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Clinical Guideline

Oscar Clinical Guideline: Hyperbaric Oxygen Therapy (CG014, Ver. 10)

Hyperbaric Oxygen Therapy

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

The Plan considers Systemic Hyperbaric Oxygen Therapy (HBOT) medically necessary when the criteria below for certain medical conditions are met for a prior authorization review. According to the Undersea and Hyperbaric Medical Society, hyperbaric oxygen therapy applies an increased pressure of ≥1 atmosphere absolute at sea level with ≥95% oxygen to the body leading to augmented oxygen levels in the blood to accelerate improvement of conditions. There has been FDA clearance of approval for specific indications. Most commonly, it is used to treat chronic complex diabetic wounds of the lower limbs. The Plan does not consider medically necessary the topical application of oxygen under any circumstances.

Definitions

"Hyperbaric Oxygen Therapy" (HBOT) is a method in which the entire body is exposed to oxygen under increased atmospheric pressure.

"Continuous Topical Oxygen Therapy" (CTOT) is a portable unit that can provide continuous flow of atmospheric (normobaric) oxygen to the wound up to 24 hours a day and 7 days a week. This does not require the member to be in-clinic and immobilized for therapy.

"Standard Wound Care" in patients with diabetic wounds includes the 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 off-loading; and necessary treatment to resolve any infection that might be present.

Clinical Indications

General Indications

In addition to condition-specific criteria (outlined below), The Plan considers HBOT medically necessary when ALL of the following criteria are met:

1. HBOT must be prescribed and administered by the licensed treating physician; *and*
2. HBOT must be administered in a chamber (such as the single-patient unit or multiplace unit); *and*
3. Continued HBOT is limited to 30 day authorization periods unless otherwise noted in the criteria below. Continued HBOT is subject to review for medical necessity and is indicated only when ALL of the following criteria are met:
    a. Adherence to hyperbaric oxygen therapy; *and*
    b. Evidence of improvement during the authorization period, e.g., reduction in the size of wound and reduction in signs of infection and/or inflammation.

Condition-Specific Indications

The Plan considers HBOT medically necessary when General Indications AND at least one of the following indications are met:

1. *Acute air or gas embolism* - 1 treatment may be indicated; additional treatments may be indicated only if symptoms persist.
2. *Acute carbon monoxide poisoning* - 1 to 3 total treatments may be indicated depending on persistence of clinical symptoms.
3. *Acute traumatic peripheral ischemia*, when there is immediate threat of permanent dysfunction, loss of limb, or death.
4. *Anemia*, when ALL of the following criteria are met:
    a. Patient unable or unwilling to receive a red blood cell transfusion; *and*
    b. Emergent treatment, as indicated by 1 or more of the following:
        i. Active hemolysis with progressive anemia; *or*
        ii. Acute blood loss or active massive hemorrhage; *or*
        iii. Hypovolemic shock.
5. *Burns* (large or severe burns treated at a specialized burn center).
6. *Central retinal artery occlusion,* when started within 24 hours of symptom onset - Treatment is typically indicated until CRA recanalization has occurred (usually 24-72 hours).
7. *Chronic diabetic ulcer*, when ALL of the following criteria are met:

a. Severe wound (Wagner Grade III or higher) based on at least ONE of the following criteria:
    i. Deep ulceration to tendon causing tendonitis or non-infected bone; *or*
    ii. Deep ulcer with infection (e.g., abscess, osteomyelitis, or joint sepsis); *or*
    iii. Localized gangrene (ischemia) of the forefoot or heel.
b. Prior evaluation and treatment of underlying peripheral vascular and/or neuropathic disease; *and*
c. Documented 30-day trial of conventional wound care for diabetes with minimal to no healing and meets ALL of the following:
    i. Glycemic optimization; *and*
    ii. Wound is not infected or has been treated with antibiotics.
d. Treatment is indicated daily and meets ALL of the following:
    i. Evaluation of the wound occurs at least every 30 days during HBOT and demonstrates measurable signs of healing; *and*
    ii. Treatment is ordered for no more than 40 HBOT treatments to allow for review of the evaluation.

