RETIRED Local Coverage Determination (LCD):
HYPERBARIC **Oxygen (HBO) Therapy (L35021)**

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Please Note: This is a Retired LCD.

Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Novitas Solutions, Inc.	A and B MAC	04111 - MAC A	J - H	Colorado
Novitas Solutions, Inc.	A and B MAC	04112 - MAC B	J - H	Colorado
Novitas Solutions, Inc.	A and B MAC	04211 - MAC A	J - H	New Mexico
Novitas Solutions, Inc.	A and B MAC	04212 - MAC B	J - H	New Mexico
Novitas Solutions, Inc.	A and B MAC	04311 - MAC A	J - H	Oklahoma
Novitas Solutions, Inc.	A and B MAC	04312 - MAC B	J - H	Oklahoma
Novitas Solutions, Inc.	A and B MAC	04411 - MAC A	J - H	Texas
Novitas Solutions, Inc.	A and B MAC	04412 - MAC B	J - H	Texas
Novitas Solutions, Inc.	A and B MAC	04911 - MAC A	J - H	Colorado New Mexico Oklahoma Texas
Novitas Solutions, Inc.	A and B MAC	07101 - MAC A	J - H	Arkansas
Novitas Solutions, Inc.	A and B MAC	07102 - MAC B	J - H	Arkansas
Novitas Solutions, Inc.	A and B MAC	07201 - MAC A	J - H	Louisiana
Novitas Solutions, Inc.	A and B MAC	07202 - MAC B	J - H	Louisiana
Novitas Solutions, Inc.	A and B MAC	07301 - MAC A	J - H	Mississippi
Novitas Solutions, Inc.	A and B MAC	07302 - MAC B	J - H	Mississippi
Novitas Solutions, Inc.	A and B MAC	12101 - MAC A	J - L	Delaware
Novitas Solutions, Inc.	A and B MAC	12102 - MAC B	J - L	Delaware
Novitas Solutions, Inc.	A and B MAC	12201 - MAC A	J - L	District of Columbia

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Novitas Solutions, Inc.	A and B MAC	12202 - MAC B	J - L	District of Columbia
Novitas Solutions, Inc.	A and B MAC	12301 - MAC A	J - L	Maryland
Novitas Solutions, Inc.	A and B MAC	12302 - MAC B	J - L	Maryland
Novitas Solutions, Inc.	A and B MAC	12401 - MAC A	J - L	New Jersey
Novitas Solutions, Inc.	A and B MAC	12402 - MAC B	J - L	New Jersey
Novitas Solutions, Inc.	A and B MAC	12501 - MAC A	J - L	Pennsylvania
Novitas Solutions, Inc.	A and B MAC	12502 - MAC B	J - L	Pennsylvania
Novitas Solutions, Inc.	A and B MAC	12901 - MAC A	J - L	Delaware District of Columbia Maryland New Jersey Pennsylvania

LCD Information

Document Information

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CMS National Coverage Policy

IOM Citations:

- CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*
  - Chapter 6, Section 20.5 Outpatient Therapeutic Services
  - Chapter 15, Section 60 Services and Supplies
- CMS IOM Publication 100-03, *Medicare National Coverage Determinations (NCD) Manual*
  - Chapter 1, Part 1, Section 20.29 Hyperbaric Oxygen Therapy
- CMS IOM Publication 100-04, *Medicare Claims Processing Manual*
  - Chapter 32, Section 30 Hyperbaric Oxygen (HBO) Therapy
- CMS IOM 100-08, *Medicare Program Integrity Manual*
  - Chapter 13, Section 13.5.4 Reasonable and Necessary Provision in an LCD

Social Security Act (Title XVIII) Standard References:

- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.
- Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.
- Title XVIII of the Social Security Act, Section 1862(a)(13)(C) addresses routine foot care.

Federal Register References:

- Title 42 Code of Federal Regulations (CFR) 413.65 Requirements for a determination that a facility or an organization has provider-based status.
- Title 42 CFR 410.26(a)(2) Services and supplies incident to a physician's professional services: Conditions, Definitions, Direct supervision.
- Title 42 CFR 410.32(b)(3)(ii) Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions, Diagnostic x-ray and other diagnostic tests, Levels of supervision, Direct supervision.
- Title 42 CFR 410.27(f) Outpatient hospital or CAH services and supplies incident to a physician or nonphysician practitioner service.
- Title 42 CFR 410.42(a) Limitations on coverage of certain services furnished to hospital outpatients, General rule.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.

History/Background and/or General Information

For purposes of coverage under Medicare, **HYPERBARIC OXYGEN THERAPY (HBOT)** 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 pressure. Either a mono-place chamber pressurized with pure O_2 or a larger multi-place 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 augments oxygenation to all parts of the body; and
2. It replaces inert gas in the bloodstream with OXYGEN, which is then metabolized by the body; and
3. It may stimulate the formation of a collagen matrix and angiogenesis; and
4. It acts as a bactericide for certain susceptible bacteria.

Developed as treatment for decompression illness, this modality is an established therapy for treating medical disorders such as carbon monoxide (CO) poisoning, gas gangrene, acute decompression illness and air embolism. Hyperbaric oxygen (HBO) therapy is also considered acceptable as adjunctive therapy in the treatment of sequella of acute vascular compromise and in the management of some disorders that are refractory to standard medical and surgical care or the result of radiation injury.

