobacco smoke is a major precipitant of asthma symptoms in children and adults

### Special Considerations

#### Antibiotics

Not recommended for treatment of acute asthma exacerbations except as needed for comorbid conditions

#### Beta Blockers

Nonselective beta blockers can cause asthma symptoms in 25% of asthmatic patients who take them and thus nonselective beta blockers should be avoided with asthma patients

#### MAOIs

Avoid sympathomimetic bronchodilators.

### Children

- **Infants and Young Children:**
  - Diagnosis in infants can be difficult.
  - Assess difficulty breathing, changes in respiration rate, altered sleep patterns, retractions, irritability, lethargy, decreased appetite, weight loss.
  - Consider a diagnostic trial of inhaled bronchodilators and anti-inflammatory medication

Consider long-term control therapy for: > 3 wheezing episodes in the past year that lasted > 1 day and affected sleep and risk factors for development of asthma present

- Risk factors: parental history of asthma or diagnosis of atopic dermatitis or 2 of a) diagnosed allergic rhinitis, b) wheezing apart from colds, c) peripheral blood eosinophilia

- **School-age Children and Adolescents:**
  - Instruct parents and child in use of all medications, devices.
  - Provide a written asthma management plan for the student’s school (including action plan, long-term control medication and prevention of EIB if appropriate, and trigger factors to avoid)
Promote active participation in physical activities, exercise, and sports. Older children should be allowed to carry and self-administer quick relief medications (with physician and parent approval).

**Older Adults**
Due to a high prevalence of other obstructive lung diseases, a 2-3 week trial of systemic steroids will determine disease reversibility
- Asthma medications may have increased adverse effects in the elderly; adjust as needed
- Medications for other diseases may exacerbate asthma

**Pregnancy**
Adequate control is essential during pregnancy. For most drugs used to treat asthma and rhinitis, there is little to suggest an increased risk to the fetus. (except brompheniramine, epinephrine, and alpha-adrenergic compounds)

**Managing Special Situations**
- **Seasonal Asthma:** Treat according to the step-wise approach for long-term management.
- **Cough Variant:** Seen especially in young children, Cough is the principal symptom, occurring frequently at night. Monitor day and afternoon PEF. Therapeutic trials with ICS or bronchodilator may be helpful in diagnosis. Treat according to step-wise approach to long-term management of asthma.
- **Prolonged night cough:** may also be due to allergic rhinitis, sinusitis, GERD
- **Exercise-Induced Bronchospasm (EIB):** Anticipate in all asthma patients. Teachers and coaches should be notified that a child has EIB. Recommended treatment is inhaled beta2-agonists (effective with 80% of patients), cromolyn sodium or nedocromil shortly before exercise (5-15 minutes).
- **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. If systemic corticosteroids received during past 6 months, hydrocortisone IV should be given during surgical period.

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. This guideline was developed using published clinical information and is not intended to imply coverage, limitations or exclusions. Please see individual plan coverage.
References

American Psychiatric Association: Practice Guideline for the Treatment of Patients with Major Depressive Disorder (Revision). American Journal of Psychiatry 2000; 157 (April supplement)


PHP 2002 Preventive Health Recommendations
### Stepwise Approach to Managing Asthma Long Term for Adults and Children > 5 years old

#### Step 1: Mild Intermittent
(PEF ≥80% Predicted)
PEF variability < 20%

- Symptoms ≤ 2 days/week
- Nocturnal symptoms ≤ 2 nights/month
- Asymptomatic and normal PEF between exacerbations
- Exacerbations brief (from a few hours to a few days); intensity may vary

#### Step 2: Mild-Persistent
(PEF ≥80% Predicted)
PEF variability 20-30%

- Symptoms > 2/ week but < 1x/day
- Nocturnal symptoms 3-4/ month
- Exacerbations may affect activity

#### Step 3: Moderate-Persistent
(PEF >60-<80% Predicted)
PEF variability >30%

- Daily symptoms
- Nocturnal symptoms >1x/wk
- Daily use of inhaled short-acting beta2-agonist
- Exacerbations affect activity
- Exacerbations ≥ 2 times a week; may last days

#### Step 4: Severe-Persistent
(PEF ≤60% Predicted)
PEF variability >30%

- Continual symptoms
- Frequent nocturnal symptoms
- Limited physical activity
- Frequent exacerbations

### Therapy*

- **Quick Relief:** Short-acting inhaled beta2-agonist as needed
- **Long Term Control, daily:**
  - Inhaled corticosteroids (low to medium dose) AND long-acting beta2-agonist (preferred)
  - Alternative Treatment
    - Inhaled corticosteroids (increased within medium-dose range)
    - Inhaled corticosteroids (low-medium dose) and either leukotriene modifier or theophylline
    - If needed (particularly in patients with recurring severe exacerbations)
      - Inhaled corticosteroid (medium dose) and long-acting beta2-agonist (preferred)
      - Or, alternative
      - Inhaled corticosteroid (medium) and either leukotriene modifier or theophylline

### Education*

- Teach basic facts about asthma
- Teach inhaler/spacer/holding chamber technique
- Discuss roles of medications
- Develop self-management plan
- Develop action plan for when and how to take rescue actions, especially for patients with a history of severe exacerbations
- Discuss appropriate environmental control measures to avoid exposure to known allergens and irritants

---

**Step Down**
Review treatment every 1 to 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 (avoidance of allergens or other factors that contribute to asthma severity).

*All therapy should include patient education about prevention (including environmental control where appropriate) as well as control of symptoms.*
**Attachment B**

**Stepwise Approach to Managing Infants and Children 0-5 years old with Acute or Chronic Asthma**

**Step 1**
Mild Intermittent (PEFR>80% Predicted)

- Symptoms ≤ 2 days/week
- Nocturnal symptoms ≤ 2 nights/month
- Asymptomatic and normal PEF between exacerbations
- Exacerbations brief (from a few hours to a few days); intensity may vary

**Therapy**
Quick Relief: Inhaled short-acting beta₂-agonist as needed (≤3x/day)
AND
Long Term Control, daily:
- Inhaled corticosteroid (low dose) with nebulizer or MDI with spacer/holding chamber and face mask (preferred)
  - Alternative Therapy
    - Cromolyn sodium (nebulizer preferred; or MDI)
    - Leukotriene receptor antagonist

**Education**
- Teach basic facts about asthma
- Teach inhaler/spacer/holding chamber technique
- Discuss roles of medications
- Develop self-management plan
- Develop action plan for when and how to take rescue actions, especially for patients with a history of severe exacerbations
- Discuss appropriate environmental control measures to avoid exposure to known allergens and irritants
- Consider asthma specialist referral for children < 3 yrs for Step 2 Care

