LCD for HYPERBARIC Oxygen Therapy (HBO) (L27575)

Contractor Information

Contractor Name
Palmetto GBA

Contractor Number
01101

Contractor Type
MAC - Part A

LCD Information

LCD ID Number
L27575

LCD Title
HYPERBARIC Oxygen Therapy (HBO)

Contractor's Determination Number
J1A-08-0019-L

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CMS National Coverage Policy

Language quoted from Centers for Medicare and Medicaid Services (CMS). National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals is italicized throughout the policy. NCDs and coverage provisions in interpretive manuals are not subject to the Local Coverage Determination (LCD) Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, italicized text represents quotation from one or more of the following CMS sources:

Title XVIII of the Social Security Act (SSA), §1862(a)(1)(A) excludes expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Title XVIII of the Social Security Act (SSA), §1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

42 CFR §410.27(f) defines direct physician supervision in a hospital outpatient setting.
Primary Geographic Jurisdiction
California - Entire State

Oversight Region
Region I

Original Determination Effective Date
For services performed on or after 08/20/2008

Original Determination Ending Date

Revision Effective Date
For services performed on or after 10/01/2008

Revision Ending Date

Indications and Limitations of Coverage and/or Medical Necessity
1. Abstract:

This LCD is a clarification of the NCD as found in CMS Manual System, Pub. 100-03, Medicare National Coverage Determination (internet-Only Manual).

For purposes of coverage under Medicare, hyperbaric oxygen (HBO) therapy is a modality in which the entire body is exposed to oxygen under increased atmospheric pressure The patient is entirely enclosed in a pressure chamber breathing 100% oxygen (O₂) at greater than one atmosphere (atm) pressure. Either a monoplace chamber pressurized with pure O₂ or a larger multiplace chamber pressurized with compressed air where the patient receives pure O₂ by mask, head tent, or endotracheal tube may be used.)

Hyperbaric oxygen therapy serves four primary functions:

1. It increases the concentration of dissolved oxygen in the blood, which enhances perfusion;
2. It stimulates the formation of a collagen matrix so that new blood vessels may develop;
3. It replaces inert gas in the bloodstream with oxygen, which is then metabolized by the body; and
4. It works as a bactericide.

Developed as treatment for decompression illness, this modality is an established therapy for treating medical disorders such as carbon monoxide poisoning and gas gangrene. HBO is also considered acceptable in treating acute vascular compromise and as adjuvant therapy in the management of disorders that are refractory to standard medical and surgical care.

For outpatient settings other than Comprehensive Outpatient Rehabilitation Facilities (CORFs), references to "physicians" throughout this policy include non-physicians: nurse practitioners, clinical nurse specialists and physician assistants. Such non-physician practitioners may certify, order, and establish the plan of care for hyperbaric oxygen therapy services as authorized by State law. (See Sections 1861(s)(2) and 1862(a)(14) of Title XVIII of the Social Security Act; 42 CFR, Sections 410.74, 410.75, 410.76 and 419.22; 58 FR 18543, April 7, 2000.)

Topical application of oxygen does not meet the definition of HBO therapy as stated above. Also, its clinical efficacy has not been established. Therefore, no Medicare reimbursement may be made for the topical application of oxygen.

2. Indications:

Program reimbursement for HBO therapy will be limited to that which is administered in a chamber (including the one man unit) and is limited to the following conditions: (See the UTILIZATION section of this LCD for condition specific limitations and coverage guidelines.)

1. Acute carbon monoxide intoxication
2. Decompression illness
3. Gas embolism
4. Gas gangrene
5. Acute traumatic peripheral ischemia
6. Crush injuries and suturing of severed limbs
7. Progressive necrotizing infections (necrotizing fasciitis)
8. Acute peripheral arterial insufficiency
9. Preparation and preservation of compromised skin grafts
10. Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management
11. Osteoradionecrosis as an adjunct to conventional treatment
12. Soft tissue radionecrosis as an adjunct to conventional treatment
13. Cyanide poisoning
14. Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment
15. Diabetic wounds of the lower extremities in patients who meet the following three criteria:
   a. Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes;
   b. Patient has a wound classified as Wagner grade III or higher; and
   c. Patient has failed an adequate course of standard wound therapy.

