Preauthorization is required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals: • With wounds, burns, or infections</td>
<td>Interventions of interest are: • Topical hyperbaric oxygen therapy</td>
<td>Comparators of interest are: • Dressings • Débridement • Medication</td>
<td>Relevant outcomes include: • Overall survival • Symptoms • Change in disease status • Functional outcomes</td>
</tr>
<tr>
<td>Individuals: • With chronic diabetic ulcers</td>
<td>Interventions of interest are: • Systemic hyperbaric oxygen therapy</td>
<td>Comparators of interest are: • Standard wound care • Advanced wound therapy</td>
<td>Relevant outcomes include: • Symptoms • Change in disease status</td>
</tr>
<tr>
<td>Individuals: • With carbon monoxide poisoning</td>
<td>Interventions of interest are: • Systemic hyperbaric oxygen therapy</td>
<td>Comparators of interest are: • Breathing oxygen at standard pressure</td>
<td>Relevant outcomes include: • Overall survival • Symptoms</td>
</tr>
<tr>
<td>Individuals: • With radionecrosis, osteoradionecrosis, and treatment of irradiated jaw</td>
<td>Interventions of interest are: • Systemic hyperbaric oxygen therapy</td>
<td>Comparators of interest are: • Débridement • Medication</td>
<td>Relevant outcomes include: • Symptoms • Change in disease status</td>
</tr>
<tr>
<td>Individuals: • With chronic refractory osteomyelitis</td>
<td>Interventions of interest are: • Systemic hyperbaric oxygen therapy</td>
<td>Comparators of interest are: • Medication • Surgical therapy</td>
<td>Relevant outcomes include: • Symptoms • Change in disease status</td>
</tr>
<tr>
<td>Individuals: • With acute thermal burns</td>
<td>Interventions of interest are: • Systemic hyperbaric oxygen therapy</td>
<td>Comparators of interest are: • Cooling therapy • Medication</td>
<td>Relevant outcomes include: • Overall survival • Symptoms • Change in disease status</td>
</tr>
<tr>
<td>Individuals: • With acute surgical and traumatic wounds</td>
<td>Interventions of interest are: • Systemic hyperbaric oxygen therapy</td>
<td>Comparators of interest are: • Dressings • Débridement • Medication</td>
<td>Relevant outcomes include: • Overall survival • Symptoms • Change in disease status</td>
</tr>
<tr>
<td>Individuals: • With bisphosphonate-related osteonecrosis of the jaw</td>
<td>Interventions of interest are: • Systemic hyperbaric oxygen therapy</td>
<td>Comparators of interest are: • Medication • Surgical therapy</td>
<td>Relevant outcomes include: • Symptoms • Change in disease status</td>
</tr>
<tr>
<td>Individuals: • With necrotizing soft</td>
<td>Interventions of interest are: • Systemic hyperbaric</td>
<td>Comparators of interest are: • Medication</td>
<td>Relevant outcomes include: • Overall survival</td>
</tr>
<tr>
<td>Populations</td>
<td>Interventions</td>
<td>Comparators</td>
<td>Outcomes</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>----------------------------------------</td>
<td>--------------------------------------------------</td>
<td>----------</td>
</tr>
</tbody>
</table>
| tissue infections                   | oxygen therapy                         | • Surgical therapy                               | • Symptoms  
  • Change in disease status       |
| **Individuals:**                    |                                        |                                                  |          |
| • With acute coronary syndrome      | Interventions of interest are:          | Comparators of interest are:                     | Relevant outcomes include:  
  • Systemic hyperbaric oxygen therapy  
  • Medication                     | • Overall survival  
  • Symptoms  
  • Change in disease status  
  • Functional outcomes |
|                                    | • Surgical therapy                     |                                                  |          |
| **Individuals:**                    |                                        |                                                  |          |
| • With acute ischemic stroke       | Interventions of interest are:          | Comparators of interest are:                     | Relevant outcomes include:  
  • Systemic hyperbaric oxygen therapy  
  • Tissue plasminogen activator  
  • Endovascular procedure         | • Overall survival  
  • Symptoms  
  • Change in disease status  
  • Functional outcomes |
|                                    | • Surgical therapy                     |                                                  |          |
| **Individuals:**                    |                                        |                                                  |          |
| • With motor dysfunction associated with stroke | Interventions of interest are:          | Comparators of interest are:                     | Relevant outcomes include:  
  • Systemic hyperbaric oxygen therapy  
  • Physical therapy                | • Symptoms  
  • Functional outcomes |
|                                    | • Surgical therapy                     |                                                  |          |
| **Individuals:**                    |                                        |                                                  |          |
| • With Bell palsy                   | Interventions of interest are:          | Comparators of interest are:                     | Relevant outcomes include:  
  • Systemic hyperbaric oxygen therapy  
  • Self-care (e.g., artificial tears, eyepatch)  
  • Medication                       | • Overall survival  
  • Symptoms  
  • Change in disease status  
  • Functional outcomes |
|                                    | • Surgical therapy                     |                                                  |          |
