Hyperbaric Oxygen Therapy

Ask the Contractor Teleconference (ACT) 04/20/2017

For specific claim information, please call the Provider Contact Center (PCC) at 855-696-0705 or you can submit a Provider Outreach and Education (POE) education request form via www.palmettogba.com/jma/forms. If you are treating a condition that is not listed as a covered indication per National Coverage Determination (NCD) or if it is considered “off-labeled” then you will need to submit acceptable compendia or peer literature to support hyperbaric oxygen therapy (HBOT) as reasonable and necessary. Abstracts are not acceptable. Additional resources can be found on UpToDate.com, FDA guidelines or Journals of Medicine.

- The Centers for Medicare and Medicaid Services (CMS) posted a Medicare Learning Network (MLN) article in September 2016 that provided information and tips for HBO therapy. CMS directed its Supplemental Medical Review Contractor to review claims for HBO services from April 2012 to March 2013. Over the course of the study, 2,000 claims were reviewed showing a 58% error rate based on regulatory guidelines. The study found that the documentation lacked sufficient information to support that HBO services were reasonable and necessary. The documentation was missing the following:
  - Specific timelines and goals for therapy. For example, the documentation simply stated “continue HBO” or “until healed”
  - Radiology and pathology reports confirming diagnosis, such as osteomyelitis or gas gangrene
  - Progress or lack of improvement of the treated condition


- In October 2016 Palmetto GBA revealed that a pre-payment service specific probe review (first link below) would be implemented for HBO for claims processed from Oct 2016-Dec 2016. It listed the documentation the providers should submit for review with the results of the review posted on February 1, 2017 (second link below with results).

  http://www.palmettogba.com/palmetto/providers.nsf/DocsCat/JM-Part-A~AJ6QGM7254

- Palmetto GBA provided an HBO webcast on December 21, 2016, which is available for video playback. The handout is also available on our website at:
CMS posted a MLN article in July 2015 with information on page 8 for calculating the total number of 30 minute intervals billable under the Current Procedural Terminology (CPT) G0277. This information is also noted in the webcast handouts on slides 29-31 as well as on the CMS MLN link below.


All claims should contain a history that addresses the cause or indication for HBO’s origin. The history needs to be consistent with why the beneficiary is receiving HBO as treatment for a covered indication per the NCD.

Example: The beneficiary received HBO on October 16, 2016 for a progressive necrotizing infection of a left lower extremity. The physician’s history and physical from 2015 indicated the beneficiary had a venous stasis ulcer and now in 2016 the beneficiary suddenly has a necrotizing infection. The only documentation submitted was a progress note on August 1, 2016 indicating HBO would be indicated as treatment for venous stasis ulcer and the HBO treatment note on October 16, 2016 indicating the beneficiary has a necrotizing infection to his left lower extremity, this is not sufficient history. The documentation would need to include the radiology or pathology reports indicating progression to a necrotizing infection as HBO is not considered reasonable and necessary as treatment for stasis ulcers.

Although the NCD does not specifically address treatment plan or plan of care (POC) requirements, our Medical Affair’s department indicate that each claim should include a history of the condition, failed treatments, current condition of the wound or area being treated, expected outcomes of HBO therapy (measurable goals), progress or lack of and the beneficiary’s response to HBO treatment.

The goals should be individualized to the beneficiary’s condition and contain the outcomes of HBO treatment. We have seen documentation include nursing goals, but they are not directed towards wound care. Some of the nursing goals would include vital signs, monitoring for anxiety while in the chamber, oxygen toxicity, etc. However, again, these are not directed towards wound care or the outcomes of HBO.

Palmetto cannot hold a provider to any particular format for a treatment plan. Treatment plans or POC can be included in the physician’s assessment and plan within the history and
physical, office visit notes or a separate treatment plan. At a minimum, the POC should include the diagnosis, measurable outcomes, type, amount, duration and frequency of the specific therapy service.

