Subject: Hyperbaric Oxygen Therapy (HBO)

Background: HBO is used to treat a variety of conditions including carbon monoxide poisoning, tissue injuring due to radiation exposure, trauma, chronic wounds, surgery, or infection. During the therapy patients breathe and are exposed to pure oxygen at a pressure typically 2 to 3 times greater than the atmospheric pressure. It is intended to either accelerate or cause healing that would not ordinarily occur. Depending on the condition being treated, HBO can work through increasing systemic blood oxygen levels, increasing ambient pressure while reducing blood nitrogen levels (countering the primary cause and mechanism of decompression sickness), increasing the oxygen levels in wounded tissue, and/or exposing anaerobic bacteria to a pure oxygen environment.

Topical oxygen therapy is an actively researched miniaturization of HBO meant to be fit over affected limbs when systemic effects are considered unnecessary to treatment, such as in cases of chronic wounds and anaerobic bacterial infection. In some models, such as one that is a plastic bag designed to be fitted over an affected limb and inflated with pure oxygen to a high pressure, topical oxygen therapy is capable of being deployed in conventional inpatient settings. Trials establishing if and when topical oxygen therapy is effective are ongoing.

Prior authorization:

Prior authorization is required for all outpatient Hyperbaric Oxygen Therapy (HBO) provided to members enrolled in Harvard Pilgrim Health Care (HPHC) Commercial (HMO, POS, and PPO) products.

Policy and Coverage Criteria:

Initiation of therapy:

Harvard Pilgrim Health Care (HPHC) considers hyperbaric oxygen therapy (HBO) as reasonable and medically necessary when documentation confirms ANY of the following conditions:

- **Outpatient therapy:**
  - Preparation and preservation of hypoxia- or decreased-prefusion-compromised skin grafts and flaps, supported by photograph (with ruler for scale), identification flap/graft type, graft surgeon identification, surgical exploration results, and transcutaneous oxygen tension testing results indicating hypoxia (TcPO2 less than 40mmHg on room air), when conventional treatment failure is indicated by ANY of the following:
    - Etiology of compromise cannot be identified
    - Etiology of compromise cannot be corrected surgically
    - Compromise persists despite correction of all identified etiologies
  - Adjunctive treatment with conventional therapy for ANY of the following WHEN unresponsive to conventional therapy alone:
    - Osteo- or soft tissue radionecrosis when chronic and refractory to conventional medical and surgical management that includes debridement or resection of nonviable tissue along with antibiotic therapy
      - If treatment is for osteoradionecrosis of the jaw, there is evidence of bony resorption or overt fracture in a previously irradiated mandible
    - Chronic refractory osteomyelitis unresponsive to (or in a case contraindicating) at least surgical debridement and a six-week course of parenteral antibiotics
    - Progressive necrotizing infections (necrotizing fasciitis, Meleney’s ulcer), with conventional treatment having included inpatient antibiotics, surgical debridement, and, when indicated, skin grafts
Actinomycosis refractory to antibiotics and surgical treatment
- Sudden sensorineural hearing loss (SSNHL) according to standard definition (hearing decline of at least 30 decibels in at least three sequential frequencies in no more than three days) as an addition to corticosteroid treatment when initiation of HBO treatment is within fourteen days of onset
  - Adjunctive treatment of diabetic ulcerations/wounds of the lower extremities when BOTH of the following are confirmed:
    - Ulcers have a severity of at least Wagner grade III
    - Ulcers have not healed appreciably after thirty days of standard wound therapy, including ALL the following when appropriate
      - Assessment and correction of vascular condition in affected limb(s)
      - Nutritional adjustment
      - Glucose control improvement
      - Debridement
      - Maintenance of granulation tissue cleanliness and moisture with dressings
      - Appropriate off-loading
      - Treatment of any infection

**Documentation requirements for continuation of therapy:**

All conditions being treated with adjunctive HBO, including treatment of compromised grafts and diabetic ulcerations, must be evaluated and documented at least every fifteen sessions and at least every thirty days of treatment. Documentation should include photographs with clear indications of scale. Harvard Pilgrim Health Care (HPHC) considers adjunctive HBO as not medically necessary when following any thirty-day period in which measurable signs of healing have not been demonstrated.

