Molina Clinical Policy
Hyperbaric Oxygen Therapy (HBOT) and Topical Oxygen Therapy (TOT): Policy No. 050

Last Approval:4/13/2023
Next Review Due By: April 2024

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

The Undersea and Hyperbaric Medical Society defines systemic hyperbaric oxygen therapy (HBOT) as a treatment in which a patient breathes near 100% oxygen intermittently while inside a treatment chamber at a pressure higher than sea level pressure (e.g., >1 atmosphere absolute, atm abs). Treatment can be carried out in either a mono- or multi-place chamber. The former accommodates a single patient; the entire chamber is pressurized with near 100% oxygen, and the patient breathes the ambient chamber oxygen directly. The latter holds two or more people (patients, observers, and/or support personnel); the chamber is pressurized with compressed air while the patients breathe near 100% oxygen via masks, head hoods, or endotracheal tubes (UHMS, 2019).

No standard protocol has been identified for HBOT sessions. Regardless of the type of chamber used, the interval between sessions and the total number of treatments varies according to the severity of the condition and physician treatment plan. Acute conditions may be treated with only one or two sessions, while chronic conditions may require treatment with 30 or more sessions. During the sessions, chamber pressure is generally maintained between 2.5 and 3.0 atm for a duration of 45 to 300 minutes. The only absolute contraindication to HBOT is untreated pneumothorax. Patients with a history of seizure disorder or those taking certain antineoplastic drugs associated with pulmonary toxicity may be at increased risk of complications, and the decision to use HBOT in these instances should be made on a case-by-case basis (Mechem & Manaker, 2023).

Topical oxygen therapy (TOT), also known as continuous diffusion of oxygen (CDO), involves the application of gaseous oxygen to a cutaneous wound and can be administered on an outpatient basis in a clinic or medical office setting or at home. The original mode of administering TOT is via a chamber or gas-impermeable bag which encloses the affected limb, while a newer alternative uses a portable oxygen concentrator to refine and deliver atmospheric oxygen to a wound site via cannula. According to The Centers for Medicare and Medicaid Services (CMS) and the UHMS, to meet the definition of HBOT, oxygen must be delivered by inhalation within a pressurized chamber, thus this type of oxygen therapy does not constitute HBOT. (UHMS, 2019; CMS, 2017).

The United States Food & Drug Administration (FDA) regulates hyperbaric oxygen (HBO) chambers as Class II medical devices, and there are several different chambers (both mono-place and multi-place chambers) that have been cleared for marketing via the 510(k) process (Product Code CBF, hyperbaric chamber). Devices that are not implantable and pose no risk of fatal outcome to the consumer should they malfunction are assigned Class II status and must meet FDA performance standards. TOT devices are regulated by the FDA as Class II devices, and numerous devices have been approved via the FDA 510(k) process. A list of these devices can be found by searching the 501(k) premarket notification database with the product code KPJ.

COVERAGE POLICY

1. Hyperbaric Oxygen Therapy (HBOT) **is considered medically necessary** and may be authorized for any of the following conditions:
   a. Acute cyanide poisoning; **OR**
   b. Acute peripheral artery insufficiency; **OR**
   c. Acute traumatic peripheral ischemia or severe crush injuries (Grade III) as an adjunct to conventional treatment when loss of function, limb, or life is threatened; **OR**
   d. Actinomycosis refractory to antibiotics and surgical treatment; **OR**
   e. Air or gas embolism; **OR**
   f. Chronic refractory osteomyelitis as an adjunctive therapy when **ALL** the following criteria are met:
      - Documentation of refractory stage 3B or 4B osteomyelitis; **AND**
      - Osteomyelitic lesions persist for more than six weeks after treatment is initiated; **AND**
      - No improvement after adequate antibiotic treatments and operative procedure (if a surgical candidate) are performed.