Example:
Assessment and Plan: A beneficiary with confirmed chronic refractory osteomyelitis of the left foot. Transcutaneous oxygen measurements (TCOM) showed decreased oxygen tissue tension localized to the wound bed that does improve with supplemental oxygen. Microvascular damage likely due to extensive trauma/surgeries. HBOT is warranted for increased tissue oxygen tension that will promote neovascularization, mobilization of immune cells and improved wound healing. The beneficiary has no contraindication to HBO. Transcutaneous oxygen values are consistent with local tissue hypoxia as a component of the failure to heal. I recommend treatment will consist of 2.0 ATA for 110 minutes 5 days a week for 40 treatments as the beneficiary may require less, depending on clinical response.

Progress notes need to reflect the beneficiary’s response to treatment. If a beneficiary had a wound vac at the start of HBO with copious amounts of drainage and 30 days later they did not have wound vac or drainage had decreased then the beneficiary or family may say “wound has gotten better, there’s less drainage in the wound vac or the wound vac was discontinued a week ago.”

**Frequently Asked Questions**

1. Decision Memo for Hyperbaric Oxygen (HBO) Therapy (Section C, Topical Oxygen) (CAG-00060R) (information available on the CMS.gov website): On April 3, CMS published a Decision Memo for HBO therapy after receiving a reconsideration request to remove the coverage exclusion of Continuous Diffusion of Oxygen Therapy (CDO) from NCD Manual 20.29, Section C. After examining the evidence, CMS has decided that no National Coverage Determination is appropriate at this time concerning the use of topical oxygen for the treatment of chronic wounds and will amend NCD 20.29 by removing Section C, Topical Application of Oxygen. Medicare coverage of topical oxygen for the treatment of chronic wounds will be determined by the local contractors. Will Palmetto GBA cover this?

   **Answer:** No, Palmetto GBA will not allow coverage of topical oxygen at this time for the treatment of chronic wounds as it is not recommended by HBO providers and the results are questionable.

2. Please discuss how reviewers define “chronicity and refractoriness” as related to the covered conditions listed on NCD 20.29
**Answer:** For “chronicity and refractoriness” under #10 for chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management. A radiology or pathology report confirming it is chronic refractory osteomyelitis would be acceptable. If the radiology report is not available, then the physician would need to note in the progress notes or somewhere in the documentation that “per discussion with Dr. Paul, the radiology results indicate chronic refractory osteomyelitis or X-ray results show the wound on the left lower leg is chronic refractory osteomyelitis.” Please note that if the radiology results show acute osteomyelitis, then that is not acceptable as the wound must be chronic refractory osteomyelitis prior to HBO initiated. The documentation would also need to indicate any prior failed treatments for the osteomyelitis i.e. antibiotics as antibiotics would probably be the first line of treatment for osteomyelitis, wound care, surgical debridement, etc.

3. Under item #15 on NCD 20.29, there is a statement about HBO as adjunctive treatment after no signs of healing for at least 30 days. This statement goes on to discuss diabetic wounds. Is this statement related to only diabetic wounds or is it relevant to all covered conditions under NCD 20.29?

**Answer:** The yellow highlighted section below is primarily for diabetic wounds and ulcers. The green highlighted section refers to all covered indications on the NCD 20.29.

The use of HBO therapy is covered as adjunctive therapy only after there are no measurable signs of healing for at least 30–days of treatment with standard wound therapy and must be used in addition to standard wound care. Standard wound care in patients with diabetic wounds includes: assessment of a patient’s vascular status and correction of any vascular problems in the affected limb if possible, optimization of nutritional status, optimization of glucose control, debridement by any means to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, appropriate off-loading, and necessary treatment to resolve any infection that might be present. Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days. Wounds must be evaluated at least every 30 days during administration of HBO therapy. Continued treatment with HBO therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

4. One of the denial reasons listed is “the recommended protocol was not ordered and followed.” What does this mean? There is no “recommended protocol” listed in the NCD.

**Answer:** All claims need documentation to substantiate or support the diagnosis or condition being treated.

Example: If a beneficiary has a chronic non-healing wound and the radiology report indicates it is acute osteomyelitis, then HBO will not be considered reasonable and
necessary as the recommended protocol was not followed. The NCD states it has to be chronic refractory osteomyelitis and not acute. With osteomyelitis, the records would need to show any failed treatments i.e. antibiotics, wound care, surgical debridement, etc. prior to HBO initiated.

