

Hyperbaric Oxygen Therapy Clinical Coverage Criteria

Overview

Hyperbaric oxygen is a medical procedure requiring a physician's prescription and oversight. Hyperbaric oxygen is delivered within a hard sided hyperbaric chamber that meets the American Society of Mechanical Engineers and Pressure Vessels for Human Occupancy (ASME-PVHO-1) code, and the National Fire Protection Agency (NFPA 99) code and standards for hyperbaric chambers, at a pressure of not less than 2.0 ATA while breathing physician prescribed medical grade oxygen for an amount of time that is typically between 90-120 minutes per treatment.

Hyperbaric oxygen chambers may be monoplace or multiplace (monoplace chambers are designed to accommodate one person, multiplace chambers are designed to accommodate two or more people). Hyperbaric oxygen chambers are Class II devices reviewed by the FDA under the 510(K) pre-market approval process for the treatment of indications approved/accepted by the Hyperbaric Oxygen Therapy Committee of the Undersea and Hyperbaric Medical Society (UHMS).

Hyperbaric oxygen chambers are found in hospitals, outpatient medical clinics, independent hyperbaric clinics, commercial facilities (such as oil and natural gas drilling rigs), military bases, and veteran's hospitals. The Undersea and Hyperbaric Medical Society (UHMS) has established criteria for accreditation of hyperbaric treatment facilities designed to ensure safe and clinically appropriate treatments,

A course of hyperbaric oxygen therapy varies greatly by diagnosis. Scientifically supported hyperbaric treatments are usually delivered at pressures between 1.9 to 3.0 ATA. Hyperbaric oxygen therapy is standard of care for many medical conditions including decompression sickness, carbon monoxide poisoning, diabetic wounds, delayed radiation injury, necrotizing fasciitis, gas gangrene, refractory osteomyelitis, and several other conditions proven by peerreviewed research. Most disorders require a series of treatments delivered daily for several weeks. These treatments should be prescribed and supervised by qualified physicians with appropriate training (UHMS, 2024).

Hyperbaric treatment at minimally elevated chamber pressures (mild hyperbaric oxygen) is unproven. Mild hyperbaric oxygen therapy is currently considered to be exposures delivered at pressures lower than 1.5 ATA. Hyperbaric oxygen has been under study for traumatic brain injury in several randomized controlled trials. Although one of these studies is a positive trial at a treatment pressure of 1.5 ATA, such treatments are at this time considered investigational (UHMS, 2024).

Topical hyperbaric oxygen therapy delivers 100% oxygen to a localized area (e.g., over a wound). The efficacy of topical HBOT has not been proven in randomized controlled clinical trials (Shapshak and Kelly, 2018).

Policy

This Policy applies to the following Fallon Health products:

☑ Medicare Advantage (Fallon Medicare Plus, Fallon Medicare Plus Central)

☑ MassHealth ACO

- ☑ NaviCare HMO SNP
- ☑ NaviCare SCO
- ☑ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
- □ Community Care

Fallon Health requires prior authorization for non-emergent hyperbaric oxygen therapy.

Services for the treatment of an emergency medical condition do not require prior authorization. Emergent hyperbaric oxygen therapy can involve several treatments in the first 24 hours for best outcomes. A course of hyperbaric oxygen treatment varies greatly by diagnosis. Post-stabilization services are covered services related to an emergency medical condition provided after a member's condition has stabilized in order to maintain the stabilized condition or improve or resolve the member's condition. The Plan requires prior authorization for post-stabilization hyperbaric oxygen therapy.

Medicare Advantage (Fallon Medicare Plus, Fallon Medicare Plus Central)

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Medicare statutes and regulations do not have coverage criteria hyperbaric oxygen therapy. Medicare has an NCD Hyperbaric Oxygen Therapy (20.29). National Government Services, Inc., the Part A/B Medicare Administrative Contractor with jurisdiction in the Plan's service area does not have an LCD related to hyperbaric oxygen therapy (Medicare Coverage Database search 07/01/2024). Noridian Healthcare Solutions, LLC has an LCD: Oxygen and Oxygen Equipment (L33797) that addresses non-coverage of topical oxygen delivery systems (E0446) and topical hyperbaric oxygen chambers (A4575).

Coverage criteria for hyperbaric oxygen therapy are fully established by Medicare, therefore, the Plan's coverage criteria are not applicable.

Link: NCD Hyperbaric Oxygen Therapy (20.29)

Indications and Limitations of Coverage

A. Covered Conditions

Program reimbursement for HBO therapy will be limited to that which is administered in a chamber (including the one man unit) and is limited to the following conditions:

- 1. Acute carbon monoxide intoxication,
- 2. Decompression illness,
- 3. Gas embolism,
- 4. Gas gangrene,
- Acute traumatic peripheral ischemia. HBO therapy is a valuable adjunctive treatment to be used in combination with accepted standard therapeutic measures when loss of function, limb, or life is threatened.
- 6. Crush injuries and suturing of severed limbs. As in the previous conditions, HBO therapy would be an adjunctive treatment when loss of function, limb, or life is threatened.
- 7. Progressive necrotizing infections (necrotizing fasciitis),
- 8. Acute peripheral arterial insufficiency.
- 9. Preparation and preservation of compromised skin grafts (not for primary management of wounds),

- Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management.
- 11. Osteoradionecrosis as an adjunct to conventional treatment,
- 12. Soft tissue radionecrosis as an adjunct to conventional treatment,
- 13. Cyanide poisoning,
- 14. Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment,
- 15. Diabetic wounds of the lower extremities in patients who meet the following three criteria:
 - a. Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes;
 - b. Patient has a wound classified as Wagner grade III or higher; and
 - c. Patient has failed an adequate course of standard wound therapy.