Covered Indications

Detailed information regarding the covered conditions for HBO therapy may be found in the National Coverage Determination (NCD) 20.29. Please refer to CMS IOM Publication 100-03, *Medicare National Coverage Determinations (NCD) Manual*, Chapter 1, Part 1, Section 20.29 Hyperbaric Oxygen Therapy for full coverage information.

SPECIFIC CONDITIONS

The guidelines below are presented relative to specific treatment conditions and include criteria for diagnosis with expected frequency and duration of treatment.

1. Patients manifesting signs and symptoms of serious carbon monoxide poisoning (e.g., transient or prolonged unconsciousness, neurologic signs, cardiovascular dysfunction or severe acidosis) should be referred for HBO therapy regardless of carboxyhemoglobin (COHb) level, as COHb levels do not correlate with signs and symptoms. However, referral of patients with COHb greater than or equal to 25% is reasonable or when neuropsychological testing is abnormal. Treatment should begin at the time of diagnosis. Optimal dosing (pressure, duration, frequency) is not known but optimal benefit from HBOT occurs in those treated with the least delay after exposure. The majority of facilities offer single session HBOT to CO-poisoned patients; however, in selected patients repeated treatments may yield better outcome. Several protocols have been developed; however, most offer 2.8-3.0 atmosphere absolute (ATA) initial compression, then 2 ATA for 120-140 minutes, occasionally followed by additional 2 sessions for 90 minutes in six to twelve hour intervals, without further HBOT. Even with appropriate HBOT some patients will develop cognitive or other neurologic sequela which does not appear to be altered by continued HBOT. Children may be treated safely but may still have long-term problems. Pregnant women may be treated safely. Evidence of fetal distress is indication of need for HBOT despite normal carboxyhemoglobin levels and the absences of symptoms in the mother.
2. Decompression Illness (Sickness) is the result of inert gas bubbles in tissues or blood causing organ dysfunctions. It can be caused by a reduction in ambient pressure during ascent from a dive, rapid altitude excursion or a hyperbaric/hypobaric chamber. The resulting clinical manifestations include joint pain (bends), cutaneous eruptions or rashes, neurological dysfunction, cardiorespiratory symptoms and pulmonary edema, shock and death. Diagnosis of decompression injury is made on the basis of signs and symptoms after a dive or altitude exposure, manifest as paresthesia, hypesthesia, joint pain, skin rash and malaise while more serious signs may be motor weakness, ataxia, dyspnea, hypotension and shock leading to death. All symptoms manifest within 24 hours unless there is an additional insult. Treatment of choice for decompression illness is HBO therapy with mixed gases. The result is immediate reduction in the volume of bubbles. Recommended treatment is administration of 100% oxygen (1 ATA) at ground level or at elevated pressure (HBO) when feasible. The majority of symptoms will resolve with supportive measures; however, it is generally agreed that complete resolution is most likely to occur with HBO therapy. The treatment prescription is highly variable and case specific, however the great majority of cases respond to a single treatment. Although a small minority of divers with severe neurological injury may not reach a clinical plateau until 15-20 repetitive treatments have been administered (less than 2.82 ATA), formal statistical analysis supports the efficacy of no more than 5-10 repetitive treatments for most individuals. A summary of current recommendations for adjunctive therapy is available on the Undersea and Hyperbaric Society website (https://www.uhms.org).[1]
3. Air or 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. Arterial gas embolism (AGE), classically described during submarine escape training, can also occur as a result of blast injury, mechanical ventilation, penetrating chest trauma, chest tube placement and bronchoscopy. Venous gas embolism classically occurred after compressed gas diving or rapid exposure to altitude; however, medical intervention is the most common cause. Accidental intravenous air injection may occur with cardiopulmonary bypass accidents, gastrointestinal endoscopy, hydrogen peroxide irrigation, arthroscopy, central venous catheter placement or disconnection, endoscopic or laparoscopic procedures, and dental procedures, to name only a few possible scenarios. Clinical deficits can occur after intra-arterial injections of very small volumes of air while larger intravenous injection is often asymptomatic. Presumptive diagnosis of AGE is made on the basis of clinical criteria. Diagnostic imaging is unnecessary as it has low diagnostic sensitivity (and may delay therapy) but may exclude other etiologies for the symptoms. HBO therapy, the treatment of choice, is most effective when initiated early. Immediate treatment is airway management, maintenance of blood pressure and administration of high oxygen concentration with HBOT as quickly as the patient can be stabilized. Administration of repetitive treatments is recommended until there is no further improvement, typically after no more than one to two hyperbaric sessions, but occasionally as many as 5.

