

MEDICAL POLICY	Hyperbaric Oxygen Therapy (All Lines of Business Except Medicare)	
Effective Date: 07/01/2020  <div style="text-align: right;">7/1/2020</div>	Section: MED	Policy No.: 252
	Technology Assessment Committee Approved Date: 6/16 Medical Policy Committee Approved Date: 8/92; 4/95; 8/97; 1/98; 1/00; 1/01; 2/03; 10/03; 9/04; 11/05; 11/07; 11/08; 7/10; 2/11; 6/13; 4/14; 2/15; 8/15; 8/17; 5/18; 3/19; 5/19; 06/2020	
Medical Officer	Date	

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayn Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business except Medicare

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

Note: Hyperbaric oxygen therapy performed concurrently with negative pressure wound therapy is not covered.

- I. The following criteria are based on the Undersea and Hyperbaric Medical Society’s (UHMS) Hyperbaric Oxygen Therapy Indications: 13th Edition.^{1,2} Hyperbaric oxygen therapy (HBOT), performed within the UHMS treatment guidelines, may be considered **medically necessary and covered** for the following UHMS indications:

UHMS Indication	UHMS Treatment Guideline
Acute thermal burn injury	30 sessions; UHMS indicates it is rare to exceed 40-50 sessions

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Air or gas embolism	2 sessions; UHMS indicates 5-10 sessions may be necessary
<p>Arterial insufficiencies (At least one of the following criteria [A. <u>or</u> B] must be met):</p> <p>A. Diabetic lower extremity wounds when all of the following (1.-4.) additional criteria are met:</p> <ol style="list-style-type: none"> 1. Patient with Type 1 or Type 2 Diabetes with lower extremity wound due to diabetes; and 2. Wagner grade III or higher wound severity (see Policy Guidelines section); and 3. Patient has failed adequate course of standard wound therapy (see Policy Guidelines section); and 4. Re-evaluations at 30 days must show continued progress. <p>B. Arterial insufficiency ulcer when at least one of the following (1.-2.) criteria are met:</p> <ol style="list-style-type: none"> 1. The patient has persistent hypoxia despite attempts at increasing blood flow; or 2. Wound failure continues despite maximum revascularization. 	<p>Treatment varies depending upon the severity of the wound and the type of chamber used.</p> <ul style="list-style-type: none"> - For multiplace and monoplace chambers UHMS recommends 90-120 minute sessions once or twice daily (i.e., 30-60 sessions in a 30 day time span). - When stabilized, once daily treatment is recommended.
Carbon monoxide poisoning	5 sessions
Central Retinal Artery Occlusion (CRAO) when HBOT treatment is initiated within 24 hours of vision loss	<ul style="list-style-type: none"> - If vision shows improvement, treat with 90 minutes sessions for a minimum of 3 days. - Continue treatment until there is three consecutive days with no clinical improvement.
Compartment syndrome	<ul style="list-style-type: none"> - Twice a day for 24-36 hours with oxygen breathing for 90 minutes each, or a single treatment a day for 120 minutes. - For residual complications after fasciotomy, treatments should be twice a day for 7-10 days, or when condition is stabilized such that no additional benefit is received.
Compromised skin grafts and flaps	<ul style="list-style-type: none"> - Initial treatment is for 90-120 minutes. - Once the flap or graft is stable, once daily treatments may suffice.

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Crush injuries	<ul style="list-style-type: none"> - Two or more treatments a day with oxygen breathing for 90 minutes each, or a single treatment a day for 120 minutes.
Cyanide poisoning	5 sessions
Decompression sickness	10 sessions
Gas gangrene	10 sessions
Idiopathic sudden sensorineural hearing loss: moderate to profound (≥ 41 dB) when HBOT treatment is initiated within 14 days of symptom onset.	20 sessions
<p>Intracranial abscess (includes cerebral abscess, subdural empyema, and epidural empyema) when HBOT is used as an adjunctive therapy in patients who meet at least one of the following (A.-E.) criteria:</p> <ul style="list-style-type: none"> A. Multiple abscesses; or B. Abscesses in a deep or dominant location; or C. Immune compromised; or D. In situations where surgery is contraindicated or where the patient is a poor surgical risk; or E. No response or further deterioration in spite of standard surgical (e.g., 1-2 needle aspirates) and antibiotic treatment. 	<ul style="list-style-type: none"> - Treatment should be administered for 60-90 minutes once or twice daily, depending up the severity of the condition.
Necrotizing soft-tissue infections	<ul style="list-style-type: none"> - Treatment is given for 90 minutes twice daily during the initial phase of therapy, until there is no longer evidence of progression and infection is under control. - Once the patient's condition is stabilized, and prior to treatment cessation, treatment once daily may be instituted to assure relapse will not occur.
Radiation necrosis	60 sessions
Refractory osteomyelitis (stage 3B and 4B)(see Policy Guidelines section)	40 postoperative sessions over a 4-6 week period
Severe anemia when transfusion is not possible	HBOT therapy should be continued with taper of both time and frequency until red blood cells have been replaced by patient regeneration or the patient can undergo blood transfusion.