**Step 2**
Mild-Persistent (PEFR>80% Predicted)

- Symptoms > 2/week but < 1/day
- Nocturnal symptoms 3-4 nights/month
- Exacerbations may affect activity

**Therapy**
Quick Relief: Inhaled short-acting beta₂-agonist as needed (≤3x/day)
AND
Long Term Control, daily:
- Inhaled corticosteroid (medium dose) as monotherapy (preferred)
  - Or
  - Inhaled corticosteroid (low dose) AND long-acting inhaled beta₂-agonist (preferred)
  - Alternative Treatment
    - Inhaled corticosteroids (low dose) and either leukotriene receptor antagonist or theophylline

If needed (particularly in patients with recurring severe exacerbations)
- Inhaled corticosteroid (medium dose) and long-acting beta₂-agonist (preferred)
  - Or, alternative
  - Inhaled corticosteroid (medium) and either leukotriene receptor antagonist or theophylline

**Education**
Step 1 actions plus:
- Teach self-monitoring/peak flow meter use
- Refer to group education if available; asthma specialist
- Review and update self-management plan

**Step 3**
Moderate-Persistent (PEFR 60-80% Predicted) Poor symptom control with Step 2

- Daily symptoms
- Nocturnal symptoms ≥ 1 night/week
- Daily use of inhaled short-acting beta₂-agonist and
- Exacerbations affect activity

**Therapy**
Quick Relief: Inhaled short-acting beta₂-agonist as needed (≤3x/day)
AND
Long Term Control, daily:
- Inhaled corticosteroid (high dose) AND long-acting inhaled beta₂-agonists
  - AND, if needed
    - Systemic corticosteroids (2mg/kg/day, generally do not exceed 60mg/day)
      - (Make repeat attempts to reduce systemic corticosteroids and maintain control with high-dose inhaled corticosteroids)

**Education**
Steps 2 and 3 actions plus:
- Refer to individual education counseling, asthma specialist

**Step 4**
Severe-Persistent (PEFR <60% Predicted)

- Continual symptoms
- Frequent nocturnal symptoms
- Limited physical activity
- Frequent exacerbations

**Therapy**
Quick Relief: Inhaled short-acting beta₂-agonist as needed (<3x/day)
AND
Long Term Control, daily:
- Inhaled corticosteroid (low dose) with nebulizer or MDI with spacer/holding chamber and face mask (preferred)
  - Alternative Therapy
    - Cromolyn sodium (nebulizer preferred; or MDI)
    - Leukotriene receptor antagonist

**Education**
Step 1 actions plus:
- Teach self-monitoring/peak flow meter use
- Refer to group education if available; asthma specialist
- Review and update self-management plan

**Step Down**
Review treatment every 1 to 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 (avoidance of allergens or other factors that contribute to asthma severity).

* All therapy should include patient/parent education about prevention (including environmental control where appropriate) as well as control of symptoms.
Clinical Practice Guidelines – CVD Prevention in Women

**STRATEGIES FOR CLINICAL PRACTICE**

<table>
<thead>
<tr>
<th>Risk Group</th>
<th>Framingham Global Risk</th>
<th>Clinical Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Risk</td>
<td>&gt;20%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Established CHD</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cerebrovascular disease</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Peripheral arterial disease</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Abdominal aortic aneurysm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Diabetes mellitus</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chronic kidney disease</td>
</tr>
</tbody>
</table>

- 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.
### 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

### CLINICAL RECOMMENDATIONS

<table>
<thead>
<tr>
<th>Lifestyle Interventions</th>
</tr>
</thead>
<tbody>
<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>
</tbody>
</table>
**Clinical Recommendations**

<table>
<thead>
<tr>
<th>Major Risk Factor Interventions</th>
<th>Blood pressure: Encourage an optimal blood pressure of 120/80mmHg through lifestyle approaches (Class I, Level B). Pharmacotherapy is indicated when blood pressure is &gt;140/90mmHg. Thiazide diuretics should be a part of the drug regimen for most patients unless contraindicated (Class I, Level A).</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lipids: Optimal levels of lipids and lipoproteins in women are LDL-C &lt;100mg/dL, HDL-C &gt;50mg/dL, triglycerides &lt;150mg/dL and non-HDL-C (total cholesterol minus HDL) &lt;130mg/dL and should be encouraged through lifestyle approaches (Class I, Level B).</td>
</tr>
<tr>
<td></td>
<td>• High Risk Women:</td>
</tr>
<tr>
<td></td>
<td>• If LDL-C is elevated, saturated fat intake should be reduced to &lt;7% of calories, cholesterol to &lt;200mg/d, and trans fatty acid intake should be reduced.</td>
</tr>
<tr>
<td></td>
<td>• Initiate LDL-C lowering therapy (preferably a statin) simultaneously with lifestyle therapy if LDL-C &gt;100mg/dL (Class I, Level B) and initiate statin therapy in high risk women when LDL-C &lt;100mg/dL unless contraindicated</td>
</tr>
</tbody>
</table>

- 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 <35 in. (Class I, Level B)
- Psychosocial factors: Women with CVD should be evaluated for depression and refer/treat when indicated. (Class IIa, Level B)
- Omega 3 fatty acids: As an adjunct to diet, supplementation may be considered in high risk women.
- 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).
(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.
  - 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).

### CLINICAL RECOMMENDATIONS

<table>
<thead>
<tr>
<th>Preventive Drug Interventions</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aspirin:</strong></td>
<td></td>
</tr>
<tr>
<td>- 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).</td>
<td></td>
</tr>
<tr>
<td>- 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).</td>
<td></td>
</tr>
<tr>
<td><strong>Beta-Blockers</strong>: 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).</td>
<td></td>
</tr>
<tr>
<td><strong>ACE Inhibitors</strong>: Should be used (unless contraindicated) in high risk women (Class I, Level A).</td>
<td></td>
</tr>
<tr>
<td>Atrial Fibrillation/Stroke Prevention</td>
<td>ARBs: Should be used in high risk women with clinical evidence of heart failure or an ejection fraction &lt;40% who are intolerant to ACEI (Class I, Level B).</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>• 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 (&lt;1%/y) or high risk of bleeding (Class I, Level A).</td>
</tr>
<tr>
<td></td>
<td>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 (&lt;1%) (Class I, Level A).</td>
</tr>
<tr>
<td>Class III</td>
<td>• 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).</td>
</tr>
<tr>
<td></td>
<td>• Antioxidant Supplements: Antioxidant vitamin supplements should not be used to prevent CVD pending the results of ongoing trails (Class III, Level A).</td>
</tr>
<tr>
<td></td>
<td>• Aspirin – Lower Risk: Routine aspirin use in lower risk women is not recommended pending the results of ongoing trials (Class III, Level B).</td>
</tr>
</tbody>
</table>
### Classification and Levels of Evidence