| **Individuals:**                    |                                        |                                                  |          |
| • With traumatic brain injury       | Interventions of interest are:          | Comparators of interest are:                     | Relevant outcomes include:  
  • Systemic hyperbaric oxygen therapy  
  • Medication  
  • Surgical therapy  
  • Rehabilitation                   | • Symptoms  
  • Functional outcomes |
|                                    | • Surgical therapy                     |                                                  |          |
| **Individuals:**                    |                                        |                                                  |          |
| • With inflammatory bowel disease   | Interventions of interest are:          | Comparators of interest are:                     | Relevant outcomes include:  
  • Systemic hyperbaric oxygen therapy  
  • Medication  
  • Surgical therapy               | • Symptoms  
  • Change in disease status  
  • Functional outcomes |
|                                    | • Surgical therapy                     |                                                  |          |
| **Individuals:**                    |                                        |                                                  |          |
| • With idiopathic sudden sensorineural hearing loss | Interventions of interest are:          | Comparators of interest are:                     | Relevant outcomes include:  
  • Systemic hyperbaric oxygen therapy  
  • Medication  
  • Surgical therapy               | • Symptoms  
  • Functional outcomes |
|                                    | • Surgical therapy                     |                                                  |          |
| **Individuals:**                    |                                        |                                                  |          |
| • With delayed-onset muscle soreness | Interventions of interest are:          | Comparators of interest are:                     | Relevant outcomes include:  
  • Systemic hyperbaric oxygen therapy  
  • Conservative care (e.g., massage)  
  • Medication                         | • Symptoms  
  • Functional outcomes |
|                                    | • Surgical therapy                     |                                                  |          |
| **Individuals:**                    |                                        |                                                  |          |
| • With autism spectrum disorder     | Interventions of interest are:          | Comparators of interest are:                     | Relevant outcomes include:  
  • Systemic hyperbaric oxygen therapy  
  • Behavioral therapy  
  • Medication                        | • Symptoms  
  • Functional outcomes |
|                                    | • Surgical therapy                     |                                                  |          |
| **Individuals:**                    |                                        |                                                  |          |
| • With cerebral palsy               | Interventions of interest are:          | Comparators of interest are:                     | Relevant outcomes include:  
  • Systemic hyperbaric oxygen therapy  
  • Physical therapy  
  • Medication                        | • Symptoms  
  • Functional outcomes |
|                                    | • Surgical therapy                     |                                                  |          |
| **Individuals:**                    |                                        |                                                  |          |
| • With vascular dementia            | Interventions of interest are:          | Comparators of interest are:                     | Relevant outcomes include:  
  • Systemic hyperbaric oxygen therapy  
  • Rehabilitation  
  • Medication                        | • Symptoms  
  • Functional outcomes |
|                                    | • Surgical therapy                     |                                                  |          |
| **Individuals:**                    |                                        |                                                  |          |
| • With radiotherapy adverse effects | Interventions of interest are:          | Comparators of interest are:                     | Relevant outcomes include:  
  • Systemic hyperbaric oxygen therapy  
  • Medication                        | • Symptoms  
  • Functional outcomes |
|                                    | • Surgical therapy                     |                                                  |          |
| **Individuals:**                    |                                        |                                                  |          |
| • With idiopathic femoral neck necrosis | Interventions of interest are:          | Comparators of interest are:                     | Relevant outcomes include:  
  • Systemic hyperbaric oxygen therapy  
  • Physical therapy  
  • Medication                        | • Symptoms  
  • Change in disease status         |
Hyperbaric oxygen therapy (HBOT) involves breathing 100% oxygen at pressures between 1.5 and 3.0 atmospheres (atm). It is generally applied systemically with the patient inside a hyperbaric chamber. HBOT can also be applied topically; that is, the body part to be treated is isolated (e.g., in an inflatable bag and exposed to pure oxygen). HBOT has been investigated for various conditions that have potential to respond to increased oxygen delivery to the tissues.