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- II. Hyperbaric oxygen therapy is considered **investigational and is not covered** when criterion I. above is not met, including, but not limited to any of the following:
- A. Acute coronary syndrome
 - B. Acute ischemic stroke
 - C. Acute surgical and traumatic wounds
 - D. AIDS/HIV
 - E. Alzheimer's disease
 - F. Asthma
 - G. Autism Spectrum Disorder
 - H. Bell's Palsy
 - I. Blindness
 - J. Brain injury including traumatic (TBI) and chronic brain injury
 - K. Cerebral Palsy
 - L. Concurrent treatment with other non-standard wound care (e.g., wound vac, negative pressure wound therapy)
 - M. Delayed onset muscle soreness and closed soft tissue injury
 - N. Depression
 - O. Fracture healing
 - P. Headache- migraine and cluster
 - Q. Heart disease
 - R. Hepatitis
 - S. Lower extremity injury (e.g., sprain, tendonitis, fracture, dislocation)
 - T. Multiple Sclerosis
 - U. Non-healing lower extremity wound (e.g., ischemic ulcer) with no arterial blood flow
 - V. Otitis externa
 - W. Parkinson's disease
 - X. Posttraumatic stress disorder and acute stress disorder
 - Y. Pressure ulcers
 - Z. Shoulder injury
 - AA. Spinal cord injury
 - BB. Tumor sensitization to radiotherapy
 - CC. Vascular dementia
 - DD. Venous ulcers
 - EE. Wound caused by or not healing due to a foreign body reaction (e.g., mesh, suture)
- III. Topical hyperbaric oxygen therapy is considered **not medically necessary and is not covered** for all indications.

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POLICY GUIDELINES

Wagner Grading System for Diabetic Foot Infections³

- Grade 0 - Intact Skin
- Grade 1 - Superficial ulcer of skin or subcutaneous tissue
- Grade 2 - Ulcers extend into tendon, bone, or capsule
- Grade 3 - Deep ulcer with osteomyelitis, or abscess
- Grade 4 - Gangrene of toes or forefoot
- Grade 5 - Midfoot or hindfoot gangrene

Standard Wound Therapy¹

Defined as 30 days of treatment including assessment and correction of vascular abnormalities, optimization of nutritional status and glucose control, debridement, moist wound dressing, off-loading, and treatment of infection.

Osteomyelitis Staging⁴

Anatomic type

- **Stage 1:** Medullary osteomyelitis

Medullary osteomyelitis denotes infection confined to the intramedullary surfaces of the bone. Hematogenous osteomyelitis and infected intramedullary rods are examples of this anatomic type.

- **Stage 2:** Superficial osteomyelitis

Superficial osteomyelitis is a true contiguous focus infection of bone; it occurs when an exposed infected necrotic surface of bone lies at the base of a soft-tissue wound.

- **Stage 3:** Localized osteomyelitis

Localized osteomyelitis is usually characterized by a full thickness, cortical sequestration which can be removed surgically without compromising bony stability.

- **Stage 4:** Diffuse osteomyelitis

Diffuse osteomyelitis is a through-and-through process that usually requires an intercalary resection of the bone to arrest the disease process. Diffuse osteomyelitis includes those infections with a loss of bony stability either before or after debridement surgery.

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Physiologic class of host

- **Class A** denotes a normal host
- **Class B** denotes a host with systemic compromise, local compromise, or both
- **Class C** denotes a host for whom the morbidity of treatment is worse than that imposed by the disease itself

CPT/HCPCS CODES

All Lines of Business	
Prior Authorization Required	
99183	Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session
G0277	Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval
Not Covered	
A4575	Topical hyperbaric oxygen chamber, disposable
E0446	Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories

DESCRIPTION

Hyperbaric Oxygen Therapy (HBOT)

The Undersea and Hyperbaric Medical Society (UHMS) defines hyperbaric oxygen therapy (HBOT) as “an intervention in which an individual breathes near 100% oxygen intermittently while inside a hyperbaric chamber that is pressurized to greater than sea level pressure.”² For certain indications, HBOT is the primary treatment modality while in other indications it is an adjunctive treatment to surgical or pharmacological interventions. Clinical treatments may take place in a Class A (multi-chamber) or Class B (mono-chamber) system. A Class A system holds two or more people while a Class B system holds only the patient.

