

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. According to the Undersea and Hyperbaric Medical Society (2023), "the most common and acceptable clinical hyperbaric treatment pressures range between 2.0 and 3.0 [atmospheres absolute]" with pressures varying based on the indication HBOT is being used to treat. Treatment can be carried out in either a monoplace or multiplace chamber. A monoplace chamber accommodates a single patient. The entire monoplace chamber is pressurized with near 100% oxygen, and the patient breathes the ambient chamber oxygen directly. A multiplace chamber holds two or more people that may be patients, observers, and/or support personnel. The multiplace chamber is pressurized with compressed air while the patients breathe near 100% oxygen via masks, head hoods, or endotracheal tubes (UHMS 2023).

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 sessions. During the sessions, chamber pressure is generally maintained between 2.5 and 3.0 atmospheres for a duration of 45 to 300 minutes with most treatments lasting 60-90 minutes depending on indication. 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, also known as continuous diffusion of oxygen, 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 topical oxygen therapy 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 and the Undersea Hyperbaric Medical Society, oxygen must be delivered by inhalation within a pressurized chamber to meet the definition of HBOT, thus this type of oxygen therapy does not constitute HBOT (UHMS 2018; CMS 2017).

Regulatory Status

The United States Food & Drug Administration (FDA) regulates HBOT chambers as Class II medical devices, and there are several different chambers (both monoplace and multiplace 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. Topical oxygen therapy 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 510(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
 - b. Acute peripheral artery insufficiency
 - 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
 - d. Actinomycosis refractory to antibiotics and surgical treatment
 - e. Air or gas embolism
 - f. Chronic refractory osteomyelitis as an adjunctive therapy when **ALL** of the following criteria are met:
 - There is documentation of refractory stage 3B or 4B osteomyelitis.
 - Osteomyelitic lesions persist for more than six weeks after treatment is initiated.
 - There is no improvement after adequate antibiotic treatment(s) and operative procedures (if a surgical candidate) are performed.
 - g. Gas Gangrene (clostridial myositis and myonecrosis) as an adjunctive therapy to antibiotics and surgical management
 - h. Necrotizing soft tissue infections (e.g., necrotizing fasciitis)
 - i. Osteoradionecrosis as an adjunct to conventional treatment
 - 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)
 - k. Soft tissue radionecrosis as an adjunct to conventional treatment
 - l. Severe carbon monoxide poisoning
 - m. Severe decompression sickness.
2. HBOT **is considered medically necessary** as an adjunctive therapy in wound care only if there are no measurable signs of healing for a minimum of 30 days of standard conventional treatment. HBOT **must** be used in addition to standard wound care and **ALL** of the following criteria must be met:
 - a. Severe non-healing Type 1 or 2 Diabetes Mellitus lower extremity wound due to DM.
 - 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.
 - Wagner grade 4, deep ulcer with abscess, osteomyelitis, or joint sepsis.
 - Wagner grade 5, localized gangrene of forefoot or heel.
 - c. Minimal to no healing following 30 consecutive days of appropriate wound care (including moist-retentive wound care) including **ALL** of the following:
 - Antibiotic treatment when indicated.
 - Evaluation and correction of underlying peripheral vascular disease or neuropathic disease (if applicable).
 - Optimal glycemic control.
 - Optimal nutritional status.
 - Pressure reduction or off-loading.
 - Topical wound treatment (e.g., saline, hydrogels, hydrocolloids, alginates).
 - Wound debridement by any means to remove devitalized tissue.

Continuation of Therapy

1. 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.
2. 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. 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

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prior to authorization of additional HBOT.

Limitations and Exclusions

1. Topical oxygen therapy is considered experimental, investigational, and unproven for any condition due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes.
2. HBOT is considered not medically necessary and excluded for any condition not listed above due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes.
3. Absolute contraindications for HBOT 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. 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 conflicting outcome data. Although small studies have shown potential for topical oxygen therapy 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. A summary of relevant studies is below.

Hyperbaric Oxygen Therapy

Li et al. (2024) completed a meta-analysis and systematic review to determine if HBOT is a safe and effective adjunct treatment for patients suffering from an acute ischemic stroke. Only randomized controlled trials comparing HBOT to non-HBOT treatments (either no HBOT treatment or placebo) were included and participants had to have an ischemic stroke diagnosed using computed tomography or magnetic resonance imaging. Participants were excluded if they had a hemorrhagic stroke or contraindications to oxygen therapy. A total of eight studies with 493 participants (HBOT = 493, non-HBOT or placebo = 254) were included in the meta-analysis. Outcomes measured included National Institutes for Health Stroke Scale scores, Barthel index, modified Rankin Scale Score, tumor necrosis factor alpha, soluble intercellular adhesion molecule-1, soluble vascular cell adhesion molecule-1, serum E-selectin, C-reactive protein, and the rate and severity of adverse events. Results revealed that, although the HBOT group experienced improvement in most of the measured outcomes, there was no statistically significant difference between either group for any of the outcomes. Researchers determined that their "findings do not support the routine use of HBOT for improving clinical outcomes in [acute ischemic stroke]."