### Description

Hyperbaric oxygen therapy (HBOT) involves breathing 100% oxygen at pressures between 1.5 and 3.0 atmospheres (atm). It is generally applied systemically with the patient inside a hyperbaric chamber. HBOT can also be applied topically; that is, the body part to be treated is isolated (e.g., in an inflatable bag and exposed to pure oxygen). HBOT has been investigated for various conditions that have potential to respond to increased oxygen delivery to the tissues.

### Summary of Evidence

For individuals who have wounds, burns or infections who receive topical HBOT, the evidence includes case series and one randomized controlled trial (RCT). Relevant outcomes are overall survival, symptoms, change in disease status, and functional outcomes. The single small RCT (N=28) and uncontrolled studies do not provide sufficient data that topical HBOT is efficacious. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have chronic diabetic ulcers who receive systemic HBOT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms and change in disease status. Meta-analyses of RCTs found significantly higher diabetic ulcer healing rates with HBOT than with control conditions. One meta-analysis, but not the other, found that HBOT was associated with a significantly lower rate of major amputation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have carbon monoxide poisoning who receive systemic HBOT, the evidence includes RCTs and a systematic review. Relevant outcomes are overall survival and symptoms. A meta-analysis of available RCT data in a Cochrane review did not find that HBOT is associated with a significantly lower risk of neurologic deficits after carbon monoxide poisoning. The evidence is insufficient to determine the effects of the technology on health outcomes.
For individuals who have radionecrosis, osteoradionecrosis, or treatment of irradiated jaw who receive systemic HBOT, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms and change in disease status. A Cochrane review of RCTs found evidence that HBOT improved radionecrosis and osteoradionecrosis outcomes and resulted in better outcomes prior to tooth extraction in an irradiated jaw. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have chronic refractory osteomyelitis who receive systemic HBOT, the evidence includes case series. Relevant outcomes are symptoms and change in disease status. The case series tended to find high rates of successful outcomes in patients with chronic refractory osteomyelitis treated with HBOT. However, controlled studies are needed to determine conclusively the impact of HBOT on health outcomes compared with other interventions. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have acute thermal burns who receive systemic HBOT, the evidence includes RCTs and a systematic review. Relevant outcomes are overall survival, symptoms, and change in disease status. Only two RCTs were identified and both were judged to have poor methodologic quality. Evidence from well-conducted controlled trials is needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have acute surgical and traumatic wounds who receive systemic HBOT, the evidence includes RCTs, controlled nonrandomized studies, and systematic reviews. Relevant outcomes are overall survival, symptoms, change in disease status, and functional outcomes. Four RCTs were identified. There was considerable heterogeneity across trials (e.g., patient population, comparison group, outcomes). This heterogeneity prevented pooling of study findings and limits the ability to draw conclusions about the impact of HBOT on health outcomes for patients with acute surgical and traumatic wounds. Additional evidence from high-quality RCTs is needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have bisphosphonate-related osteonecrosis of the jaw who receive systemic HBOT, the evidence includes one RCT. Relevant outcomes are symptoms and change in disease status. The RCT was unblinded and did not find a significant benefit of HBOT for most health outcomes compared with standard care. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have necrotizing soft tissue infections who receive systemic HBOT, the evidence includes systematic reviews and a retrospective cohort study. Relevant outcomes are overall survival, symptoms, and change in disease status. A Cochrane review did not identify any RCTs. Another systematic review identified a retrospective cohort study, which did not find better outcomes after HBOT than after standard care without HBOT in patients with necrotizing soft tissue infections. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have acute coronary syndrome who receive systemic HBOT, the evidence includes RCTs and a systematic review. Relevant outcomes are overall survival, symptoms, change in disease status, and functional outcomes. A Cochrane review identified six RCTs. There were two pooled analyses, with mixed findings. The analyses found significantly lower rates of death with HBOT but not a significant improvement in left ventricular function. Additional RCT data are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have acute ischemic stroke who receive systemic HBOT, the evidence includes RCTs and a systematic review. Relevant outcomes are overall survival, symptoms, change in disease status, and functional outcomes. Cochrane reviewers could only pool data for one outcome (mortality at three to six months) and for that outcome there was no significant difference between active and sham HBOT treatments. The evidence is insufficient to determine the effects of the technology on health outcomes.