UHMS Approved HBOT Indications

UHMS Indication	Description
Acute thermal burn injury	Anatomic, physiologic, endocrinologic, and immunologic alterations due to a burn injury. ⁵
Air or gas embolism	When one or more air bubbles enter a vein or artery and block it. ⁶
Diabetic lower extremity wounds	An open sore or ulcer, most commonly located on the bottom of the foot, caused by diabetes-related circulatory issues. ⁷
Carbon monoxide poisoning	Carbon monoxide is an odorless, colorless gas that can be deadly upon exposure. ⁸

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Central Retinal Artery Occlusion (CRAO)	A disease of the eye where the flow of blood through the central retinal artery is blocked (occluded). ⁹
Compartment syndrome	A condition that occurs when pressure within the muscles builds to dangerous levels. This pressure can decrease blood flow, which prevents nourishment and oxygen from reaching nerve and muscle cells. ¹⁰
Compromised skin grafts and flaps	Skin grafts and flaps is a technique used in reconstructive surgery where a type of tissue is lifted from a donor site and moved to a recipient site. In tissue compromised by irradiation or decreased oxygen supply, HBOT is used to maximize viability of the graft or flap. ¹¹
Crush injuries	An injury that occurs when force or pressure is put on a body part. This injury happens when part of the body is compressed between two heavy objects. ¹²
Cyanide poisoning	Cyanide toxicity is a rare form of poisoning due to exposure to cyanide. Cyanide exposure occurs relatively frequently in patients with smoke inhalation. ¹³
Decompression sickness	Injuries caused by a rapid increase in the pressure that surrounds you, of either air or water. It occurs most commonly in scuba or deep-sea divers, although it also can occur during high-altitude or unpressurized air travel. ¹⁴
Gas gangrene	A highly lethal soft tissue infection of skeletal muscle caused by toxin and gas producing <i>Clostridium</i> bacteria species. ¹⁵
Intracranial abscess (includes cerebral abscess, subdural empyema, and epidural empyema)	A collection of pus, immune cells, and other material in the brain, usually from a bacterial or fungal infection. ¹⁶
Necrotizing soft-tissue infections	A rare but severe type of bacterial infection that can destroy the muscles, skin, and underlying tissue. ¹⁷
Radiation necrosis	Damage done to non-osseous tissues by ionizing radiation during the course of radiotherapy for cancer. ¹⁸
Refractory osteomyelitis (stage 3B and 4B)	A bone infection that has not responded to appropriate medical treatment (refractory). ¹⁹
Severe anemia when transfusion is not possible	Hemoglobin concentrations below 8.0 g/dL. ²⁰ Some religions prevent people from receiving blood transfusions.
Idiopathic sudden sensorineural hearing loss (ISSHL)	Unexplained unilateral hearing loss with onset over a period of less than 72 hours. ²¹

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Topical Oxygen Therapy (TOT)

TOT is intended to increase wound oxygenation and promote wound healing. There are two types of TOT:

- Hyperbaric TOT (HTOT): “The affected limb is enclosed in a chamber or gas-impermeable bag, and the chamber is filled with oxygen pressurized slightly above atmospheric pressure. HTOT requires patient immobility during in-clinic treatment sessions, which may last 90 minutes once per day for weeks.”²²
- Continuous TOT (CTOT): An alternative to HTOT that does not require patient immobilization or in-clinic administration. CTOT can also be used at the same time as dressings and offloading. “A portable oxygen concentrator refines and delivers atmospheric (normobaric) oxygen to the wound site through a cannula.”²²

REVIEW OF EVIDENCE

The medically necessary indications for hyperbaric oxygen therapy is based on the Undersea and Hyperbaric Medical Society’s (UHMS) Hyperbaric Oxygen Therapy Indications: 13th Edition.^{1,2} Therefore, an evidence review was not conducted for these indications.

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of hyperbaric oxygen therapy for indications not included in the UHMS recommendation. A review of evidence was also conducted for the use of topical hyperbaric oxygen therapy. Below is a summary of the available evidence identified through May 2020.

Investigational Indications for Hyperbaric Oxygen Therapy

All of the following purported indications for hyperbaric oxygen therapy (HBOT) are considered investigational. This investigational stance is supported by one, or more, of the following (1) a Cochrane systematic review (2) an evidence-based clinical practice guideline, and/or (3) an FDA consumer warning against the use of HBOT for that indication. See the associated reference for more information.

- Acute coronary syndrome^{23,24}
- Acute ischemic stroke^{25,26}
- Acute surgical and traumatic wounds²⁷
- AIDS/HIV²⁵
- Alzheimer’s disease²⁵
- Asthma²⁵
- Autism Spectrum Disorder^{28,29}
- Bell’s Palsy^{24,25,30}
- Brain injury including traumatic (TBI) and chronic brain injury^{24,25,31}
- Cerebral Palsy²⁵
- Delayed onset muscle soreness and closed soft tissue injury³²

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- Depression²⁵
- Fracture healing^{24,33}
- Headache- migraine and cluster^{24,25,34}
- Heart disease²⁵
- Hepatitis²⁵
- Lower extremity injury (e.g., sprain, tendonitis, fracture, dislocation)³⁵
- Multiple Sclerosis^{25,36}
- Otitis externa^{24,37}
- Parkinson’s disease²⁵
- Posttraumatic stress disorder and acute stress disorder³⁸
- Pressure ulcers³⁹
- Shoulder injury⁴⁰
- Spinal cord injury²⁵
- Tumor sensitization to radiotherapy⁴¹
- Vascular dementia^{24,42}
- Venous ulcers²⁴

