

Hyperbaric Oxygen Therapy – Systemic

Policy Number: **M070301666**
Effective Date: **3/1/2007**
Sponsoring Department: **Health Care Services**
Impacted Department(s): **Health Care Services**

Type of Policy: Internal External

Data Classification: Confidential Restricted Public

Applies to (Line of Business):

- Corporate (All)
- State Products, if yes which plan(s): MediSource; MediSource Connect; Child Health Plus; Essential Plan
- Medicare, if yes, which plan(s): MAPD; PDP; ISNP; CSNP
- Commercial, if yes, which type: Large Group; Small Group; Individual
- Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

Applicable to Vendors? Yes No

Purpose and Applicability:

To set forth the medically necessary criteria for systemic hyperbaric oxygen therapy (HBOT).

Policy:

Systemic HBOT Criteria – Commercial, Self-Funded, and Medicare Advantage:

Hyperbaric Oxygen Therapy may be considered medically necessary and a covered benefit for the following indications:

NOTE: Preauthorization is required prior to first treatment. It will require repeat authorization after the initial approval according to the following schedule:

1. Acute carbon monoxide intoxication, 3 treatments allowed;
2. Decompression illness, 10 treatments ;
3. Gas embolism, 10 treatments;
4. Gas gangrene, 10 treatments;
5. 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. 10 treatments.
6. Progressive necrotizing infections (necrotizing fasciitis), 30 treatments;
7. Acute peripheral arterial insufficiency, 30 treatments;
8. Preparation and preservation of compromised skin grafts (not for primary management of wounds), 20 treatments;
9. Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management, 30 treatments;
10. Osteoradionecrosis as an adjunct to conventional treatment, 30 treatments;
11. Soft tissue radionecrosis as an adjunct to conventional treatment, 30 treatments;
12. Cyanide poisoning, 3 treatments;
13. 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** with no measurable signs of healing for at least 30 consecutive days. 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. Dated color photographic documentation with a ruler must be submitted prior to commencement of hyperbaric treatment.
 - (i) Standard wound care in patients with diabetic wounds includes:
 1. Documentation of an assessment of a patient’s vascular status and correction of any vascular problems in the affected limb if possible,
 2. optimization of nutritional status,
 3. optimization of glucose control,
 4. debridement by any means to remove devitalized tissue,
 5. maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings,
 6. appropriate off-loading (including total contact cast and removable cast boot), and
 7. necessary treatment to resolve any soft tissue or bony infection that might be present.

(ii) Continuation of wound treatment:

1. Continued treatment with HBO therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.
2. Wounds must be evaluated, with submission of dated color photographic documentation with a ruler, after 15 treatments/every 30 days during administration of HBO therapy.
3. Dates of debridement must be noted in clinical documentation.

Commercial, Self-Funded, Medicare Advantage, MediSource, MediSource Connect, and Essential Plan Discontinuation of Treatment:

HBO treatments should be discontinued when any of the following occurs:

- Member heals; or
- Member is unable to tolerate treatment; or
- Member fails to improve.

Commercial and Self-Funded Additional Criteria:

1. Diabetic foot ulcer:

a. pretreatment requirements:

- (i) Documentation and submission of an assessment of a patient's vascular status prior to treatment must be documented by a completed arterial Doppler study with measurement of the ankle brachial index (ABI), toe brachial index (TBI) and pulse volume recording. With correction of any vascular problems in the affected limb if possible, with a referral to a vascular surgeon or interventional radiologist if indicated.
- (ii) Documentation of transcutaneous tissue oxygenation (PtcO₂) levels is required, for all Diabetic Foot Ulcers (DFU's), as follows:

- PtcO₂ value equal to or greater than 35 mmHg on room air.
- PtcO₂ values less than 35 mmHg on room air that meet one or more of the following:
 - PtcO₂ increase to greater than 100 mmHg while breathing 100% O₂ via mask at normal atmospheric pressure.
 - PtcO₂ increase to greater than 200 mmHg while breathing 100% O₂ inside the hyperbaric chamber at 2.0 – 2.4 ATA.

Above testing must be completed by the first scheduled HBO treatment and, if criteria not met, HBO treatments must be discontinued.

b. Wound evaluation after every 15 treatments/30 days.

2. Osteoradionecrosis

- a. HBO is covered pre and post dental extractions with 20 preoperative and 10 postoperative treatments.
- b. Prophylaxis protocol is indicated to prepare the patient for the irradiated mandible.

3. Exclusions:

The use of systemic HBO is considered experimental and investigational for the following conditions because of insufficient evidence in the peer-reviewed medical literature establishing HBO to be more effective than conventional therapies:

- Pyoderma gangrenosum
- Intra-abdominal abscess, pseudomembranous colitis (antibiotic-induced colitis)

- Intracranial abscesses
- Organ transplantation and storage
- Acute cerebral edema
- Pulmonary emphysema
- Cognitive impairment (e.g., senility, senile dementia)
- Non-vascular causes of chronic brain syndrome (e.g., Alzheimer’s disease, Pick’s disease, Korsakoff’s disease)
- Multiple sclerosis
- Migraine or cluster headaches
- Meningitis
- Closed head and/or spinal cord injury
- Myocardial infarction, unless due to acute CO poisoning
- Cardiogenic shock
- Sickle cell crisis or hematuria
- Bone grafts or non-union of fracture
- Arthritic disease
- Ophthalmologic disease
- Hepatic necrosis
- Lepromatous leprosy
- Aseptic necrosis of the femoral head and neck
- Cystic acne
- Melasma
- Actinic skin damage
- Lyme disease
- Cerebral palsy
- Reflex sympathetic dystrophy (complex regional pain syndrome)
- Necrotizing arachnidism (Brown recluse spider bite)
- Bell’s palsy
- Legg-Calve-Perthes disease
- Crohn’s disease
- Osteoporosis
- Cancer
- HIV infection
- Facial neuritis
- Tinnitus
- Interstitial cystitis
- Acute coronary syndrome
- Ischemia due to lupus vasculitis.