<table>
<thead>
<tr>
<th>Classification</th>
<th>Class I</th>
<th>Intervention is useful and effective</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Class IIa</td>
<td>Weight of evidence is in favor of usefulness/efficacy</td>
</tr>
<tr>
<td></td>
<td>Class IIb</td>
<td>Usefulness/efficacy is less well established by evidence/opinion</td>
</tr>
<tr>
<td></td>
<td>Class III</td>
<td>Intervention is not useful/effective and may be harmful</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Level of Evidence</th>
<th>A</th>
<th>Sufficient evidence from multiple randomized trials</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B</td>
<td>Limited evidence from single randomized trial or other nonrandomized studies</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>Based on expert opinion, case studies, or standard of care</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.
Reference

## PHYSICAL ASSESSMENT

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>History</td>
<td>Inquire about history of hypertension, diabetes, hypercholesterolemia, coronary artery disease, alcohol and illicit drug use</td>
</tr>
<tr>
<td>Vital Signs</td>
<td>Assess at each visit:</td>
</tr>
<tr>
<td></td>
<td>- Weigh and review patient’s self-reported daily weight record</td>
</tr>
<tr>
<td></td>
<td>- Pulse rate</td>
</tr>
<tr>
<td></td>
<td>- Blood pressure</td>
</tr>
<tr>
<td></td>
<td>- Respiratory rate</td>
</tr>
<tr>
<td>Cardiac</td>
<td>Assess at each visit:</td>
</tr>
<tr>
<td></td>
<td>- Jugular vein distention</td>
</tr>
<tr>
<td></td>
<td>- Cardiac gallop (third or fourth heart sound)</td>
</tr>
<tr>
<td>Extremities</td>
<td>Assess at each visit for peripheral edema.</td>
</tr>
<tr>
<td>Lung</td>
<td>Assess at each visit for pulmonary rales.</td>
</tr>
</tbody>
</table>

## PSYCHOLOGICAL ASSESSMENT

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression Screen</td>
<td>A high index of suspicion for depression should be maintained. Assess regularly and initiate treatment as needed.</td>
</tr>
</tbody>
</table>

* Refer to PHP Preventive Health Guidelines

## TESTS

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluation of ventricular function</td>
<td>Perform echocardiography or other studies to evaluate cardiac structure and function and repeat as clinically indicated.</td>
</tr>
</tbody>
</table>
# Cardiovascular Health Practice Guidelines

## Outpatient Management of Congestive Heart Failure

<table>
<thead>
<tr>
<th>STAGING AND RECOMMENDED THERAPY</th>
<th>Stage A</th>
<th>Stage B</th>
<th>Stage C</th>
</tr>
</thead>
</table>
| **Patients at high risk for CHF but without structural heart disease or symptoms of CHF** (e.g., patients with systolic hypertension, coronary artery disease, diabetes mellitus, or history of cardiotoxic drugs, alcohol abuse or family history of cardiomyopathy) | • Treat hypertension  
• Encourage smoking cessation  
• Treat lipid disorders  
• Encourage regular exercise  
• Discourage alcohol intake, illicit drug use  
• ACEI in patients with a history of atherosclerotic vascular disease, diabetes mellitus, hypertension and associated cardiovascular risk factors | • All measures in Stage A  
• ACEI 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 | • All measures in Stage A  
• Drugs for routine use:  
  o Diuretics, in patients who have evidence of fluid retention  
  o ACEI  
  o Beta-blockers, in patients with no or minimal fluid retention  
  o Digitalis  
  o Spironolactone in patients with recent or current (NYHA) Class IV symptoms, preserved renal function and a normal potassium concentration  
• Dietary salt restriction |

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*Clinical Practice Guidelines – Congestive Heart Failure*

Authorized by: Medical Management Guideline Committee. Approved: 05/21/98. Revised: 04/13/00; 04/11/02; 03/16/04
### Stage D

**End-stage disease; Refractory CHF 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)

- All measures under Stage A, B and C
- Mechanical assist devices
- Heart transplantation
- Continuous intravenous inotropic infusions for palliation
- Biventricular pacemaker to be considered in patients with prolonged QRS
- Hospice care

### THERAPY

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ACE Inhibitors (ACEI)</strong></td>
<td>In the absence of contraindications, start ACEI in patients with any of the following: Stages C or D chronic CHF, Stage B CHF with either a history of recent or remote MI or with low ejection fraction, and Stage A CHF 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 CHF]). ARBs should be considered in patients who are intolerant to ACEI.</td>
</tr>
<tr>
<td><strong>Beta-Blockers</strong></td>
<td>Initiate and continue indefinitely in patients with any of the following: Stages C or D CHF, Stage B CHF 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.</td>
</tr>
<tr>
<td><strong>Diuretics</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Digitalis</strong></td>
<td>Initiate in patients for the treatment of symptoms of CHF, unless contraindicated</td>
</tr>
</tbody>
</table>

---

*Clinical Practice Guidelines – Congestive Heart Failure*  
Authorized by: Medical Management Guideline Committee. Approved: 05/21/98. Revised: 04/13/00; 04/11/02; 03/16/04
| **Antiplatelet Agents/ anticoagulants** | 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.) |
| **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 >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 > 200 mg/dL, then non-HDL should be <130 mg/dL  
Emphasize weight management and physical activity. |
| **Smoking/Tobacco** | 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. |
| **Routine Weight Monitoring** | Educate patient to routinely monitor weight and maintain a weight log. Instruct patient on weight variances that should be reported to the provider. |
| **Symptom Recognition** | Educate patient of symptoms to report to provider that may indicate worsening condition. |
Low sodium diet | 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.

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.

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.