For individuals who have motor dysfunction associated with stroke who receive systemic HBOT, the evidence includes one RCT. Relevant outcomes are symptoms and functional outcomes. The RCT, which used a crossover design, found better outcomes with HBOT at two months than with delayed treatment. However, the trial had a number of methodologic limitations (e.g., lack of patient blinding, heterogeneous population, high dropout rate) that make it difficult to draw conclusions about the efficacy of HBOT. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have Bell palsy who receive systemic HBOT, the evidence includes a systematic review. Relevant outcomes are symptoms, change in disease status, and functional outcomes. A Cochrane review did not identify any RCTs meeting selection criteria; the single RCT found did not have a blinded outcome assessment. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have traumatic brain injury who receive systemic HBOT, the evidence includes RCTs and systematic reviews. Relevant outcomes are overall survival, symptoms, change in disease status, and functional outcomes. RCTs were heterogenous in terms of intervention protocols, patient populations, and outcomes reported. Systematic reviews conducted pooled analyses only on a minority of the published RCTs and these findings were mixed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have inflammatory bowel disease who receive systemic HBOT, the evidence includes RCTs, observational studies and a systematic review. Relevant outcomes are symptoms, change in disease status and functional outcomes. Only one small RCT has been published, and this study did not find a significant improvement in health outcomes when HBOT was added to standard medical therapy. A systematic review of RCTs and observational studies found a high rate of bias in the literature (e.g., attrition and reporting bias). The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have idiopathic sudden sensorineural hearing loss (ISSHL) who receive systemic HBOT, the evidence includes RCTs and a systematic review. Relevant outcomes are overall survival, symptoms, change in disease status, and functional outcomes. A Cochrane review of RCTs had mixed findings. Some outcomes (i.e., improvement in hearing of all frequencies, >25% return of hearing) were better with HBOT than with a control intervention, but more than 50% return of hearing did not differ significantly between groups. The RCTs had methodologic limitations. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have delayed-onset muscle soreness who receive systemic HBOT, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms and functional outcomes. A Cochrane review of RCTs found worse short-term pain outcomes with HBOT than with a control condition and no difference in longer term pain or other outcomes (e.g., swelling). The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have autism spectrum disorder who receive systemic HBOT, the evidence includes one RCT and a systematic review. Relevant outcomes are symptoms and functional outcomes. A Cochrane review identified one RCT on HBOT for autism spectrum disorder and this trial did not find significantly better outcomes with HBOT than with sham. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have cerebral palsy who receive systemic HBOT, the evidence includes two RCTs. Relevant outcomes are symptoms and functional outcomes. One RCT was stopped early due to futility and the other did not find significantly better outcomes with HBOT than with a sham intervention. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have vascular dementia who receive systemic HBOT, the evidence includes one RCT and a systematic review. Relevant outcomes are symptoms and functional outcomes. The Cochrane review identified
only one RCT with methodologic limitations. Well-conducted controlled trials are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have radiotherapy adverse effects who receive systemic HBOT, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms and functional outcomes. A systematic review concluded that more RCTs are needed. The two RCTs identified had mixed findings. One found no short-term benefit with HBOT, but some benefits 12 months after radiotherapy; the other RCT did not find a significant benefit of HBOT 12 months after radiotherapy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have idiopathic femoral neck necrosis who receive systemic HBOT, the evidence includes one RCT. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The RCT had a small sample and only reported short-term (i.e., six week) outcomes. Larger well-conducted RCTs reporting longer term outcomes are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have migraine who receive systemic HBOT, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The Cochrane review conducted only one pooled analysis, and that outcome was reported in the immediate posttreatment period. Meta-analysis of three RCTs found significantly greater relief of migraine symptoms with HBOT than a comparator intervention within 45 minutes of treatment. Longer term data are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have herpes zoster who receive systemic HBOT, the evidence includes one RCT. Relevant outcomes are symptoms and change in disease status. The RCT was unblinded and only reported short-term (i.e., six week) outcomes. Additional well-conducted RCTs with longer follow-up are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have fibromyalgia who receive systemic HBOT, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status and functional outcomes. There were only two RCTs and they had relatively small samples and methodologic limitations (e.g., quasi-randomization, no or uncertain sham control for a condition with subjective outcomes susceptible to a placebo effect). Moreover, the HBOT protocols varied. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have multiple sclerosis who receive systemic HBOT, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms and functional outcomes. A Cochrane review of RCTs did not find a significant difference in outcomes when patients with multiple sclerosis were treated with HBOT versus a comparator intervention. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have cancer and are undergoing chemotherapy who receive systemic HBOT, the evidence includes one RCT and a systematic review. Relevant outcomes are overall survival and change in disease status. The single RCT did not find a significant difference in survival for cancer patients who received HBOT prior to chemotherapy compared with usual care. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy

Topical hyperbaric oxygen therapy is considered investigational.

Systemic hyperbaric oxygen pressurization may be considered medically necessary in the treatment of the following conditions:
• non-healing diabetic wounds of the lower extremities in patients who meet the following three criteria:
  a) patient has type 1 or type 2 diabetes and has a lower extremity wound that is due to diabetes;
  b) patient has a wound classified as Wagner grade 3 or higher (see Policy Guidelines); and
  c) patient has no measurable signs of healing after 30 days of an adequate course of standard wound therapy;
• acute traumatic ischemia, e.g., crush injuries, reperfusion injury, compartment syndrome;
• decompression sickness;
• gas embolism, acute;
• cyanide poisoning, acute;
• acute carbon monoxide poisoning;
• soft-tissue radiation necrosis (e.g., radiation enteritis, cystitis, proctitis) and osteoradionecrosis;
• pre- and post-treatment for patients undergoing dental surgery (non-implant-related) of an irradiated jaw;
• gas gangrene (clostridial myonecrosis);
• profound anemia with exceptional blood loss: only when blood transfusion is impossible or must be delayed; and
• chronic refractory osteomyelitis.

Hyperbaric oxygen pressurization is considered **investigational** in all other situations, included but not limited to the treatment of the following conditions:
• compromised skin grafts or flaps;
• acute osteomyelitis;
• bisphosphonate-related osteonecrosis of the jaw;
• necrotizing soft tissue infections;
• acute thermal burns;
• acute surgical and traumatic wounds;
• chronic wounds, other than those in patients with diabetes who meet the criteria specified in the medically necessary statement;
• spinal cord injury;
• traumatic brain injury;
• inflammatory bowel disease (Crohn disease or ulcerative colitis);
• brown recluse spider bites;
• bone grafts;
• carbon tetrachloride poisoning, acute;
• cerebrovascular disease, acute (thrombotic or embolic) or chronic;
• fracture healing;
• hydrogen sulfide poisoning;
• intra-abdominal and intracranial abscesses;
• lepromatous leprosy;
• meningitis;
• pseudomembranous colitis (antimicrobial agent-induced colitis);
• radiation myelitis;
• sickle cell crisis and/or hematuria;
• demyelinating diseases, e.g., multiple sclerosis, amyotrophic lateral sclerosis;
• retinal artery insufficiency, acute;
• retinopathy, adjunct to scleral buckling procedures in patient with sickle cell peripheral retinopathy and retinal detachment;
• pyoderma gangrenosum;
• acute arterial peripheral insufficiency;
• acute coronary syndromes and as an adjunct to coronary interventions including, but not limited to, percutaneous coronary interventions and cardiopulmonary bypass;
• idiopathic sudden sensorineural hearing loss (ISSNHL);
• refractory mycoses: mucormycosis, actinomycosis, conidiobolus coronato;
• cerebral edema, acute;
• migraine;
• in vitro fertilization;
• cerebral palsy;
• tumor sensitization for cancer treatments including, but not limited to, radiotherapy or chemotherapy;
• delayed onset muscle soreness;
• idiopathic femoral neck necrosis;
• chronic arm lymphedema following radiotherapy for cancer;
• radiation-induced injury in the head and neck, except as noted earlier in the medically necessary statement;
• early treatment (beginning at completion of radiation therapy) to reduce side effects of radiotherapy;
• autism spectrum disorders;
• Bell palsy;
• acute ischemic stroke;
• motor dysfunction associated with stroke;
• herpes zoster;
• vascular dementia;
• fibromyalgia; and
• mental illness (i.e., posttraumatic stress disorder, generalized anxiety disorder or depression).