Topical Hyperbaric Oxygen Therapy

As indicated by the evidence review, topical hyperbaric oxygen therapy (HBOT) has been predominantly investigated as a treatment of chronic wounds.⁴³⁻⁵² In 2020, Hayes updated an evidence review evaluating topical oxygen therapy for chronic wound healing.²² The review identified three randomized controlled trials (RCT) as eligible for inclusion. Sample sizes ranged from 20 to 130 patients and follow-up times varied from 8 to 12 weeks. Outcomes of interest included complete wound healing, time to complete wound healing, and complications.

The results indicated that topical hyperbaric oxygen therapy may provide an incremental benefit to standard wound care for healing chronic diabetic foot ulcers that have failed to respond to wound care alone. However, not all studies reported a benefit and there is still insufficient outcome and safety data to inform meaningful conclusions. Additionally, all studies evaluated topical HBOT for chronic diabetic foot ulcers; therefore, the evidence is insufficient to inform evidence-based conclusions regarding topical HBOT for other types of chronic wounds.

Hayes determined the available evidence to be of low quality. Hayes concluded the following ratings:

- D2 (insufficient evidence)—For the use of continuous topical oxygen therapy in adults with diabetes-related foot ulcers that are refractory to standard wound care.
- D2 (insufficient evidence)—For the use of continuous topical oxygen therapy for any other chronic wound type other than DFU.
- D2 (insufficient evidence)—For the use of hyperbaric topical oxygen therapy for any chronic wound type.²²

CLINICAL PRACTICE GUIDELINES

Undersea and Hyperbaric Medical Society (UHMS)

The UHMS 2014 Hyperbaric Oxygen Therapy Indications recommends the following (A.-Q.) indications and treatment guidelines for systemic hyperbaric oxygen therapy (HBOT).^{1,2} The UHMS hyperbaric oxygen therapy committee convenes annually to review research and clinical data and render recommendations regarding the clinical efficacy and safety of HBOT. The approved indications are those which are supported by in vitro and in vivo pre-clinical research data as well as extensive positive clinical experience. "Evidence considered by the committee includes sound physiologic rationale; in vivo or in vitro studies that demonstrate effectiveness; controlled animal studies; prospective controlled clinical studies; and extensive clinical experience from multiple, recognized hyperbaric medicine centers."² The committee requires that experimental and clinical evidence submitted for the efficacy of HBOT treatment for a disorder is at least as efficacious as any other accepted treatment modality for that disorder.

The following are the most recently approved (2014) UHMS indications and treatment guidelines for HBOT:

- A. **Acute Thermal Burn Injury** – Recommended for patients with serious burns, i.e., partial or full thickness burns covering greater than 20% of total body surface area or with involvement of the hands, face, feet or perineum. Treatment should begin as soon as possible following injury, often during initial resuscitation. Treatments should be given for 90 minutes 3 times within the first 24 hours, and twice daily thereafter at 2.0-2.4 ATA (atmospheres absolute) of oxygen. For large burns of 40% or greater, treatment for 10-14 days is recommended. Treatment beyond 20-30 sessions is usually utilized to optimize grafting success. It is rare to exceed 40-50 sessions.
- B. **Air or Gas Embolism** – Initial treatment should follow U.S. Navy Table #6, using 2.82 ATA of oxygen. Usual treatment involves 1-2 sessions, but may require 5-10.
- C. **Arterial Insufficiencies** – Treatment varies depending upon the severity of the condition and the type of chamber used. In large multiplace chambers, treatments delivered between 2.0 and 2.5 ATA of oxygen for 90-120 minutes once or twice daily is standard. In monoplace chambers, treatment at 2.0 ATA of oxygen for 90-120 minutes once or twice daily is standard. Once the patient is stabilized, once daily treatment is recommended. Details for specific conditions are below:
 1. **Diabetic lower extremity wounds** –
 - a. Patient with Type 1 or Type 2 Diabetes with lower extremity wound due to diabetes; and
 - b. Wagner grade III or higher wound severity; and
 - c. Patient has failed an adequate course of standard wound therapy (defined as 30 days of standard treatment including assessment and correction of vascular abnormalities, optimization of nutritional status and glucose control, debridement, moist wound dressing, off-loading, and treatment of infection; and
 - d. Re-evaluations at 30 days must show continued progress.