**References:**


Cardiovascular Health Practice Guidelines
Outpatient Management of Congestive Heart Failure


### MEDICATIONS

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>RECOMMENDATIONS</th>
</tr>
</thead>
</table>
| **Beta-Blockers** | Indicated in post-MI, unstable angina, and non-ST segment MI. 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 |
### MEDICATIONS

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>RECOMMENDATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Calcium Channel Blockers</strong></td>
<td>For ischemic symptoms when beta-blockers are not successful or contraindicated. Short acting dihydropyridine antagonists (e.g., nifedipine) should be avoided.</td>
</tr>
<tr>
<td><strong>Antiplatelet Drugs</strong></td>
<td><strong>Aspirin</strong></td>
</tr>
<tr>
<td></td>
<td>Indicated in post-MI, unstable angina, non-ST segment MI. Prescribe 75 to 325 mg/d in the absence of contraindications.</td>
</tr>
<tr>
<td></td>
<td><strong>Relative Contraindications:</strong></td>
</tr>
<tr>
<td></td>
<td>• Blood dyscrasias</td>
</tr>
<tr>
<td></td>
<td>• Severe hepatic disease</td>
</tr>
<tr>
<td></td>
<td>• Active GI Bleeding</td>
</tr>
<tr>
<td></td>
<td><strong>Antiplatelet Drugs:</strong></td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Anticoagulation Therapy</strong></td>
<td><strong>Consider long-term anticoagulation post-MI for the following patients:</strong></td>
</tr>
<tr>
<td></td>
<td>• Post-MI patients who are unable to take aspirin daily* or other antiplatelet agents</td>
</tr>
<tr>
<td></td>
<td>• Post-MI patients with persistent atrial fibrillation</td>
</tr>
<tr>
<td></td>
<td>• Post-MI patients with left ventricular thrombus</td>
</tr>
<tr>
<td></td>
<td>*If patient is receiving antiplatelet therapy, specific formulas contain antithrombin properties that may preclude further anticoagulation requirements.</td>
</tr>
<tr>
<td><strong>Digoxin</strong></td>
<td>Indicated in patients with heart failure due to left ventricular systolic dysfunction (EF &lt;35-40%) who are not adequately responsive to ACE inhibitors and diuretics and in patients with atrial fibrillation or who require additional rate control.</td>
</tr>
<tr>
<td></td>
<td><strong>Precautions and Close Monitoring:</strong></td>
</tr>
<tr>
<td></td>
<td>• Elderly patients</td>
</tr>
<tr>
<td></td>
<td>• Patients with impaired renal function</td>
</tr>
</tbody>
</table>
### Cardiovascular Health Practice Guideline

**Outpatient Management of Coronary Artery Disease 2003**

<table>
<thead>
<tr>
<th>MEDICATIONS</th>
<th>RECOMMENDATIONS</th>
</tr>
</thead>
</table>
| **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

Consider angiotensin receptor blockers (ARBs) in patients with intolerance to ACE inhibitor therapy. **Refer to PHP Diabetic Clinical Practice Guideline.** |

| **Cholesterol-Lowering Agents** | Advise all patients with CAD to follow the AHA Step II diet. Patients with LDL levels > 125 mg/dL despite the AHA Step II diet should be placed on drug therapy with the goal of reducing LDL to <100 mg/dL. Patients with normal plasma cholesterol levels who have a HDL cholesterol level of <35 mg/dL should receive therapy designed to elevate the HDL level, such as increased physical activity. |
## Cardiovascular Health Practice Guideline
### Outpatient Management of Coronary Artery Disease 2003

<table>
<thead>
<tr>
<th>TESTS</th>
<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>
<td></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>
<td></td>
</tr>
<tr>
<td><strong>Lipid Profile</strong></td>
<td>Perform cholesterol 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>
<td></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>
</table>
| **Depression Screen** | Routine screening for adults. **  
** Refer to PHP Preventive Health Recommendations. |

<table>
<thead>
<tr>
<th><strong>EDUCATION AND COUNSELING</strong></th>
<th></th>
</tr>
</thead>
</table>
| **Smoking Cessation** | Assessment of smoking status at each visit.  
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. |

**Education and Self-Management Principles**

This includes:
- Nutrition Counseling  
- Weight Management  
- Exercise/Physical Activity

Advise all patients with CAD about symptoms of AMI and instruct how to seek help if symptoms occur.

Advise patient and family on lower sodium, lower fat, lower cholesterol and higher fiber diet.

Recommend AHA Step II diet, which is low in saturated fat and cholesterol (<7% of total calories as saturated fat and <200 mg/d cholesterol).

Advise patient to achieve or maintain healthy weight (BMI of 25.0-30.0 is considered overweight, BMI >30.0 is considered obese).

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.

Advise patient when to return to previous levels of activity, sexual activity, driving, and employment.
# Cardiovascular Health Practice Guideline

**Outpatient Management of Coronary Artery Disease 2003**

## EDUCATION AND COUNSELING

| 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 are diabetics, 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. Approved by the Medical Management Guideline Committee in December 2003.
Cardiovascular Health Practice Guideline
Outpatient Management of Coronary Artery Disease 2003

References:


### Guidelines for the Treatment of Major Depressive Disorder – 2004

**Authorized By:** Medical Management Guideline Committee  
**Approval Date:** 04/08/99  
**Revision Date:** 04/12/01; 04/10/03; 05/25/04

<table>
<thead>
<tr>
<th>INTERVENTION</th>
<th>RECOMMENDATION</th>
</tr>
</thead>
</table>
| **Stage I.**  
**Acute Phase** | **Duration:** Up to 3 months  
**Goal:** Induce Remission |
| **Assessment and Treatment Planning (1-2 visits)** |  
• Diagnosis of Major Depressive Disorder (MDD) made using DSM-IV criteria  
• Possible alternative psychiatric diagnoses (e.g., anxiety, bipolar disorder, chemical dependency) or medical diagnoses had been ruled out  
• Medical disorder or medications which may contribute to depressive symptoms:  
  • Medications such as: carbidopa/ levodopa, beta-blockers, clonidine, benzodiazepines, barbiturates, anticonvulsants, corticosteroids, narcotics  
  • Medical conditions such as: hypothyroidism, Cushing’s disease, CVA, MI, CHF, Parkinson’s, Alzheimer’s, MS, SLE, AIDS, RA, cancer  
    • Treat optimally the general medical condition and re-evaluate  
    • Consider concurrent treatment of depression  
• Assess complaint severity, psychosis, suicide / homicide risk  
• Assess: 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  
• Obtain history (previous episodes, family history, precipitating factors)  
• Assess current and previous history of substance use disorders  
• Evaluate and address functional impairments  
• Education: Emphasize that condition is medical; progress is good with treatment; take medications as prescribed  
• Mild MDD: use either medication or psychotherapy as initial treatment  
• Moderate to Severe MDD: requires medication [I. vs AJP 2002 p 1354]  
• 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 |
## Medication Treatment