**Exclusions:** Harvard Pilgrim Health Care (HPHC) considers topical oxygen therapy as experimental/investigational regardless of place of setting.

HPHC policies are based on medical science, and written to apply to the majority of people with a given condition. Individual members’ unique clinical circumstances, and capabilities of the local delivery system are considered when making individual UM determinations.

Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g. Benefit Handbook, Certificate of Coverage) for member-specific benefit information.
- Intra-abdominal abscess
- Inflammatory bowel disease (Crohn’s Disease, ulcerative colitis)
- Brown recluse spider bites

**Supporting Information:**

During HBO therapy, patients breathe pure oxygen gas at high pressure, usually 2 to 3 times greater than atmospheric pressure. The elevated concentration and pressure of the oxygen result in higher levels of oxygen absorption by blood plasma and by non-poisoned hemoglobin, elevating oxygen delivery to the tissues. Multi-place chambers allow closer monitoring of critically ill patients, while single occupancy chambers are most appropriate for the treatment of chronic medical conditions in stable patients. Chamber pressure is usually maintained between 2.5 and 3.0 atm, with treatment lasting 45 to 300 minutes depending upon the indication. Acute therapy may require only one or two treatments, while chronic medical conditions may warrant up to 30 or more sessions. Typically, hyperbaric therapy is administered with pressurized oxygen or air. Pressures exceeding 2.8 to 3.0 atm, particularly over prolonged exposure hyperbaric periods, dramatically increase the risk of both neurologic and pulmonary oxygen toxicity. Helium/oxygen (heliox) or nitrogen/oxygen (nitrox) mixtures are indicated only in certain instances of decompression illness. The only absolute contraindication to HBO therapy is untreated pneumothorax. Relative contraindications include obstructive lung disease, upper respiratory or sinus infections, recent ear surgery or injury, fever, and claustrophobia. Pregnancy was once believed to represent a contraindication to HBO, but now is considered an impetus to pursue HBO therapy among patients with CO intoxication. Patients with a history of a seizure disorder, pneumothorax, or chest surgery are at highest risk for complications related to barotrauma or central nervous system oxygen toxicity.

The safety and efficacy of HBO therapy has been validated in peer-reviewed literature for a number of selected conditions.

HBO is considered standard of care in the primary treatment of acute carbon monoxide poisoning, air or gas embolism, and decompression sickness. It has also been shown to be effective as an adjunctive therapy in the treatment of acute cyanide poisoning, gas gangrene, crush injuries and suturing of severed limbs, compromised skin grafts, progressive necrotizing infections, chronic refractory osteomyelitis, osteoradionecrosis and soft tissue radionecrosis, as well as treatment of chronic, non-healing, lower extremity diabetic wounds. HBO has historically been a standard therapy for many other conditions, most notably including thermal burns, but its effectiveness in such cases has been brought into question in recent decades by improvements in medical care, recent research, and, in many cases, severe deficiencies in the research base from when HBO was adopted as standard. Treatment of sudden sensorineural hearing loss (SSNHL) in addition to corticosteroid treatment is considered standard of care.

Appropriate indications have been reviewed and assessed by groups such as the Agency for Healthcare Research and Quality, Undersea and Hyperbaric Medical Society, American College of Hyperbaric Medicine, and the Alberta Heritage Foundation for Medical Research. Collective literature notes that HBO therapy should not be a replacement for other standard successful therapies.

The number of hyperbaric oxygen sessions required for treatment varies widely depending on indication, as HBO treats different conditions through different mechanisms. HBO primarily treats decompression sickness by mediating and mitigating the decompression process, as so is often delivered as one long session when treating decompression sickness. For oxygen deprivation conditions like carbon monoxide poisoning, the primary purpose of HBO is to increase systemic oxygen levels, such that a course of treatment consists of three sessions. The primary purpose of HBO for topical wounds is to support or prevent complications during the natural healing process, so that thirty or more sessions of HBO may be required.

