LCD for Hyperbaric Oxygen Therapy (HBO) (L25204)

Contractor Information

Contractor Name
National Government Services, Inc.

Contractor Number
00180

Contractor Type
FI

LCD Information

LCD ID Number
L25204

LCD Title
Hyperbaric Oxygen Therapy (HBO)

Contractor's Determination Number
L25204 R2

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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):
Section 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.

Section 1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

Code of Federal Regulations:
42 CFR 410.27(f) defines direct physician supervision in a hospital outpatient setting.

42 CFR 410.26(a)(2) and 410.32(b)(3)(ii) defines direct physician supervision in a physician office setting.

CMS Publications:

CMS Pub 100-4, Medicare Claims Processing Manual, Chapter 32, Section 30.1, Hyperbaric Oxygen Therapy (HBO).

Primary Geographic Jurisdiction
Massachusetts
Maine

Oversight Region
Region I

Original Determination Effective Date
For services performed on or after 12/01/2007

Original Determination Ending Date

Revision Effective Date
For services performed on or after 12/01/2008

Revision Ending Date
01/31/2009

Indications and Limitations of Coverage and/or Medical Necessity
This LCD consolidates and replaces all previous policies and publications on this subject by the carrier and fiscal intermediary predecessors of National Government Services (AdminaStar Federal, Anthem Health Plans of New Hampshire, Associated Hospital Service, Empire Medicare Services, Group Health Incorporated (GHI), HealthNow, First Coast Service Options, and United Government Services).

This revised LCD is effective for all National Government Services jurisdictions on July 18, 2008 with these exceptions: for Connecticut – Part B the LCD is effective on August 1, 2008; for Upstate New York – Part B, the LCD is effective on September 1, 2008; and for New York and Connecticut – Part A, the LCD is effective on November 14, 2008. For New York – Part A (contract 00308), the content of this LCD is currently in effect but the LCD will be transferred to the J-13 contract number 13201 on November 14, 2008.
1. Abstract:

This LCD is a clarification of the NCD as published in CMS Pub 100-3, Medicare National Coverage Determinations Manual, Section 20.29.

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 \((O_2)\) at greater than one atmosphere (atm) pressure. Either a monoplace chamber pressurized with pure \(O_2\) or a larger multiplace chamber pressurized with compressed air where the patient receives pure \(O_2\) 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.

(Cross reference: Section 20.29 of the CMS Pub 100-3, Medicare National Coverage Determinations Manual.)

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.

4. Other Comments:

For claims submitted to the fiscal intermediary: This coverage determination also applies within states outside the primary geographic jurisdiction with facilities that have nominated National Government Services to process their claims.

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

Limitation of liability and refund requirements apply when denials are likely, whether based on medical necessity or other coverage reasons. The provider/supplier must notify the beneficiary in writing, prior to rendering the service, if the provider/supplier is aware that the test, item or procedure may not be covered by Medicare. The limitation of liability and refund requirements do not apply when the test, item or procedure is statutorily excluded, has no Medicare benefit category or is rendered for screening purposes.

Notice to beneficiaries related to discharge and coverage notification, as described in CMS Publication 100-04, Medicare Claims Processing Manual, Chapter 2, Sections 80-80.2, applies.

Hospitals have been instructed to provide Hospital-Issued Notices of Noncoverage (HINNs) to beneficiaries prior to admission, at admission, or at any point during an inpatient stay if the hospital determines that the care the beneficiary is receiving, or is about to receive, is not covered because it is:

- Not medically necessary;
- Not delivered in the most appropriate setting; or
- Is custodial in nature.

For outpatient settings other than CORFs, references to "physicians" throughout this policy include non-physicians, such as nurse practitioners, clinical nurse specialists and physician assistants. Such non-physician practitioners, with certain exceptions, may certify, order and establish the plan of care for Hyperbaric Oxygen 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.)
Coverage Topic
Doctor Office Visits
Hospital Care (Inpatient)
Outpatient Hospital Services

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>Code</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.

Please note that not all revenue codes apply to every type of bill code. Providers are encouraged to refer to the FISS revenue code file for allowable bill types. Similarly, not all revenue codes apply to each CPT/HCPCS code. Providers are encouraged to refer to the FISS HCPCS file for allowable revenue codes.

Revenue codes 096X, 097X and 098X are to be used only by Critical Access Hospitals (CAHs) choosing the optional payment method (also called Option 2 or Method 2) and only for services performed by physicians or practitioners who have reassigned their billing rights. When a CAH has selected the optional payment method, physicians or other practitioners providing professional services at the CAH may elect to bill their carrier or assign their billing rights to the CAH. When professional services are reassigned to the CAH, the CAH must bill the FI using revenue codes 096X, 097X or 098X.

