CLINICAL MEDICAL POLICY and PRIOR-AUTHORIZATION POLICY	
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Disclaimer

Gateway Health℠ (Gateway) medical payment and prior-authorization policy is intended to serve only as a general reference resource regarding payment and coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Gateway provides coverage under the medical-surgical benefits of the Company's Medicaid products for medically necessary hyperbaric oxygen therapy (HBOT) services for specific medical conditions.

This clinical medical policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrants individual consideration, based upon review of applicable medical records on a case-by-case basis.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Commonwealth of Pennsylvania (PA) Department of Human Services (DHS) and all applicable state and federal regulations.

DEFINITIONS

Prior Authorization Review Panel (PARP) – A panel of representatives from within the PA Department of Human Services who have been assigned organizational responsibility for review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

PROCEDURES

1) Systemic hyperbaric oxygen therapy is considered medically necessary in the treatment of any of the following conditions:
    1) Acute gas or air embolism

2) Acute traumatic ischemia (e.g., crush injuries, reperfusion injury, compartment syndrome)
3) Acute cyanide poisoning
4) Acute carbon monoxide poisoning
5) Chronic deep non- healing wounds in patients who meet all of the following criteria:
    - A lower extremity wound, not superficial lesion
    - Type I or type II diabetes
    - Assessment & correction of all underlying vascular problems in the affected limb, when possible
    - All necessary treatment to resolve any infection has been completed
    - A wound classified as Wagner* grade 3 or higher
    - There are no measurable signs of healing after 30 days of an adequate course of standard wound therapy
    - The HBOT therapy is used in conjunction with standard therapy
6) Decompression sickness (the 'Bends')
7) Gas gangrene (i.e., clostridial myositis and myonecrosis)
8) Pre- and post-treatment for patients undergoing dental surgery (non-implant related) of an irradiated jaw
9) Emergent profound anemia when one of the following are met:
    a. Active hemolysis with progressive anemia
    b. Active massive hemorrhage
    c. Severe signs or symptoms unresponsive to volume replacement (e.g., tachycardia, hypotension
10) Soft-tissue radiation necrosis, osteoradionecrosis, and chronic or delayed radiation enteritis, cystitis, or proctitis
11) Idiopathic sudden moderate to profound sensorineural hearing loss (ISSNHL), when treatment is within three months of diagnosis
12) Compromised skin grafts and flaps
13) Prophylactic pre- and post-treatment for members undergoing dental surgery of a radiated jaw
14) Central Retinal Artery Occlusion (CRAO)
15) Chronic refractory osteomyelitis, unresponsive to conventional surgical and medical treatment
16) Progressive necrotizing infections (necrotizing fasciitis, Fournier's gangrene, polymicrobial progressive necrotizing infections

2) Technical Requirements

Gateway provides coverage for full body HBOT therapy for the conditions listed above as medically necessary per the following criteria:

- Treatment occurs in a full body monoplace or multiplace chamber
- The patient is provided 100% systemic oxygen
- The chamber can reach a pressurization of at least 1.4 ATA
- A qualified and trained in hyperbaric medicine physician is onsite

3) Length of Coverage

The Undersea and Hyperbaric Medical Society's 1999 and 2008 Hyperbaric Oxygen Therapy Committee Report recommends utilization review of need for continued HBOT at the following treatment thresholds:

a) Gas or air embolism, acute –5 to 10 treatments
b) Carbon monoxide poisoning - 5 treatments
c) Chronic non-healing wounds - 30 treatments (one or two treatments daily)
d) Decompression Sickness – 5 to 10 treatments
e) Gas gangrene – up to 10 treatments
f) Acute Traumatic:
    i. Crush injury – 3 treatments per day for 48 hours followed by 2 treatments per day over the 2nd 48 hours and 1 treatment per day over the third period of 48 hours. (3 – 12 treatments)
    ii. Compartment syndrome – 2 treatments per day for 24 to 36 hours
    iii. Reperfusion injury - 1 treatment
g) Radiation tissue injury, chronic - 60 treatments
h) Chronic refractory osteomyelitis - no recommendations were made for a total number of treatments. For patients that respond to initial treatment with antibiotics, surgical debridement and HBO therapy, HBOT should be continued for approximately 4 to 6 weeks, for 20 – 40 postoperative treatments.
i) Severe anemia – HBOT treatments should continue until such time that red blood cells have been satisfactorily replaced by patient regeneration or the patient can undergo transfusion
j) Soft tissue necrosis – 30 to 60 treatments
k) Chronic wound - 30 days of treatment
l) Idiopathic sudden sensorineural hearing loss- 20 treatments
m) Skin grafts and flaps (compromised) – 6 to 40 treatments
n) Necrotizing soft tissue infections – 5 to 30 treatments
o) Thermal burns – 5 to 45 treatments

4) Potential Complications of HBOT
Frequent injuries caused by HBOT are categorized as barotrauma. These injuries are caused by pressure as a result of an inability to equalize pressure from an air- containing space and the surrounding environment (Kindwall, 2004). Other complications include visual refraction changes (progr4essive myopia and cataracts) and oxygen toxicity (seizures, dry cough, chest pain or burning and decrease vital capacity).