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- 2. **Arterial insufficiency ulcers** – May benefit patients who have persistent hypoxia despite attempts at increasing blood flow or when wound failure continues despite maximum revascularization.
 - 3. **Pressure ulcers** – Not recommended for the routine treatment of decubitus ulcers. May be necessary for support of skin flaps and grafts showing evidence of ischemic failure, when the ulcer develops in the field of previous irradiated area for pelvic or perineal malignancies, or when progressive necrotizing soft tissue infection or refractory osteomyelitis is present.
 - 4. **Venous stasis ulcers** – May be required to support skin grafting in patients with concomitant peripheral arterial occlusive disease and hypoxia not corrected by control of edema.
- D. **Carbon Monoxide Poisoning** – Actual treatment pressure and time will vary, but compressions should be between 2.4 and 3.0 ATA of oxygen. In patients with persistent neurologic dysfunction after the initial treatment, subsequent treatments may be performed within 6-8 hours and continued once or twice daily until there is no further improvement in cognitive functioning. No more than 5 sessions should be needed to treat.
 - E. **Central Retinal Artery Occlusion (CRAO)** – Patients presenting within 24 hours of symptoms should be considered for immediate HBOT. Initiation of treatment should begin with delivery of 1 ATA of oxygen at the highest possible FiO₂. If there is no response within 5 minutes, then refer to HBOT at 2 ATA of oxygen as an adjunct to other interventions. If vision improves, treat with 90 minutes of 2 ATA BID for a minimum of 3 days. If vision does not improve within 5 minutes of 2 ATA of oxygen, press to a maximum of 2.8 ATA of oxygen, if no improvement occurs within 20 minutes at 2.8 ATA of oxygen, consider following U.S. Navy Table #6. If vision does improve, continue treatment at effective pressure for 90 minutes BID. Continue treatment until there is three consecutive days with no clinical improvement. If the patient is a non-responder, initial treatment should be considered day 1 of treatment.
 - F. **Compartment syndrome** – Treatment twice a day for 24-36 hours with oxygen breathing for 90 minutes each, or a single treatment a day for 120 minutes. For residual complications after fasciotomy, treatments should be twice a day for 7-10 days, or when condition has stabilized such that no additional benefit is received. Pressures should be 2.0 ATA in monoplace chambers and 2.4 ATA of oxygen in multiplace chambers.
 - G. **Compromised Skin Grafts and Flaps** – Initial treatment is for 90-120 minutes at 2.0-2.5 ATA of oxygen. Once the flap or graft is stable, once daily treatments may suffice.
 - H. **Crush Injuries** – Two or more treatments a day with oxygen breathing for 90 minutes each, or a single treatment a day for 120 minutes. Pressures should be 2.0 ATA of oxygen in monoplace chambers and 2.4 ATA of oxygen in multiplace chambers.
 - I. **Cyanide Poisoning** – Patients with cyanide poisoning frequently present with simultaneous carbon monoxide poisoning. Please see "**Carbon Monoxide Poisoning**" above for treatment recommendations.
 - J. **Decompression Sickness** – Treatment times vary, depending upon length of time elapsed between symptoms and initiation of treatment and between residual symptoms after initial treatment. Complete resolution is most likely with early HBOT following U.S. Navy oxygen treatment tables with initial recompression to 2.82 ATA of oxygen. Repeat treatments may be recommended until clinical stability is achieved, and should be administered step-wise as long as

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improvement occurs. Complete resolution of symptoms or lack of improvement on two consecutive treatments establishes the end point. No more than 5-10 treatments per individual are considered the norm.

- K. **Gas Gangrene** – Treatment should be administered for 90 minutes 3 times within the first 24 hours with 3.0 ATA of oxygen, and then twice daily for the next 2-5 days. The decision to terminate treatment depends upon the patient's response to HBOT therapy. If the patient remains toxic, the treatment needs to be extended. No more than 10 sessions should be needed to treat.
- L. **Intracranial Abscess (includes cerebral abscess, subdural empyema, and epidural empyema)** – Treatment should be administered at 2.0-2.5 ATA of oxygen for 60-90 minutes once or twice daily, depending upon the severity of the condition.
- M. **Necrotizing Soft-Tissue Infections** – HBOT treatments are given at a pressure of 2.0-2.5 ATA of oxygen and range from 90 minutes twice daily during the initial phase of therapy, until there is no longer evidence of progression and infection is considered under control. If the diagnosis is in doubt and clostridial myositis and myonecrosis are still in the differential diagnosis, treatment at 2.8-3.0 ATA is recommended, using the gas-gangrene protocol of 3 treatments in the first 24 hours. Once the patient's condition is stabilized, and prior to treatment cessation, treatment once daily may be instituted to assure relapse will not occur.
- N. **Radiation Necrosis** – 30-60 treatments for 90-120 minutes at 2.0-2.5 ATA of oxygen daily followed by debridement or resection, depending upon stage of condition.
- O. **Refractory Osteomyelitis** – Patients with Cierny-Mader stage 1 and 2 should primarily be treated with antibiotics and limited surgical debridement. HBOT is not recommended for these patients. Patients with refractory stage 3B and 4B osteomyelitis should be considered candidates for HBOT. Treatment should be given for 90-120 minutes at 2.3-2.5 ATA of oxygen once daily for 5 days per week. Approximately 20-40 postoperative treatments should be delivered over a 4-6 week period.
- P. **Severe Anemia** – Pulsed HBOT provides a way to clinically rectify oxygen debt in severe anemia when transfusion is not possible. The patient initially can be treated with 2.0-3.0 ATA of oxygen with air breaks for up to 3-4 hours with surface interval titrated to avert symptoms of recurring oxygen debt. Surface intervals between treatments may be lengthened, with the support of adjunctive hematinics, until hemoglobin concentrations are sufficient to allow adequate oxygen delivery at standard pressures.
- Q. **Idiopathic Sudden Sensorineural Hearing Loss (ISSHL)** – the recommended treatment profile consists of 100% O₂ at 2.0 to 2.5 atmospheres absolute for 90 minutes daily for 10 to 20 treatments. The 2.4 ATA treatment pressure is probably most practical, especially for facilities with multiplace chamber operations. Patients with no known contraindications to steroid therapy should also be treated concomitantly with oral corticosteroids. Continued consultation and follow-up with an otolaryngologist is recommended.