- Patients with moderate to severe symptoms, psychosis, elevated suicide or homicide risk need medication. Consider medication as initial therapy for mild MDD
- 65-70% of patients respond to the 1st antidepressant [A].
- Antidepressant effectiveness is generally comparable between and within classes [A]
- Selection of antidepressant depends on: [I, B]
  - Short/long term side effects
  - Safety, tolerability
  - Patient preference, convenience, concerns
  - History of prior response of patient or family member to medication
  - Concurrent medical illness
  - Concomitant non-psychotropic medications
  - Likelihood of adherence based on history
  - Cost of medication
- Education (i.e., expected duration, side effects) may reduce premature discontinuation
- In patients > 65 years old, use lower doses of antidepressants and avoid TCAs
- Caution: Screen for bipolar disorder/family history, as 30-50% of patients with bipolar disorder will develop acute mania when started on antidepressant medication
- MAOIs: reserve for patients who do not respond to other drugs

## Consideration for Psychotherapy

- Consider psychotherapy as alternative to medication for patients with mild depression [I, A], or with preference for non-pharmacological therapy
- If no response in 6 weeks, or partial response within 12, consider medications
- Consider psychotherapy, in addition to medication, for persons with:
  - Depressive episode of 2+ years
  - Hx of 2+ episodes of MDD with poor inter-episode recovery
  - History of partial response to previous trials of drugs or psychotherapy
  - Prominent psychosocial issues
  - History of treatment adherence problems
  - Personality disorder

## Repeat Evaluations During Months 1-3

- Monitor initial acute treatment every 1-2 weeks (e.g., response, side effects, psychosocial supports, suicidal tendencies) [D]
- By 6 weeks (or 4 weeks if severely ill):
  - If positive response – continue treatment at same dose
  - If partial or no symptomatic relief, reassess: diagnosis; adequacy of treatment; adequacy of medication dosage and compliance [I]
- Recommended options:
  - For partial or no response: Increase medication. Monitor response every 2 weeks
  - 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
  - Augment with agents such as lithium, stimulants or anticonvulsants
  - Addition of psychotherapy

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*Clinical Practice Guidelines – Depression Management*
### Guidelines for the Treatment of Major Depressive Disorder – 2004

#### INTERVENTION

<table>
<thead>
<tr>
<th>RECOMMENDATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>• If some symptoms persist, do not change medication - re-evaluate at week 12</td>
</tr>
<tr>
<td>• 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)</td>
</tr>
</tbody>
</table>

#### 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
- 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
  - Psychotherapy generally not useful unless patient unable to take medication
  - 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 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.
Guidelines for the Treatment of Major Depressive Disorder – 2004

Level of Evidence

<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


CalOptima. Treatment Guidelines: Major Depression in Adults. Revised 12/02


Colorado Clinical Guidelines Collaborative. Major Depression Disorder in Adults. Revised 4/3/01


Practice Guideline for the Treatment of Patients With Major Depression American Psychiatric Association, April 2000


**ROUTINE EXAMINATION**

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>RECOMMENDATION</th>
</tr>
</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, 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 Goals:  
Patients with diabetes should be treated to a systolic blood pressure < 130 mmHg.  
Patients with diabetes should be treated to a diastolic blood pressure < 80 mmHg.  
Children: correlate to age-adjusted 90th percentile.  
Patients with hypertension (systolic ≥ 140 mmHg or diastolic ≥ 90 mmHg) should receive drug therapy in addition to lifestyle and behavioral therapy. (A)  
Orthostatic measurement of blood pressure should be performed when clinically indicated to assess for the presence of autonomic neuropathy. (E) |
| **Weight**                        | Every routine diabetes visit.  
Children: target age-related normative values. |
| **Foot Examination**              | All individuals with diabetes should receive an annual foot examination to identify high-risk foot conditions. This examination should include assessment of protective sensation, foot structure and biomechanics, vascular status, and skin integrity. (E)  
People with one or more high-risk foot conditions should be evaluated more frequently for the development of additional risk factors. (E)  
People with neuropathy should have a visual inspection of their feet at every visit with a health care professional. (E)  
Evaluation of neurological status should include a quantitative somatosensory threshold test using the Semmes-Weinstein 5.07 (10-g) monofilament (E)  
Initial screening for peripheral vascular disease should include a history for claudication and an assessment of the pedal pulses. Consider obtaining an ABI, as many patients with PAD are asymptomatic. (E) |
<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>RECOMMENDATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retinal Eye Examination</td>
<td>Comprehensive dilated examination by ophthalmologist or optometrist knowledgeable and experienced in management of diabetic retinopathy is recommended.</td>
</tr>
<tr>
<td></td>
<td>Initial dilated and comprehensive eye testing is recommended:</td>
</tr>
<tr>
<td></td>
<td>• Within 3-5 years after diagnosis of type 1 diabetes once patient is 10 years of age or older. Clinical judgement should be exercised based on prepubertal duration of diabetes (B)</td>
</tr>
<tr>
<td></td>
<td>• Shortly after the time of diagnosis for type 2 diabetes (B)</td>
</tr>
<tr>
<td></td>
<td>• Prior to conception and during 1st trimester of pregnancy, for women with pre-existing diabetes (B)</td>
</tr>
<tr>
<td></td>
<td>Annual testing is recommended for both type 1 and type 2 diabetic patients thereafter. Abnormal findings necessitate more frequent follow up. 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. (B)</td>
</tr>
<tr>
<td>Depression</td>
<td>Probe for emotional/physical factors linked to depression routinely; treat aggressively with counseling, medication and/or referral.</td>
</tr>
<tr>
<td></td>
<td>**Refer to PHP Depression Guideline.</td>
</tr>
<tr>
<td>Preconception Counseling</td>
<td>Preconception counseling is recommended to all women of childbearing age in order to optimize self-management skills. Women contemplating pregnancy should be evaluated, and if indicated, treated for diabetes retinopathy, nephropathy, neuropathy, and CVD. (E)</td>
</tr>
<tr>
<td></td>
<td>A1C test levels should be normal or as close to normal as possible (&lt;1% above the upper limits of normal) before conception is attempted. (B)</td>
</tr>
<tr>
<td>Hemoglobin A1C (A1C) Testing and Control</td>
<td>A1C testing is recommended at initial visit and at least two times per year thereafter in diabetics with stable glycemic control. (E)</td>
</tr>
<tr>
<td></td>
<td>Quarterly testing is recommended for patients who are not meeting glycemic goals or whose therapy has changed. (E)</td>
</tr>
<tr>
<td></td>
<td>Target goal &lt; 7.0% (B)</td>
</tr>
<tr>
<td></td>
<td>More stringent goals (i.e. a normal A1c, &lt;6%) can be considered in individual patients. (B)</td>
</tr>
</tbody>
</table>
**ROUTINE EXAMINATION**

