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# Clinical UM Guideline

**Subject:** Hyperbaric Oxygen Therapy (Systemic/Topical)
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## Description

This document addresses the use of hyperbaric oxygen therapy (HBOT), which can be applied systemically, topically, or to one or more limbs alone. HBOT involves the use of pressurized room air, 100% oxygen, or room air enriched with a specific concentration of oxygen. The premise of HBOT is that the increased pressure results in increased oxygen levels in systemic circulation and the body's tissues with the goal of improving healing of wounds, injuries or to support oxygen transport in acutely anemic or hypoxic individuals.

## Clinical Indications

**Medically Necessary:**

Systemic hyperbaric oxygen pressurization is considered **medically necessary** in the treatment of any of the following conditions when performed in accordance with Undersea and Hyperbaric Medical Society (UHMS) guidelines:

A. Acute peripheral arterial insufficiency; **or**
B. Acute thermal burns: deep second degree or third degree in nature;**or**
C. Acute traumatic ischemia; **or**
D. Carbon monoxide poisoning; **or**
E. Central retinal artery occlusion (CRAO); **or**
F. Chronic non-healing wounds in the following situations:
    1. Diabetic lower extremity wounds, when the following criteria are met:
        a. As a component of diabetic ulcer management (for example, careful attention to infection control, aggressive surgical debridement, evaluation and correction of vascular insufficiency, extremity offloading, improving glycemic control, and when applicable, encouraging smoking cessation); **and**
        b. Wagner grade III or higher wound severity;**and**
        c. Wound has not responded to 30 days of appropriate conservative treatment;**and**
        d. For continued hyperbaric oxygen therapy, wound shows measurable signs of healing, defined as at least 20% reduction in wound surface area, when evaluated at 30 day intervals; **or**
    2. Arterial insufficiency ulcers in the following situations:
        a. At least one of the following:
            i. Persistent hypoxia despite attempts at increasing blood flow;**or**
            ii. When wound failure continues despite maximum revascularization;**and**
        b. For continued hyperbaric oxygen therapy, wound shows measurable signs of healing, defined as at least 20% reduction in wound surface area, when evaluated at 30 day intervals; **or**
    3. Pressure ulcers in the following situations:
        a. At least one of the following:
            i. Postoperative support of skin graft or flaps showing evidence of ischemic failure;**or**
            ii. In the field of previous irradiated area for pelvic or perineal malignancies;**or**
            iii. When progressive necrotizing soft tissue infection or refractory osteomyelitis is present;**and**
        b. For continued hyperbaric oxygen therapy, wound shows measurable signs of healing, defined as at least 20% reduction in wound surface area, when evaluated at 30 day intervals; **or**
    4. Venous stasis ulcers in the following situations:
        a. When supporting skin grafting or flap reconstruction in individuals with concomitant peripheral arterial occlusive disease; **and**
        b. hypoxia not corrected by control of disease; **and**
        c. For continued hyperbaric oxygen therapy, wound shows measurable signs of healing, defined as at least 20% reduction in wound surface area, when evaluated at 30 day intervals; **or**
G. Chronic refractory osteomyelitis; **or**
H. Compartment syndrome; **or**
I. Compromised skin graft or flaps (enhancement of healing in selected wounds);**or**
J. Crush injuries; **or**
K. Cyanide poisoning; **or**
L. Decompression sickness; **or**
M. Delayed radiation injury, including osteoradionecrosis, soft tissue radiation necrosis, and radiation cystitis;**or**
N. Gas or air embolism; **or**
O. Gas gangrene (for example, clostridial myositis and myonecrosis);**or**
P. Idiopathic Sudden Sensorineural Hearing Loss (ISSHL) in individuals with a magnitude of hearing loss of at least 70 decibels, after inadequate response to glucocorticoid treatment; **or**
Q. Intracranial abscess; **or**
R. Necrotizing soft-tissue infections; **or**
S. Prophylactic pre and post treatment for individuals undergoing dental surgery of a radiated jaw;**or**
T. Severe anemia with exceptional blood loss, when transfusion is impossible or delayed.

**Not Medically Necessary:**

Topical hyperbaric oxygen is considered **not medically necessary** in all cases.

Limb specific hyperbaric oxygen pressurization is considered **not medically necessary** in all cases.

Systemic hyperbaric oxygen pressurization is considered **not medically necessary** for all other conditions not previously listed, including but not limited to the following:

A. Osteonecrosis of the jaw when the cause is not radiation necrosis (osteoradionecrosis);
B. Preoperative treatment for jaw osteomyelitis;
C. Stroke
D. Tinnitus;
E. Traumatic brain injury;
F. Venous stasis ulcers, pressure ulcers and non-pressure ulcers except in the subset of individuals noted above.

