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*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is required.** 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.*

Description

Hyperbaric oxygen therapy (HBO) involves breathing 100% oxygen at a pressure of more than one atmosphere (atm). Hyperbaric oxygen therapy is generally applied systemically with the patient inside a hyperbaric chamber. It 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.

Background

Hyperbaric oxygen therapy (HBO) is a technique of delivering higher pressures of oxygen to the tissues. Two methods of administration are available. In systemic or large chamber hyperbaric oxygen, 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 hyperbaric oxygen therapy can be used to treat systemic illness, such as air or gas embolism, carbon monoxide poisoning, clostridial gas gangrene, etc. 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 oxygen 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. Topical hyperbaric oxygen 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 oxygen 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.

Regulatory Status

In February 1999, the Numobag™ Kit (Numotech, Inc.; Woodland Hills, CA) for application of topical hyperbaric therapy was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices.

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

Policy (Formerly Corporate Medical Guideline)

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 three or higher (see Policy Guidelines); and
 - c) patient has no measurable signs of healing after 30 days or 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;
- chronic refractory osteomyelitis;

Hyperbaric oxygen pressurization is considered **investigational** in 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;
- severe or refractory Crohn's disease;
- 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;
- early treatment (beginning at completion of radiation therapy) to reduce side effects of radiation therapy;
- autism spectrum disorders;
- Bell's palsy;
- acute ischemic stroke;
- motor dysfunction associated with stroke;
- herpes zoster; and
- vascular dementia.

Policy Guideline

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.

Below are suggestions from the Undersea and Hyperbaric Medical Society's (UHMS) 2008 Hyperbaric Oxygen Therapy Committee report on utilization of hyperbaric oxygen therapy (HBO) (1):

- 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 may be every additional 30 days after that.
- Crush injury, compartment syndrome and other acute traumatic ischemias:
 - Reperfusion injury: One treatment
 - Crush injury: Eight treatments (three times per day for two days, then twice a day for two days and daily for two days)
 - 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: HBO 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 HBO, therapy should be continued for approximately four-six weeks. Utilization review is indicated after 30-40 sessions.

Medicare Advantage

For Medicare Advantage, the above policy statements and guidelines apply except that these additional conditions may be considered **medically necessary**:

- Progressive necrotizing infections (necrotizing fasciitis),
- Acute peripheral arterial insufficiency,
- Preparation and preservation of compromised skin grafts (not for primary management of wounds),
- Actinomyces, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment.

Benefit Application

A physician, who is appropriately qualified for supervising HBO therapy, must be in attendance, meaning available by beeper and present within the facility.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

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

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