

**Applicable to:**  
Medicaid (KY)  
Medicare (KY)

## **Hyperbaric Oxygen Therapy (HBOT)**

**Policy Number: HS-204**

**Original Effective Date: 2/22/2019**

**Revised Date(s): N/A**

### **APPLICATION STATEMENT**

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

### **DISCLAIMER**

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on [www.wellcare.com](http://www.wellcare.com). Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

### **BACKGROUND**

Per CMS, for purposes of coverage under Medicare, hyperbaric oxygen therapy (HBOT) is a modality in which the entire body is exposed to oxygen under increased atmospheric pressure. The patient is entirely enclosed in a pressure chamber breathing 100% oxygen (O<sub>2</sub>) at greater than one atmosphere (atm) pressure. Either a mono-place chamber pressurized with pure O<sub>2</sub> or a larger multi-place chamber pressurized with compressed air where the patient receives pure O<sub>2</sub> by mask, head tent, or endotracheal tube may be used.<sup>1,2,3</sup>

Hyperbaric Oxygen Therapy serves four primary functions:<sup>2,3</sup>

1. It increases the concentration of dissolved oxygen in the blood, which augments oxygenation to all parts of the body
2. It replaces inert gas in the bloodstream with oxygen, which is then metabolized by the body
3. It may stimulate the formation of a collagen matrix and angiogenesis
4. It acts as a bactericide for certain susceptible bacteria.

Hyperbaric oxygen therapy is used to treat a variety of diagnoses in both the inpatient and outpatient setting. Some of the most common conditions treated in the outpatient wound clinic setting are as follows:

**Chronic Refractory Osteomyelitis** - Covered HBO therapy is an adjunctive therapy used with the appropriate antibiotics and surgical debridement to eliminate the necrotic bone acting as a foreign body. When the site of the bone infection is not amenable to debridement or resection, HBOT may be indicated to enhance systemic therapy though is not indicated as primary therapy alone.<sup>2,3</sup>

**Osteoradionecrosis and Soft Tissue Radiation Injury** - HBO's use in the treatment of Osteoradionecrosis and Soft Tissue Radiation Injury (Radionecrosis) is one part of an overall plan of care that also includes debridement or resection of nonviable tissue in conjunction with antibiotic therapy. A consistent cause and effect of radiation injury is vascular obliteration and stromal fibrosis or scarring; subsequently, the known impact of hyperbaric oxygen therapy, stimulation of angiogenesis, is an important mechanism of recovery. The goal of HBO treatment is to increase the

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oxygen tension in both hypoxic bone and tissue to stimulate growth in functioning capillaries, fibroblastic proliferation and collagen synthesis.<sup>2,3</sup>

HBOT treatment can be indicated in the preoperative and postoperative management of existing osteoradionecrosis or soft tissue radionecrosis, but must be utilized as an adjunct to conventional therapy. Beneficiaries suffering from soft tissue damage or bone necrosis present with disabling, progressive, painful tissue breakdown, bleeding, bladder dysfunction, wound dehiscence, infection, tissue loss and graft or flap loss.<sup>2,3</sup>

Prerequisite for treatment includes history of radiation treatment to the region of the documented injury, terminating at least 6 months prior to onset of signs or symptoms and/or planned surgical intervention at the site. Numerous forms of soft tissue radiation necrosis and treatment with HBOT have been documented with beneficial effect. Tissues previously irradiated with subsequent planned surgery appear to benefit from HBOT surrounding the surgery with decreased mortality from large vessel necrosis. For this reason patients who manifesting signs and symptoms of radiation injury will be approved for coincidental HBOT, without the histologic diagnosis of ongoing osteoradionecrosis or soft tissue radionecrosis.<sup>2,3</sup>

Coverage for osteoradionecrosis of the jaw is limited to cases with evidence of overt fracture or bony resorption. Data to justify HBOT prophylaxis for osteoradionecrosis in a previously irradiated mandible undergoing tooth extraction is lacking at this time.<sup>2,3</sup>

HBO is not covered to prepare the patient for dental extraction, when radiation therapy has not been done at least 6 months prior, in order to prevent the development of osteoradionecrosis.<sup>2,3</sup>

**Actinomycosis** - Actinomycosis is a bacterial infection caused by *Actinomyces Israelii*. Findings include slow growing granulomas that later break down, discharging viscid pus containing yellow granules. The treatment includes prolonged administration of appropriate antibiotics with surgical incision and draining of accessible lesions. When the disease process has been shown refractory to antibiotics and surgery, HBO therapy may be considered reasonable and necessary.<sup>2,3</sup>

**Diabetic Wounds** - Wound volume or surface area is expected to measurably diminish over 30 days of wound care with adjunctive HBOT. Continued treatment with HBO therapy is non-covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment. "Measurable signs of healing" are best defined as specific, documented, clinical evidence of healing. Physician statements should be descriptive and complete with interval measurements to substantiate wound improvement.<sup>2,3</sup>