3. Limitations:

All other indications not listed above are not covered under the Medicare program.
Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

<table>
<thead>
<tr>
<th>Bill Type</th>
<th>Description</th>
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<tr>
<td>11x</td>
<td>Hospital-inpatient (including Part A)</td>
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<tr>
<td>13x</td>
<td>Hospital-outpatient (HHA-A also) (under OPPS 13X must be used for ASC claims submitted for OPPS payment -- eff. 7/00)</td>
</tr>
<tr>
<td>85x</td>
<td>Special facility or ASC surgery-rural primary care hospital (eff 10/94)</td>
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Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

Revenue codes only apply to providers who bill these services to the fiscal intermediary. Revenue codes do not apply to physicians, other professionals and suppliers who bill these services to the carrier.

<table>
<thead>
<tr>
<th>Revenue Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>0413</td>
<td>Respiratory services-hyperbaric oxygen therapy</td>
</tr>
<tr>
<td>0940</td>
<td>Other therapeutic services-general classification</td>
</tr>
<tr>
<td>0960</td>
<td>Professional fees-general classification</td>
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<tr>
<td>0969</td>
<td>Professional fees-other</td>
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<tr>
<td>0982</td>
<td>Professional fees-outpatient services</td>
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<tr>
<td>0987</td>
<td>Professional fees-hospital visit</td>
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CPT/HCPCS Codes

<table>
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<th>Code</th>
<th>Description</th>
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<tr>
<td>99183</td>
<td>PHYSICIAN ATTENDANCE AND SUPERVISION OF HYPERBARIC OXYGEN THERAPY, PER SESSION</td>
</tr>
<tr>
<td>C1300</td>
<td>HYPERBARIC OXYGEN UNDER PRESSURE, FULL BODY CHAMBER, PER 30 MINUTE INTERVAL</td>
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</tbody>
</table>
ICD-9 Codes that Support Medical Necessity

It is the responsibility of the provider to code to the highest level specified in the ICD-9-CM (e.g., to the fourth or fifth digit). The correct use of an ICD-9-CM code listed below does not assure coverage of a service. The service must be reasonable and necessary in the specific case and must meet the criteria specified in this determination.

Claims for HBO for the treatment of diabetic wounds of the lower extremities require documentation of dual diagnoses. An ICD-9-CM code from either the 249.70-279.71, 249.80-249.81, 250.70-250.73 or 250.80-250.83 range (representing a diabetes-related problem) and one of the following ICD-9-CM codes: 707.10, 707.12, 707.13, 707.14, 707.15, or 707.19 (representing a lower extremity wound) must be reported.

Claims for HBO submitted with ICD-9-CM codes 040.0, 444.21, 444.22, 444.81, 728.86, or 999.1 are presumed to be HBO therapy provided to inpatients requiring acute/emergent treatment. Services rendered on an outpatient basis (using outpatient bill types) will be considered medically unnecessary and will be denied.

039.0 - 039.9  CUTANEOUS ACTINOMYCOTIC INFECTION - ACTINOMYCOTIC INFECTION OF UNSPECIFIED SITE

040.0  GAS GANGRENE

249.70  SECONDARY DIABETES MELLITUS WITH PERIPHERAL CIRCULATORY DISORDERS, NOT STATED AS UNCONTROLLED, OR UNSPECIFIED

249.71  SECONDARY DIABETES MELLITUS WITH PERIPHERAL CIRCULATORY DISORDERS, UNCONTROLLED

249.80  SECONDARY DIABETES MELLITUS WITH OTHER SPECIFIED MANIFESTATIONS, NOT STATED AS UNCONTROLLED, OR UNSPECIFIED

249.81  SECONDARY DIABETES MELLITUS WITH OTHER SPECIFIED MANIFESTATIONS, UNCONTROLLED

250.70 - 250.73  DIABETES WITH PERIPHERAL CIRCULATORY DISORDERS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED - DIABETES WITH PERIPHERAL CIRCULATORY DISORDERS, TYPE I [JUVENILE TYPE], UNCONTROLLED

