**CHRONIC REFRACTORY OSTEOMYELITIS**

While no randomized clinical trials exist, the overwhelming majority of published animal data, human case series, and prospective trials support HBOT as a safe and effective adjunct to the management of refractory osteomyelitis. Further, when used appropriately, HBOT appears to reduce the total need for surgical procedures, required antibiotic therapy and, consequently, overall healthcare expenditures. [1]

In most cases, the best clinical results are obtained when HBOT is administered in conjunction with culture-directed antibiotics and scheduled to begin soon after thorough surgical debridement. A course of 4-6 weeks of combined HBOT and antibiotic therapy should be sufficient to achieve the desired clinical results. If osteomyelitis fails to resolve or recurs after a total of 6 weeks of continuous culture-directed antibiotics and HBOT (30-40 sessions), then additional surgical bony debridement will likely be required to eradicate residual infection.

The medical record documentation must support medical necessity (and evidence of complex medical decision making) of the services and provide an accurate description and diagnosis of the medical condition supporting the use of HBOT is reasonable and medically necessary.

Sample documentation: Mr. Jones has been aggressively managed by Dr. Smith (Ortho), Dr. Abrams (ID), and Dr. Black (Wound Care) over the past 6 weeks. He is now at HBOT number 40. His clinical blood markers (CRP and ESR) have regressed but are now climbing again. Imaging shows a continued bony defect with a fistulogram/sinogram suggesting that the bone is the source of drainage. A bone biopsy and saucerization is scheduled for next week. Based on the clinical course, we have agreed to continue HBOT to a total of 60 treatments.

The submitted medical record must support the use of the selected ICD-10 code(s). The submitted CPT/HCPCS code must describe the service performed.

Below we explain in detail what needs to be documented and provide sample statements that can be adapted to suit your needs.

**HISTORY AND PHYSICAL**

- An initial assessment including a history and physical that clearly substantiates the condition for which HBO is recommended.
- Prior medical, surgical and/or hyperbaric treatments.
- Past medical records must be available to document chronicity, and the refractory nature of the disease.

**PHYSICAL EXAM**

- Documentation of the failure to resolve the following: surgical bony debridement and appropriate course of antibiotics.
- Documentation of specific antibiotic administration for a minimum of 4-6 weeks.
- Documented evidence of bone culture sensitivities, plain X-ray, Tagged WBC bone scan, CT, or MRI demonstrating osteomyelitis.
- Documented consideration of removal of all orthopedic hardware or other foreign bodies within the infected bone.
- Document CRP and ESR response and trends
- Documented evidence of wound chronicity despite standard wound care.
  - Initial Ulcer size - beginning of 30 days of standard wound care.
  - Ulcer size – (current) Following standard wound care
- Documentation of optimization of nutritional status
  - Albumin
  - Pre-Albumin
IMPRESSION

1. Refer to ICD – 10 crosswalk – single diagnosis code meets medical necessity for **Chronic Refractory Osteomyelitis**

PLAN

"A typical hyperbaric regimen for a patient with chronic refractory osteomyelitis consists of daily hyperbaric oxygen treatments at 2.0 or 2.4 ATA for 90 to 120 minutes of oxygen breathing at pressure. The site of the infection is monitored on a regular basis. Consultation with the orthopaedic surgeon and infectious disease specialists will occur throughout the patient’s treatment period. Hyperbaric oxygen treatments continue until there are signs of healing and no osteomyelitis present. The number of treatment generally varies between 30 and 40, however can be extended to 60 depending on the severity of the disease process."

RISK ASSESSMENT

☐ Risk benefit ratio in favor of offering hyperbaric oxygen therapy

"The patient was informed of the possible risks and complications of hyperbaric oxygen therapy. These include, but are not limited to, fire, barotrauma of the ears, sinuses, and lungs to include air embolism, central nervous system oxygen toxicity resulting in seizure, cataracts, myopia, and exacerbation of congestive heart failure.

Having no absolute contraindication to hyperbaric oxygen therapy, the patient will be offered treatment 2.0 ATA for 90 minutes OR at 2.5 ATA for 90 minutes with two inter-current ten minute air breaks (Where pseudomonas or E. coli is isolated). Forty treatments will initially be provided on a once daily basis Monday through Friday. Thereafter, a re-evaluation of the patient’s clinical progress will be in order to determine if additional treatments may be required."

INDICATION FOR HYPERBARIC OXYGEN THERAPY (HBOT)

"Refractory osteomyelitis is a chronic osteomyelitis that persists or recurs after appropriate interventions have been performed, or where acute osteomyelitis does not respond to accepted management techniques. Hyperbaric oxygen, when combined with appropriate antibiotics, nutritional support, surgical debridement and reconstruction, provides a useful clinical adjunct in the management of refractory bone infections. Addition of hyperbaric oxygen to appropriate clinical management produces an infection arrest rate of nearly 80%.

Hyperbaric oxygen benefits healing by enhancing bacterial phagocytosis activity of white blood cells. Next, certain antibiotics require an oxygen-mediated pathway in order to transport the medication across bacterial walls. Third, there is evidence that osteogenesis and osteoclast remodeling is an oxygen-dependent activity. Finally, osteomyelitis is characterized by both acute and chronic forms of hypoxia. Hyperbaric oxygen raises tissue levels of oxygen, decreases edema, decreases tissue hypoxia, enhances neovascularization, and supports new collagen and bone formation."