Standard treatment schedules are those of the U.S. Navy (U.S. Navy Diving Manual available at https://www.navsea.navy.mil/Home/SUPSALV/00C3-Diving/Diving-Publications/).[2]

4. Clostridial Myositis and Myonecrosis (Gas Gangrene) is an acute, rapidly invasive infection of the muscle characterized by profound toxemia, extensive edema, massive death of tissue and variable degree of gas production. The diagnosis of gas gangrene is based on clinical data supported by the demonstration of Gram-positive rods from the fluids of the involved tissues as well as a virtual absence of leukocytes. Culture results are unpredictable while sialidase immunoassays may allow accurate identification of the Clostridium species. Tissue gas seen in a feather-like pattern radiologically, associated with crepitus, is an early and characteristic sign. An associated thin serosanguinous exudate with a sickly, sweet odor associated with disproportionate pain is essentially diagnostic. The onset of gangrene can occur one to six hours after injury and presents with severe and sudden pain at the infected area. The goal of HBO therapy is to stop alpha-toxin production, requiring tissue oxygen concentrations of 250 millimeters of mercury (mm Hg), to inhibit 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 stain. The greatest reduction in mortality results from treatment utilizing HBOT, antibiotic therapy and surgery. 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, for up to 15 sessions. The actual decision for termination of therapy is dependent upon the patient's response to HBO therapy.
5. Crush injuries, suturing of severed limbs, acute traumatic peripheral ischemia (ATI), and acute peripheral arterial insufficiency associated with arterial embolism and thrombosis share the common pathophysiology of Reperfusion Injury. Acute traumatic ischemia is the result of injury by external force or violence, compromising circulation to an extremity. Similarly Acute Peripheral Arterial insufficiency (APAI) is acute onset of ischemia of an extremity secondary to arterial embolus or thrombus. Presentation is within hours to a few days after the event. The extremity is then at risk for tissue loss and necrosis with subsequent amputation. Emergent surgical intervention is imperative if the extremity is to be salvaged. Secondary complications are frequently seen: infection, non-healing wounds, and non-united fractures despite the restoration of circulation, due to the reactive edema which presents post restoration of blood flow. The goal of HBO therapy is to enhance oxygen at the tissue level to support viability during the post injury period. When tissue oxygen tensions fall below 30 mm 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:
    - Increased oxygen delivery per unit of blood flow or enhanced tissue oxygenation,
    - Edema reduction, and
    - Reduction in the complication rates for infection, nonunion and amputation.

    The use of HBOT is expected to be in support of the definitive surgical procedure (re-implantation, embolectomy, thrombectomy, decompression of a compartment syndrome or removal of the flow limiting condition of the limb).

    HBO is indicated within the first 4-6 hours of the acute event, AND only after documented restoration of the blood circulation. For reperfusion injuries, crush injuries or pending compartment syndrome, therapy beyond 2-3 days has not shown beneficial salvage or further limit to loss of tissue or limb. Post fasciotomy demarcation may require up to 2 weeks of twice daily treatments prior to definitive determination of benefit. Therapy initiated or continued longer than two weeks from the inciting injury has not been determined to be beneficial. Beyond two weeks the condition is considered chronic and would not be considered reasonable and necessary. The usual treatment schedule is two to three 90 minute treatment periods daily for the first 24- 48 hours. Additional 90 minute treatment sessions daily for the next 2-3 days may be required. For acute traumatic peripheral ischemia, crush injuries and recently restored severed limbs, with resultant compartment syndromes, HBOT is a valuable adjunctive treatment to be used in combination with accepted standard surgical and pharmacologic therapeutic measures, when loss of function, limb, or life is threatened. Edema or after effects of acute arterial insufficiency may be treated by limited HBO therapy similar to that of crush injuries or acute ischemia with reperfusion signs, if they are persistent after reconstructive surgery has restored large vessel function and perfusion. Reperfusion injury treatment with HBOT is not expected to exceed 15 sessions

over the course of a 3-7 day acute treatment.