5) HBOT will be considered medically necessary for those conditions listed above.
Scientific evidence has not been established for conditions other than those listed above.

6) The following procedures are considered not medically necessary because there is insufficient evidence in the peer-reviewed published medical literature regarding the effectiveness and safety for these applications of HBOT
Direct topical application of oxygen administered to an open wound;
Devices used in the topical application of oxygen

7) Contraindications
a) Relative contraindications to the use of HBOT include prior chest surgery, lung disease, untreated pneumothorax, viral infections, recent middle ear surgery, optic neuritis, seizure disorders, high fever, and congenital spherocytosis and claustrophobia.

b) Absolute contraindications to HBOT (Latham, 2014) include untreated pneumothorax, concurrent administration of disulfuram (Antabuse); concurrent administration of doxorubicin, bleomycin, disulfiram, sulfamylon and cisplatinum; and administration to premature infants (due to the risk of retrolental fibroplasias). It was also noted that a clinical trial is currently underway to evaluate the efficacy of HBOT in the treatment of bisphosphonate- associated osteonecrosis.

8) Pediatric Considerations
   a) Due to the proportion of surface area to body mass that is much greater in children than adults, care must be taken to ensure that a child remains warm without causing hyperthermia. The child must be able to focus and equalize their ears for HBOT to prevent middle ear barotrauma. If the child cannot, tympanostomy tubes should be considered.

9) Post-payment Audit Statement
   a) The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Gateway Health Plan® at any time pursuant to the terms of your provider agreement.

10) Place of Service
   a) HBOT is typically an outpatient procedure. HBOT provided in an inpatient setting requires individual case review.

11) Governing Bodies Approval
   a) Hyperbaric oxygen 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.

Wagner Grade Wound Classification

The Wagner classification system is used to assess wound parameters in individuals with diabetes, including the depth of penetration, the presence of osteomyelitis or gangrene, and the extent of tissue necrosis. The wound grades are defined as follows:

Grade 0 - No open lesion
Grade I - Superficial ulcer, not involving subcutaneous tissue
Grade II - Deep ulcer with penetration through the subcutaneous tissue potentially exposing tendon, bone, or joint capsule
Grade III - Deep ulcer penetrates deeper than Grade II and has evidence of abscess (pus) or osteomyelitis (bone infection)
Grade IV - Gangrene present in the toe(s)
Grade V - Gangrene of the foot requiring amputation

Burn Classifications

Thermal Burn

The depth of the burn injury is related to contact temperature, duration of contact of the external heat source, and the thickness of the skin. Because the thermal conductivity of skin is low, most thermal burns involve the epidermis and part of the dermis. The most common thermal burns are associated with flames, hot liquid, hot solid objects and steam. The depth of the burn largely determines the healing potential and the need for surgical grafting.

Classification

The traditional classification of burns as first, second, third degree was replaced by a system reflecting the need for surgical intervention. The term fourth degree is still used to describe the most severe burns. The current designations of burn depth are classified as the following:

- Superficial or epidermal (first degree): superficial or epidermal burns involve only the epidermal layer of skin.
- Partial thickness (second degree): partial thickness burns involve the epidermis and portions of the dermis. They are characterized as either superficial or deep:
    - Superficial: These burns characteristically form blisters within 24 hours between the epidermis and dermis.
    - Deep: These burns extend into the deeper dermis and are characteristically different from superficial partial thickness burns. Deep burns damage hair follicles and glandular tissue.

- Full thickness (third degree): these burns extend through and destroy all layers of the dermis and often injure the underlying subcutaneous tissues.
- Fourth degree-are deep and potentially life threatening injuries that extend through the skin into underlying tissues such as the fascia, muscle and/or bone.