<table>
<thead>
<tr>
<th>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>
</tr>
<tr>
<td>0969</td>
<td>Professional fees-other</td>
</tr>
</tbody>
</table>
CPT/HCPCS Codes

99183  PHYSICIAN ATTENDANCE AND SUPERVISION OF HYPERBARIC OXYGEN THERAPY, PER SESSION

C1300  HYPERBARIC OXYGEN UNDER PRESSURE, FULL BODY CHAMBER, PER 30 MINUTE INTERVAL

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 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

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

440.23  ATHEROSCLEROSIS OF NATIVE ARTERIES OF THE EXTREMITIES WITH ULCERATION

444.21
<table>
<thead>
<tr>
<th>Code</th>
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<tr>
<td>444.22</td>
<td>Arterial Embolism and Thrombosis of Upper Extremity</td>
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<tr>
<td>444.81</td>
<td>Arterial Embolism and Thrombosis of Lower Extremity</td>
</tr>
<tr>
<td>444.81</td>
<td>Embolism and Thrombosis of Iliac Artery</td>
</tr>
<tr>
<td>526.4</td>
<td>Inflammatory Conditions of Jaw</td>
</tr>
<tr>
<td>526.89</td>
<td>Other Specified Diseases of the Jaws</td>
</tr>
<tr>
<td>595.82</td>
<td>Irradiation Cystitis</td>
</tr>
<tr>
<td>707.10 - 707.19</td>
<td>Unspecified Ulcer of Lower Limb - Ulcer of Other Part of Lower Limb</td>
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<tr>
<td>728.86</td>
<td>Necrotizing Fasciitis</td>
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<td>730.10</td>
<td>Chronic Osteomyelitis Site Unspecified</td>
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<td>730.11</td>
<td>Chronic Osteomyelitis Involving Shoulder Region</td>
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<tr>
<td>730.12</td>
<td>Chronic Osteomyelitis Involving Upper Arm</td>
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<td>Chronic Osteomyelitis Involving Forearm</td>
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<td>730.14</td>
<td>Chronic Osteomyelitis Involving Hand</td>
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<tr>
<td>730.15</td>
<td>Chronic Osteomyelitis Involving Pelvic Region and Thigh</td>
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<td>730.16</td>
<td>Chronic Osteomyelitis Involving Lower Leg</td>
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<td>Chronic Osteomyelitis Involving Ankle and Foot</td>
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<td>730.18</td>
<td>Chronic Osteomyelitis Involving Other Specified Sites</td>
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<td>730.19</td>
<td>Chronic Osteomyelitis Involving Multiple Sites</td>
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<tr>
<td>902.53</td>
<td>Injury to Iliac Artery</td>
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<td>903.01</td>
<td>Injury to Axillary Artery</td>
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<td>903.1</td>
<td>Injury to Brachial Blood Vessels</td>
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<td>904.0</td>
<td>Injury to Common Femoral Artery</td>
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<td>904.41</td>
<td>Injury to Popliteal Artery</td>
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<td>909.2</td>
<td>Late Effect of Radiation</td>
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<td>927.00 - 927.09</td>
<td>Crushing Injury of Shoulder Region - Crushing Injury of Multiple Sites of Upper Arm</td>
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<td>927.10</td>
<td>Crushing Injury of Forearm</td>
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<tr>
<td>927.11</td>
<td>Crushing Injury of Elbow</td>
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927.20 CRUSHING INJURY OF HAND(S)
927.21 CRUSHING INJURY OF WRIST
927.8 CRUSHING INJURY OF MULTIPLE SITES OF UPPER LIMB
927.9 CRUSHING INJURY OF UNSPECIFIED SITE OF UPPER LIMB
928.00 CRUSHING INJURY OF THIGH
928.01 CRUSHING INJURY OF HIP
928.10 CRUSHING INJURY OF LOWER LEG
928.11 CRUSHING INJURY OF KNEE
928.20 CRUSHING INJURY OF FOOT
928.21 CRUSHING INJURY OF ANKLE
928.3 CRUSHING INJURY OF TOE(S)
928.8 CRUSHING INJURY OF MULTIPLE SITES OF LOWER LIMB
928.9 CRUSHING INJURY OF UNSPECIFIED SITE OF LOWER LIMB
929.0 - 929.9 CRUSHING INJURY OF MULTIPLE SITES NOT ELSEWHERE CLASSIFIED - CRUSHING INJURY OF UNSPECIFIED SITE
958.0 AIR EMBOLISM AS AN EARLY COMPLICATION OF TRAUMA
986 TOXIC EFFECT OF CARBON MONOXIDE
987.7 TOXIC EFFECT OF HYDROCYANIC ACID GAS
989.0 TOXIC EFFECT OF HYDROCYANIC ACID AND CYANIDES
990 EFFECTS OF RADIATION UNSPECIFIED
993.3 CAISSON DISEASE
996.52 MECHANICAL COMPLICATION OF PROSTHETIC GRAFT OF OTHER TISSUE NOT ELSEWHERE CLASSIFIED
996.90 - 996.99 COMPLICATIONS OF UNSPECIFIED REATTACHED EXTREMITY - COMPLICATION OF OTHER SPECIFIED REATTACHED BODY PART
999.1 AIR EMBOLISM AS A COMPLICATION OF MEDICAL CARE NOT ELSEWHERE CLASSIFIED

Diagnoses that Support Medical Necessity
Not Applicable
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
Not Applicable

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. Refer to the attached Appendix A.