   OR
   g. Gas Gangrene (clostridial myositis and myonecrosis) as an adjunctive therapy to antibiotics and surgical management; **OR**
   h. Necrotizing soft tissue infections (necrotizing fasciitis); **OR**
   i. Osteoradionecrosis as an adjunct to conventional treatment; **OR**
   j. Preparation and preservation of compromised skin, preexisting grafts or flaps that are showing signs of failure or necrosis, (not for primary management of wounds); **OR**
   k. Soft tissue radionecrosis as an adjunct to conventional treatment; **OR**
   l. Severe carbon monoxide poisoning; **OR**
   m. Severe decompression sickness.

2. As an adjunctive treatment in wound care, HBOT **is considered medically necessary** as adjunctive therapy only if there are no measurable signs of healing for minimally 30 days of standard conventional treatment and must be used in addition to standard wound care. The following criteria must be met:

   a. Severe non-healing Type 1 or 2 Diabetes Mellitus (DM) lower extremity wound due to DM; **AND**
   b. Severe wound documented by Wagner grading with **ONE or more** of the following:
      - Wagner grade 3 wound, deep ulcer to tendon, capsule, or bone; **OR**
      - Wagner grade 4, deep ulcer with abscess, osteomyelitis, or joint sepsis; **OR**
      - Wagner grade 5, localized gangrene of forefoot or heel.

   AND

   c. Minimal to no healing following 30 consecutive days of appropriate wound care (including moist-retentive wound care) including **ALL** the following:
      - Antibiotic treatment when indicated; **AND**
      - Evaluation and correction of underlying peripheral vascular disease or neuropathic disease (if applicable); **AND**
      - Optimal glycemic control; **AND**
      - Optimal nutritional status; **AND**
      - Pressure reduction or off-loading; **AND**
      - Topical wound treatment (e.g., saline, hydrogels, hydrocolloids, alginates); **AND**
      - Wound debridement by any means to remove devitalized tissue.

Continuation of Therapy

Medically necessary conditions other than wounds are initially authorized for up to 20 sessions. Prior authorization is required if additional treatments are deemed necessary by the treating provider. Wounds must be evaluated at least every 30 days or 20 sessions (whichever comes first) during administration of HBOT. A progress report must be requested prior to authorization of additional HBOT.

Continued treatment with HBOT is considered **not medically necessary** if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

Limitations and Exclusions

1. Topical oxygen therapy (TOT) **is considered experimental, investigational, and unproven** because the clinical efficacy has not been proven for any condition.

2. Hyperbaric oxygen therapy (HBOT) **is considered not medically necessary** and excluded because there is insufficient evidence in the peer reviewed medical literature for any of the following conditions that include but are not limited to:
   a. Acute cerebral edema
   b. Acute or chronic cerebral vascular insufficiency
   c. Acute thermal and chemical pulmonary damage (e.g., smoke inhalation with pulmonary insufficiency)
   d. Aerobic septicemia
   e. Anaerobic septicemia and infection other than clostridial
   f. Arthritic Diseases
   g. AIDS/HIV
   h. Alzheimer's Disease
   i. Asthma
   j. Bell’s Palsy
   k. Cardiogenic shock
   l. Cerebral Palsy
   m. Chronic peripheral vascular insufficiency
   n. Cutaneous, decubitus, and stasis ulcers
   o. Depression
   p. Exceptional blood loss anemia
   q. Hepatic necrosis
   r. Migraines
   s. Multiple Sclerosis
   t. Myocardial infarction
   u. Nonvascular causes of chronic brain syndrome (Pick’s disease, Alzheimer’s disease, Korsakoff’s disease)
   v. Organ storage
   w. Organ transplantation
   x. Parkinson’s
   y. Pulmonary emphysema
   z. Senility
   aa. Sickle cell anemia
   bb. Skin burns (thermal)
   cc. Spinal cord injury
   dd. Sports injury
   ee. Stroke
   ff. Systemic aerobic infection
   gg. Tetanus