Summary of Literature

Hyperbaric oxygen therapy (HBO) is a procedure that delivers higher pressures of oxygen to the tissues. There are two methods of administering HBO therapy:

- Systemic HBO
  This form of therapy enables patients to breathe 100% oxygen intermittently while inside a treatment chamber at a pressure higher than sea level. The treatment chamber can be either a monoplace or multiplace chamber. The monoplace chamber only accommodates one patient at a time and the entire chamber is pressurized with near 100% oxygen. The patient breathes the ambient chamber oxygen directly. The multiplace chamber can hold two or more people and the chamber is pressurized with compressed air. The patient breathes near 100% oxygen via masks, head hoods or endotracheal tubes.
- Topical oxygen therapy
  This type of HBO therapy delivers 100% oxygen directly to an open, moist wound at a pressure slightly higher than ambient pressure. It is has been proposed that the high concentrations of oxygen diffuse directly into the wound to increase the local cellular oxygen tension, which in turn promotes healing. According to the Undersea and Hyperbaric Medical Society (UHM), topical oxygen should not be termed hyperbaric oxygen since doing so suggests topical oxygen treatment is equivalent or identical to hyperbaric oxygen. UHM does not recommend the application of topical oxygen outside the structure of a clinical trial because its use in wound healing has yet to be adequately supported by scientific data.

A number of technology assessments, societies and organizations have systematically reviewed the evidence supporting the use of hyperbaric oxygen (HBO) for each of the indications for which it has been used. These include, but are not limited to Blue Cross Blue Shield Technology Evaluation Center (TEC) assessments, the Cochrane Collaboration, the Agency for Healthcare Research and Quality (AHRQ), the Undersea and Hyperbaric Medical Society Committee (UHMSC) guidelines, the American College of Hyperbaric Medicine (ACHM) and the Alberta Heritage Foundation for Medical Research (AHFMR).

The Undersea and Hyperbaric Medical Society (UHMS) published new guidelines in 2003. The UHMS's Hyperbaric Oxygen Therapy Committee continues to consider HBO to be appropriate for these conditions:

1. Air or gas embolism
2. Carbon monoxide poisoning and carbon monoxide complicated by cyanide poisoning
3. Clostridal myositis and myonecrosis (gas gangrene)
4. Crush injury, compartment syndrome and other acute traumatic ischemias
5. Decompression sickness
6. Enhancement of healing in selected problem wounds
7. Exceptional blood loss (anemia)
8. Intracranial Abscess
9. Necrotizing soft tissue infections
10. Osteomyelitis (refractory)
11. Delayed radiation injury (soft tissue and bony necrosis)
12. Skin grafts and flaps (compromised)
13. Thermal burns

14. Idiopathic Sudden Sensorineural Hearing Loss
15. Central Retinal Artery Occlusion

In contrast to the Undersea and Hyperbaric Medical Society guidelines, the Blue Cross Blue Shield Association (BCBSA) TEC Assessments concluded that there was inadequate literature to validate the effectiveness of systemic hyperbaric oxygen for the following conditions:

- Compromised skin grafts
- Acute thermal burns
- Chronic refractory osteomyelitis
- Necrotizing soft tissue infections
- Brown recluse spider bites

In 2012, the American Academy of Otolaryngology-Head and Neck Surgery published a clinical guideline on treatment of sudden hearing loss. The guideline includes a statement that HBO may be considered a treatment option for patients who present within 3 months of a diagnosis of ISSNHL. The document states, "Although HBOT is not widely available in the United States and is not recognized by many U.S. clinicians as an intervention for ISSNHL, the panel felt that the level of evidence for hearing improvement, albeit modest and imprecise, was sufficient to promote greater awareness of HBOT as an intervention for [this condition]."

The American College of Hyperbaric Medicine (2012) supports the use of hyperbaric oxygen for treatment for the following conditions (approved indications):

1. Air or Gas Embolism
2. Carbon Monoxide Poisoning
3. Clostridial Myositis and Myonecrosis (Gas Gangrene)
4. Crush Injury, Compartment Syndrome or other Acute Traumatic Ischemias
5. Decompression Sickness
6. Enhancement of Healing in Select Problem Wounds
7. Extreme Anemia
8. Intracranial Abscess
9. Necrotizing Soft Tissue Infections
10. Osteomyelitis (Refractory)
11. Delayed Radiation Injury (Soft Tissue and Bony Necrosis)
12. Skin Flaps & Grafts (Compromised)
13. Thermal Burns
14. Idiopathic Sudden Sensorineural Hearing Loss
15. Central Retinal Artery Occlusion

The American College of Hyperbaric Medicine supports the treatment of patients with non- approved indications only in a research setting under the guidelines of formal protocol which has had the approval of an institutional Investigational Review Board.

The ACHM supports the continued performance of well-designed clinical trials in these areas, especially those that are prospective, randomized, and controlled. If sufficient convincing data demonstrate that HBO2 treatment is associated with favorable risk-benefit and cost-benefit ratios for an indication which is not currently on the above approved list, the ACHM will endorse application of hyperbaric therapy for the specific supported indication.