250.80 - 250.83  DIABETES WITH OTHER SPECIFIED MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED - DIABETES WITH OTHER SPECIFIED MANIFESTATIONS, TYPE I [JUVENILE TYPE], UNCONTROLLED

444.21  ARTERIAL EMBOLISM AND THROMBOSIS OF UPPER EXTREMITY

444.22  ARTERIAL EMBOLISM AND THROMBOSIS OF LOWER EXTREMITY

444.81  EMBOLISM AND THROMBOSIS OF ILIAC ARTERY
526.4 INFLAMMATORY CONDITIONS OF JAW
526.89 OTHER SPECIFIED DISEASES OF THE JAWS
595.82 IRRADIATION CYSTITIS
707.10 - 707.19 UNSPECIFIED ULCER OF LOWER LIMB - ULCER OF OTHER PART OF LOWER LIMB
707.22 PRESSURE ULCER, STAGE II
707.23 PRESSURE ULCER, STAGE III
707.24 PRESSURE ULCER, STAGE IV
728.86 NECROTIZING FASCIITIS
730.10 CHRONIC OSTEOMYELITIS SITE UNSPECIFIED
730.11 CHRONIC OSTEOMYELITIS INVOLVING SHOULDER REGION
730.12 CHRONIC OSTEOMYELITIS INVOLVING UPPER ARM
730.13 CHRONIC OSTEOMYELITIS INVOLVING FOREARM
730.14 CHRONIC OSTEOMYELITIS INVOLVING HAND
730.15 CHRONIC OSTEOMYELITIS INVOLVING PELVIC REGION AND THIGH
730.16 CHRONIC OSTEOMYELITIS INVOLVING LOWER LEG
730.17 CHRONIC OSTEOMYELITIS INVOLVING ANKLE AND FOOT
730.18 CHRONIC OSTEOMYELITIS INVOLVING OTHER SPECIFIED SITES
730.19 CHRONIC OSTEOMYELITIS INVOLVING MULTIPLE SITES
902.53 INJURY TO ILIAC ARTERY
903.01 INJURY TO AXILLARY ARTERY
903.1 INJURY TO BRACHIAL BLOOD VESSELS
904.0 INJURY TO COMMON FEMORAL ARTERY
904.41 INJURY TO POPLITEAL ARTERY
909.2 LATE EFFECT OF RADIATION
927.00 - 927.09 CRUSHING INJURY OF SHOULDER REGION - CRUSHING INJURY OF MULTIPLE SITES OF UPPER ARM
927.10 CRUSHING INJURY OF FOREARM
927.11 CRUSHING INJURY OF ELBOW
927.20 CRUSHING INJURY OF HAND(S)
927.21 CRUSHING INJURY OF WRIST
CRUSHING INJURY OF MULTIPLE SITES OF UPPER LIMB
CRUSHING INJURY OF UNSPECIFIED SITE OF UPPER LIMB
CRUSHING INJURY OF THIGH
CRUSHING INJURY OF HIP
CRUSHING INJURY OF LOWER LEG
CRUSHING INJURY OF KNEE
CRUSHING INJURY OF FOOT
CRUSHING INJURY OF ANKLE
CRUSHING INJURY OF TOE(S)
CRUSHING INJURY OF MULTIPLE SITES OF LOWER LIMB
CRUSHING INJURY OF UNSPECIFIED SITE OF LOWER LIMB
CRUSHING INJURY OF MULTIPLE SITES NOT ELSEWHERE CLASSIFIED - CRUSHING INJURY OF UNSPECIFIED SITE
AIR EMBOLISM AS AN EARLY COMPLICATION OF TRAUMA
TOXIC EFFECT OF CARBON MONOXIDE
TOXIC EFFECT OF HYDROCYANIC ACID GAS
TOXIC EFFECT OF HYDROCYANIC ACID AND CYANIDES
EFFECTS OF RADIATION UNSPECIFIED
CAISSON DISEASE
MECHANICAL COMPLICATION OF PROSTHETIC GRAFT OF OTHER TISSUE NOT ELSEWHERE CLASSIFIED
COMPLICATIONS OF UNSPECIFIED REATTACHED EXTREMITY - COMPLICATION OF OTHER SPECIFIED REATTACHED BODY PART
AIR EMBOLISM AS A COMPLICATION OF MEDICAL CARE NOT ELSEWHERE CLASSIFIED