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>RECOMMENDATION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Proteinuria Screening</strong></td>
<td>Microalbuminuria screening is recommended for:</td>
</tr>
<tr>
<td></td>
<td>- Type 1 diabetic individuals - &gt; 5 years diabetes duration. (E) Clinical judgement should be exercised based on prepubertal duration of diabetes</td>
</tr>
<tr>
<td></td>
<td>- Type 2 diabetic individuals – to begin at the time of diagnosis (E)</td>
</tr>
<tr>
<td></td>
<td>Thereafter, annual microalbuminuria screening is recommended in place of routine urinalysis, in the absence of previously diagnosed proteinuria.</td>
</tr>
</tbody>
</table>

Definitions of abnormalities in albumin excretion:

<table>
<thead>
<tr>
<th>Category</th>
<th>Normal</th>
<th>Microalbuminuria</th>
<th>Clinical albuminuria</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>24-h collection (mg/24 h)</td>
<td>Timed Collection (µg/min)</td>
<td>Spot Collection (µg/mg creatinine)</td>
</tr>
<tr>
<td></td>
<td>&lt;30</td>
<td>&lt;20</td>
<td>&lt;30</td>
</tr>
<tr>
<td></td>
<td>30-299</td>
<td>20-199</td>
<td>30-299</td>
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<tr>
<td></td>
<td>≥ 300</td>
<td>≥ 200</td>
<td>≥ 300</td>
</tr>
</tbody>
</table>

Two of three specimens collected within a 6 month period should be abnormal before considering a patient to have crossed one of these diagnostic thresholds.
**ROUTINE TESTING**

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>RECOMMENDATION</th>
</tr>
</thead>
</table>
| **Lipid Testing and Control**     | At least annually and more often if needed to achieve goals. However, in adults with low-risk lipid values, 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  
  • HDL > 40 mg/dl men and > 50 mg/dl women  
  *Refer to PHP Outpatient Management of Coronary Artery Disease guideline  
  Children: In children and adolescents with diabetes, LDL cholesterol should be lowered to <100 mg/dl using diet as well as medications based on LDL level and other CVD risk factors in addition to diabetes. (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. (C)  
  **Refer to PHP Preventive Health Recommendations.** |
| **Testing for 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/ macroalbuminuria.  
  In patients without prior history of an event or symptoms strongly suggesting CHD, screening exercise stress testing is warranted for diabetic patients with the following (E):  
  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  
  • Two or more risk factors listed above  
  Patients with abnormal exercise ECG and patients unable to perform an exercise ECG require additional/ alternative testing. Type of testing and need for referral to a cardiologist depend on severity of underlying or suspected disease. |
<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>
<tr>
<td>Anti-hypertensive Agents</td>
<td>Initial drug therapy for hypertension may be with ACE inhibitors, ARBs, beta-blockers, calcium channel blockers or diuretics. Additional drugs may be chosen from these classes or another drug class. (A)</td>
</tr>
<tr>
<td></td>
<td>Multiple drug therapy is generally required to achieve blood pressure targets. (B)</td>
</tr>
<tr>
<td></td>
<td>All patients with diabetes and hypertension should be treated with a regimen that includes either an ACE inhibitor or 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)</td>
</tr>
<tr>
<td></td>
<td>If ACE inhibitors, ARBs, or diuretics are used, monitor renal function and serum potassium levels. (E)</td>
</tr>
<tr>
<td></td>
<td>In patients over age 55 years, with hypertension or without hypertension but with another cardiac risk factor (history of cardiovascular disease, dyslipidemia, microalbuminuria, smoking), an ACE inhibitor (if not contraindicated) should be considered to reduce the risk of cardiovascular events. (A)</td>
</tr>
<tr>
<td>ACE Inhibitor/ARBs Use for Proteinuria</td>
<td>In the treatment of albuminuria/nephropathy, both ACE inhibitors and ARBs can be used:</td>
</tr>
<tr>
<td></td>
<td>• In hypertensive type 1 diabetics with any degree of albuminuria, ACE inhibitors have been shown to delay the progression of nephropathy (A)</td>
</tr>
<tr>
<td></td>
<td>• In hypertensive type 2 diabetics with microalbuminuria either ACE inhibitors or ARBs have been shown to delay the progression to macroalbuminuria (A)</td>
</tr>
<tr>
<td></td>
<td>• In hypertensive type 2 diabetics with macroalbuminuria and renal insufficiency (serum creatinine &gt;1.5 mg/dl), ARBs have been shown to delay the progression of nephropathy (A)</td>
</tr>
<tr>
<td></td>
<td>• If one class is not tolerated, the other should be substituted (E)</td>
</tr>
<tr>
<td></td>
<td>If ACE Inhibitors or ARBs are used, monitor serum potassium levels for the development of hyperkalemia. (B)</td>
</tr>
<tr>
<td>Hyperlipidemia Agents</td>
<td>Patients who do not achieve lipid goals with lifestyle modifications require pharmacological therapy. (A)</td>
</tr>
<tr>
<td></td>
<td>Lowering LDL cholesterol with a statin is associated with a reduction in cardiovascular events. (A)</td>
</tr>
<tr>
<td></td>
<td>In people with diabetes over the age of 40 with a total cholesterol ≥ 135 mg/dl, statin therapy to achieve an LDL reduction of ~30% regardless of baseline LDL levels may be appropriate. (A)</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>
</tbody>
</table>
## MEDICATIONS

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>RECOMMENDATION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Antiplatelet Agents / Aspirin Use</strong></td>
<td>Use aspirin therapy (75-162 mg/day) as a secondary prevention strategy in individuals with diabetes who have a history of myocardial infarction, vascular bypass procedure, stroke or transient ischemic attack, peripheral vascular disease, claudication, and/or angina. (A) Use aspirin therapy (75-162 mg/day) as a primary prevention strategy in those with 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) 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>
</tbody>
</table>
# EDUCATION and COUNSELING