POLICY SUMMARY

The medically necessary indications for hyperbaric oxygen therapy are based on the Undersea and Hyperbaric Medical Society’s (UHMS) Hyperbaric Oxygen Therapy Indications: 13th Edition. Additionally, the FDA follows UHMS for determining the FDA-approved indications for HBOT.

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There are numerous investigational indications for hyperbaric oxygen therapy. There is insufficient published evidence to adequately evaluate the efficacy and/or safety of these indications. Additional good-quality research, as well as approval by the UHMS and FDA, is required to support other purported indications for HBOT. There is also insufficient evidence to permit reliable conclusions regarding topical HBOT. Further studies of good methodological quality are required to establish the efficacy and safety of topical HBOT. Additional studies also need to demonstrate an improvement in patient health outcomes with topical HBOT compared to standard, systemic HBOT.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

U.S. Food and Drug Administration (FDA)

The FDA approved indications for hyperbaric oxygen therapy (HBOT) are based on the Undersea and Hyperbaric Medical Society (UHMS) recommended indications for HBOT.⁵³ Therefore, HBOT is FDA-approved for the following indications:

- Acute Thermal Burn Injury
- Air or Gas Embolism
- Arterial Insufficiencies
- Carbon Monoxide Poisoning
- Central Retinal Artery Occlusion (CRAO)
- Compartment syndrome
- Compromised Skin Grafts and Flaps
- Crush Injuries
- Cyanide Poisoning Decompression Sickness
- Gas Gangrene
- Intracranial Abscess (includes cerebral abscess, subdural empyema, and epidural empyema)
- Necrotizing Soft-Tissue Infections
- Radiation Necrosis
- Refractory Osteomyelitis

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- Severe Anemia
- Idiopathic Sudden Sensorineural Hearing Loss (ISSHL)

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

REFERENCES

1. Undersea, Committee HMSHO, Weaver LK. *Hyperbaric Oxygen Therapy Indications: The Hyperbaric Oxygen Therapy Committee Report*. Best Publishing Company; 2014.
2. Lindell K. Weaver M. Undersea and Hyperbaric Oxygen Medical Society: Hyperbaric Oxygen Therapy Indications (Description and References). https://www.uhms.org/images/indications/UHMS_HBO2_Indications_13th_Ed_Front_Matter_References.pdf. Published 2014. Accessed 05/20/2020.
3. Wheelless' Textbook of Orthopedics. http://www.wheellesonline.com/ortho/wagner_grading_system_for_diabetic_foot_infections. Accessed 05/22/2020.
4. The Osteomyelitis Center of Central Florida: Staging System for Long Bone Osteomyelitis. <https://www.osteomyelitiscenter.com/staging-of-osteomyelitis.html>. Accessed 05/22/2020.
5. Garner WL, Magee W. Acute burn injury. *Clinics in plastic surgery*. 2005;32(2):187-193.
6. Healthline: What is an air embolism? <https://www.healthline.com/health/air-embolism>. Published 2017. Accessed 05/22/2020.
7. Memorial Herman Wound Care: Diabetic Wounds of the Lower Extremities. <http://www.memorialhermann.org/wound-care/diabetic-foot-wounds/>. Accessed 05/22/2020.
8. The Centers for Disease Control and Prevention: Carbon Monoxide Poisoning. <https://www.cdc.gov/co/faqs.htm>. Accessed 05/22/2020.
9. Medscape: Central Retinal Artery Occlusion. <https://emedicine.medscape.com/article/1223625-overview>. Accessed 05/22/2020.
10. American Academy of Orthopedic Surgeons (AAOS): Compartment Syndrome. <https://orthoinfo.aaos.org/en/diseases--conditions/compartment-syndrome/>. Accessed 05/22/2020.
11. Undersea and Hyperbaric Medical Society (UHMS): Compromised Skin Graft or Flaps. <https://www.uhms.org/12-compromised-grafts-and-flaps.html>. Accessed 05/22/2020.
12. Medline Plus: Crush Injury. <https://medlineplus.gov/ency/article/000024.htm>. Accessed 05/22/2020.
13. Medscape: Cyanide Toxicity. <https://emedicine.medscape.com/article/814287-overview>. Accessed 05/22/2020.
14. Harvard Health Publishing. Harvard Medical School: Decompression Sickness. Published: January, 2019. https://www.health.harvard.edu/a_to_z/decompression-sickness-a-to-z. Accessed 05/22/2020.