## Coding

*The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.*

*Systemic HBOT:*
**When services are Medically Necessary:**

**CPT**

| | |
|---|---|
| 99183 | Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session |

**HCPCS**

| | |
|---|---|
| G0277 | Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval |

**ICD-10 Procedure**

| | |
|---|---|
| 5A05121 | Extracorporeal hyperbaric oxygenation, intermittent |
| 5A05221 | Extracorporeal hyperbaric oxygenation, continuous |

**ICD-10 Diagnosis**

| | |
|---|---|
| A42.0-A42.9 | Actinomycosis |
| A48.0 | Gas gangrene |
| B36.0-B36.9 | Other superficial mycoses |
| B37.0-B37.9 | Candidiasis |
| B46.0-B46.9 | Zygomycosis |
| B48.0-B48.8 | Other mycoses, not elsewhere classified |
| B49 | Unspecified mycosis |
| D62 | Acute posthemorrhagic anemia |
| G06.0 | Intracranial abscess and granuloma |
| H34.10-H34.13 | Central retinal artery occlusion |
| H70.201-H70.229 | Petrositis |
| I74.2-I74.9 | Embolism and thrombosis of arteries (upper/lower extremities, iliac artery) |
| I96 | Gangrene, not elsewhere classified |
| I99.9 | Unspecified disorder of circulatory system |
| K62.7 | Radiation proctitis |
| L08.0-L08.9 | Other local infections of skin and subcutaneous tissue |
| L59.8-L59.9 | Other disorders of the skin and subcutaneous tissue related to radiation |
| L88 | Pyoderma gangrenosum |
| M27.2 | Inflammatory conditions of jaws |
| M72.6 | Necrotizing fasciitis |
| M79.9 | Soft tissue disorder, unspecified |
| M79.A11-M79.A9 | Nontraumatic compartment syndrome |
| M86.30-M86.69 | Chronic osteomyelitis |
| M86.8X0-M86.8X9 | Other osteomyelitis |
| M86.9 | Osteomyelitis, unspecified |
| N30.40-N30.41 | Irradiation cystitis |
| S07.0XXA-S07.9XXS | Crushing injury of head |
| S17.0XXA-S17.9XXS | Crushing injury of neck |
| S28.0XXA-S28.0XXS | Crushed chest |
| S38.001A-S38.1XXS | Crushing injury of abdomen, lower back, pelvis and external genitals |
| S45.001A-S45.099S | Injury of axillary artery |
| S45.801A-S45.999S | Unspecified injury of other blood vessels at shoulder and upper arm level |
| S47.1XXA-S47.9XXS | Crushing injury of shoulder and upper arm |
| T20.20XA-T20.29XS | Burn of second degree of head, face, and neck |
| T20.30XA-T20.39XS | Burn of third degree of head, face, and neck |
| T21.20XA-T21.29XS | Burn of second degree of trunk |
| T21.30XA-T21.39XS | Burn of third degree of trunk |
| T22.20XA-T22.299S | Burn of second degree of shoulder and upper limb, except wrist and hand |
| T22.30XA-T22.399S | Burn of third degree of shoulder and upper limb, expect wrist and hand |
| T23.201A-T23.299S | Burn of second degree of wrist and hand |
| T23.301A-T23.399S | Burn of third degree of wrist and hand |
| T24.201A-T24.299S | Burn of second degree of lower limb, except ankle and foot |
| T24.301A-T24.399S | Burn of third degree of lower limb, except ankle and foot |
| T25.211A-T25.299S | Burn of second degree of ankle and foot |
| T25.311A-T25.399S | Burn of third degree of ankle and foot |
| T31.0-T31.99 | Burns classified according to extent of body surface involved |
| T57.3X1A-T57.3X4S | Toxic effect of hydrogen cyanide |
| T58.01XA-T58.94XS | Toxic effect of carbon monoxide |
| T65.0X1A-T65.0X4S | Toxic effect of cyanides |
| T66.XXXA-T66.XXXS | Radiation sickness, unspecified |
| T70.3XXA-T70.3XXS | Caisson disease [decompression sickness] |
| T79.0XXA-T79.0XXS | Air embolism (traumatic) |

| | |
|---|---|
| T79.A0XA-T79.A0XS | Compartment syndrome, unspecified |
| T79.A11A-T79.A9XS | Traumatic compartment syndrome |
| T86.820-T86.829 | Complications of skin graft (allograft)(autograft) |

**When services may be Medically Necessary when criteria are met:**
For the procedure codes listed above for the following diagnoses

| **ICD-10 Diagnosis** | |
|---|---|
| E08.00-E11.9 | Diabetes mellitus |
| E13.00-E13.9 | Other specified diabetes mellitus |
| H90.3-H90.A32 | Sensorineural hearing loss |
| I73.89 | Other specified peripheral vascular diseases |
| I73.9 | Peripheral vascular disease, unspecified |
| L89.000-L89.95 | Pressure ulcer |
| L97.101-L97.929 | Non-pressure chronic ulcer of lower limb, not elsewhere classified |
| L98.411-L98.499 | Non-pressure chronic ulcer of skin, not elsewhere classified |
| S01.00XS-S01.95XS | Open wound of head [range with 7th character S] |
| S11.011S-S11.95XS | Open wound of neck [range with 7th character S] |
| S21.001S-S21.95XS | Open wound of thorax [range with 7th character S] |
| S31.000S-S31.839S | Open wound of abdomen, lower back, pelvis and external genitals [range with 7th character S] |
| S41.001S-S41.159S | Open wound of shoulder and upper arm [range with 7th character S] |
| S51.001S-S51.859S | Open wound of elbow and forearm [range with 7th character S] |

**When services are Not Medically Necessary:**
For the procedure codes listed above when criteria are not met or for all other diagnoses not listed, or when the code describes a procedure or situation designated in the Clinical Indications section as not medically necessary.