Diagnoses that Support Medical Necessity
N/A

ICD-9 Codes that DO NOT Support Medical Necessity
All other ICD-9-CM codes not specified above are not reimbursable under the Medicare program.

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

General Information

Documentation Requirements
The patient's medical record must contain documentation that fully supports the medical necessity for services addressed by this LCD. (See "Indications and Limitations of Coverage.") This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

1. Documentation in the medical record should support the specific condition being treated with HBO therapy and the medical necessity of such treatment. This documentation shall be available and submitted when requested by the Medicare contractor. Documentation submitted must include:
a. An initial assessment and medical history detailing the condition requiring HBO therapy and a physical exam. The medical history should list prior treatments including antibiotic therapy and surgical interventions.
b. Documentation of current adjunctive treatment should include type of treatment and the effectiveness of same.
c. Physician progress notes and any communication between physicians detailing past or future (proposed) treatments.
d. Established goals for HBO therapy.
e. HBO therapy treatment records describing the physical findings and the treatment rendered (including ascent time, descent time, total compression time, dose of oxygen, pressurization level, documentation of attendance, and a recording of events).
f. The effect of treatment upon the established goals for HBO therapy.
g. Condition specific information such as:
  - documentation of laboratory tests (positive gram-stain smear or culture) that confirm the diagnosis of gas gangrene is required;
  - radiographic tests that confirm the clinical diagnosis of gas gangrene;
  - documentation supporting a threatened loss of function, limb, or life;
  - surgical and pathology reports for treatment of necrotizing faciitis;
  - definitive radiographic findings or positive bone culture with sensitivity studies to confirm the diagnosis of osteomyelitis, and documentation of failed antibiotic therapy and surgical management.
  - history of radiation therapy (including date and anatomical site of radiation therapy), with documentation of fracture or resorption of bone, and radiographic studies, if available, to confirm the diagnosis of osteoradionecrosis;
  - history of radiation therapy and clinical photographs of the necrotic site will help support the medical necessity of HBO services for soft tissue radionecrosis;
  - documentation that the patient has type I or type II diabetes and a lower extremity wound (due to diabetes) classified as Wagner grade III or higher that has failed to respond to an adequate course of standard therapy. For treatment of diabetic wounds of the lower extremities, documentation must also reflect that there have been no measurable signs of healing for at least 30 days of treatment with standard wound therapy and that the HBO therapy is used in addition to standard wound care with wound evaluation at least every 30 days during HBO therapy. 

NOTE: the ‘Wagner Ulcer Classification System’ is defined in the ‘Decision Memo for Hyperbaric Oxygen Therapy for Hypoxic Wounds and Diabetic Wounds of the Lower Extremities’ (CAG-00060N)’ published by CMS.

Appendices

http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=37
for Decision Memo for Hyperbaric Oxygen Therapy for Hypoxic Wounds and Diabetic Wounds of the Lower Extremities’ (CAG-00060N)’ published by CMS.

Utilization Guidelines

Utilization guidelines are presented relative to specific treatment conditions:
1. **Acute carbon monoxide intoxication** induces hypoxic stress and may result in injury to the cardiac and central nervous systems. HBO produces a higher rate of dissociation of carbon monoxide from hemoglobin than occurs at sea level pressure. Chamber compressions should be between 2.5 and 3.0 atmospheres absolute (ATA). Patients with persistent neurological dysfunction may require subsequent treatments within six to eight hours, continuing once or twice daily until there is no further improvement in cognitive functioning.