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. It may be confused with Clostridial infection though seldom produces gas in the tissues. The histologic hallmark is extensive inflammation and necrosis of the subcutaneous fat, fascia and muscle. Numerous bacterial types may produce bullous lesions with foul or fermented aroma. 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 hours for the first day in conjunction with surgical debridement of infected and necrotic tissue, and then twice daily for a maximum of 10 treatments.
7. Preparation and preservation of compromised skin grafts utilizes HBO therapy for graft salvage in cases where hypoxia or decreased perfusion has compromised viability. This indication does not include HBO treatment that is empiric treatment or prophylactic maintenance of grafts or solely for preparation of a wound bed for receiving a graft (except to the extent that treatment of the wound is otherwise reasonable and necessary for coverage under another provision of NCD 20.29 and this LCD). HBOT to artificial skin grafts (e.g., bioengineered or allogeneic skin substitutes) is not covered. (Please refer to NCD 20.29 and Program Memorandum AB 00 15, Change Request (CR) 1138 for further information)
   Treatments are given intensively initially for up to 72 hours followed by re-evaluation of the wound. It is not unusual to receive 2-3 treatments per day for up to 3 days post creation of the graft when viability appears threatened. When the graft appears stable, treatments are reduced to daily or discontinued. The number of sessions provided to enhance graft survival is not expected to exceed 20.
8. Per NCD 20.29, Medicare covers the adjunctive use of HBO therapy for chronic refractory osteomyelitis that has been shown to be unresponsive to conventional medical and surgical management. Inherent in this coverage statement is that the osteomyelitis must be chronic and refractory to usual standard of care management (i.e., prolonged antibiotics therapy preferably directed by appropriate culture and sensitivity information, drainage of the abscesses, immobilization of the affected extremity, and surgical debridement with removal of infected bone). HBO for osteomyelitis that is not documented to be chronic and refractory to conventional treatment, and HBO not provided in an adjunctive fashion, is not covered. Covered HBO therapy is an adjunctive therapy used with the appropriate antibiotics and surgical debridement to eliminate the necrotic bone acting as a foreign body. When the site of the bone infection is not amenable to debridement or resection, HBOT may be indicated to enhance systemic therapy though is not indicated as primary therapy alone.
   HBO treatments are usually delivered daily for a period of 90-120 minutes and it is not unusual to receive daily treatments following major debridement surgery. The usual course of therapy lasts 4-6 weeks with daily sessions lasting 90-120 minutes up to a maximum of 60 treatments within a 12 month period as designated by the CMS pre-authorization project. Additional treatments may be considered reasonable and necessary on redetermination.
9. HBO’s use in the treatment of Osteoradionecrosis and Soft Tissue Radiation Injury (Radionecrosis) is one part of an overall plan of care that also includes debridement or resection of nonviable tissue in conjunction with antibiotic therapy. A consistent cause and effect of radiation injury is vascular obliteration and stromal fibrosis or scarring; subsequently the known impact of hyperbaric oxygen therapy, stimulation of angiogenesis, is an important mechanism of recovery. A reduction in fibrosis of soft tissue as well as mobilization and increase of stem cells within radiated tissue has been documented predominantly in animal studies; however, the impact of HBOT is likely to involve all these mechanisms.
   HBO treatment can be indicated in the preoperative and postoperative management of existing osteoradionecrosis or soft tissue radionecrosis, but must be utilized as an adjunct to conventional therapy. Beneficiaries suffering from soft tissue damage or bone necrosis present with disabling, progressive, painful

tissue breakdown, bleeding, bowel or bladder dysfunction, wound dehiscence, infection, tissue loss and graft or flap loss.

Prerequisite for treatment includes history of radiation treatment to the region of the documented injury, terminating at least 6 months prior to onset of signs or symptoms or planned surgical intervention at the site. Numerous forms of soft tissue radiation necrosis and treatment with HBOT have been documented with beneficial effect. Tissues previously irradiated with subsequent planned surgery appear to benefit from HBOT surrounding the surgery with decreased morbidity from large vessel necrosis. For this reason patients manifesting signs and symptoms of radiation injury will be approved for coincidental HBOT, without the histologic diagnosis of ongoing osteoradionecrosis or soft tissue radionecrosis.

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 are designed around the stages of radionecrosis and typically last 90-120 minutes at 2.0 to 2.5 ATA. The duration of HBO therapy for these patients is highly individualized but is not expected to exceed 4-8 weeks therapy. The Marx mandibular osteoradionecrosis protocol extends from 30-60 treatments based on stage I-III, adhering to the established principle that all necrotic bone must be debrided. Soft tissue radionecrosis usually responds with 30-40 treatments, followed by reconstruction if deemed necessary. An additional 10 treatments is usual following the reconstruction for support of the underlying and surrounding tissue. All treatment is individualized and should be assessed for benefit and outcome each 30 days.

No demonstrable evidence of improvement post two 30 day periods of HBOT (2.0-2.5 ATA, for 90 to 120 minutes, 5 days per week) suggests lack of benefit and subsequent treatments will be denied as not medically reasonable and necessary. No benefit has been demonstrated for treatment of acute radiation injury or burn, usually manifest coincident with radiation therapy or within the ensuing 6 months of the therapy.

Documentation of mitigating factors contributing to injury coincident to the radiation or other factors may allow reimbursement for treatment not traditionally meeting criteria for radionecrosis.

Coverage for osteoradionecrosis of the jaw is limited to cases with evidence of overt fracture or bony resorption. Data to justify 'HBOT prophylaxis for osteoradionecrosis' in a previously irradiated mandible undergoing tooth extraction is lacking at this time; subsequently this is a non-covered service.

HBO is not covered to prepare the patient for dental extraction when radiation therapy has not been done at least 6 months prior, in order to prevent the development of osteoradionecrosis.

10. Individuals with CO poisoning may also have been exposed to cyanide and the combination may have synergistic toxicity. Severe cyanide poisoning is rapidly fatal while symptoms of mild cyanide poisoning may mimic CO poisoning. Along with supportive care (ventilation, supplemental oxygen and blood pressure support) a cyanide antidote may be administered, some of which may yield unreliable monitoring results (hydroxocobalamin). Nitrites which induce methemoglobinemia, potentially impair the oxygen-carrying capacity of hemoglobin and are now considered contraindicated in the setting of concomitant CO poisoning. Treatment protocol and dosing is directed to the Carbon Monoxide poisoning as that for cyanide poisoning appears to be theoretical and not well substantiated by human studies.
11. Actinomycosis is a bacterial infection caused by Actinomyces Israelii. Findings include slow growing granulomas that later break down, discharging viscid pus containing yellow granules. The treatment includes prolonged administration of appropriate antibiotics with surgical incision and draining of accessible lesions. When the disease process has been shown refractory to antibiotics and surgery, HBO therapy may be considered reasonable and necessary.
12. Treatment of diabetic wounds of the lower extremities: Refer to #15 of the covered indications of NCD 20.29. Adjunctive treatment of an ulcer of the lower extremity deemed to be secondary to the neuropathic effects of diabetes will be allowed no more than 40 treatments (90-120 minutes daily) without documentation of improvement. Wound volume or surface area is expected to measurably diminish over 30 days of wound care with adjunctive HBOT. Continued treatment with HBO therapy is non-covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment. ”Measurable signs of healing” are best defined as specific, documented, clinical evidence of healing. Physician statements should be descriptive and complete with interval measurements to substantiate wound improvement.