Appendices

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-odorated 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. [42 CFR 410.26(a)(2) and 410.32(b)(3)(ii)]

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. [42 CFR 410.27(f)]

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**


Advisory Committee Meeting Notes

Carrier Advisory Committee Meeting Dates:

06/13/2007 (New York)
06/13/2007 (New Jersey)
06/25/2007 (Indiana)
06/28/2007 (Kentucky)
This coverage determination does not reflect the sole opinion of the contractor or contractor Medical Director. Although the final decision rests with the contractor, this determination was developed in consultation with representatives from Advisory Committee members and/or from various state and local provider organizations.

Any Carrier Advisory Committee (CAC) related information, including Start Date and End Date of Comment Period, reflects the last time this LCD passed through the Comment and Notice process. Formal comment is not required for LCDs being adopted as part of the MAC transition.

Start Date of Comment Period

06/01/2007

End Date of Comment Period

07/16/2007

Start Date of Notice Period

06/03/2008

Revision History Number

R#2

Revision History Explanation

R2 (effective 12/01/2008): Source of revision - External inquiry. ICD-9-CM code 440.23 will be added to the list of covered diagnoses. No comment and notice periods required and none given. This addition is effective 11/01/2008 although this revision is dated 12/01/2008.

This LCD was revised to add the Jurisdiction 13 (J-13) MAC contractor numbers.

This revised LCD is effective for all National Government Services jurisdictions on July 18, 2008 with these exceptions: for Connecticut – Part B the LCD is effective on August 1, 2008; for Upstate New York – Part B, the LCD is effective on September 1, 2008; and for New York and Connecticut – Part A, the LCD is effective on November 14, 2008. For New York – Part A (contract 00308), the content of this LCD is currently in effect but the LCD will be transferred to the J-13 contract number 13201 on November 14, 2008.

The CMS Statement of Work for the J13 Medicare Administrative Contract (MAC) requires that the contractor retain the most clinically appropriate LCD within the jurisdiction. This NGS policy is being promulgated to the J13 MAC as the most clinically appropriate LCD within that jurisdiction.

The NGS roster of LCDs has been developed under the combined experience of seven Medicare contractor medical directors. The criteria for inclusion in this roster includes areas of identified CERT errors, especially repetitive errors; high volume/high dollar/pervasive problems; patient safety issues; potential for automation; beneficiary access to new technology; implementation of NCD; narrative medical necessity parameters for medical review and provider education; and CMS/law enforcement mandates.
NGS LCDs have undergone an advice and comment process from the providers in 23 states. This advice and comment process, the most comprehensive among all Medicare contractors, has ensured that NGS policies have benefited from the most in-depth and scientifically rigorous scrutiny. The NGS policy development process has resulted in the most clinically appropriate LCDs for providers and Medicare beneficiaries.

08/18/2008 - In accordance with Section 911 of the Medicare Modernization Act of 2003, fiscal intermediary number 00454 was removed from this LCD as the claims processing for American Samoa, California, Guam, Hawaii, Nevada and Northern Mariana Islands was transitioned to Palmetto GBA, the Part A/Part B MAC contractor in these states.

11/14/2008 - In accordance with Section 911 of the Medicare Modernization Act of 2003, fiscal intermediary number 00308 is removed from this LCD. Effective on this date, claims processing for Delaware is performed by Highmark Medicare Services, the Part A/Part B MAC contractor for this state, and the claims processing for New York and Connecticut is performed by National Government Services under the J-13 MAC contract; carrier number 00805 is removed, and claims processing for New Jersey is performed by Highmark Medicare Services, the Part A/Part B MAC contractor for this state.

**Reason for Change**

**Last Reviewed On Date**

12/01/2008

**Related Documents**

Article(s)
A44555 - Hyperbaric Oxygen Therapy (HBO Therapy) - Supplemental Instructions Article (SIA)

**LCD Attachments**

HBO for Hypoxic Wounds and Diabetic Wounds (HTM - 188,052 bytes)

**Other Versions**

Updated on 01/20/2009 with effective dates 02/01/2009 - N/A
Updated on 11/25/2008 with effective dates 12/01/2008 - N/A
Updated on 10/24/2008 with effective dates 11/14/2008 - 11/30/2008
Updated on 08/06/2008 with effective dates 08/18/2008 - 11/13/2008
Updated on 07/06/2008 with effective dates 07/18/2008 - 08/17/2008
Updated on 05/22/2008 with effective dates 07/18/2008 - N/A
Updated on 09/19/2007 with effective dates 12/01/2007 - N/A