2. **Decompression illness** (gas bubbles in tissue or blood in volumes sufficient enough to interfere with the function of an organ or to cause alteration in sensation) resulting from rapid decompression during ascent presents clinical manifestations ranging from skin eruptions to shock and death. Treatment of choice for decompression illness is HBO therapy with mixed gases. The result is immediate reduction in the volume of bubbles. The treatment prescription is highly variable and case specific. The depths could range between 60 to 165 feet of sea water for durations of 1.5 to over 14 hours. The patient may or may not require repeat dives.

3. **Gas embolism** occurs when gases enter the venous or arterial vasculature embolizing in a large enough volume to compromise the function of an organ or body part and results in ischemia to the affected areas. Air emboli may occur as a result of surgical procedures (e.g., cardiovascular surgery, intra-aortic balloons, arthroplasties, or endoscopies), use of monitoring devices (e.g., Swan-Ganz introducer, infusion pumps), in nonsurgical patients (e.g., diving, ruptured lung in respirator-dependent patient, injection of fluids into tissue space), or traumatic injuries (e.g., gunshot wounds, penetrating chest injuries). HBO therapy, the treatment of choice, is most effective when initiated early. Therapy is directed toward reducing the volume of gas bubbles and increasing the diffusion gradient of the embolized gas. Treatment modalities range from high pressure to low pressure mixed gas dives.

4. **Clostridial myositis and myonecrosis** (gas gangrene) is an acute, rapidly growing invasive infection of the muscle characterized by profound toxemia, extensive edema, massive death of tissue and variable degree of gas production. The most prevalent toxin is the alpha-toxin which in itself is hemolytic, tissue-necrotizing and lethal. The diagnosis of gas gangrene is based on clinical data supported by a positive gram-stained smear or culture obtained from tissue fluids. X-ray radiographs, if obtained, can visualize tissue gas. The onset of gangrene can occur one to six hours after injury and presents with severe and sudden pain at the infected area. The skin overlying the wound progresses from shiny and tense, to dusky, then bronze in color. The infection can progress as rapidly as six inches per hour. Hemorrhagic vesicles may be noted. A thin, sweet-odored exudate is present. Swelling and edema occur. The noncontractile muscles progress to dark red to black in color. The goal of HBO therapy is to stop alpha-toxin production thereby inhibiting further bacterial growth at which point the body can use its own host defense mechanisms. HBO treatment starts as soon as the clinical picture presents and is supported by a positive gram-stained smear. A treatment approach utilizing HBO, is adjunct to antibiotic therapy and surgery. Initial surgery may be limited to opening the wound. Debridement of necrotic tissue can be performed between HBO treatments when clear demarcation between dead and viable tissue is evident. The usual treatment consists of oxygen administered at 3.0 ATA pressure for 90 minutes three times in the first 24 hours. Over the next four to five days, treatment sessions twice a day are usual. The sooner HBO treatment is initiated, the better the outcome in terms of life, limb and tissue saving.

5. **Crush injuries and suturing of severed limbs, acute traumatic peripheral ischemia (ATI), and acute peripheral arterial insufficiency associated with arterial embolism and thrombosis**: Acute traumatic ischemia is the result of injury by external force or violence compromising circulation to an extremity. The extremity is then at risk for necrosis or amputation. Secondary complications are frequently seen: infection, non-healing wounds, and non-united fractures. The goal of HBO therapy is to enhance oxygen at the tissue level to support viability. When tissue oxygen tensions fall below 30mm Hg., the body’s ability to respond to infection and wound repair is compromised. Using HBO at 2-2.4 ATA, the tissue oxygen tension is raised to a level such that the body’s responses can become functional again. The benefits of HBO therapy for this indication are:
a. increased oxygen delivery per unit of blood flow or enhanced tissue oxygenation,
b. edema reduction and
c. reduction in the complication rates for infection, nonunion and amputation. The usual treatment schedule is three 1.5 hour treatment periods daily for the first 48 hours. Additionally, two 1.5 hour treatment sessions daily for the next 48 hours may be required. On the fifth and sixth days of treatment, one 1.5 hour session would typically be utilized. At this point in treatment, outcomes of restored perfusion, edema reduction and either demarcation or recovery would be sufficient to guide discontinuing further treatments. For acute traumatic peripheral ischemia, crush injuries and suturing of severed limbs, Hyperbaric Oxygen Therapy is a valuable adjunctive treatment to be used in combination with accepted standard therapeutic measures, when loss of function, limb, or life is threatened. Arterial insufficiency ulcers may be treated by HBO therapy if they are persistent after reconstructive surgery has restored large vessel function.