*Topical HBOT:*
**When services are Not Medically Necessary:**

| **HCPCS** | |
|---|---|
| A4575 | Topical hyperbaric oxygen chamber, disposable<br>Note: topical HBOT is considered not medically necessary |

| **ICD-10 Diagnosis** | |
|---|---|
| | All diagnoses |

## Discussion/General Information

Systemic Hyperbaric Oxygen Therapy

Systemic hyperbaric oxygen therapy (HBOT) involves the inhalation of pure oxygen gas while enclosed in a high-pressure chamber (defined as pressure greater than standard atmospheric pressure). The pressures used are usually between 1.4 to 3.0 atmospheres absolute (atm abs or ATA). The therapy works by supersaturating the blood tissues with oxygen via increased atmospheric pressure as well as increased oxygen concentrations. Studies have demonstrated that this therapy increases the available oxygen to the body by 10 to 20 times normal levels. Treatment may be carried out in either a monoplace chamber pressurized with pure oxygen or in a larger, multiplace chamber pressurized with compressed air, in which case the individual receives pure oxygen by mask, head tent, or endotracheal tube. The number and duration of treatment sessions and the atmospheric pressure during treatment varies depending on the specific condition being treated, the severity of the condition, and the procedures developed by individual hospitals and clinics. These individual procedures vary widely and have made the evaluation of the efficacy of hyperbaric oxygen therapy difficult.

The position regarding systemic hyperbaric oxygen is based on guidelines published by the Undersea and Hyperbaric Medical Society (UHMS) (2019). These guidelines provide recommendations for indications where hyperbaric oxygen therapy has been demonstrated to provide clinical benefits. For the majority of these indications, there are adequate data to provide guidance regarding treatment duration, frequency and depth of pressurization. One exception is idiopathic sudden sensorineural hearing loss, which is discussed separately below.

*Undersea and Hyperbaric Medical Society Guidelines:*

The UHMS Hyperbaric Oxygen Therapy Committee (14th edition, 2019) recommended indications, along with the recommended treatment dose and number of treatment sessions is as follows:

- **Air or gas embolism** – Recommend using U.S. Navy Table 6 or equivalent. Treat 1 session to clinical plateau. Usual treatment involves 1-2 sessions, but may require 5-10.
- **Acute peripheral arterial insufficiency** – Recommend 2 to 3 treatments in the first 24 hours and then twice daily treatments until the tissue at risk subsides.
- **Acute thermal burns** – Recommend 2 to 2.4 ATA twice daily for up to 30 sessions.
- **Acute traumatic ischemia** – Use 2 to 2.4 ATA twice a day for 2 to 7 days.
- **Carbon monoxide poisoning** – Use up to 3 ATA for 1 to 3 sessions or to clinical plateau.
- **Central Retinal Artery Occlusion (CRAO)** – Recommend 2 to 2.8 ATA or U.S. Navy Table 6 or equivalent. Treat twice daily to clinical plateau, which typically occurs in less than a week, plus 3 days.
- **Clostridial myositis, Clostridial myonecrosis (Gas gangrene)-** Use 2.4 to 3 ATA 3 times in the first 24 hours and then use twice daily for the next 2 to 5 days.
- **Chronic refractory osteomyelitis –** Patients with refractory stage 3 or 4 osteomyelitis are most likely to benefit from adjunctive hyperbaric oxygen therapy, especially when complicated by adverse local or systemic factors. Use 2 to 3 ATA for 20 to 40 sessions.
- **Compartment syndrome** – Use 2 to 2.4 ATA twice a day for 2 to 7 days.
- **Compromised skin grafts and flaps –** Use 2 to 2.5 ATA twice daily for up to 20 sessions.
- **Crush injury** – Use 2 to 2.4 ATA twice a day for 2 to 7 days.
- **Cyanide poisoning** – Patients with cyanide poisoning frequently present with simultaneous carbon monoxide poisoning. Please see **"Carbon Monoxide Poisoning"** above for treatment recommendations.