MEDICAL POLICY	Hyperbaric Oxygen Therapy (All Lines of Business Except Medicare)
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15. Shahab Qureshi M, FACP. Medscape: Clostridial Gas Gangrene. <https://emedicine.medscape.com/article/214992-overview>. Published 2017. Accessed 05/20/2020.
16. Medline Plus: Brain Abscess. <https://medlineplus.gov/ency/article/000783.htm>. Accessed 05/22/2020.
17. Medline Plus: Necrotizing Soft Tissue Infection. <https://medlineplus.gov/ency/article/001443.htm>. Accessed 05/22/2020.
18. American College of Hyperbaric Medicine: Radiation Necrosis. <http://achm.org/soft-tissue-radionecrosis/>. Accessed 05/22/2020.
19. Undersea and Hyperbaric Medical Society: Osteomyelitis (Refractory). <https://www.uhms.org/10-osteomyelitis-refractory.html>. Accessed 05/22/2020.
20. University of Maryland Medical Center: Anemia. <https://www.umms.org/ummc/health-services/shock-trauma/services/hyperbaric-medicine?si=ummc>. Accessed 05/22/2020.
21. Rauch SD. Clinical practice. Idiopathic sudden sensorineural hearing loss. *The New England journal of medicine*. 2008;359(8):833-840.
22. Hayes. Health Technology Assessment. Topical Oxygen Therapy for Chronic Wound Healing. Nov 21, 2017. Annual Review: Mar 4, 2020. https://evidence.hayesinc.com/report/dir.topicaloxwound311?_ga=2.57821801.296794708.1590494915-1995923823.1570058383. Accessed 3/19/2018.
23. Bennett MH, Lehm JP, Jepsen N. Hyperbaric oxygen therapy for acute coronary syndrome. *The Cochrane database of systematic reviews*. 2015(7):Cd004818.
24. Health Evidence Review Commission (HERC) Coverage Guidance: Indications for Hyperbaric Oxygen Therapy. <https://www.oregon.gov/oha/HPA/DSI-HERC/EvidenceBasedReports/Indications-for-HBOT.pdf>. Published 2014. Accessed 05/20/2020.
25. U.S. Food and Drug Administration Consumer Alert: Hyperbaric Oxygen Therapy. <https://www.fda.gov/forconsumers/consumerupdates/ucm364687.htm>. Accessed 05/22/2020.
26. Bennett MH, Weibel S, Wasiaik J, Schnabel A, French C, Kranke P. Hyperbaric oxygen therapy for acute ischaemic stroke. *The Cochrane database of systematic reviews*. 2014(11):Cd004954.
27. Eskes A, Vermeulen H, Lucas C, Ubbink DT. Hyperbaric oxygen therapy for treating acute surgical and traumatic wounds. *The Cochrane database of systematic reviews*. 2013(12):Cd008059.
28. Xiong T, Chen H, Luo R, Mu D. Hyperbaric oxygen therapy for people with autism spectrum disorder (ASD). *The Cochrane database of systematic reviews*. 2016;10:Cd010922.
29. In: *Autism: The Management and Support of Children and Young People on the Autism Spectrum*. Leicester (UK)2013.
30. Holland NJ, Bernstein JM, Hamilton JW. Hyperbaric oxygen therapy for Bell's palsy. *The Cochrane database of systematic reviews*. 2012(2):Cd007288.
31. Bennett MH, Trytko B, Jonker B. Hyperbaric oxygen therapy for the adjunctive treatment of traumatic brain injury. *The Cochrane database of systematic reviews*. 2012;12:Cd004609.
32. Bennett M, Best TM, Babul S, Taunton J, Lepawsky M. Hyperbaric oxygen therapy for delayed onset muscle soreness and closed soft tissue injury. *The Cochrane database of systematic reviews*. 2005(4):Cd004713.
33. Bennett MH, Stanford RE, Turner R. Hyperbaric oxygen therapy for promoting fracture healing and treating fracture non-union. *The Cochrane database of systematic reviews*. 2012;11:Cd004712.