8. *Compromised skin grafts or flaps, where hypoxia or decreased perfusion has compromised viability acutely* when ALL of the following criteria are met:
    a. Correctable causes of the flap failure have been explored and adequately addressed prior to initiation of HBOT.
    b. Treatment is indicated for 2 times per day until the graft or flap appears viable, then 1 time per day until healed.
    c. Efficacy of therapy should be reviewed after 20 treatments and discontinued if no clinical improvement.
9. *Crush injuries and compartment syndrome*, when there is immediate threat of permanent dysfunction, loss of limb, or death - Treatment is indicated for 7 days or 14 treatment sessions. Treatment typically should occur twice a day for two days, then daily for two days.
10. *Carbon monoxide poisoning, with or without Cyanide poisoning.*
11. *Decompression illness* - Treatment should be rapid and repeated up to 10 times only if symptoms persist.
12. *Idiopathic sudden sensorineural hearing loss* when ALL of the following criteria are met:
    a. Audiometry showing a 30-dB hearing loss at 3 consecutive frequencies; *and*
    b. Other underlying potential causes have been ruled out or are not applicable; *and*
    c. HBOT is given in conjunction with standard of care steroid therapy; *and*
    d. 15 to 20 total treatments may be indicated once daily only when HBOT is initiated within 3 months after onset.
13. *Intracranial abscess* when ALL of the following criteria are met:
    a. The patient has multiple abscesses, abscesses in a deep or dominant location, or is immunocompromised; *and*

b. The patient has not responded to or is deteriorating despite standard of care, surgical and/or antibiotic treatment; or is not a candidate for surgery due to high risks or contraindications; *and*
c. Treatment may be indicated for 1-2 times per day; *and*
d. Efficacy of therapy should be reviewed after 20 treatments and discontinued if no clinical improvement.

14. *Necrotizing soft tissue infections and gas gangrene (Clostridial myositis and myonecrosis)*
    a. Documentation from a treating physician stating HBOT is used in conjunction with surgical debridement and antibiotics.
    b. Treatment is ordered and indicated for 2 times per day until there is no further extension of necrosis in previously debrided areas.
    c. Efficacy of therapy should be reviewed after 30 treatments and discontinued if no clinical improvement.
15. *Osteomyelitis* when ALL of the following criteria are met:
    a. The diagnosis is confirmed by imaging or biopsy; *and*
    b. Documentation from a treating physician confirms that the patient is unresponsive to conventional medical and surgical management; and the patient has completed at least 6 weeks of appropriate IV antibiotic therapy, and has undergone surgery without resolution or has documented justification for why surgery is not an option.
16. *Radiation injury*; up to 40 HBOT treatments are indicated, when ONE of the following criteria are met:
    a. Osteoradionecrosis (e.g., radiation-induced osteonecrosis of the jaw) as an adjunct to conventional treatment; *or*
    b. Soft tissue radionecrosis as an adjunct to conventional treatment; *or*
    c. Radiation-induced hemorrhagic cystitis; *or*
    d. Radiation-induced proctitis; *or*
    e. Prophylactic prevention of osteonecrosis of the jaw following tooth extraction in an irradiated field:
        i. Prior to surgery, treatment is ordered and indicated for 20 HBOT treatments.
        ii. Immediately after surgery, treatment is ordered and indicated for 10 HBOT treatments.

Experimental or Investigational / Not Medically Necessary

Absolute Contraindications for Hyperbaric Oxygen

- Concurrent administration of the antibiotic cream mafenide (Sulfamylon)
- Concurrent administration of disulfiram (Antabuse)
- Concurrent administration of antineoplastic agent doxorubicin
- Concurrent or past administration of antineoplastic agents bleomycin or cisplatin (Platinol)
- Premature infants (birth prior to 37 weeks gestation)
- Untreated pneumothorax

Experimental or Investigational

The Plan considers the use of HBOT to be experimental and investigational in the treatment of the following conditions including but not limited to:

- Actinomycosis
- Acute cerebral edema
- Acute coronary syndrome
- Acute or chronic cerebrovascular insufficiency
- Acute thermal and chemical pulmonary damage (i.e., smoke inhalation with pulmonary insufficiency)
- Aerobic infection
- AIDS/HIV
- Alzheimer's disease
- Anaerobic infection other than Clostridial
- Anoxic brain injury
- Arthritic diseases
- Asthma
- Autism
- Bell's palsy
- Cancer
- Cardiogenic shock
- Cerebral palsy
- Chronic fatigue syndrome
- Chronic peripheral vascular insufficiency
- Coronary artery disease
- COVID-19 or Long COVID
- Cutaneous, decubitus, and venous stasis ulcers
- Depression
- Fibromyalgia
- Fractures or fracture non-union
- Heart disease
- Hepatic necrosis
- Hepatitis
- Inflammatory bowel disease
- Ischemic stroke
- Lyme disease
- Malignant otitis externa
- Meningioma
- Migraine and cluster headaches
- Multiple sclerosis

- Myocardial infarction
- Non-compromised skin grafts and flaps
- Osteonecrosis of the jaw (not induced by radiation)
- Osteoporosis
- Parkinson's disease
- Post-concussive syndrome
- Pulmonary emphysema
- Following Radiation injuries:
    - Radiation-induced retinitis pigmentosa
    - Radiation-induced retinopathy
    - Radiation-induced neurologic injury
    - Radiation-induced xerostomia
    - Radiation-induced soft tissue injury (unless the above criteria is met)
- Senility
- Sickle cell anemia
- Spinal cord injury
- Stroke
- Surgical wound dehiscence
- Tetanus
- Tinnitus
- Traumatic brain injury
- Vascular dementia

Topical Application of Oxygen

This method of oxygen administration does not meet the definition of HBOT as stated above and there are no high quality evidence-based studies of its use in the literature. In 2022, Hayes rated topical oxygen therapy for chronic wound healing as D2. According to Hayes, clinical evidence suggests that it is associated with a reduction in wound size and pain; however, only 1 study evaluated complete wound closure. The comparative effectiveness is unclear due to the poor quality and lack of studies evaluating HBOT with a competing alternative. No guidance currently recommends use of topical HBOT. (UHMS, 2018). A recent small, randomized control trial (Yu et al. 2016) claimed a significant difference in healing rates between patients receiving topical oxygen therapy and those receiving standard wound care. However, the study was underpowered and it is unclear how many patients were included in each of the ulcer "stage" groups and statistical analysis is lacking. In addition, a small case series of 3 patients (Agarwal et al. 2015) described a device for applying topical oxygen and stated that these patients required fewer debridements, but there was no control group. A larger, multi-center study (Dryden et al. 2016) evaluated topical oxygen gel for both acute and chronic wounds with delayed healing, but again was simply observational and did not compare outcomes to any control group. While these study results may be promising in regard to topical oxygen therapy (TOT), as a treatment modality for including but not limited to chronic non-healing wounds, additional randomized comparative controlled studies are

required to assess the effectiveness of this therapy. Currently, there are no society guidelines that provide recommendations regarding the use of TOT. The current evidence is insufficient in determining the effects of this technology on net health outcomes and supports the categorization of topical oxygen therapy as experimental and investigational. Experimental and investigational treatments are not covered by the Plan. Topical HBOT includes boot or bag systems and single limb or sacral chambers.

Applicable Billing Codes

CPT/HCPCS Codes considered medically necessary if criteria are met:	
Code	*Description*
99183	Physician attendance and supervision of hyperbaric oxygen therapy, per session
G0277	Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval
ICD-10 codes *considered experimental or investigational*:	
A00.0 - A00.9	Cholera
A01.00 - A01.09	Typhoid fever
A02.0 - A02.9	Other salmonella infections
A03.0 – A03.9	Shigellosis
A04.1	Enterotoxigenic Escherichia coli infection
A04.2	Enteroinvasive Escherichia coli infection
A04.3	Enterohemorrhagic Escherichia coli infection
A04.4	Other intestinal Escherichia coli infections
A04.5	Campylobacter enteritis
A04.6	Enteritis due to Yersinia enterocolitica
A04.8	Other specified bacterial intestinal infections
A04.9	Bacterial intestinal infection, unspecified
A05.0	Foodborne staphylococcal intoxication
A05.1	Botulism food poisoning
A05.3	Foodborne Vibrio parahaemolyticus intoxication