6. The principal treatment for progressive necrotizing infections (necrotizing fasciitis) is surgical debridement and systemic antibiotics. HBO therapy is recommended as an adjunct only in those settings where mortality and morbidity are expected to be high despite aggressive standard treatment. Progressive necrotizing fasciitis is a relatively rare infection. It is usually a result of a group A streptococcal infection beginning with severe or extensive cellulitis that spreads to involve the superficial and deep fascia, producing thrombosis of the subcutaneous vessels and gangrene of the underlying tissues. A cutaneous lesion usually serves as a portal of entry for the infection, but sometimes no such lesion is found. The histologic hallmark is extensive inflammation and necrosis of the subcutaneous fat, fascia and muscle. Numerous polymorphonuclear leukocytes and mononuclear cells are present in the upper layers of the dermis. Hyperbaric oxygen may be a beneficial adjunct for a subset of patients with anaerobic gram negative necrotizing fasciitis. The recommended HBO treatment protocol is 90 minutes at 2.5 ATA every 8 hrs for the first day and then twice daily for a total or maximum of 10 treatments.

7. Preparation and preservation of compromised skin grafts utilizes HBO therapy for graft or flap salvage in cases where hypoxia or decreased perfusion have compromised viability. This indication is not for primary management of wounds. HBO therapy enhances flap survival. Treatments are given at a pressure of 2.0 to 2.5 ATA lasting from 90-120 minutes. It is not unusual to receive treatments twice a day. When the graft or flap appears stable, treatments are reduced to daily. Should a graft or flap fail, HBO therapy may be used to prepare the already compromised recipient site for a new graft or flap. It does not apply to the initial preparation of the body site for a graft. HBO therapy is not necessary for normal, uncompromised skin grafts or flaps. Medicare coverage does not apply to artificial skin grafts.

8. Chronic refractory osteomyelitis persists or recurs following appropriate interventions. These interventions include the use of antibiotics, drainage of the abscess, immobilization of the affected extremity, and surgical debridements with removal of the sequestrum. HBO therapy is an adjunctive therapy used with the appropriate antibiotics and surgical debridement to eliminate the dead bone. Antibiotics are chosen on the basis of bone culture and sensitivity studies. HBO therapy can elevate the oxygen tensions found in infected bone to normal or above normal levels. This mechanism enhances healing and the body’s antimicrobial defenses. It is believed that HBO therapy augments the efficacy of certain antibiotics (gentamicin, tobramycin, and amikacin). Finally, the body’s osteoclast function of removing necrotic bone is dependent on a proper oxygen tension environment. HBO therapy provides this environment. HBO treatments are delivered at a pressure of 2.0 to 2.5 ATA for a duration of 90-120 minutes. It is not unusual to receive daily treatments following major debridement surgery. The number of treatments required vary on an individual basis. Medicare can cover the use of HBO therapy for chronic refractory osteomyelitis that has been shown to be unresponsive to conventional medical and surgical management.
9. HBO’s use in the treatment of osteoradionecrosis and soft tissue radionecrosis is one part of an overall plan of care that also includes debridement or resection of nonviable tissue in conjunction with antibiotic therapy. Soft tissue flap reconstruction and bone grafting may also be indicated. HBO treatment can be indicated in the preoperative and postoperative management of existing osteoradionecrosis or soft tissue radionecrosis. HBO therapy must be utilized as an adjunct to conventional therapy. The patients who suffer from soft tissue damage or bone necrosis present with disabling, progressive, painful tissue breakdown such as wound dehiscence, infection, tissue loss and graft or flap loss. The goal of HBO treatment is to increase the oxygen tension in both hypoxic bone and tissue to stimulate growth in functioning capillaries, fibroblastic proliferation and collagen synthesis. The recommended daily treatments last 90-120 minutes at 2.0 to 2.5 ATA. The duration of HBO therapy for these patients is highly individualized.