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>RECOMMENDATION</th>
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</thead>
<tbody>
<tr>
<td>Education and Self-management Principles</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. (B)</td>
</tr>
<tr>
<td>This includes</td>
<td>Physical Activity: A regular physical activity program, adapted to any complications, is recommended for all patients with diabetes who are capable of participating. (B)</td>
</tr>
<tr>
<td>• diabetes disease process and treatment options</td>
<td>Self-Monitoring Blood Glucose (SMBG): Instruct the patient in SMBG and routinely evaluate the patient’s technique and ability to use data to adjust therapy. (E)</td>
</tr>
<tr>
<td>• nutritional management</td>
<td>Foot Care: Patients with diabetes and high-risk foot conditions should be educated regarding their risk factors and appropriate management. (E)</td>
</tr>
<tr>
<td>• physical activity</td>
<td>Women with diabetes who are contemplating pregnancy should be evaluated and, if indicated, treated for diabetic retinopathy, nephropathy, neuropathy and cardiovascular disease. (E)</td>
</tr>
<tr>
<td>• medications</td>
<td></td>
</tr>
<tr>
<td>• monitoring</td>
<td></td>
</tr>
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<td>• acute complications</td>
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<td>• chronic complications</td>
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<tr>
<td>• goal setting and problem solving</td>
<td></td>
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<tr>
<td>• psychosocial adjustment</td>
<td></td>
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<tr>
<td>• preconception care, pregnancy and gestational diabetes management</td>
<td></td>
</tr>
</tbody>
</table>

## Smoking Cessation Counseling

Advise all patients not to smoke. (A)

Include smoking cessation counseling and other forms of treatment as a routine component of diabetes care. (B) This can be accomplished by assessing the smoking status and history, and counseling on smoking prevention and cessation. (E)

---

### ADA Evidence Grading System

**A**

Clear 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.

**B**

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.

**C**

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.

**E**

Expert consensus or clinical experience.

---

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.

Clinical Practice Guidelines – Diabetes Management

Authorized by: Medical Management Guideline Committee. Approved: 02/13/98. Revised: 04/13/00; 04/11/02; 03/16/04
References


# Preventive Health Recommendations for 2004

**Developed Based on Scientific Evidence**

### Understanding this handout:
The green columns contain recommendations from various nationally recognized medical organizations. The gray column contains information regarding what your Medicare benefit coverage includes. PacifiCare/Secure Horizon is the administrator of your Medicare benefits. You and your primary care physician should discuss what preventive health care screenings are necessary for you.

<table>
<thead>
<tr>
<th>ASSESSMENT</th>
<th>25–64 years</th>
<th>65+ years</th>
<th>Medicare Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast Cancer Screening</td>
<td>• Screening mammography, with or without clinical breast exam, every 1 to 2 years for women age 40 and older&lt;br&gt;• Inform of potential benefits, limitations, and possible harms of mammography in making decisions about when to begin screening</td>
<td>• Screening mammography, with or without clinical breast exam, every 1 to 2 years for women age 40 and older&lt;br&gt;• Inform of potential benefits, limitations, and possible harms of mammography in making decisions about when to begin screening</td>
<td>• Female breast exams are covered every 1 to 2 years based on risk factors&lt;br&gt;• Females over the age of 39 are covered for annual screening mammograms&lt;br&gt;• One baseline mammogram females age 35-39</td>
</tr>
<tr>
<td>Cardiovascular Disease Prevention</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>
<td>As medically necessary</td>
</tr>
<tr>
<td>Cervical Cancer Screening</td>
<td>At least every 3 years for women who have a cervix; interval as recommended by physician based on risk factors</td>
<td>May discontinue regular testing after age 65 in women who have had adequate recent screenings in which test results have been consistently normal and who are otherwise not at risk</td>
<td>All female beneficiaries are covered for Pap smears once every 2 years or annually for those who have had an abnormal Pap in the preceding 3 years or are otherwise high risk for cervical or vaginal cancer</td>
</tr>
<tr>
<td>Chlamydia</td>
<td>• Routine for sexually active females aged 25 and younger&lt;br&gt;• Routine for other asymptomatic females at increased risk for infection</td>
<td>Routine for asymptomatic females at increased risk for infection</td>
<td>As medically necessary</td>
</tr>
<tr>
<td>High Blood Pressure (Hypertension)</td>
<td>Periodic screening</td>
<td>Periodic screening</td>
<td>As medically necessary</td>
</tr>
</tbody>
</table>

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Approved by PHS Medical Management Guideline Committee 3/16/04. (040406A-PHS_PPO 4/04).
## Preventive Health Recommendations for 2004

**Developed Based on Scientific Evidence**

### References:
- Approved by PHS Medical Management Guideline Committee 3/16/04. (040406A-PHS_PPO 4/04).

### Assessment

<table>
<thead>
<tr>
<th>ASSESSMENT</th>
<th>25–64 years</th>
<th>65+ years</th>
<th>Medicare Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorectal Cancer Screening</td>
<td>Routine screening beginning at age 50 for men and women at average risk with interval determined by method. Potential screening options include home Fecal Occult Blood Test (FOBT), flexible sigmoidoscopy, the combination of home FOBT and flexible sigmoidoscopy, colonoscopy, and double-contrast barium enema</td>
<td>Routine screening with interval determined by method. Potential screening options include home Fecal Occult Blood Test (FOBT), flexible sigmoidoscopy, the combination of home FOBT and flexible sigmoidoscopy, colonoscopy, and double-contrast barium enema</td>
<td>- Fecal Occult Blood Tests are covered annually age 50 and over</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Flexible sigmoidoscopy is covered every 4 years for individuals 50 and over</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Screening colonoscopy every 10 years (but not within 4 years of a screening flexible sigmoidoscopy) or every 2 years for individuals at high risk of colorectal cancer</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Screening barium enema covered as an alternative to either a screening sigmoidoscopy or a screening colonoscopy, same frequency parameters apply. For individuals not at high risk of colorectal cancer – screening barium enema covered every 4 years.</td>
</tr>
</tbody>
</table>

### Lipid Disorder Screening

- Routine screening for males age 35 and older and females age 45 and older
- Routine screening for younger adults if other risk factors for coronary heart disease exist

### Depression Screening

- Routine screening for adults

### Notes:
- As medically necessary
### Preventive Health Recommendations for 2004

Developed based on scientific evidence

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Diabetes-Type 2</td>
<td>Screening of adults with hypertension or hyperlipidemia</td>
<td>Screening of adults with hypertension or hyperlipidemia</td>
<td>As medically necessary</td>
</tr>
<tr>
<td>Hearing</td>
<td></td>
<td>At physician discretion</td>
<td>Routine hearing screening is not a Medicare-covered benefit</td>
</tr>
<tr>
<td>Height and Weight</td>
<td>Periodically</td>
<td>Periodically</td>
<td>Not a Medicare-covered benefit</td>
</tr>
<tr>
<td>Obesity</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>Not a Medicare covered benefit</td>
</tr>
<tr>
<td>Osteoporosis Screening</td>
<td>Routine screening beginning at age 60 for women at increased risk of osteoporotic fracture</td>
<td>Routine screening for women</td>
<td>Bone mass measurement varies with health status</td>
</tr>
</tbody>
</table>
| Prostate Cancer Screening | Discuss risks and benefits of screening with medical professional | Discuss risks and benefits of screening with medical professional | • Annual screening digital rectal examinations for men aged 50 and over  
  • Annual screening PSA tests for men aged 50 and over |
| Tuberculosis Screening | All persons at increased risk of developing tuberculosis                   | All persons at increased risk of developing tuberculosis                   | As medically necessary                                   |
| Vision Screening   | Refer high-risk individuals for evaluation by eye specialist; frequency at physician discretion | Refer high-risk individuals for evaluation by eye specialist; frequency at physician discretion | Glaucoma screening once every 12 months for high risk individuals,  
  individuals with a family history of glaucoma,  
  individuals with diabetes,  
  or African-Americans age 50 and older. |