A05.4	Foodborne Bacillus cereus intoxication
A05.5	Foodborne Vibrio vulnificus intoxication
A05.8	Other specified bacterial foodborne intoxications
A05.9	Bacterial foodborne intoxication, unspecified
A06.0 - A06.9	Amebiasis
A07.0 - A07.9	Other protozoal intestinal diseases
A08.0 - A08.9	Viral and other specified intestinal infections
A15.0 - A19.9	Tuberculosis
A20.0 - A28.9	Certain zoonotic bacterial diseases
A30.0 - A49.9	Other bacterial diseases
A50.01 - A64	Infections with a predominantly sexual mode of transmission
A65 - A69.9	Other spirochetal diseases
A70 - A74.9	Other diseases caused by chlamydiae
A75.0 - A79.9	Rickettsioses
A80.0 - A89	Viral and prion infections of the central nervous system
A90 - A99	Arthropod-borne viral fevers and viral hemorrhagic fevers
B00.0 - B09	Viral infections characterized by skin and mucous membrane lesions
B10.0 - B10.89	Other human herpesviruses
B15.0 - B19.9	Viral hepatitis
B20	Human immunodeficiency virus [HIV] disease
B25.0 - B34.9	Other viral diseases
B35.0 - B49	Mycoses
B50.0 - B64	Protozoal diseases

B65.0 - B83.9	Helminthiases
B85.0 - B89	Pediculosis, acariasis and other infestations
B90.0 - B94.9	Sequelae of infectious and parasitic diseases
B95.0 - B95.8	Streptococcus, Staphylococcus, and Enterococcus as the cause of diseases classified elsewhere
B96.1	Klebsiella pneumoniae [K. pneumoniae] as the cause of diseases classified elsewhere
B96.20 - B96.29	Escherichia coli [E. coli] as the cause of diseases classified elsewhere
B96.3	Hemophilus influenzae [H. influenzae] as the cause of diseases classified elsewhere
B96.4	Proteus (mirabilis) (morganii) as the cause of diseases classified elsewhere
B96.5	Pseudomonas (aeruginosa) (mallei) (pseudomallei) as the cause of diseases classified elsewhere
B96.6	Bacteroides fragilis [B. fragilis] as the cause of diseases classified elsewhere
B96.81 - B96.89	Other specified bacterial agents as the cause of diseases classified elsewhere
B97.0 - B97.89	Viral agents as the cause of diseases classified elsewhere
B99.8 - B99.9	Other infectious diseases
C00.0 - C96.Z	Malignant neoplasms
D00.00 - D09.9	In situ neoplasms
D32.0 - D32.9	Benign neoplasm of meninges
D42.0 - D42.9	Neoplasm of uncertain behavior of meninges
D57.00 - D57.819	Sickle-cell disorders
F01.50 - F01.C4	Vascular dementia
F07.81	Postconcussional syndrome
F32.0 - F32.A	Depressive episode

F33.0 - F33.9	Major depressive disorder, recurrent
F84.0	Autistic disorder
G30.0 - G30.9	Alzheimer's disease
G35	Multiple sclerosis
G43.001 - G43.E19	Migraine
G44.001 - G44.009	Cluster headaches and other trigeminal autonomic cephalgias (TAC)
G44.011 - G44.019	Episodic cluster headache
G44.021 - G44.029	Chronic cluster headache
G51.0	Bell's palsy
G62.82	Radiation-induced polyneuropathy
G80.0 - G80.9	Cerebral Palsy
G93.1	Anoxic brain damage, not elsewhere classified
G93.32	Myalgic encephalomyelitis/chronic fatigue syndrome
G93.6	Cerebral edema
G98.0	Neurogenic arthritis, not elsewhere classified
H31.021 - H31.029	Solar retinopathy
H60.20 - H60.23	Malignant Otitis Externa
H93.11 - H93.19	Tinnitus
I05.0 - I09.9	Chronic rheumatic heart diseases
I20.0 - I25.9	Ischemic heart diseases
I27.0 - I27.9	Other pulmonary heart diseases