Coverage for osteoradionecrosis of the jaw is limited to cases with evidence of overt fracture or bony resorption. HBO is not covered to prepare the patient for dental extraction in order to prevent the development of osteoradionecrosis.

10. Cyanide poisoning carries a high risk of mortality. Victims of smoke inhalation frequently suffer from both carbon monoxide and cyanide poisoning. The traditional antidote for cyanide poisoning is the infusion of sodium nitrite. This treatment can potentially impair the oxygen carrying capacity of hemoglobin. Using HBO therapy as an adjunct therapy adds the benefit of increased plasma dissolved oxygen. HBO’s benefit for the pulmonary injury related to smoke inhalation remains experimental. The HBO treatment protocol is to administer oxygen at 2.5 to 3.0 ATA for up to 120 minutes during the initial treatment. Most patients with combination cyanide and carbon monoxide poisoning will receive only one treatment.

11. Actinomycosis is a bacterial infection caused by Actinomyces israelii. Its symptoms include slow growing granulomas that later break down, discharging viscid pus containing minute yellowish granules. The treatment includes prolonged administration of antibiotics (penicillin and tetracycline). Surgical incision and draining of accessible lesions is also helpful. Only after the disease process has been shown refractory to antibiotics and surgery, could HBO therapy be covered by Medicare. HBO therapy must be utilized as an adjunct to conventional therapy.

12. Treatment of diabetic wounds of the lower extremities in patients who meet all three (3) of the following criteria:
   a. Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes; and
   b. Patient has a wound classified as Wagner grade III or higher (Grade 2 – ulcer penetrates to tendon, bone or joint; Grade 3 – lesion has penetrated deeper than grade 2 and there is abscess, osteomyelitis, pyarthrosis, plantar space abscess, or infection of the tendon and tendon sheaths; Grade 4 – gangrene of the forefoot; Grade 5 – gangrene of the entire foot); and
   c. Patient has failed an adequate course of standard wound therapy. The use of HBO therapy will be covered as adjunctive therapy only after there are no measurable signs of healing for at least 30 days of treatment with standard wound therapy and must be used in addition to standard wound care. Standard wound care in patients with diabetic wounds includes;

   i. Assessment of a patient’s vascular status and correction of any vascular problems in the affected limb if possible,
   ii. Optimization of nutritional status,
   iii. Optimization of glucose control,
   iv. Debridement by any means to remove devitalized tissue,
   v. Maintenance of clean, moist bed of granulation tissue with appropriate moist dressings,
   vi. Appropriate off-loading, and
   vii. Necessary treatment to resolve any infection that might be present.
Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days. Wounds must be evaluated at least every 30 days during administration of HBO therapy. Continued treatment with HBO therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

NOTE: As with #8 above, standard therapy for osteomyelitis includes surgical debridement/excision of the infected nidus of bone.

Utilization guidelines that are applicable to all of the above conditions:

The diagnosis should be established by the referring or treating physician prior to the initiation of HBO therapy.

Continued HBO therapy without documented evidence of effectiveness does not meet the Medicare definition of medically necessary treatment.

HBO therapy should not be a replacement for other standard successful therapeutic measures. Depending on the response of the individual patient and the severity of the original problem, treatment may range from less than 1 week to several months duration, the average being 2 to 4 weeks. The use of hyperbaric oxygen for more than 2 months, (30 days for the treatment of diabetic wounds) regardless of the condition of the patient, may be subject to review for medical necessity before further reimbursement is made.