3. Absolute contraindications include the following:
   a. Untreated pneumothorax

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

There is a large body of published peer-reviewed scientific literature, including systematic reviews and randomized controlled trials that support the effectiveness, safety and improvement of net health outcomes of HBOT for many conditions including: decompression illness, arterial or air gas embolism, cyanide and carbon monoxide poisoning, gas gangrene, necrotizing infections, soft tissue radionecrosis and osteoradionecrosis, non-healing wounds in diabetes mellitus, peripheral artery insufficiency, actinomycosis, skin grafts and flaps, acute traumatic ischemia or crush injuries and osteomyelitis. For evidence-based and peer-reviewed sources on these indications, please refer to UHMS, 2019; Machem & Manaker, 2021; Armstrong & Meyer, 2021; McCulloch & Asla, 2021; Bennett et al., 2016; Bennett et al., 2012; Buckley et al., 2011; Clarke et al., 2008; Annane et al., 2004; Weaver, 2020; Guo et al., 2003; Chen et al., 2017; Ouahmane et al., 2023; Zhang et al., 2022; Moreira et al. 2022.

There is insufficient evidence in the published peer-reviewed scientific literature to support HBOT for any of the conditions outlined in the coverage exclusions section above. The published literature is from low quality studies and primarily consists of case series and retrospective reviews with small heterogeneous patient populations, short-term follow-ups and has reported conflicting and various outcome data. For evidence-based and peer-reviewed sources on these indications, please refer to AHRQ, 2003; AHRQ, 2006; Hayes, 2009b; Hayes, 2016; Hayes, 2008b; Hayes 2021a; Hayes, 2021b; Hayes, 2009c; Bennet et al., 2015a; Bennet et al., 2005; Bennet et al., 2018; Bennet et al., 2015b; Bennet et al., 2012a; Bennet et al., 2012b; Bennet et al., 2014; Eskes et al., 2013; Kranke et al., 2015; Philips & Jones, 2013; Villanueva et al, 2004; Rossignol et al., 2009; Esposito & Worthington, 2013; Xiao et al., 2012; Holland et al., 2012; Fedorko et al, 2016.

Although small studies have shown potential for topical oxygen therapy (TOT) to aid in diabetic foot ulcer healing, larger, randomized controlled trials are needed to validate findings. There is currently insufficient evidence in the peer reviewed medical literature for any condition treated with topical oxygen therapy (Hayes, 2017a; Thanigaimani et al., 2021; Connaghan et al., 2021; Yu et al., 2016; Frykberg et al., 2020; Niederauer et al., 2018; Niederauer et al., 2017; Driver et al., 2017; Pasek et al., 2023).

The **Undersea & Hyperbaric Medical Society** has published a detailed list of indications for HBOT along with rational. The list includes, but is not limited to, the following indications: carbon monoxide poisoning, cyanide poisoning, gas gangrene, traumatic ischemias such as crush injury, decompression sickness, acute peripheral artery insufficiency, refractory osteomyelitis, compromised grafts and flaps, and certain soft tissue and bony radiation injuries (UHMS, 2019).

CODING & BILLING INFORMATION

CPT Code

CPT	Description
99183	Physician attendance and supervision of hyperbaric oxygen therapy, per session

HCPCS Codes

HCPCS	Description
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 DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

4/13/2023	Policy reviewed. Coverage criteria updated to include initial authorization of up to 20 sessions with prior authorization being required for additional sessions. Updated Overview, Summary of Medical Evidence, and References.
4/13/2022	Policy reviewed, updated Overview, Summary, References. Updated policy name to include Topical Oxygen Therapy.
4/5/2021	Policy reviewed, no changes to criteria. Updated references.
4/23/2020	Policy reviewed, no changes to criteria.
6/19/2019	Policy reviewed, no changes to criteria.
3/8/2018	Policy reviewed, no changes to criteria.
12/16/2009	MCR no longer scheduled for revision.
04/30/2008	New policy.

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Government Agencies

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Peer Reviewed Publications

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National and Specialty Organizations

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*