- **Decompression sickness** – Use U.S. Navy Treatment Table 6 or equivalent for 1 session up to a clinical plateau. Typically no more than 1 to 2 treatment sessions are needed.
- **Diabetic lower extremity wounds, selected individuals and healing of other problem wounds**– Use 2 to 2.5 ATA daily for 3 to 4 weeks. For HBOT to continue, reevaluation at 30-day intervals must show continued progress in healing.
- **Intracranial abscess (includes cerebral abscess, subdural empyema, and epidural empyema**) – Treatment should be administered at 2.0-2.5 ATA of oxygen 1 to 2 times a day for up to 3 weeks.
- **Necrotizing soft-tissue infections** – Use 2 to 2.5 ATA twice daily until stabilization occurs.
- **Radiation Necrosis** –
    1. **Mandibular osteoradionecrosis, laryngeal necrosis, other soft tissue head and neck, chest wall necrosis, radiation cystitis, radiation proctitis, miscellaneous abdominal pelvic injuries, cutaneous necrosis** – 2 to 2.4 ATA daily for 90 minutes.
    2. **Neoadjuvant hyperbaric oxygen therapy before dental extractions**– 2 to 2.4 ATA, typically 20 treatments before extraction and 10 treatments after.
- **Sudden sensorineural heating loss** – Recommend 2 to 2.4 ATA for 10 to 20 sessions.
- **Severe Anemia** – Use 2 to 3 ATA for 3 or 4 times a day until there is replacement of red blood cells by regeneration or transfusion.

In 2012, the American Academy of Neurology and the American Headache Society released guidelines regarding the use of complementary treatments for episodic migraine prevention in adults (Holland, 2012). These guidelines concluded that the data are conflicting or inadequate to support or refute hyperbaric oxygen for migraine prevention.

Several systematic reviews and meta-analyses on HBOT for diabetic-related lower limb ulcers have recently been published (Brouwer, 2019; Golledge, 2019; Lalieu, 2020; Sharma, 2021; Zhang, 2022). The 2021 systematic review by Sharma and colleagues included 12 randomized controlled trials (RCTs) and 2 controlled non-randomized trials comparing HBOT and standard treatment for treatment of diabetic foot ulcers. In a pooled analysis of 11 studies reporting complete ulcer healing, the number of completely healed ulcers was significantly higher after HBOT than after standard treatment (odds ratio [OR], 0.29; 95% confidence interval [CI], 0.14 to 0.61; p<0.001). Similarly, a pooled analysis of 7 trials found a significantly lower rate of major amputation in individuals treated with HBOT compared with standard therapy (relative risk [RR], 0.60; 95% CI, 0.39 to 0.92; p=0.02). There was not a statistically significant rate of minor amputation in the HBOT and standard therapy groups in a pooled analysis of 8 trials (RR, 0.82; 95% CI, 0.93 to 1.90; p=012).

As stated above, for continued treatment of wounds with HBOT, the UHMC recommends re-evaluation at 30-day intervals to show continued progress in healing. In an analysis of data from two trials with individuals who had diabetic foot ulcers or venous leg ulcers, Cardinal and colleagues (2008) found that wound surface area significantly predicted the rate of wound healing at 12 weeks. A 20% to 40% reduction of wound area in 2 and 4 weeks is often cited as a likely and reliable predictive indicator of healing (Flanagan, 2003).

A 2021 systematic review and meta-analysis on HBOT for necrotizing soft-tissue infections (Hedetoft, 2021) identified 31 comparative studies, 10 of which were judged to be at high risk of bias and were excluded from the quantitative analysis. There was a total of 48,744 participants in the 21 included studies, 1237 of which (2.5%) received HBOT. A pooled analysis of the 21 studies found a significantly lower odds of in-hospital mortality in individuals who received HBOT versus those who did not receive HBOT (OR, 0.44; 95% CI, 0.33 to 0.58).

*Tinnitus and Idiopathic Sudden Sensorineural Hearing Loss*

In October of 2011, the UHMS added ISSHL to their list of indications. The UHMS Hyperbaric Oxygen Indications 14th edition (2019) stated that ISSHL is “the abrupt onset of hearing loss, usually unilaterally and upon wakening, that involves a hearing loss of at least 30 decibels (dB) occurring within three days over at least three contiguous frequencies.” The document also stated, “there is a scarcity of literature regarding the use of HBO2 therapy as a primary treatment for ISSHL. HBO2 is usually an adjunctive therapy with medical therapies or as salvage therapy following failure of medical therapy.”

The rationale for the UHMS recommendation on ISSHL was based upon the findings of a 2012 Cochrane Review by Bennett and colleagues. The Cochrane review identified seven small RCTs, which were generally considered to be of low quality. Although the Cochrane review stated that, “for people with acute ISSHL, the application of HBOT significantly improved hearing”, as noted by the UHMS, the Cochrane review’s conclusions went on to state that the clinical significance of HBOT for treatment of ISSHL “remains unclear”. The 2019 UHMS guidelines also cited the Cvorovic (2013) RCT in the section on salvage therapy for ISSHL. The Cvorovic (2013) study involved 50 individuals who had failed primary therapy for SSHL. Participants were assigned to either HBOT (n=25) or intratympanic steroid treatment. There were significant differences between hearing thresholds at all frequencies before and after the HBOT. Similarly, there were significant differences between hearing thresholds at most frequencies (except 2 kHz) before and after the treatment in the intratympanic treatment group. There were no significant differences between HBOT and steroid treatment at 4 of the 5 frequencies. At 2 kHz, HBOT was found to be superior to steroid treatment.