Medicare Advantage Additional Criteria:

1. Coverage for osteoradionecrosis of the jaw is limited to cases with evidence of overt fracture or bony resorption.
2. HBO is not covered to prepare the patient for dental extraction in order to prevent the development of osteoradionecrosis.

3. Exclusions:

Medicare Advantage does not reimburse HBOT for the following conditions:

- Cutaneous, decubitus, and stasis ulcers
- Chronic peripheral vascular insufficiency
- Anaerobic septicemia and infection other than clostridial
- Skin burns (thermal)
- Senility
- Myocardial infarction
- Cardiogenic shock
- Sickle cell anemia
- Acute thermal and chemical pulmonary damage, i.e., smoke inhalation with pulmonary insufficiency
- Acute or chronic cerebral vascular insufficiency
- Hepatic necrosis
- Aerobic septicemia
- Nonvascular causes of chronic brain syndrome (Pick's disease, Alzheimer's disease, Korsakoff's disease)
- Tetanus
- Systemic aerobic infection
- Organ transplantation
- Organ storage
- Pulmonary emphysema
- Exceptional blood loss anemia
- Multiple Sclerosis
- Arthritic Diseases
- Acute cerebral edema

MediSource, MediSource Connect, and Essential Plan:

MediSource, MediSource Connect, and Essential Plan cover systemic hyperbaric oxygen therapy utilizing the Commercial criteria above.

Background:

Hyperbaric Oxygen therapy (HBO₂) is a treatment in which a patient breathes 100% oxygen intermittently, while inside a treatment chamber, at a pressure that is higher than sea-level atmospheric pressure. The increased partial pressure of oxygen in the vasculature hyper oxygenates the plasma as well as the tissue around a hypoxic wound or irradiated area and this hyperoxia stimulates the release and up-regulation of growth factors and stem cells leading to improved healing.

Hyperbaric Oxygen Therapy should only be used for appropriate indications and should be an adjunct to, and not a substitute for, appropriate therapeutic measures and comprehensive wound care. Typical treatment pressures should be 2.0 Atmospheres Absolute (ATA) or above.

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

Pre-Authorization Required? Yes No

Pre-authorization is required for this service.

Definitions

Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days.

Hyperbaric Oxygen Therapy (HBOT) is a technique of delivering higher pressures of oxygen to the tissues. There are two methods of administration available for HBOT, systemic and topical.

Wound healing is defined as improvement occurring in either surface area or depth of the wound. Lack of improvement of a wound is defined as a lack of progress in these quantitative measurements.

Wagner Wound Classification system is the most widely system used for classifying diabetic foot ulcers. The system provides for grading an ulcer on a scale from zero to five. The features of the Wagner system are as follows for each grade:

- Grade 0 – No open lesions; may have deformity or cellulitis
- Grade 1 - Superficial ulcers (full thickness or partial thickness)
- Grade 2 - Ulcers extension to ligament, tendon, the joint capsule or deep fascia without abscess or osteomyelitis.
- Grade 3 - Deep ulcer with abscess, osteomyelitis and/or joint sepsis.
- Grade 4 - Gangrene (decay of body tissues) in the forefoot (anterior third of the foot) or heel region(s).
- Grade 5 - Extensive gangrenous involvement of the entire foot

References

Related Policies, Processes and Other Documents

Topical Oxygen Therapy; Policy No. M20150417024

Non-Regulatory references

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Huang ET, Mansouri J, Murad MH, et al; UHMS CPG Oversight Committee. A clinical practice guideline for the use of hyperbaric oxygen therapy in the treatment of diabetic foot ulcers. *Undersea Hyperb Med*. 2015 May-Jun;42(3):205-47.

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Regulatory References

Centers for Medicare and Medicaid [web site]. National Coverage Determinations Manual (NCD) for Hyperbaric Oxygen Therapy (20.29). Available at: [https://www.cms.gov/medicare-coverage-](https://www.cms.gov/medicare-coverage-database/details/ncd-)

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New York State Medicaid Program Physician – Procedure Codes Section 2 – Medicine, Drugs and Drug Administration Manual. April 2023 Available at:

https://www.emedny.org/ProviderManuals/Physician/PDFS/Physician_Procedure_Codes_Sect2.pdf

Accessed February 22, 2024.

New York State Department of Health; Division of Managed Care CovQuest, Hyperbaric Oxygen Treatment for osteoradionecrosis following proposed dental work; MA - 00089. August 9, 2002.

This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes No

Revision Date	Owner	Notes
5/1/2024	Health Care Services	Reviewed
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8/1/2016	Medical Management	Revised
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