    NOTE: Failure to respond to standard wound care occurs when there are no measurable signs of healing (per

NCD 20.29) for at least 30 consecutive days of appropriate wound care during which the patient has documented evidence of "optimization for wound healing" and there is no appreciable change in the wound. Documentation of all aspects of optimization defined by the NCD (clarified by this LCD) and the absence of improvement in the wound characteristics constitutes stalled wound healing and suggests that it may benefit from adjunctive HBOT.

NOTE: An ankle brachial index of not less than .6 is considered the standard required for healing of a lesion on a diabetic's foot. Alternative measurements of toe pressures, plethysmography or similar demonstration of small vessel perfusion may be considered if viable results cannot be obtained in the situation of calcified or non-compressible vessels of the foot and ankle. Transcutaneous oxygen measurements cannot predict whether a patient will respond to HBOT but may provide insight into the response to HBOT or revascularization. HBOT should not be used as a substitute for revascularization.

NOTE: As with #8 above, standard therapy for osteomyelitis underlying a chronic ulcer, or mal perforans ulcer, includes surgical debridement/excision of the infected nidus of bone.

Hyperbaric Oxygen Therapeutic Services

Therapeutic services are hospital outpatient services furnished incident to the services of a physician (or NPP) in the treatment of patients.

Appropriate "physician supervision" is a requirement for Medicare coverage of Hyperbaric Oxygen Therapeutic Services.

Supervision levels for therapeutic services to hospital outpatients, including critical access hospital outpatients have changed. Please refer to the CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 6, Section 20.5 Outpatient Therapeutic Services and to Chapter 15, Section 60 Services and Supplies for complete information regarding supervision requirements.

NOTE: The Office of the Inspector General (OIG), in the report, 'Hyperbaric Oxygen Therapy, Its Use and Appropriateness,' published October, 2000, links the quality of care to the physical presence of the physician during the entire treatment for the purpose of managing the patient's overall care.

Provider Qualifications/Certification

While HBO can be a life-saving or limb preserving therapy, there are significant complications and precautions that may be associated with HBOT. Complications present infrequently in individual patients receiving HBOT within single or multi-place chambers, but are potentially severe and life-threatening. Tympanic membrane injury is most common and can be accompanied by systemic response including vomiting, aspiration and seizures while in the confines of the HBO chamber. Oxygen toxicity with chest pain, seizures, altered states of consciousness or anxiety require prompt evaluation. The occurrence of a pneumothorax, with possible tension component, requires **immediate** differentiation from lesser issues and appropriate intervention**. Thus, the Scope of Practice for a physician supervising HBOT must include all components of patient evaluation necessary to evaluate the potential HBOT recipient and to ensure that there is no relative contraindication to treatment.** The physician supervising HBOT should be both cognizant of the potential hazards of the therapy and have the capability to provide appropriate treatment of the complication should it arise. **Supervising Physician's documented training shall include the experience and expertise necessary to diagnose and treat the established complications of HBOT occurring while the patient is under his care. These potential complications include tension pneumothorax, respiratory decompensation secondary to aspiration, seizures, acute tympanic membrane injury, signs of oxygen toxicity and hypoxia as well as differentiation of these problems from anxiety or claustrophobia.** All potential treatment of medical and surgical emergencies arising in the patient receiving HBOT must be within the scope of practice of the physician providing supervision.

Qualified Providers may supervise HBOT services, if such service including definitive evaluation of the patient is included within their State Scope of Practice, or if their required supervision or collaborative agreement is with a physician qualified to provide HBOT services and if the provider meets the educational requirements identified herein.

Physicians (or NPPs) supervising Hyperbaric Oxygen Therapy should be certified in Hyperbaric Medicine by the American Board of Emergency Medicine (ABEM), the American Board of Preventive Medicine (ABPM) or the American Osteopathic Conjoint Committee of Undersea and Hyperbaric Medicine (AOCUHM) or other entity adopting a Hyperbaric Medicine training protocol by **completion of a minimum 40-hour training experience in a nationally recognized program offering AMA Category I CME credits (40 hours) (e.g., American College of Hyperbaric Medicine [ACHM], The Undersea and Hyperbaric Medical Society [UHMS], National Baromedical Services [NBS]).**

Advanced Cardiac Life Support (ACLS) training and certification of supervising physicians (and NPP) is required in all points of service and for any physician or NPP supervising HBOT in all locations.

The Facility shall ensure that there is adequate documentation of physician supervision for the procedure during the time when Medicare patients are receiving services.