The 2012 Cochrane review, discussed above, also addressed HBOT for treatment of tinnitus. Only two trials reported mean improvement in tinnitus or the proportion of individuals with tinnitus and findings were mixed. Data were not suitable for pooling. The review concluded that no beneficial effect of HBOT on tinnitus was found.

In 2019, the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) published an updated clinical practice guideline on sudden hearing loss. The following definition of sudden hearing loss was used:

- Sudden hearing loss is defined as a rapid onset, occurring over a 72-hour period, of a subjective sensation of hearing impairment in one or both ears.
- Sudden sensorineural hearing loss (SNHL) is a sub-set of SHL that (a) is sensorineural in nature and (b) meets certain audiometric criteria.
  (a) Sensorineural hearing loss indicates an abnormality of the cochlea, auditory nerve, or higher aspects of central auditory perception or processing.
  (b) The most frequently used audiometric criterion is a decrease in hearing of ≥30 decibels (dB), affecting at least 3 consecutive frequencies. Because premorbid audiometry is generally unavailable, hearing loss is defined as related to the opposite ear’s thresholds.
- Idiopathic sudden sensorineural hearing loss (ISSNHL) is defined as SSNHL with no identifiable cause despite adequate investigation

The guideline group supported hyperbaric oxygen therapy combined with steroid therapy for treatment of sudden sensorineural hearing loss. For initial treatment, they recommend initiating hyperbaric oxygen therapy within 2 weeks of the condition’s onset and, for salvage therapy, within 1 month of onset. The recommendation on hyperbaric oxygen therapy was rated “Grade B, systematic review of RCTs with methodological limitations” and was based primarily on the 2012 Cochrane review by Bennett and colleagues,

discussed above.

A 2018 systematic review and meta-analysis (Rhee 2018) addressed HBOT versus medical therapy alone for treatment of ISSHL. The authors identified 3 RCTs and 16 non-randomized comparative studies, published through February 2018, that compared HBOT plus medical therapy versus medical therapy alone. Medical therapies used in the studies included betamethasone, prednisone, and dexamethasone. Fourteen of the 16 non-randomized studies were retrospective. In a pooled analysis, the rate of complete hearing recovery was 264 of 897 cases (29.4%) in the HBOT plus medical therapy group and 241 of 1167 (20.7%) in the medical therapy alone group. A meta-analysis significantly favored the HBOT plus medical therapy group for this outcome (pooled OR, 1.61; 95% CI: 1.05 to 2.44). The outcome variable assessing any hearing recovery also significantly favored the HBOT plus medical therapy group (pooled OR, 1.43, 95% CI, 1.20 to 1.66). The authors conducted analyses separately for individuals with severe to profound hearing loss (≥ 70 decibels [dB]) and those with mild to moderate hearing loss (< 70 dB). A pooled analysis of the outcome 'any hearing recovery' significantly favored HBOT plus medical therapy in the individuals with severe to profound hearing loss (OR, 1.92; 95% CI, 1.25 to 2.94), but there was not a statistically significant difference between groups in individuals with mild to moderate hearing loss (OR, 1.08; 95% CI, 0.81 to 1.43).

A meta-analysis by Lei and colleagues (2021) focused on studies comparing HBOT and intratympanic steroids for treatment of sudden sensorineural hearing loss (SSNHL). The author noted the definition of SSNHL is, "abrupt hearing loss of more than 30 dB over three consecutive frequencies in less than 3 days." The meta-analysis included six studies, three RCTs and three retrospective cohort studies. In a pooled analysis, the authors did not find a statistically significant difference between HBOT versus intratympanic steroid treatment in the proportion of individuals with hearing improvement (RR, 1.09; 95% CI, 0.83 to 1.42; p=0.55).

Joshua and colleagues (2022) published a meta-analysis of three RCTs evaluating HBOT in adults at least 18 years old with SSNHL. The reviewers used the AAO-HNS definition of sudden hearing loss, discussed above. A pooled analysis of data from the three studies showed a significantly absolute hearing gain after HBOT versus a control condition (mean difference [MD], 10.3 dB; 95% CI, 6.5 to 14.1 dB). A pooled analysis of two studies found a significantly higher proportion of individuals experienced hearing recovery (defined as a hearing gain of at least 10 dB) after HBOT than control (OR, 4.3; 95% CI, 1.60 to 11.68).