The use of HBO therapy is covered as adjunctive therapy only after there are no measurable signs of healing for at least 30 days of treatment with standard wound therapy and must be used in addition to standard wound care. Standard wound care in patients with diabetic wounds includes assessment of a patient's vascular status and correction of any vascular problems in the affected limb if possible, optimization of nutritional status, optimization of glucose control, debridement by any means to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, appropriate offloading, and necessary treatment to resolve any infection that might be present. Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days. Wounds must be evaluated at least every 30 days during administration of HBO therapy. Continued treatment with HBO therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

B. Noncovered Conditions

All other indications not specified under §270.4(A) are not covered under the Medicare program. No program payment may be made for any conditions other than those listed in §270.4(A). See NCD for list of conditions not covered.

C. Topical Application of Oxygen

Topical application of oxygen was removed from NCD 20.29 effective for dates of service on and after 04/03/17, Medicare Administrative Contractors (MACs) acting within their respective jurisdictions may determine coverage of topical application of oxygen for chronic non-healing wounds. The CMS decision to remove the section on topical application of oxygen from the Hyperbaric Oxygen Therapy NCD was because the topical application of oxygen does not meet the definition of hyperbaric oxygen therapy. In addition, CMS adds this note, "Though a MAC may decide to cover this procedure, there shall be no coverage for any separate or additional payment for any physician's professional services related to this procedure (CMS Transmittal 203NCD, Date: 11/17/2017)."

MassHealth ACO

Fallon Health follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

MassHealth does not have Guidelines for Medical Necessity Determination for hyperbaric oxygen therapy, therefore, Fallon Health Clinical Coverage Criteria are applicable (MassHealth website search 07/01/2024).

NaviCare HMO SNP, NaviCare SCO

For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with

jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Fallon Health Clinical Coverage Criteria

Effective for dates of service on or after August 1, 2024, Fallon Health will use InterQual® Criteria when making medical necessity determinations for hyperbaric oxygen therapy.

For coverage criteria, refer to the InterQual® Criteria in effect on the date of service:

- InterQual® CP:Procedures, Hyperbaric Oxygen Therapy
- InterQual® CP:Procedures, Hyperbaric Oxygen Therapy (Pediatric)

Fallon Health makes InterQual criteria available to the public through the transparency tool on our website, effective January 1, 2024.

The FDA advises that hyperbaric oxygen therapy should only be provided by a hospital or facility that has been properly accredited by the **Undersea and Hyperbaric Medicine Society**.

Exclusions

- Topical oxygen therapy (A4575, E0446) and any professional services related to this therapy.
- Any use of HBOT for which there is not a recommendation from the Hyperbaric Oxygen
 Therapy Committee of the Undersea and Hyperbaric Medical Society (UHMS), including but
 not limited to the treatment of decubitus ulcers, Lyme disease, migraine of any etiology,
 complex regional pain syndrome, fibromyalgia, cerebral palsy, autistic disorder, or chronic
 fatigue syndrome, or to prevent mandibular osteoradionecrosis pre- and/or post-dental
 extraction, or intraoral implant failure.
- Hyperbaric treatment at minimally elevated chamber pressures (mild hyperbaric oxygen) for which there is no clinical evidence of effectiveness. Mild hyperbaric oxygen therapy is currently considered to be exposures delivered at pressures lower than 1.5 ATA.
- HBOT is not covered for the prevention of mandibular osteoradionecrosis (including but not limited to pre and/or post dental extraction).
- HBOT is not covered to prevent complications or improve survival of intraoral implants in an irradiated field.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Code	Description
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

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HCPCS G0277 description is per 30 minutes. Additional units may be billed for sessions requiring at least 16 minutes of the next 30 minute intervals. Less than 16 minutes should not be billed.

1 unit G0277 should be billed for HBO session duration between 16 and 45 minutes 2 units G0277 should be billed for HBO session duration between 46 and 75 minutes 3 units G0277 should be billed for HBO session duration between 76 and 105 minutes 4 units G0277 should be billed for HBO session duration between 106 and 135 minutes

References

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- 2. Noridian Healthcare Solutions, LLC. Local Coverage Determination (LCD): Oxygen and Oxygen Equipment (L33797). Original Effective Date 10/1/2015. Revision Effective Date 04/01/2023.
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Policy history

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06/25/2021 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section), 07/02/2024 (annual review, updated Medicare and MassHealth information in Policy section, adopted

InterQual criteria, updated References).

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.