Huang et al. (2023) completed a meta-analysis and systematic review to determine the efficacy of HBOT as a treatment option for necrotizing soft tissue infections. Inclusion criteria included studies that were either clinical trials or observational studies comparing HBOT to non-HBOT treatments in participants diagnosed with necrotizing soft tissue infections (including necrotizing fasciitis or Fournier's gangrene). A total of 23 studies with 49,152 patients (HBOT =

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1448, control = 47,704) were included in the meta-analysis. The primary outcome measured was mortality rate and secondary outcomes measured included the number of debridements, amputation rates, and complications. Results showed that the mean mortality rate was significantly lower in the HBOT group compared to the non-HBOT group (10.6% vs 25.6%, $p < 0.05$). The number of debridements was reported in eight of the studies included in meta-analysis and found that the number of debridements was higher in the HBOT group compared to the non-HBOT group ($p < 0.05$). Amputation rates were reported in six studies and complications were reported in five studies and meta-analysis of both found no significant differences between the HBOT and non-HBOT groups ($p > 0.05$) with the exception of multi-organ dysfunction syndrome. The rate of multi-organ dysfunction syndrome was reported in 2 studies and was found to be lower in the HBOT group ($p < 0.05$). Sub-group analyses of each outcome were completed for a Fournier's gangrene subgroup and a non-Fournier's gangrene subgroup. Sub-group analyses showed that the mortality rate was also significantly lower in the HBOT group compared to the non-HBOT group for both sub-groups ($p < 0.05$). In addition, the number of debridements was higher in the HBOT group within the non-Fournier's gangrene subgroup while there were no statistically significant differences noted in the Fournier's gangrene subgroup for either the HBOT or non-HBOT groups. Researchers noted that the retrospective nature of this study limits the strength of evidence and therefore suggest additional research to establish efficacy.

Fakkert et al. (2023) completed a meta-analysis and systematic review to determine if the time-to-HBOT following an iatrogenic cerebral arterial gas embolism caused by an invasive medical procedure affected outcomes. The meta-analysis included 10 studies with a total of 263 patients. Results of the meta-analysis showed that "patients with favorable outcomes were treated significantly earlier than those with unfavorable outcomes." The overall probability of a favorable outcome was 65% when HBOT was started immediately compared to 30% when HBOT was initiated > 15 hours following embolism manifestation. Further delays after 20-25 hours did not appear to affect outcomes. Researchers noted a limitation of this study was the inability to further categorize patients based on additional factors that could have affected outcomes.

Zhang et al. (2022) completed a meta-analysis and systematic review of 20 randomized controlled trials to determine the efficacy of HBOT in the treatment of diabetic foot ulcers. Inclusion criteria included studies that were randomized controlled trials comparing HBOT to conventional or placebo treatment in patients with diabetic foot ulcers (no limit on grade) with the following outcomes reported: 1) wound healing time, 2) wound healing rate, 3) granulation tissues formation time, 4) amputation rate, and 5) incidence of adverse events. A total of 1263 patients were included with 614 in the HBOT cohort and 649 in the conventional/placebo (control) cohort. Wound healing time was reported by three studies with only two studies eligible for analysis due to incomplete data in one of the studies. The two studies reported reduced healing times for those receiving HBOT ($p < 0.001$). Healing rates were reported in 17 studies with results showing improved healing rates in the HBOT cohort ($p < 0.0001$). Amputation rates were reported as major (amputation above the ankle joint) or minor (distal to the ankle joint). Major amputation rates were reported in six studies with results showing reduced rates for the HBOT cohort ($p < 0.01$). Minor amputation rates were reported in five studies with no differences noted between either cohort ($p = 0.055$). Adverse reactions were reported by three studies with results showing no statistically significant differences between either cohort ($p = 0.234$). Researchers noted that HBOT appears to have a "substantial benefit in healing [diabetic foot ulcers] and decreasing amputation." Limitations of this study included a relatively small number of patients included for analysis of adverse reactions.

COVID-19

Three clinical trials are currently being completed to assess the safety and efficacy of HBOT as a treatment for post-COVID syndrome. One study (NCT04842448) has an estimated completion date of June 2024 and aims to evaluate the effects of HBOT on symptoms associated with post-COVID syndrome. Another study (NCT06159309) aims to investigate the effects of HBOT on quality-of-life measures and the last study (NCT06118138) aims to document symptom progression following HBOT administration in patients with myalgic encephalomyelitis or chronic fatigue syndrome related to COVID-19 infection. Two studies have been completed (NCT04800120, NCT05977166) but no results have been published (ClinicalTrials.gov 2024).