Several RCTs have compared HBOT and medical therapy, with mixed results. Cho and colleagues (2018) randomized 60 individuals with severe to profound ISSHL to medical therapy alone (oral steroids plus intratympanic steroids) alone and medical therapy plus HBOT. Hearing improvement was assessed 3 months after treatment using the AAO-HNS criteria to determine treatment success. Using these criteria, no significant differences in hearing improvement were found between groups. In addition, there were no significant differences between groups in percent word discrimination score (WDS) gain at 1 month and 2 months, but WDS improvement was significantly higher in the study group at 3 months (p=0.035). Tong and colleagues (2020) randomly assigned 136 individuals with unilateral ISSHL to medical therapy alone (oral prednisone, vitamins and traditional Chinese drugs) or medical therapy plus HBOT. Treatment success was defined as complete recovery, marked improvement or slight improvement in hearing, an improvement of at least 15 dB. Using this definition, the success rate was 60.6% (40 of 66) in the group receiving HBOT and 42.9% (30 of 70) in the group receiving medical treatment only, p<0.05.

In summary, current evidence supports use of HBOT for ISSHL after inadequate response to glucocorticoid treatment, when the magnitude of hearing loss is of at least 70 decibels.

*Other conditions*

The use of HBOT has been proposed for a wide range of conditions in addition to those addressed by the UHMS. There are little clinical data to support HBOT for these other indications, which include cerebral edema and heat trauma. Several potential indications for which there are published RCTs are discussed below.

*Inflammatory Bowel Disease*

A 2021 systematic review of studies on HBOT for treating inflammatory bowel disease (IBD) by McCurdy and colleagues included a total of 19 studies. Of these, 3 were RCTs (Dulai 2018; Dulai 2020; Pagoldh, 2016) and the remaining 16 were case series. All 3 of the RCTs included individuals with ulcerative colitis. The RCTs had sample sizes between 10 and 20 individuals. The authors did not report a pooled analysis of RCT data.

The two studies by Dulai and colleagues both included individuals with ulcerative colitis who were hospitalized with acute flares. Dulai (2018) compared 3 days of HBOT to sham treatment and found a significantly higher rate of clinical remission, the primary outcome, at day 5 in the actively treated group (5 of 10 [50%] versus 0 of 8 [0%], p=0.08). Dulai (2020) treated all of the 20 enrolled individuals with 3 days of HBOT and the 11 individuals who responded at 3 days were randomized to an additional 2 days of HBOT or no further HBOT treatment. At day 10, compared with the 5 individuals treated for 3 days, the 6 individuals treated for 5 days had significantly lower mean partial Mayo scores (1.3 versus 4.2 points, p=0.011) and stool frequency scores (SFS) (0.7 versus 2.6 points, p=0.001), with no significant difference in rectal bleeding scores (RBS) (0.7 versus 1.6 points, p=0.188). Both studies had small sample sizes and short-term follow-up. The 2018 study was described as a pilot study and the study was terminated early due to the difficulty recruiting participants; the 2020 study was described as an exploratory study for a larger RCT.

In 2016, Glover and colleagues published an RCT on HBOT for individuals with chronic bowel dysfunction following pelvic radiotherapy; this study was not included in the McCurdy systematic review. The study randomized 55 individuals to HBOT and 29 to a sham control treatment. Active treatment included 40 90-minute sessions. The co-primary endpoints of the study were 12-month change in gastrointestinal symptoms using the inflammatory bowel disease questionnaire (IBDQ) and change in rectal bleeding score. There were not statistically significant differences between groups for either primary outcome. Median change from baseline to 12 months on the IBDQ scores was 3.5 in the HBOT group and 4 in the sham group, p=0.50. Median change in the rectal bleeding score was 3 in the HBOT group and 1 in the sham group, p=0.092.

*Spinal Cord Injury*

In 2021, Huang and colleagues published a systematic review and meta-analysis of RCTs evaluating HBOT for individuals with spinal cord injury. The review included 11 RCTs, 2 of which were published in English and 9 in Chinese. The primary outcomes were the American Spinal Injury Association (ASIA) motor and sensory scores. There was a high degree of heterogeneity among studies. Control groups included drug therapy, surgical treatment, rehabilitation therapy or a combination of the above. A pooled analysis of 10 trials found that motor function scores improved significantly more with HBOT versus a control intervention (MD, 15.84; 95% CI, 9.04 to 22.64). Similarly, a pooled analysis of 6 trials found that sensory scores improved significantly more with HBOT compared with control (MD, 66.30; 95% CI, 53.44 to 79.16). Limitations of the analysis include the small number of participants in individual trials (ranging from n=40 to n=164) and heterogeneity among studies, such as different control interventions and variability in the HBOT protocols.

*Traumatic Brain Injury*

There is also insufficient evidence on traumatic brain injury. A 2012 Cochrane review included seven RCTs evaluating HBOT as an

adjunctive treatment of traumatic brain injury. The review concluded that although HBOT may reduce the risk of death and result in statistically significant improvement in scores on the Glasgow Outcome Scale, there is a lack of evidence that the degree of improvement is clinically significant.

