Hyperbaric Oxygen Therapy

MEDICAL POLICY NUMBER: 204

Effective Date: 10/1/2023

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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 Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. 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. 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. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

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

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☒ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP 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.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

I. The following criteria are based on the Undersea and Hyperbaric Medical Society's (UHMS) Hyperbaric Oxygen Therapy Indications: 14th Edition.[1,2] Hyperbaric oxygen therapy (HBOT), performed within the UHMS treatment guidelines, may be considered **medically necessary** 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
Air or gas embolism	2 sessions; UHMS indicates 5-10 sessions may be necessary
Arterial insufficiencies (**At least one** of the following criteria [A. or B] must be met): A. Diabetic lower extremity wounds when **all** of the following (1.-4.) additional criteria are met: 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; **or** B. Arterial insufficiency ulcer when **at least one** of the following (1.-2.) criteria are met:	Treatment varies depending upon the severity of the wound and the type of chamber used. – 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.

1. The patient has persistent hypoxia despite attempts at increasing blood flow; **or** 2. Wound failure continues despite maximum revascularization.	
Carbon monoxide poisoning	5 sessions
Central Retinal Artery Occlusion (CRAO) when HBOT treatment is initiated within 24 hours of vision loss	– 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	– 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	– Initial treatment is for 90-120 minutes. – Once the flap or graft is stable, once daily treatments may suffice.
Crush injuries	– 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
Delayed radiation injury (soft tissue and bony necrosis)	30 sessions
Gas gangrene (Clostridial myositis and myonecrosis)	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
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: 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**	– Treatment should be administered for 60-90 minutes once or twice daily, depending upon the severity of the condition.

E. No response or further deterioration in spite of standard surgical (e.g., 1-2 needle aspirates) and antibiotic treatment.	
Necrotizing soft-tissue infections	– 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.

II. Hyperbaric oxygen therapy is considered **not medically necessary** 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. Frostbite
Q. Headache- migraine and cluster
R. Heart disease
S. Hepatitis
T. Lower extremity injury (e.g., sprain, tendonitis, fracture, dislocation)
U. Multiple Sclerosis

V. Non-healing lower extremity wound (e.g., ischemic ulcer) with no arterial blood flow
W. Otitis externa
X. Parkinson's disease
Y. Perianal fistulas
Z. Posttraumatic stress disorder and acute stress disorder
AA. Pressure ulcers
BB. Shoulder injury
CC. Spinal cord injury
DD. Tumor sensitization to radiotherapy
EE. Vascular dementia
FF. Venous ulcers
GG. 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** for all indications.

Link to Evidence Summary

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

Wagner Grading System for Diabetic Foot Infections[3]

- 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 Therapy[1]

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 Staging[4]

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.

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

BACKGROUND

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]
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 *Clostridium* 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]

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 an offloading. "A portable oxygen concentrator refines and delivers atmospheric (normobaric) oxygen to the wound site through a cannula."[22]

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

The FDA approved indications for hyperbaric oxygen therapy (HBOT) are based on the Undersea and Hyperbaric Medical Society (UHMS) recommended indications for HBOT.[23] 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
- Severe Anemia
- Idiopathic Sudden Sensorineural Hearing Loss (ISSHL)

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

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 June 2023.

Not Medically Necessary 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[24,25]
- Acute ischemic stroke[26,27]
- Acute surgical and traumatic wounds[28]
- AIDS/HIV[26]
- Alzheimer's disease[26]
- Asthma[26]
- Autism Spectrum Disorder[29-31]
- Bell's Palsy[25,26,32]
- Brain injury including traumatic (TBI) and chronic brain injury[25,26,33]
- Cerebral Palsy[26]
- Delayed onset muscle soreness and closed soft tissue injury[34]
- Depression[26]
- Fracture healing[25,35]
- Frostbite[36,37]
- Headache- migraine and cluster[25,26,38]
- Heart disease[26]
- Hepatitis[26]
- Lower extremity injury (e.g., sprain, tendonitis, fracture, dislocation)[39]
- Multiple Sclerosis[26,40]
- Otitis externa[25,41]
- Parkinson's disease[26]
- Posttraumatic stress disorder and acute stress disorder[42]
- Pressure ulcers[43]
- Shoulder injury[44]
- Spinal cord injury[26]
- Tumor sensitization to radiotherapy[45]
- Vascular dementia[25,46]
- Venous ulcers[25]

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.[47-56] In 2022, Hayes updated (and then archived) 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 2019 Hyperbaric Oxygen Therapy Indications recommends the following (A.-Q.) indications and treatment guidelines for systemic hyperbaric oxygen therapy (HBOT).[1,2]

- Air or gas embolism
- Carbon monoxide poisoning
- Carbon monoxide poisoning complicated by cyanide poisoning
- Central retinal artery occlusion
- Clostridial myositis and myonecrosis (gas gangrene)
- Crush injury, compartment syndrome, and other acute traumatic ischemias
- Decompression sickness
- Enhancement of healing in select problem wounds
- Exceptional blood loss (severe anemia)
- Intracranial abscess
- Necrotizing soft tissue infections
- Osteomyelitis (refractory)
- Delayed radiation injury (soft tissue and bony necrosis)
- Skin grafts and flaps (compromised)
- Thermal burns (acute)
- Idiopathic sudden sensorineural hearing loss

National Institute for Health and Care Excellence (NICE)

In 2014, the NICE published a guideline on prevention and management of pressure ulcers.[57] As part of these recommendations, investigators recommended that HBO not be used as a treatment modality for

pressure ulcers in adults, children, infants or neonates. No randomized controlled trials were identified evaluating HBO for pressure ulcers.

EVIDENCE SUMMARY

The medically necessary indications for hyperbaric oxygen therapy are based on the Undersea and Hyperbaric Medical Society's (UHMS) Hyperbaric Oxygen Therapy Indications: 14th Edition. Additionally, the FDA follows UHMS for determining the FDA-approved indications for HBOT. 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.

BILLING GUIDELINES AND CODING

CODES*		
CPT	99183	Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session
HCPCS	A4575	Topical hyperbaric oxygen chamber, disposable
	E0446	Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories
	G0277	Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
10/2023	Annual review. Investigational non coverage changed to not medically necessary. Frostbite added to not medically necessary indications.