Standard wound care in patients with diabetes involves a multifaceted approach. It is important that the following tenets of care be addressed and documented in clinical notes:

1. Tight glycemic control
  - a. Achieve a hemoglobin A1C reading of at least less than 9%, ideally as low as possible without adverse effects
  - b. If hemoglobin A1C is over 9%, demonstration of at least a 2 point reduction during active wound management
2. Optimized vascular status
  - a. Measure and periodically follow ABI (Ankle/Branchial Index)
  - b. Consideration for referral for revascularization for low ABI
  - c. If not a candidate for vascular intervention, non-invasive monitoring should demonstrate augmentation of tissue oxygen saturation with supplemental oxygen (transcutaneous oxygen measurement (TCOM), for example)
3. Aggressive offloading
  - a. When not contraindicated, total contact casting is considered the gold standard
  - b. Consider orthotist or podiatrist for patients failing alternate methods

4. Active wound management
  - a. Excisional debridement of devitalized tissue at regular intervals
  - b. Exact measurements of the area and volume of the wound performed and documented regularly
  - c. Maintain a clean, moist wound bed of granulation tissue
5. Infection management
  - a. Documentation of duration, route of administration and name of prior antibiotic therapy
  - b. Any relevant culture and sensitivity tests (ideally from infected tissue as opposed to a standard wound swab) well-documented
  - c. Inclusion or notation of any infectious disease consultations for complex cases
6. Nutrition
  - a. Counseling patients regarding the importance of protein in wound healing
  - b. Objective measurement of improvement in patients with documented malnutrition, eg. pre-albumin/albumin

#### **Wagner Ulcer Classification System<sup>4</sup>**

##### Grade

- 0 - No open lesions; may have deformity or cellulitis
- 1 - Superficial diabetic ulcer (partial or full thickness)
- 2 - Ulcer extension to ligament, tendon, joint capsule, or deep fascia without abscess or osteomyelitis
- 3 - Deep ulcer with abscess, osteomyelitis, or joint sepsis
- 4 - Gangrene localized to portion of forefoot or heel
- 5 - Extensive gangrenous involvement of the entire foot

#### **POSITION STATEMENT**

##### **Applicable To:**

- Medicaid – All Markets
- Medicare – All Markets

##### **Exclusions**

Hyperbaric oxygen therapy is *not considered medically necessary and not a covered benefit* when used to treat any of the following diagnosis:

1. Cutaneous, decubitus, and stasis ulcers.
2. Chronic peripheral vascular insufficiency.
3. Anaerobic septicemia and infection other than clostridial.
4. Skin burns (thermal).
5. Senility.
6. Myocardial infarction.
7. Cardiogenic shock.
8. Sickle cell anemia.
9. Acute thermal and chemical pulmonary damage, i.e., smoke inhalation with pulmonary insufficiency.
10. Acute or chronic cerebral vascular insufficiency
11. Hepatic necrosis
12. Aerobic septicemia
13. Nonvascular causes of chronic brain syndrome (Pick's disease, Alzheimer's disease, Korsakoff's disease)
14. Tetanus
15. Systemic aerobic infection
16. Organ transplantation
17. Organ storage
18. Pulmonary emphysema

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19. Exceptional blood loss anemia
20. Multiple Sclerosis
21. Arthritic Diseases
22. Acute cerebral edema

Hyperbaric oxygen therapy is *not considered medically necessary and not a covered benefit* when used to treat any of the following contraindications:

1. Pneumothorax is a contraindication to HBOT.
2. Pregnancy is considered a contraindication to HBOT except in the case of carbon monoxide poisoning for which it is specifically indicated on an emergent basis.
3. Simultaneous use of doxorubicin or bleomycin

It is expected that *outpatient* HBOT requests for these following conditions may be denied as not medically necessary. Such conditions can be treated with standard wound care [including topical dressings, nutritional support and wound negative pressure (NPWT)] treatment after the initial period of hospitalization unless there is evidence of graft ischemia or threatened flap:

1. Gas gangrene
2. Acute peripheral ischemia (including reperfusion conditions of arterial embolism and thrombosis, reimplantation and/or crush injuries of the extremities)
3. Progressive necrotizing fasciitis
4. Acute arterial Air or Gas Embolism
5. Carbon monoxide poisoning.
6. Cyanide poisoning
7. Decompression illness
8. Preparation and preservation of compromised skin grafts (not for primary management of wounds),

## **Coverage**

### **Initial Authorization**

Initial authorization of hyperbaric oxygen therapy is *considered medically necessary and a covered benefit* when the member meets all of the following criteria:

1. Member must meet all of the following wound care conditions:
  - A. Member has had no meaningful improvement in wound size (less than 50% improvement in wound size) after 30 days of standard wound care (6 weeks for chronic, refractory osteomyelitis) including:
    - I. Adequate glycemic control (Hgb A1 C <9%) **OR** If hemoglobin A1C is over 9%, demonstration of at least a 2 point reduction during active wound management; **AND**,
    - II. Weekly debridement; **AND**,
    - III. Nutritional treatment of malnutrition; **AND**,
    - IV. Antibiotics for infection; **AND**,
    - V. Topical wound dressings
2. Request is for hyperbaric oxygen therapy for **ONE** of the following conditions:
  - A. Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management meeting ALL of the following requirement:
    - I. Failure of wound to decrease by at least 50% in size after at least 6 weeks of medical and surgical treatment including ALL of the following:
      - a. IV antibiotics; **AND**,
      - b. Surgical debridement; **AND**,

- c. Imaging that does not support recurrent, acute osteomyelitis; **AND**,
  - d. Negative pressure wound therapy (NPWT)
- B. Osteoradionecrosis as an adjunct to conventional treatment; **OR**,
  - C. Soft tissue radionecrosis as an adjunct to conventional treatment (examples include, radiation cystitis, radiation proctitis, esophagitis); **OR**,
  - D. Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment; **OR**,
  - E. Infected diabetic wounds of the lower extremities in patients who meet ALL of the following criteria:
    - II. Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes; **AND**,
    - III. Patient has an infected wound classified as Wagner grade III or higher; **AND**,
    - IV. Documentation of excisional debridement procedures with wound measurements and appropriate dressings has been provided; **AND**,
    - V. Member has had a nutritional assessment with counseling, including having an albumin/pre-albumin with dietician consultation for those deemed malnourished; **AND**,
    - VI. Member has had deep tissue wound cultures to guide antibiotic therapy and an infectious disease consultation for complex infections, when obtainable and if applicable; **AND**,
    - VII. Member's Ankle/branchial index (ABI) is documented and if their ABI less than 0.5, specialty referral for further testing or consider transcutaneous oxygen monitoring (TCOM) to document that adequate oxygenation is achievable with HBOT
- AND**,
- 3. The number of visits requested must not exceed 15 visits; **AND**,
  - 4. Documentation must provide ruler measurements of the wound and photographs must be included; **AND**,
  - 5. All requests for hyperbaric oxygen therapy must be submitted for mandatory secondary review with full documentation of above criteria.

### **Ongoing Authorization**

Ongoing authorization of hyperbaric oxygen therapy is *considered medically necessary and a covered benefit* the member meets all of the following criteria:

- 1. Documentation must provide ruler measurements of the wound healing process and photographs must be included; **AND**,
- 2. The number of visits requested must not exceed 15 visits; **AND**,
- 3. All requests for hyperbaric oxygen therapy must be submitted for mandatory secondary review with full documentation of above criteria; **AND**,
- 4. Documentation of adherence to hyperbaric oxygen therapy; **AND**,
- 5. Documentation of evidence of improvement prior to and at 15 visits.

### **CODING**

#### **Covered CPT Codes**

**99183** Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session (Professional Component Only)

#### **Covered HCPCS Codes**

**A4575** Topical hyperbaric oxygen chamber, disposable (Not covered)

**E0446** Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories (Not covered)

**G0277** Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval (Technical Component Only)

#### **REV Codes:**

**413** Hyperbaric oxygen

**940** Other therapeutic services

**Bill Type:**

85X Critical access hospital

**Place of Service Codes:**

- 11 Office
- 19 Off campus outpatient hospital
- 21 Inpatient hospital
- 22 On campus outpatient hospital
- 49 Independent clinic

**ICD 10 Procedure Codes:**

5A05121 Extracorporeal hyperbaric oxygenation, intermittent

**Covered ICD-10 Codes:**

**All applicable diagnoses**

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

**REFERENCES**

1. National coverage determination for hyperbaric oxygen Therapy (20.29). Centers for Medicare and Medicaid Services Web site. <http://www.cms.hhs.gov/mcd/search.asp>. Published December 18, 2017. Accessed January 25, 2019.
2. Local coverage determination for hyperbaric oxygen (HBO) Therapy (L36504). Centers for Medicare and Medicaid Services Web site. <http://www.cms.hhs.gov/mcd/search.asp>. Published May 30, 2018. Accessed January 25, 2019.
3. Local coverage determination for hyperbaric oxygen (HBO) Therapy (L35021). Centers for Medicare and Medicaid Services Web site. <http://www.cms.hhs.gov/mcd/search.asp>. Published October 10, 2018. Accessed January 25, 2019.
4. Fryberg, R. Diabetic foot ulcers: pathogenesis and management. Am Fam Physician. 2002 Nov 1;66(9):1655-1663.

**MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS**

Date	Action
1/_/2019	<ul style="list-style-type: none"><li>• Approved by MPC. New.</li></ul>