### Counseling Recommendations

<table>
<thead>
<tr>
<th>COUNSELING</th>
<th>25–64 years Recommended Topic:</th>
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<th>Medicare Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dental Health</td>
<td>• Regular dental care</td>
<td>• Regular dental care</td>
<td>Not a Medicare-covered benefit</td>
</tr>
<tr>
<td></td>
<td>• Floss, brush with fluoride toothpaste daily</td>
<td>• Floss, brush with fluoride toothpaste daily</td>
<td></td>
</tr>
<tr>
<td>Diet and Exercise</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>Not a Medicare-covered benefit</td>
</tr>
<tr>
<td></td>
<td>• Adequate calcium intake (women)</td>
<td>• Adequate calcium intake (women)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Regular physical activity</td>
<td>• Regular physical activity</td>
<td></td>
</tr>
<tr>
<td>Hormone Replacement Therapy</td>
<td>Counsel women approaching menopause regarding alternatives to prevent chronic disease</td>
<td></td>
<td>Not a Medicare-covered benefit</td>
</tr>
<tr>
<td>Injury Prevention/Patient Safety</td>
<td>• Safety belts</td>
<td>• Safety belts</td>
<td>Not a Medicare-covered benefit</td>
</tr>
<tr>
<td></td>
<td>• Safety helmet for high speed activities</td>
<td>• Lap/shoulder belts</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Smoke detectors</td>
<td>• Bicycle/motorcycle helmets</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Restrict unauthorized access to firearms</td>
<td>• Smoke detectors</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• CPR training for caretakers of high-risk individuals</td>
<td>• Restrict unauthorized access to firearms</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Water safety</td>
<td>• Hot water heater &lt;120° F</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• CPR training for caretakers of high-risk individuals</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Measures to reduce risk of falling</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Water safety</td>
<td></td>
</tr>
</tbody>
</table>


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<table>
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<tr>
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<th>65+ years Recommended Topic:</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Prenatal Care</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>
<td></td>
<td>Reasonable and necessary services associated with pregnancy are covered</td>
</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>
<td></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; at 12-16 weeks’ gestation, screen for asymptomatic bacteriuria</td>
<td></td>
<td></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></td>
<td></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></td>
<td></td>
</tr>
</tbody>
</table>

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### Counseling

<table>
<thead>
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</tr>
</thead>
</table>
| Sexual Behavior             | • Sexually Transmitted Disease: All adults advised of risk factors and counseled about effective measures to prevent infection  
• Unintended pregnancy: Contraception                                                   | Sexually Transmitted Disease: All adults advised of risk factors and counseled about effective measures to prevent infection | Sexual behavior health education counseling is not a Medicare-covered benefit |
| Substance Use and Substance Abuse | • Regular screening for tobacco-use status and provide tobacco cessation interventions for those who use tobacco products  
• Regular screening for problem drinking  
• Avoid alcohol/drug use while driving, swimming, boating, etc.                                  | • Regular screening for tobacco-use status and provide tobacco cessation interventions for those who use tobacco products  
• Regular screening for problem drinking  
• Avoid alcohol/drug use while driving, swimming, boating, etc.                                  | Treatment for alcohol/drug abuse or other chemical dependency when medically necessary |

**References:** CDC Recommendations including the Immunizations Practices Advisory Committee, published in *MMWR, U.S. Preventive Services Task Force.*

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<table>
<thead>
<tr>
<th>Immunization</th>
<th>25–64 years</th>
<th>65+ years</th>
<th>Medicare Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis A</td>
<td>All adults at increased risk, in 2 doses with 2nd dose 6–18 months after 1st dose – consult your physician</td>
<td>All adults at increased risk, in 2 doses with 2nd dose 6–18 months after 1st dose – consult your physician</td>
<td>Not a Medicare-covered benefit</td>
</tr>
<tr>
<td>Hepatitis B</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>
<td>Covered for individuals who are at high or intermediate risk of contracting Hepatitis B. For example, members with end stage renal disease, hemophiliacs who are receiving Factor VIII or IX concentrates, residents of institutions, residents in same households as infected persons, homosexual men, IV substance abusers, individuals in frequent contact with blood or blood products.</td>
</tr>
<tr>
<td>Influenza</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>
<td>Flu shots are covered annually</td>
</tr>
<tr>
<td>Meningococcal</td>
<td>Consider for adults with medical indications</td>
<td>Consider for adults with medical indications</td>
<td>Not a Medicare covered benefit</td>
</tr>
<tr>
<td>Pneumococcal</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>
<td>Pneumococcal vaccine covered once in a lifetime; re-vaccination covered if medically necessary.</td>
</tr>
<tr>
<td>Rubella</td>
<td>All women of childbearing age should be screened for rubella susceptibility or, if nonpregnant, may be offered vaccination without screening</td>
<td></td>
<td>Not a Medicare-covered benefit</td>
</tr>
</tbody>
</table>

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PacifiCare/Secure Horizons Medicare+Choice Plan
PREVENTIVE HEALTH RECOMMENDATIONS FOR 2004
DEVELOPED BASED ON SCIENTIFIC EVIDENCE

<table>
<thead>
<tr>
<th>IMMUNIZATION</th>
<th>25–64 years</th>
<th>65+ years</th>
<th>Medicare Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tetanus Diphtheria</td>
<td>Booster every 10 years</td>
<td>Booster every 10 years</td>
<td>Not a Medicare-covered benefit</td>
</tr>
<tr>
<td>Varicella</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>
<td>Not a Medicare-covered benefit</td>
</tr>
</tbody>
</table>

Please refer to your Evidence of Coverage and Disclosure Information or your Schedule of Benefits brochure for additional information, including applicable coinsurance, copayments and deductibles.

The PacifiCare/Secure Horizons M+C Plan Evidence of Coverage/Disclosure Information should be consulted for the specific coverage and limitations of benefits for vaccines recommended for travel and occupational risk.


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