The ACHM does not support the treatment of non-approved conditions for financial gain, without investigational treatment protocols. The ACHM classifies as unethical, situations where the practitioner intentionally falsifies or misleads the patient or family into believing that the proposed treatment is an approved indication, or that significant literature exists to support the treatment when indeed that is not the case.

The UHMS Committee Report states that even though there are no randomized clinical trials available, the overwhelming majority of published animal data, human case series and prospective trials support HBOT therapy as a safe and effective adjunct to the management of refractory osteomyelitis.

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 literatures notes that HBOT should not be a replacement for other standard successful therapies.

Per the FDA (2013) the safety and effectiveness of HBOT has not been established for the following conditions:

- Aids/HIV
- Alzheimer's Disease
- Asthma
- Bell's Palsy
- Brain Injury
- Cerebral Palsy
- Depression
- Heart Disease
- Hepatitis
- Migraine
- Multiple Sclerosis and other demyelinating diseases
- Parkinson's Disease
- Spinal Cord injury
- Sport's injury
- Stroke

The UHMS issued the following policy statement on topical oxygen, often referred to as "topical hyperbaric oxygen therapy" (Feldmeier et al, 2005):

1. Topical oxygen should not be termed hyperbaric oxygen since doing so either intentionally or unintentionally suggests that topical oxygen treatment is equivalent or even identical to hyperbaric oxygen. Published documents reporting experience with topical oxygen should clearly state that topical oxygen not hyperbaric oxygen is being employed.
2. Mechanisms of action or clinical study results for hyperbaric oxygen cannot and should not be co-opted to support topical oxygen since hyperbaric oxygen therapy and topical oxygen have different routes and probably efficiencies of entry into the wound and their physiology and biochemistry are necessarily different.
3. The application of topical oxygen cannot be recommended outside of a clinical trial at this time based on the volume and quality of scientific supporting evidence available, nor does the Society recommend third party payor reimbursement.
4. Before topical oxygen can be recommended as therapy for non-healing wounds, its application should be subjected to the same intense scientific scrutiny to which systemic hyperbaric oxygen has been held".

Topical HBOT administered to the open wound in small limb-encasing devices is not systemic HBOT and its efficacy has not been established due to the lack of controlled clinical trials. The available in vitro evidence suggests that topical HBOT does not increase tissue oxygen tension beyond the superficial dermis. Some examples of topical HBOT devices include the TOPOX portable hyperbaric oxygen extremity and sacral chambers (Jersey City, NJ), Oxyboot and Oxyhealer from GWR Medical, L.L.P. (Chadds Ford, PA).

HBOT has been shown to be an effective method for treating diabetic foot wounds in select cases of lower extremity lesions. The results of multiple retrospective studies involving a significant number of patients have consistently indicated a high success rate in patients who had been refractory to other modes of therapy. Such evidence is lacking, however, for superficial diabetic wounds and non-diabetic cutaneous, decubitus, and venous stasis ulcers.

Central Retinal Artery Occlusion (CRAO)
In CRAO there is a sudden and painless loss of vision as the result of obstruction of the central retinal artery. This loss of vision can cause permanent vision loss. Several small studies (Hertzog, 2014 & Beiran, 2008). The use of HBOT for treatment of CRAO has been approved by the Undersea and Hyperbaric Medicine Society (2014).

Migraine
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.

Acute Peripheral Arterial Insufficiency
There are no clinical trials were identified that provide evidence of the HBOT for this condition despite a long term positive coverage determination by Medicare.

Bell's palsy, Traumatic Brain Injury, Inflammatory Bowel Disease, Autism
There is insufficient evidence that HBOT improves health outcomes in patients with these conditions.

Idiopathic sudden sensorineural hearing loss (ISSNHL)
In 2012, the American Academy of Otolaryngology-Head and Neck Surgery published a clinical guideline on treatment of sudden hearing loss.70 The guideline includes a statement that HBO may be considered a treatment option for patients who present within 3 months of a diagnosis of ISSNHL. The document states, "Although HBOT is not widely available in the United States and is not recognized by many U.S. clinicians as an intervention for ISSNHL, the panel felt that the level of evidence for hearing improvement, albeit modest and imprecise, was sufficient to promote greater awareness of HBOT as an intervention for [this condition]."

AUTHORIZATION and CODING REQUIREMENTS

HBO is typically an outpatient procedure and will require prior authorization. HBO treatment provided in an inpatient setting requires individual case review.

REIMBURSEMENT

Participating providers will be reimbursed per their Gateway Health Plan® contract.

POLICY SOURCE(s)

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