Appropriate direct physician supervision is a requirement for Medicare coverage.

In a physician office setting, “direct supervision” means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure.

In a hospital outpatient, “direct supervision” means the physician must be present and on the premises of the location and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.

HBO therapy rendered within a hospital outpatient department is considered “incident to” a physician’s (MD/DO) services and requires physician supervision. The physician supervision requirement is presumed to be met when services are performed on the hospital premises (i.e., certified as part of the hospital and part of the hospital campus); however, in all instances, it is recommended that the physician be present during the ascent and descent portions of each treatment.

For HBO therapy performed at an off-campus hospital site, the physician must be present in the office suite.


Sources of Information and Basis for Decision


• Chin-Ho Wong, Lay-Wai Khin, Kien-Seng Heng, Kok-Chai Tan, and Cheng-Ooi Low. The LRINEC (Laboratory Risk Indicator for Necrotizing Fasciitis) score: A Tool for distinguishing necrotizing faciitis from other soft tissue infections. *Critical Care Medicine.* July 2004; Volume 32, Number 7.


• Hampson NB, ed. Hyperbaric Oxygen Therapy: 1999 Committee Report. Kensington, MD: Undersea and Hyperbaric Medical Society 1999. This publication was used as a reference, especially concerning the Cierny-Mader classification of chronic refractory osteomyelitis.


• Parsons Brad and Strauss Elton. Surgical management of chronic osteomyelitis. *American Journal of Surgery.* July 1, 2004; Volume 188, Number 1, Suppl 1.


NOTE: Some of the websites used to create this policy may no longer be available.
Advisory Committee Meeting Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which include representatives from the affected provider community.

Contractor Advisory Committee meeting dates:

California -
Hawaii -
Nevada -

Start Date of Comment Period

End Date of Comment Period

Start Date of Notice Period

06/16/2008

Revision History Number

Revision #3, 10/01/2008

Revision History Explanation

Revision #3, 10/01/2008
This LCD is being revised due to the annual FY 2009 ICD-9-CM code update. Under CMS National Coverage Policy corrected the verbiage for CMS Manual System, Pub 100-04, Medicare Claims Processing Manual, §30.1. Under Indications and Limitations of Coverage and/or Medical Necessity deleted referenced manual citations that were redundant. Under Coverage Topic deleted Doctor Office Visits. Under ICD-9 Codes That Support Medical Necessity added ICD-9 codes 249.70-249.71 and 249.80-249.81 to the 2nd paragraph, "Claims for HBO for the treatment of diabetic wounds of the lower extremities require documentation of dual diagnoses...." Added ICD-9 codes 249.70, 249.71, 249.80, 249.81, 707.22, 707.23 and 707.24. Under Utilization Guidelines deleted referenced manual citations that were redundant. Under Sources of Information and Basis for Decision the references were placed in the AMA citation format. This revision becomes effective 10/01/2008.

Revision #2, 08/20/2008
This LCD is being revised to add the appropriate Bill Type Codes because the automated system transcription process was incomplete.

Revision #1, 08/20/2008
Changed the Original Determination Effective Date from 8-18-08 to 8-20-08 to comply with the date change of the J1 A/B MAC, Part A cutover date.

Reason for Change

CMS Requirement
ICD9 Addition/Deletion
Narrative Change
Other

Last Reviewed On Date
09/06/2008

Related Documents

Article(s)
A49005 - Hyperbaric Oxygen Therapy (HBO)- Supplemental Instructions

LCD Attachments
There are no attachments for this LCD.

All Versions
Updated on 09/12/2008 with effective dates 10/01/2008 - N/A
Updated on 07/27/2008 with effective dates 08/20/2008 - 09/30/2008
Updated on 07/18/2008 with effective dates 08/20/2008 - N/A
Updated on 06/08/2008 with effective dates 08/18/2008 - N/A