Policy Guidelines

Topical Hyperbaric Oxygen

Conventional oxygen tanks, typically gas, are used to supply the oxygen. An example of such a device is the AOTI Hyper-Box™.

This protocol addresses topical HBOT but not topical oxygen wound care.

Topical HBO may be performed in the office, clinic, or may be self-administered by the patient in the home. Typically, the therapy is offered for 90 minutes per day for four consecutive days. After a three-day break, the cycle is repeated. The regimen may last for eight to 10 weeks.

Systemic Hyperbaric Oxygen

The Wagner classification system of wounds is defined as follows: grade 0, no open lesion; grade 1, superficial ulcer without penetration to deeper layers; grade 2, ulcer penetrates to tendon, bone, or joint; grade 3, lesion has penetrated deeper than grade 2 and there is abscess, osteomyelitis, pyarthrosis, plantar space abscess, or infection of the tendon and tendon sheaths; grade 4, wet or dry gangrene in the toes or forefoot; grade 5, gangrene involves the whole foot or such a percentage that no local procedures are possible and amputation (at least at the below the knee level) is indicated.

Following are suggestions from the Undersea and Hyperbaric Medical Society’s (UHMS) 2008 Hyperbaric Oxygen Therapy Committee report on utilization of hyperbaric oxygen therapy HBOT (12th edition):

• Enhancement of healing in problem wounds: Treatments are performed for 90 to 120 minutes. The initial treatment schedule depends on the severity of disease. More serious conditions may require twice daily treatments; when stabilized, this can decrease to once daily. Utilization review is required after the initial 30 days of treatment and at least once every additional 30 days.

• Crush injury, compartment syndrome and other acute traumatic ischemias:
  o Reperfusion injury: One treatment
  o Crush injury: Eight treatments (three times per day for two days, then twice a day for two days and daily for two days)
  o Compartment syndrome: Three treatments (twice a day for one day and one treatment on day two).

• Decompression sickness: The majority of cases respond to a single treatment. Patients with residual defects after the initial session should receive additional treatments until they achieve clinical stability (generally no more than five to 10 treatments). Utilization review is recommended after 10 treatments.

• Gas embolism, acute: It is recommended that treatments continue until there is no additional improvement; this typically occurs after one to two treatments but occasionally up to five to 10. Utilization review is recommended after 10 treatments.

• Acute carbon monoxide poisoning and carbon monoxide poisoning complicated by cyanide poisoning: Some patients improve after a single treatment. Patients who fail to demonstrate a full recovery should receive additional treatments. In patients with persistent neurologic dysfunction after the initial treatment, further treatment can occur within six to eight hours and can be continued once or twice daily until there is no additional improvement in cognitive function. Utilization review is mandatory after the fifth treatment.

• Soft-tissue radiation necrosis (e.g., radiation enteritis, cystitis, and proctitis) and osteoradionecrosis: Most
treatment courses for radiation injury will be 30-60 treatments (once daily for 90 to 120 minutes). Utilization review is recommended after 60 treatments.