The CMS encourages physicians who perform HBO therapy to obtain adequate training in the use of HBO therapy and in Advanced Cardiac Life Support (ACLS) or Advanced Trauma Life Support (ATLS). It is also reasonable and necessary to expect the hospital or facility that provides the setting for the delivery of HBOT to complete the process of credentialing, adhering to policies set forth in this LCD as well as NCD 20.29. This would require that the attending/supervising physician provide documentation supporting credentials in hyperbaric medicine and is qualified to manage the scope of work required in the delivery of hyperbaric oxygen therapy, as well as being able to manage an acute HBOT precipitated emergency consistent with scope of practice defined by the state and facility. The appropriate certification and/or accreditation must be obtained within 6 months of this LCD becoming effective and made available to the contractor upon request.

- Limited license providers performing hyperbaric medicine services must have an unlimited licensed physician immediately available to render assistance if needed.
- Medicare reimbursement shall be limited to facilities documenting the appropriate supervision requirements for HBOT as outlined in the Medicare internet only manual. Facilities are expected to provide immediate availability of adequate emergency equipment for managing potential complications of hyperbaric oxygen therapy. Hyperbaric services performed in facilities or by providers not meeting the safety, reasonable and necessary provisions of this LCD are not covered and should not be reported to Medicare for payment as though they are covered.

Limitations

1. The following conditions are conditions that are expected to be provided in the inpatient only setting due to the acute and critical nature of the disease, concomitant conditions, and the need for correlation with other acute, invasive or monitoring services; gas gangrene, sequella of acute peripheral ischemia (including reperfusion conditions of arterial embolism and thrombosis, reimplantation or crush injuries of the extremities), necrotizing fasciitis, air embolisms, carbon monoxide/cyanide poisoning. Therefore, HBO therapy for these services in an outpatient or non-acute care setting would be considered not reasonable and necessary.
2. Pregnancy is considered a contraindication to HBOT except in the case of carbon monoxide poisoning for which it is specifically indicated on an emergent basis.

Topical Application of Oxygen

This method of administering oxygen does not meet the definition of HBO therapy as its clinical efficacy has not been established. Therefore, Medicare considers the topical application of oxygen not reasonable and necessary. Medicare reimbursement will be limited to therapy that is administered in a chamber (including single or multi-place units).

Non-Covered Conditions

Please refer to CMS IOM Publication 100-03, *Medicare National Coverage Determinations (NCD) Manual*, Chapter 1, Part 1, Section 20.29 Hyperbaric Oxygen Therapy for information related to non-covered conditions.

This LCD imposes frequency limitations. For frequency limitations please refer to the Utilization Guidelines section below.

Notice: Services performed for any given diagnosis must meet all of the indications and limitations stated in this policy, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

Summary of Evidence

N/A

Analysis of Evidence
(Rationale for Determination)

N/A

General Information

Associated Information

Refer to Local Coverage Article: Billing and Coding: Hyperbaric Oxygen (HBO) Therapy (A56714).

Documentation Requirements

1. All documentation must be maintained in the patient's medical record and made available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g.,

complete name, dates of service[s]). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.

3. The medical record documentation must support the medical necessity of the services as stated in the NCD and this policy.
4. Documentation that a trained emergency response team is available and that the setting provides the required availability of ICU services that could be needed to ensure the patient's safety if a complication occurred.
5. The documentation present in the clinical record must provide an accurate description and diagnosis of the medical condition supporting that the use of HBO is reasonable and medically necessary. The medical documentation must include but is not limited to the following:
    - An initial assessment, which includes a history and physical that clearly substantiates the condition for which HBO is recommended. This should also include any prior medical, surgical or HBO treatments.
    - Documentation of the procedure (logs) including ascent time, descent time and pressurization level. There should be a treatment plan identifying timeline and treatment goals.
    - Physicians' progress notes that describe the physical findings, type(s) of treatment(s) provided, number of treatments provided, the effect of treatment(s) received and the assessment of the level of progress made toward achieving the completion of established therapy goals.
    - Physician-to-physician communications or records of consultations, additional assessments, recommendations or procedural reports.
    - Laboratory reports (cultures or Gram stains) that confirm the diagnosis of necrotizing fasciitis are required and must be present as support for payment of HBO.
    - X-ray findings and bone cultures confirming the diagnosis of osteomyelitis are required and must be present as support for payment of HBO.
    - Documentation to support the presence of gas gangrene as proven with laboratory reports (Gram stain or cultures) and X-ray.
    - Documentation of date and anatomical site of prior radiation treatments.
    - Documentation supporting date of skin graft and compromised state of graft site.
    - For diabetic wounds of the lower extremity, the Wagner classification of the wound and the failure of an adequate course (at least 30 days) of standard wound therapy must be documented at the initiation of therapy:
        - Documentation must include criteria and exam consistency to establish the diagnosis of a Wagner's grade III wound.
        - Documentation of standard wound care in patients with diabetic wounds must include: assessment of a patient's vascular status and documentation of correction of any vascular problem sufficient to impair wound healing in the affected limb; documentation of optimization of nutritional status; documentation of optimization of glucose control; documentation of debridement by any means to remove devitalized tissue; documentation of maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings; documentation of efforts for appropriate off-loading; and documentation of necessary treatment to resolve any infection that might be present. Failure to respond to standard wound care occurs when there is no documentation of measurable signs of healing for at least 30 consecutive days post optimization for healing. The medical record must include, at a minimum, a wound evaluation at least every 30 days during administration of HBO therapy.