MEDICAL POLICY	Hyperbaric Oxygen Therapy (All Lines of Business Except Medicare)
-----------------------	--

34. Bennett MH, French C, Schnabel A, Wasiak J, Kranke P, Weibel S. Normobaric and hyperbaric oxygen therapy for the treatment and prevention of migraine and cluster headache. *The Cochrane database of systematic reviews*. 2015(12):Cd005219.
35. State of Colorado. Department of Labor and Employment. Division of Workers' Compensation. Rule17, Exhibit 6. Lower extremity injury medical treatment guidelines. Revised: January 19, 2016.
https://www.colorado.gov/pacific/sites/default/files/Rule_17_Exhibit_6_Lower_Extremity_Guideline.pdf. Accessed 05/26/2020.
36. Bennett M, Heard R. Hyperbaric oxygen therapy for multiple sclerosis. *CNS neuroscience & therapeutics*. 2010;16(2):115-124.
37. Phillips JS, Jones SE. Hyperbaric oxygen as an adjuvant treatment for malignant otitis externa. *The Cochrane database of systematic reviews*. 2013(5):Cd004617.
38. United States Department of Veterans Affairs. VA/DoD Clinical Practice Guidelines. Management of Posttraumatic Stress Disorder and Acute Stress Reaction 2017
<https://www.healthquality.va.gov/guidelines/MH/ptsd/>. Accessed 05/26/2020.
39. *The Prevention and Management of Pressure Ulcers in Primary and Secondary Care*. 2014.
<https://www.ncbi.nlm.nih.gov/pubmed/25340232>
40. State of Colorado. Department of Labor and Employment. Division of Workers' Compensation. Shoulder injury medical treatment guidelines. Effective: November 2, 2008.
https://www.colorado.gov/pacific/sites/default/files/SI_Guideline%20with%20in-text%20references_0.pdf. Accessed 05/26/2020.
41. Bennett MH, Feldmeier J, Smee R, Milross C. Hyperbaric oxygenation for tumour sensitisation to radiotherapy. *The Cochrane database of systematic reviews*. 2012(4):Cd005007.
42. Xiao Y, Wang J, Jiang S, Luo H. Hyperbaric oxygen therapy for vascular dementia. *The Cochrane database of systematic reviews*. 2012(7):Cd009425.
43. Hayes PD, Alzuhir N, Curran G, Loftus IM. Topical oxygen therapy promotes the healing of chronic diabetic foot ulcers: a pilot study. *Journal of wound care*. 2017;26(11):652-660.
44. Agarwal V, Aroor S, Gupta N, Gupta A, Agarwal N, Kaur N. New Technique of Applying Topical Oxygen Therapy as a Cost-Effective Procedure. *The Indian journal of surgery*. 2015;77(Suppl 3):1456-1459.
45. Dissemond J, Kroger K, Storck M, Risse A, Engels P. Topical oxygen wound therapies for chronic wounds: a review. *Journal of wound care*. 2015;24(2):53-54, 56-60, 62-53.
46. Tawfick WA, Sultan S. Technical and clinical outcome of topical wound oxygen in comparison to conventional compression dressings in the management of refractory nonhealing venous ulcers. *Vascular and endovascular surgery*. 2013;47(1):30-37.
47. Belley R, Buteau D, Chateau-Degat ML. Efforts in trying to better define the level of evidence on topical pressurised oxygen therapy (TPOT) for wound healing. *International wound journal*. 2013;10(6):713-715.
48. Gordillo GM, Roy S, Khanna S, et al. Topical oxygen therapy induces vascular endothelial growth factor expression and improves closure of clinically presented chronic wounds. *Clinical and experimental pharmacology & physiology*. 2008;35(8):957-964.
49. Landau Z, Sommer A, Miller EB. Topical hyperbaric oxygen and low-energy laser for the treatment of chronic ulcers. *European journal of internal medicine*. 2006;17(4):272-275.

MEDICAL POLICY	Hyperbaric Oxygen Therapy (All Lines of Business Except Medicare)
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- 50. Kalliainen LK, Gordillo GM, Schlanger R, Sen CK. Topical oxygen as an adjunct to wound healing: a clinical case series. *Pathophysiology : the official journal of the International Society for Pathophysiology*. 2003;9(2):81-87.
- 51. Landau Z, Schattner A. Topical hyperbaric oxygen and low energy laser therapy for chronic diabetic foot ulcers resistant to conventional treatment. *The Yale journal of biology and medicine*. 2001;74(2):95-100.
- 52. Landau Z. Topical hyperbaric oxygen and low energy laser for the treatment of diabetic foot ulcers. *Archives of orthopaedic and trauma surgery*. 1998;117(3):156-158.
- 53. U.S. Food and Drug Administration 510(k) Summary for Gulf Coast Hyperbarics, Inc. Rectangular Multiplace Hyperbaric Chamber (K082455). May 22, 2009.
https://www.accessdata.fda.gov/cdrh_docs/pdf8/k082455.pdf. Accessed 05/22/2020.