Several RCTs on HBOT for post-concussion symptoms due to traumatic brain injury were published after the Cochrane review. Miller and colleagues (2015) randomized 72 individuals to 40 HBOT sessions at 1.5 ATA, 40 sham treatments with room air at 1.2 ATA, or no supplemental treatments. While a significant difference was reported between both supplemental groups and the no-supplemental group (p=0.008), no differences were reported between the hyperbaric and the sham treatment groups. A 2020 crossover trial by Harch and colleagues included 63 individuals who received 40 HBOT sessions over 2 months or no treatment, in random order. Eight of 14 outcome variables improved significantly more in the treatment group than the control group. These included depression and post-traumatic anxiety symptoms.

Two 2022 systematic reviews (Alashram, 2022; Harch, 2022) each identified 6 RCTs on HBOT for treating traumatic brain injury; none of the RCTs was more recent than Hatch (2020), described above. Neither of the systematic reviews pooled study findings.

*Stroke*

There is also insufficient evidence on the use of HBOT for individuals undergoing treatment for stroke. A 2014 Cochrane review included 11 RCTs involving 705 participants (Bennett 2014). The authors reported significant variation in the methodological quality of the available trials. They were only able to pool data for case fatalities, and no significant differences were reported for case fatality rates at six months between HBOT vs. standard of care (risk ratio (RR), 0.97; p=0.96). A total of 4 of 14 scale measures of disability and functional performance were found to be improved after HBOT, including mean Trouillas Disability Scale score (mean difference, 2.2; p=0.04) and mean Orgogozo Scale score (mean difference, 27.9 points, p=0.02). The concluded;

> We found no good evidence to show that HBOT improves clinical outcomes when applied during acute presentation of ischaemic stroke. Although evidence from the 11 RCTs is insufficient to provide clear guidelines for practice, the possibility of clinical benefit has not been excluded. Further research is required to better define the role of HBOT in this condition

Two of the studies included in the Cochrane report include Efrati (2013) and Rusyniak (2003). The former included 59 subjects who were 6-36 months post-stroke. Subjects in the treatment group (n=30) were evaluated at baseline and after 40 HBOT sessions. The control/crossover group (n=29) were evaluated at baseline, after a 2-month control period of no treatment, and then again after subsequent 2-months of 40 HBOT sessions. The treatment protocol included two months of 40 sessions (5 days/ week), 90 minutes each, 100% oxygen at 2 ATA. The authors reported statistically significant improvements in NIHSS scores in the treatment group (p=0.004) and in the crossover group (p<0.0001) post HBOT vs. baseline. Significant improvements in ADLs were also reported in the Treatment and crossover groups post HBOT (p<0.001 and p<0.0001, respectively) vs. baseline. The latter study involved 33 subjects who did not receive thrombolytics over a 24 month period and then underwent HBOT for 60 minutes with 100% O2 to 2.5 ATA or sham treatment at 1.14 ATA. The authors reported no differences between the groups at 24 hours (p=0.44). However, at 3 months a larger percentage of the control subjects had a good outcome defined by their stroke scores vs. the HBOT group (NIHSS, 80% vs. 31.3%; p=0.04; Barthel Index, 81.8% vs. 50%; p=0.12; modified Rankin Scale, 81.8% vs. 31.3%; p=0.02; Glasgow Outcome Scale, 90.9% vs. 37.5%; p=0.01). All statistical significance was lost in the intent-to-treat analysis.

Overall, the quality of the available data addressing HBOT for stoke is poor and provides inconsistent results. Well-designed long-term studies are needed to better understand the benefits of this treatment method for this population.

Topical and Limb Specific Hyperbaric Oxygen Therapy

Topical HBOT involves the delivery of pure oxygen directly to an open, moist wound at a pressure slightly higher than atmospheric pressure. Limb-specific HBOT involves the use of a plastic container into which the limb to be treated is inserted and then sealed with pliable gaskets. The limb is then subjected to increased pressure and oxygen concentrations. The rest of the body is not exposed to this treatment. Topical and systemic HBOT are distinct technologies and are applied by different methods. As such, the outcomes associated with systemic HBOT cannot be extrapolated to topical therapy. Topical HBOT has been primarily evaluated as a treatment of chronic wounds, but other conditions have also been proposed as possible indications. There is currently insufficient published data from controlled trials to permit conclusions regarding topical HBOT. Additionally, evidence in the form of data from in vitro studies of limb specific HBOT have failed to demonstrate that this treatment method increases tissue oxygen tension beyond the superficial dermis, a key factor in the efficacy of HBOT.

## Definitions

Anemia: A reduction in the number of circulating red blood cells or in the total hemoglobin content of the cells.

Atmospheres absolute (ATA): The combination (or the sum) of the atmospheric pressure and the hydrostatic pressure is called atmospheres absolute (ATA). In other words, the ATA or atmospheres absolute is the total weight of the water and air above us.

Carbon monoxide poisoning: Toxicity that results from inhalation of small amounts of carbon monoxide (a poisonous gas) over a long period of time or from large amounts inhaled for a short time, which leads to decreased oxygen delivery to the body and cerebral toxicity.