Utilization Guidelines

In accordance with CMS Ruling 95-1 (V), utilization of these services should be consistent with locally acceptable standards of practice.

Use of HBOT exceeding the outlined frequencies in the covered indications will be considered Not Reasonable and Necessary. Reconsideration for extension of treatment duration will be available upon appeal.

Medicare will cover a total of 60 Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy sessions per 12 month period.

Medicare expects that treatment of most covered indications will require 5 or fewer services of Hyperbaric oxygen under pressure, full body chamber sessions per day per beneficiary. Coverage of greater than 5 of these services per day per beneficiary may require medical record review.

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. Thorough re-evaluation should be made at least every 30 days for documentation of response to therapy. Documentation to support effectiveness of the therapy must be made available upon request to the Contractor.

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 1-2 months' duration, the average being 2 to 4 weeks. The use of Hyperbaric Oxygen Therapy for more than 2 months, (30 days for the treatment of diabetic wounds) regardless of the condition of the patient, may be subject to post payment medical review for medical necessity.

Notice: This LCD imposes utilization guideline limitations. Despite Medicare's allowing up to these maximums, each patient’s condition and response to treatment must medically warrant the number of services reported for payment. Medicare requires the medical necessity for each service reported to be clearly demonstrated in the patient’s medical record. Medicare expects that patients will not routinely require the maximum allowable number of services.

Sources of Information

Contractor is not responsible for the continued viability of websites listed.

Other Contractor Policies

“Hyperbaric Oxygen (HBO) Therapy,” TrailBlazer Health Enterprises, LLC LCD, 00400 (L2084), 09000 (L8823).

(Retired June 2007) “Hyperbaric Oxygen Therapy,” Arkansas, BlueCross BlueShield (Pinnacle) LCD, (OK,NM) L8176, L12108, L12109.

Novitas Solutions, Inc. – JH Local Coverage Determination (LCD) Consolidation Narrative Justification – Most Clinically Appropriate LCD

Original JH ICD-9 Source LCD L32739, Hyperbaric Oxygen (HBO) Therapy

JL ICD-10 LCD L34979, Hyperbaric Oxygen (HBO) Therapy

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Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
08/27/2020	R24	LCD retired effective for dates of service on and after 8/27/2020.	• LCD Being Retired
01/01/2020	R23	LCD revised and published on 02/13/2020 effective for dates of service 01/01/2020 and after. Consistent with CMS Change Request 11605, the LCD has been revised to replace Internet-Only Manual (IOM) language regarding supervision with references to the appropriate citation. Please refer to the CMS Change Request for appropriate supervision requirements until the IOM is updated.	• Other (CMS Change Request 11605)
11/14/2019	R22	Consistent with CMS Change Request 10901, the LCD has been revised to remove the entire coding sections.	• Other (CMS Change Request 10901)

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07/25/2019	R21	LCD revised and published on 07/25/2019. Consistent with Change Request (CR) 10901 National Coverage Determination and Internet-Only Manual (IOM) language removed and replaced with references to appropriate citations. CPT/HCPCS and the link to the ICD-10 codes have been removed from the LCD and placed in the related Billing and Coding Article, A56714. Sources numbered and moved to the Bibliography section and standard LCD formatting changes made throughout the LCD. There has been no change to coverage in this policy with this revision.	• Other (Change in LCD process per CR 10901)
04/11/2019	R20	LCD revised and published on 04/11/2019 in response to CMS Change Request (CR) 10901 to remove reasonable and necessary IOM language and update the CMS IOM citations. Consistent with CMS CR 10901, the NCD indications and limitations have been removed from the Covered Indications and Limitations area of the LCD and replaced with a reference to the NCD. CMS IOM reference Publication 100-09 pertains to coding therefore it has been removed from the LCD. There has been no change in coverage to the LCD.	• Other (Changes in response to CMS change request)
10/19/2018	R19	LCD updated on 12/13/2018 to correct bolding issues from previous LCD version. No content changes have been made to the LCD.	• Typographical Error
10/19/2018	R18	LCD revised and published on 12/06/2018 effective for dates of service on and after 10/19/2018 to add clarification to the training experience in the "Provider Qualifications/Certification" section. Clarified that the completion of a minimum of 40-hour training experience is in a nationally recognized program offering AMA Category I CME credits (40 hours) and added National Baromedical Services (NBS) as an additional example. Per LCD annual review, updates were made to the references in the "CMS National Coverage Policy" section of the LCD. At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; therefore, not all the fields included on the LCD are applicable as noted in this policy.	• Other (Inquiry and LCD Annual Review)
04/01/2018	R17	LCD revised and published on 04/12/2018 effective for dates of	• Revisions Due To ICD-10-CM Code