Topical Oxygen Therapy

Sun et al. (2022) completed a meta-analysis and systematic review to evaluate the safety and efficacy of topical oxygen therapy as a treatment for diabetic foot ulcers. A total of 7 studies with 614 participants were included in the meta-analysis. Five studies used continuous diffusion of oxygen therapy and two studies used intermittent topical oxygen therapy. Wounds were assessed using the Texas grading system in four studies and the Wagner grading system in

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three studies. There was a relatively high risk of bias among all of the studies with two studies being funded by device manufacturers, two studies having a high risk of selective reporting due to inadequacies in the reporting of adverse events, and one study having a high risk of attrition bias. Outcomes reported included the number of ulcers that completely healed, mean ulcer area, healing time, follow-up, and quality of life. Pooled results of six studies showed that a higher number of ulcers were completely healed at either eight or 12 weeks in the topical oxygen therapy group (topical oxygen therapy = 148/346, control = 86/330, $p < 0.00001$). Five studies reported the mean ulcer area; however, two of the studies were excluded from meta-analysis due to inconsistencies in intervention durations. Pooled results for mean ulcer area, adverse events, follow-up, and quality of life suggested improved outcomes in the topical oxygen therapy groups. Healing time was reported by four studies with pooled analysis suggesting unclear effects on healing time in the topical oxygen therapy groups. Of note, one study reported significantly improved healing times in the ≥ 65 -year-old subgroup ($p < 0.05$). Researchers noted that the results of this meta-analysis were promising for the use of topical oxygen therapy as an adjunct treatment in diabetic foot ulcers. However, researchers noted more robust and well-controlled trials are needed to confirm the results of existing trials due to inconsistencies with predefined outcomes and the severity of ulcers treated with topical oxygen therapy compared to the control groups.

Frykberg et al. (2020) completed a prospective, multinational, multicenter, randomized, double-blinded, placebo-controlled randomized clinical trial “to assess the efficacy of multimodality cyclical pressure Topical Wound Oxygen (TWO2) home care therapy in healing refractory diabetic foot ulcers that had failed to heal with standard of care alone.” A total of 220 patients were enrolled in the study with 110 randomized on a 1:1 basis to either sham or active TWO2 therapy. Both treatment arms received sham or TWO2 therapy in addition to standard of care. The primary outcome measured was the percentage of ulcers achieving 100% healing at 12 weeks and secondary outcomes included ulcer recurrence, incidence of amputation, and quality of life index. Results were reported on the first 73 participants enrolled in the study (sham = 36, active TWO2 = 37) and showed that “the active TWO2 arm showed > 3.5 times the likelihood to completely heal over 12 weeks compared with the sham arm” (HR 3.64, 97.8% CI, $p = 0.013$). Ulcer recurrence was assessed at 12 months post-enrollment, with only one recurrence out of 15 healed ulcers in the active TWO2 arm and two recurrences out of five healed ulcers in the sham arm. Of note, 20 ulcers were reported as closed at 12 months in the active TWO2 arm compared to 10 in the sham arm. Overall quality of life indexes improved in both treatment arms with greater increases noted in the active TWO2 arm. Therapy compliance and off-loading device compliance was high in each treatment arm. A total of 10 serious adverse events and eight adverse events occurred in each treatment arm with two index limb amputations occurring in the active TWO2 arm compared to three index limb amputations in the sham arm. Researchers noted a major limitation of this study was the small sample size due to predetermined “hard stopping rules” that limited analysis to the first 73 patients enrolled due to a significant number of patients in the active TWO2 arm healing compared to those in the sham arm. Researchers concluded that the results of this study are promising, but additional studies are needed to determine efficacy as the current published evidence has several methodological weaknesses.

National/Specialty Organizations

The **Undersea & Hyperbaric Medical Society** has published an updated, detailed list of indications for HBOT along with rationale in 2023. 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 2023).

The **International Working Group on the Diabetic Foot (IWGDF)** published updated guidelines in 2019 on the use of interventions to enhance the healing of chronic diabetic foot ulcers. The guidelines recommend that providers “consider the use of systemic [HBOT] as an adjunctive treatment in non-healing ischemic diabetic foot ulcers despite best standard of care.” The recommendation is rated “weak” and is based on “moderate” evidence. Topical oxygen therapy is not recommended as a primary or adjunctive treatment (Rayman et al. 2020).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Code

Code	Description
99183	Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen

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	therapy, per session
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HCPCS (Healthcare Common Procedure Coding System) Codes

Code	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

04/10/2024	Policy reviewed, no changes to criteria. Updated Overview, Summary of Medical Evidence, and References. IRO Peer Review on February 21, 2024, by a practicing, board-certified physician with specialties in Undersea & Hyperbaric Medicine and Occupational Medicine.
04/13/2023	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.
04/13/2022	Policy reviewed, updated Overview, Summary, References. Updated policy name to include Topical Oxygen Therapy.
04/05/2021	Policy reviewed, no changes to criteria. Updated references.
04/23/2020	Policy reviewed, no changes to criteria.
06/19/2019	Policy reviewed, no changes to criteria.
03/08/2018	Policy reviewed, no changes to criteria.
12/16/2009	MCR no longer scheduled for revision.
04/30/2008	New policy.

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APPENDIX

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

Washington

For Medicaid reviews, consider and apply the following state-specific criteria: Health Technology Assessment (HTA) “Hyperbaric Oxygen Therapy for Tissue Damage, Including Wound Care and Treatment of Central Nervous System Conditions” Washington State Healthcare Authority, May 17, 2013.