I30.0 - I5A	Other forms of heart disease
I63.0 - I63.9	Cerebral infarction
I65.01 - I65.9	Occlusion and stenosis of precerebral arteries, not resulting in cerebral infarction
I66.01 - I66.9	Occlusion and stenosis of cerebral arteries, not resulting in cerebral infarction
I67.1 - I67.9	Other cerebrovascular diseases
I87.2	Venous insufficiency (chronic) (peripheral)
I87.311 - I87.319	Chronic venous hypertension (idiopathic) with ulcer
I87.331 - I87.339	Chronic venous hypertension (idiopathic) with ulcer and inflammation
J43.0 - J43.9	Emphysema
J44.0 - J44.89	Other chronic obstructive pulmonary disease [bronchitis with emphysema]
J68.0 - J68.9	Respiratory conditions due to inhalation of chemicals, gasses, fumes and vapors
J70.0 - J70.9	Respiratory conditions due to other external agents
K50.00 - K50.919	Crohn's disease [regional enteritis]
K52.0	Gastroenteritis and colitis due to radiation
K52.89	Other specified noninfective gastroenteritis and colitis
K71.10	Toxic liver disease with hepatic necrosis, without coma
K71.11	Toxic liver disease with hepatic necrosis, with coma
K72.00	Acute and subacute hepatic failure without coma
K72.01	Acute and subacute hepatic failure with coma
K76.2	Central hemorrhagic necrosis of liver
L40.52	Psoriatic arthritis mutilans
L55.0 - L59.9	Radiation - related disorders of the skin and subcutaneous tissue

L89.000 - L89.96	Pressure ulcer
M00.00 - M25.9	Arthropathies
M48.40xA - M48.48xS	Fatigue fracture of vertebra
M79.7	Fibromyalgia
M80.00xA - M80.0B9S	Osteoporosis with current pathological fracture
M80.80xA - M80.8B9S	Other osteoporosis with current pathological fracture
M81.0 - M81.8	Osteoporosis without current pathological fracture
M84.30XA - M84.38XS	Stress fracture
M87.180	Osteonecrosis due to drugs, jaw
M96.621- M96.69	Fracture of bone following insertion of orthopedic implant, joint prosthesis, or bone plate
M97.01XA - M97.9XXS	Periprosthetic fracture around internal prosthetic joint
N30.41	Irradiation cystitis with hematuria
P13.0	Fracture of skull due to birth injury
P13.4	Fracture of clavicle due to birth injury
R41.81	Age-related cognitive decline [senility]
R57.0	Cardiogenic shock
S06.0x0A - S06.9x9S	Intracranial injury
S12.000A - S12.9XXS	Fracture of cervical vertebra and other parts of neck
S22.000A - S22.9XXS	Fracture of rib(s), sternum and thoracic spine

S32.000A - S32.9XXS	Fracture of lumbar spine and pelvis
S42.001A - S42.92XS	Fracture of shoulder and upper arm
S52.001A - S52.92XS	Fracture of forearm
S62.001A - S62.92XS	Fracture at wrist and hand level
S72.001A - S72.92XS	Fracture of femur
S82.001A - S82.92xS	Fracture of lower leg, including ankle
S92.001A - S92.919S	Fracture of foot and toe, except ankle
T81.31XA - T81.31XS	Disruption of external operation (surgical) wound, not elsewhere classified
T81.32XA - T81.32XS	Disruption of internal operation (surgical) wound, not elsewhere classified
U07.1	COVID-19
U09.9	Post COVID-19 condition, unspecified
Z86.16	Personal history of COVID-19

CPT/HCPCS codes considered experimental or investigational:	
Code	*Description*
A4575	Topical hyperbaric oxygen chamber, disposable
E0446	Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories

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