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		service on and after 04/01/2018 to update the link and title for ICD-10 diagnosis codes related to HBO in response to Change Request 10318 issued January 18, 2018. The spreadsheet title was updated in the ICD-10 Group 1 Paragraph and ICD-10 Codes that Do Not Support Medical Necessity sections and the link was also updated in the ICD-10 Group 1 Paragraph section. Bill Type 11x was removed as it is not for inpatient services claims. At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; therfore, not all the fields included on the CLD are applicable as noted in this policy.	Changes
10/05/2017	R16	LCD revised and published on 10/05/2017 effective for dates of service on and after 10/01/2015 in response to Change Request 10086 issued on May 26, 2017 to update the link and title in Group 1 Paragraph under ICD-10 Codes that Support Medical Necessity and update the title under ICD-10 Codes that DO NOT Support Medical Necessity for the list of covered ICD-10 diagnoses code spreadsheet.	• Revisions Due To ICD-10-CM Code Changes
10/01/2016	R15	Corrected the following sentence for a typographical error with the symbol (=): "However, referral of patients with COHb greater than or equal to 25% is reasonable or when neuropsychological testing is abnormal."	• Typographical Error
10/01/2016	R14	LCD revised and published on 10/13/2016 for dates of service on and after 10/01/2016 to add reference to CR9631 and update the title and hyperlink to the download of the covered ICD-10 diagnosis code spreadsheet effective 10/01/2016.	• NCD Supplementation
07/01/2016	R13	LCD revised and posted on 8/4/2016 to correct the formatting of covered indication #15 to match the NCD formatting ensuring that the statement regarding the use of HBO therapy as adjunctive therapy is directly under #15 and to revise the coverage statement to match the NCD.	• Other (Inquiry)
07/01/2016	R12	LCD revised and published on 07/21/2016 to correct a typographical error in the Coverage Indications, Limitations, and or Medical Necessity section of this LCD under the Hyperbaric Oxygen Therapeutic Services section. The following sentence has been corrected to reflect the correct HCPCS code G0277. The Centers for Medicare and Medicaid services has not designated services 99183 or G0277 eligible for classification	• Typographical Error

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		as Non-Surgical Extended Duration Therapeutic Services, allowing transition from direct supervision to general supervision at the discretion of the supervising physician.	
07/01/2016	R11	LCD revised and published on 07/14/2016 for dates of service on and after 07/01/2016 to add reference to CR9540 and update the hyperlink and the title of the covered ICD-10 diagnosis code spreadsheet provided in CR9540 effective 07/01/2016.	• NCD Supplementation
12/31/2015	R10	LCD revised and published on 06/02/2016 for dates of service on and after 12/31/2015 to provide further clarification regarding coverage of HBO treatment for skin grafts and osteomyelitis, including reference to Change Request 1138.	• Other (Clarification)
12/31/2015	R9	LCD revised and published on 05/19/2016 for dates of service on and after 12/31/2015 to add clarification to HBO treatment of skin grafts, osteomyelitis treatment, emergency equipment in facilities and the utilization of HCPCS G0277.	• Other (Inquiry)
12/31/2015	R8	LCD revised and published on 02/19/2016 for services performed on or after 12/31/2015 to provide clarification regarding compromised skin grafts, treatment of diabetic wounds and provider training/qualifications. Link to the CMS covered diagnoses codes added to the LCD.	• Other (Inquiry)
12/31/2015	R7	LCD revised and published 12/31/2015 to add related NCD 20.29.	• Other (Clarification)
12/31/2015	R6	LCD posted for notice on 11/05/2015 to become effective 12/31/2015. 05/14/2015 Draft LCD posted for comment.	• Creation of Uniform LCDs With Other MAC Jurisdiction
10/01/2015	R5	LCD revised and published 10/08/2015 to remove diagnosis codes and added reference to NCD 20.29 for covered diagnoses effective for dates of service on and after 10/01/2015.	• NCD Supplementation
10/01/2015	R4	LCD revised and published 05/14/2015 to remove language that HBO can only be provided in inpatient or outpatient hospital settings consistent with CR 9087.	• NCD Supplementation
10/01/2015	R3	LCD revised and published 01/23/2015 to correct the publication date of the annual CPT/HCPCS code updates incorrectly listed as 01/22/2015 in revision history below.	• Revisions Due To CPT/HCPCS Code Changes • Typographical

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			Error
10/01/2015	R2	LCD revised and published on 01/22/2015 to reflect the annual CPT/HCPCS code updates. CPT/HCPCS code C1300 has been deleted and replaced with CPT/HCPCS code G0277.	• Revisions Due To CPT/HCPCS Code Changes
10/01/2015	R1	LCD revised and published on 09/11/2014 to add ICD-10-CM diagnosis codes I70.25, M27.2, N30.40, and N30.41 as covered diagnosis effective 10/01/2014 (or when ICD-10 becomes effective) per CMS Change Request 8691.	• Revisions Due To ICD-10-CM Code Changes

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)
A56714 - Billing and Coding: Hyperbaric Oxygen (HBO) Therapy

Related National Coverage Documents

NCD(s)
20.29 - Hyperbaric Oxygen Therapy

Public Version(s)

Updated on 08/27/2020 with effective dates 01/01/2020 - 08/27/2020

Updated on 02/07/2020 with effective dates 01/01/2020 - N/A
Updated on 11/08/2019 with effective dates 11/14/2019 - 12/31/2019
Updated on 07/19/2019 with effective dates 07/25/2019 - 11/13/2019
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

Keywords

N/A