Hyperbaric oxygen (HBO) chambers are regulated by the FDA as Class II medical devices, and 45 different chambers have met all requirements of the 510(k)-approval process. Devices that are not implantable and pose no risk of fatal outcome to the consumer should they malfunction are assigned Class II status and must meet FDA performance standards.
Guidelines:
The Wagner Diabetic Foot Ulcer Grade Classification System is as follows:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No open lesion</td>
</tr>
<tr>
<td>1</td>
<td>Superficial ulcer without penetration to deeper layers</td>
</tr>
<tr>
<td>2</td>
<td>Ulcer penetrates to tendon, bone, or joint</td>
</tr>
<tr>
<td>3</td>
<td>Lesion has penetrated deeper than grade 2 and there is abscess, osteomyelitis, pyarthrosis, plantar space abscess, or infection of the tendon and tendon sheaths</td>
</tr>
<tr>
<td>4</td>
<td>Wet or dry gangrene in the toes or forefoot</td>
</tr>
<tr>
<td>5</td>
<td>Gangrene involves the whole foot or such a percentage that no local procedures are possible and amputation (at least below the knee level) is indicated</td>
</tr>
</tbody>
</table>

Coding:
Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>99183</td>
<td>Physician attendance and supervision of hyperbaric oxygen therapy, per session</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0277</td>
<td>Hyperbaric oxygen under pressure, full body chamber, per 30-minute interval</td>
</tr>
</tbody>
</table>

Codes considered not medically necessary:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A4575</td>
<td>Topical hyperbaric oxygen chamber, disposable</td>
</tr>
<tr>
<td>E0446</td>
<td>Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories</td>
</tr>
</tbody>
</table>

Billing Guidelines:
Member’s medical records must document that services are medically necessary for the care provided. Harvard Pilgrim Health Care maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to HPHC upon request. Failure to produce the requested information may result in denial or retraction of payment.

30-minute intervals are counted using only the time the member is receiving HBO treatment, including 100% oxygen, descent, air breaks, and ascent. Treatment time may be rounded up if at least 16 minutes, such that one unit of treatment must be at least sixteen minutes, two units must be 46 minutes, three units must be at least 76 minutes, et cetera.

References:
Using Crohn's

Reference appropriate member materials (e.g. Benefit Handbook, Certificate of Coverage) for member

Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g. Benefit Handbook, Certificate of Coverage) for member-specific benefit information.
Hyperbaric Oxygen Therapy (HBO)


53. Hyperbaric Oxygen Therapy for Burns, Infections, and Nondiabetic Wounds. Hayesinc.com/subscriber [via subscription only].

54. Hyperbaric Oxygen Therapy for Carbon Monoxide Poisoning. Hayesinc.com/subscriber [via subscription only].

55. Hyperbaric Oxygen Therapy for Diabetic Foot Wounds. Hayesinc.com/subscriber [via subscription only].

56. Hyperbaric Oxygen Therapy for Encephalopathy Resulting from a Drug Overdose. Hayesinc.com/subscriber [via subscription only].

57. Hyperbaric Oxygen Therapy for Osteoradionecrosis. Hayesinc.com/subscriber [via subscription only].


**HPHC Medical Policy**

Hyperbaric Oxygen Therapy (HBO)

HPHC policies are based on medical science, and written to apply to the majority of people with a given condition. Individual members' unique clinical circumstances, and capabilities of the local delivery system are considered when making individual UM determinations.

Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please refer to appropriate member materials (e.g. Benefit Handbook, Certificate of Coverage) for member-specific benefit information.

Summary of Changes

<table>
<thead>
<tr>
<th>Date</th>
<th>Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>5/21</td>
<td>Annual review; criteria updated</td>
</tr>
<tr>
<td>5/20</td>
<td>Annual review, criteria and coding updated</td>
</tr>
<tr>
<td>12/17</td>
<td>Criteria refined, regulation of adjunctive use added, supporting information and background updated</td>
</tr>
<tr>
<td>4/17</td>
<td>Removed benchmarks and ICD 9 references</td>
</tr>
</tbody>
</table>

Approved by Medical Policy Committee: 5/25/21
Approved by Clinical Policy Operational Committee: 9/01; 9/07; 12/09; 12/11; 12/13; 12/15; 12/17; 5/20; 5/21
Policy Effective Date: 6/1/21
Initiated: 12/02