- Mandibular osteoradionecrosis: The initial course of treatment for patients with stage I osteoradionecrosis is 30 sessions, followed by only minor bony debridement. If response is adequate, an additional 10 treatments are given. If patients are not responding they are considered stage II and they receive more extensive surgical debridement, followed by 10 additional treatments. Patients who present as stage III patients receive 30 treatments followed by mandibular segmental resection and then an additional 10 treatments.

- Gas gangrene (i.e., clostridial myonecrosis): Recommended are three 90-minute treatments during the first 24 hours and then two treatments per day for the next two to five days, depending on the patient’s initial response. Utilization review is indicated after 10 treatments.

- Severe anemia: HBOT can be considered for severe anemia when patients cannot receive blood products due to medical, religious or strong personal preference reasons. Treatment can occur for periods of up to three or four hours three to four times a day if patients receive intra-treatment air breaks. HBO treatment should be continued with taper of both time and frequency until red blood cells have been satisfactorily replaced by patient regeneration or the patient can undergo transfusion.

- Chronic refractory osteomyelitis: No recommendations were made for the total number of treatments required. For patients who respond to initial treatment with antibiotics, surgical debridement and HBOT, therapy should be continued for approximately four to six weeks. Utilization review is indicated after 30-40 sessions.

Medicare Advantage

For Medicare Advantage, the above medically necessary policy statements and guidelines apply with these additional conditions:

- Progressive necrotizing infections (necrotizing fasciitis),
- Acute peripheral arterial insufficiency, when related to trauma, arterial embolism and thrombosis,
- Preparation and preservation of compromised skin grafts (not for primary management of wounds),
- Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment,
- Osteoradionecrosis of the jaw limited to cases with evidence of overt bony fracture or bony reabsorption,
- Suturing of severed limbs.

Background

HBOT is a technique of delivering higher pressures of oxygen to the tissues. Two methods of administration are available. In systemic or large hyperbaric oxygen chamber, the patient is entirely enclosed in a pressure chamber and breathes oxygen at a pressure greater than one atmosphere (atm; the pressure of oxygen at sea level). Thus, this technique relies on systemic circulation to deliver highly oxygenated blood to the target site, typically a wound. In addition, systemic HBOT can be used to treat systemic illness, such as air or gas embolism, carbon monoxide poisoning, or clostridial gas gangrene. Treatment may be carried out either in a monoplace chamber pressurized with pure oxygen or in a larger, multiplace chamber pressurized with compressed air, in which case the patient receives pure oxygen by mask, head tent, or endotracheal tube.
Topical hyperbaric therapy is a technique of delivering 100% oxygen directly to an open, moist wound at a pressure slightly higher than atmospheric pressure. It is hypothesized that the high concentrations of oxygen diffuse directly into the wound to increase the local cellular oxygen tension, which in turn promotes wound healing. Devices consist of an appliance to enclose the wound area (frequently an extremity) and a source of oxygen; conventional oxygen tanks may be used. The appliances may be disposable and may be used without supervision in the home by well-trained patients. Topical hyperbaric therapy has been investigated as a treatment of skin ulcerations resulting from diabetes, venous stasis, postsurgical infection, gangrenous lesion, decubitus ulcers, amputations, skin graft, burns, or frostbite.

Note that this protocol does not address topical oxygen therapy in the absence of pressurization.

**Regulatory Status**

In February 1999, the Numobag™ Kit (Numotech, Woodland Hills, CA) for application of topical oxygen hyperbaric therapy was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. FDA determined that this device was substantially equivalent to existing devices. Another example is the AOTI Hyper-Box™ (AOTI Ltd., Galway, Ireland), which was cleared by FDA in 2008.

In May 2005, the ATA Monoplace Hyperbaric System (ATA Hyperbaric Chamber Manufacturing) was cleared for marketing by FDA through the 510(k) process. FDA determined that this device was substantially equivalent to existing hyperbaric devices. Product Code: CBF.

In 2013, FDA published a statement warning that non-FDA approved uses of HBOT may endanger the health of patients.¹ If patients mistakenly believe that HBOT devices have been proven safe for uses not cleared by FDA, they may delay or forgo proven medical therapies.

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.