Chronic: Of a long duration; a disease that persists or progresses over time.

Cierny-Mader system for osteomyelitis:

Anatomic type:

- Stage 1: medullary osteomyelitis
- Stage 2: superficial osteomyelitis
- Stage 3: localized osteomyelitis
- Stage 4: diffuse osteomyelitis

Physiologic class:

- A host: healthy
- B host:
  - Bs: systemic compromise
  - Bl: local compromise
  - Bls: local and systemic compromise
- C host: treatment worse than the disease

Compartmental syndrome: Any condition in which a structure, such as a nerve or tendon, is being constricted in a space and is no

longer able to move freely in the compartment.

Decompression sickness: A condition that develops in divers subjected to rapid reduction of air pressure after coming to the surface following exposure to compressed air.

Gangrene: The death of tissue or bone, usually resulting from a deficient or absent blood supply.

Gas embolism: Obstruction of a blood vessel by a gas bubble.

Idiopathic Sudden Sensorineural Hearing Loss: hearing loss (with no identifiable cause despite adequate investigation) occurring over a 72-hour period that is sensorineural in nature, affecting at least 3 consecutive frequencies.

Ischemia: A local and temporary deficiency of blood supply due to an obstruction of the circulation.

Limb specific hyperbaric oxygen: A therapy that involves sealing an individual's leg or arm into an airtight container and exposing that limb to pure oxygen greater than one atmosphere of pressure.

Mycosis: Any condition caused by a fungus.

Necrosis: A condition where cells or tissues are dead or dying.

Osteomyelitis: Inflammation of the bone due to infection.

Osteoradionecrosis: Death of bone following irradiation.

Prophylactic: Any agent or treatment that contributes to the prevention of infection or disease.

Pyoderma gangrenosum: A condition of the skin leading to open ulcers.

Systemic hyperbaric oxygen: A therapy that involves sealing an individual inside a room or container, then exposing the individual to pure oxygen at greater than one atmosphere of pressure.

Thermal: Related to heat.

Tinnitus: A condition where an individual has the perception of sound in their head when no outside sound is present. It is typically referred to as "ringing in the ears" or "head noise," but other forms of sound have been described such as hissing, roaring, pulsing, whooshing, chirping, whistling and clicking.

Topical hyperbaric oxygen: A therapy that involves sealing skin wounds under a plastic cover and then exposing the wound to pure oxygen at greater than one atmosphere of pressure; an alternate form of this therapy involves the application of a mist of water droplets to the wound that are saturated with dissolved oxygen.

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## Index



**The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.**

## History

| Status | Date | Action |
|---|---|---|
| Revised | 05/11/2023 | Medical Policy & Technology Assessment Committee (MPTAC) review. Added continuation criteria to each section on chronic non-healing wounds in MN statement and revised hierarchy in these sections. Removed first NMN statement. Updated Discussion/General Information and References sections. |
| Reviewed | 02/16/2023 | MPTAC review. Updated Discussion/General Information and References sections. |
| Revised | 02/17/2022 | MPTAC review. Added bullet point on ISSHL with criteria to MN statement and deleted bullet point from NMN statement. Updated Discussion/General Information and References sections. Updated coding section with diagnosis code range H90.3-H90.A32. |
| Revised | 11/11/2021 | MPTAC review. In section of medically necessary statement on chronic non-healing wounds, added bullet point on criteria for continued treatment beyond 30 days. Updated Discussion/General Information and References sections. |
| Reviewed | 11/05/2020 | MPTAC review. Updated Discussion/General Information and References sections. Reformatted Coding section. |

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|---|---|---|
| | 05/19/2020 | In Discussion section, added note to the section on Undersea and Hyperbaric Medicine society guidelines that Idiopathic Sudden Sensorineural Hearing Loss (ISSHL) is considered 'not medically necessary'. |
| Reviewed | 11/07/2019 | MPTAC review. Updated Discussion/General Information and References sections. |
| Revised | 01/24/2019 | MPTAC review. Updated Clinical Indications with additional details on treatment of wounds and jaw conditions consistent with Undersea and Hyperbaric Medicine Society recommendations. Parentheses with refractory osteomyelitis removed from chronic refractory osteomyelitis in medically necessary statement.<br>Added to not medically necessary statement: Idiopathic Sudden Sensorineural Hearing Loss (ISSHL), osteonecrosis of the jaw when the cause is not radiation necrosis (osteoradionecrosis), preoperative treatment for jaw osteomyelitis, traumatic brain injury and venous stasis ulcers, pressure ulcers and non-pressure ulcers except in the subset of individuals noted in the medically necessary statement.<br>Discussion/General Information and References updated. |
| New | 07/26/2018 | MPTAC review. Initial document development. Moved content of MED.00005 Hyperbaric Oxygen Therapy (Systemic/Topical) to new clinical utilization management guideline document with the same title. |

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