Example: If the beneficiary has a diabetic ulcer, Wagner stage II and the physician wants to initiate HBO as “preventive” so the wound will not advance to Wagner stage III, then HBO is not considered reasonable and necessary at that time as the recommended protocol was not followed.

5. Is it necessary for a patient with chronic refractory osteomyelitis (CRO) to have an open wound at the site of the osteomyelitis?

**Answer:** No, an open wound is not a requirement for chronic refractory osteomyelitis as long as the documentation supports it is chronic and not acute. The records would also need to show any failed treatments i.e. antibiotics, wound care, surgical debridement, etc. prior to HBO initiated.

6. Would Medicare cover HBO therapy in the following scenario?
   - A patient has a long history of chronic refractory osteomyelitis and has been treated with antibiotic therapy and bone debridement’s intermittently over nine months or longer. The patient is referred to the facility for HBOT. The patient has been followed by an infectious disease physician who has documented that the patient has not been receiving antibiotics for the last two months due to the prolonged previous treatments. However, the patient’s records demonstrate multiple courses of antibiotic therapy over the year.

**Answer:** Yes, as long as the documentation supports prior failed treatments and an explanation as to why the beneficiary was currently not on any antibiotics or receiving wound care prior to HBO initiated.

7. What type of documentation should be provided to support continued use of HBOT for a patient with CRO that does not have an open wound at the site after having had 40 HBO treatments?

**Answer:** Wounds must be evaluated at least every 30 days during administration of HBO therapy. Continued treatment with HBO therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment. Documentation would need to show that HBO is helping the patient and resolving the osteomyelitis. Documentation would need to include the patient’s response to treatments.
Example: If the patient has a decubitus ulcer with osteomyelitis, then documentation would need to support that the osteomyelitis is chronic refractory with historical documentation and failed treatments. If the CRO resolves with 40 HBO treatments, then continued HBOT will not be considered reasonable and necessary as a decubitus ulcer is not on the list of covered indications.

8. What medical documentation would support that a patient has osteoradionecrosis (ORN) or soft tissue radionecrosis (STRN)?

Example: The oral surgeon “ruled-out” other conditions and provided a diagnosis based on the patient’s past history of radiation treatments and the patient’s current symptoms. Would documentation of the oral surgeon’s process of diagnosing the condition support medical necessity?

Answer: Yes, if diagnostic results are not available then the HBOT physician would need to indicate in the progress notes that “per discussion with the oral surgeon Dr. Smith, radiodensities in radiolucencies on patient’s radiographic imaging of the mandible confirm ORN” is acceptable too. Also, for ORN and STRN the documentation should include the radiation history (area treated and approximately when) and a description of the ORN or STRN manifestations i.e. examination of the patient’s oral cavity showed mandibular excursion limited to about 60%, decayed teeth, thickening of oral mucosa, recession of gingiva and xerostomia, pain, blood loss, tissue necrosis, infections, non-healing ulcerations, visible bone, etc.

Our Medical Affairs department received some feedback regarding osteoradionecrosis primarily of the mandible. HBO therapy is useful as an essential peri-operative staging modality of what is termed the Marx protocol. ORN of the mandible is expected to be diagnosed by an oral-maxillofacial/head and neck surgeon, possibly upon referral by a dentist, a radiation oncologist, or a primary care physician (PCP). It is common for the oral-maxillofacial/head and neck surgeons to be familiar with the Marx protocol. There are different stages associated with this protocol, Stage 1, 2 and 3; continuing to provide HBO therapy in Stage 1 disease beyond 30 treatments and in the absence of surgical involvement does not represent standard of care. HBO is not being employed in the same manner as diabetic ulcer healing. Rather, the goal is to induce angiogenesis and radiation damage tissues to support surgical reconstruction.

References:


The NCD states, “Standard wound care in patient with diabetic wounds includes: assessment of a patient’s vascular status and correction of any vascular problems in the affected limb if possible...” This appears to imply that a patient may be eligible for HBO therapy if it is not possible for their vascular problem to be corrected. How does Palmetto interpret this statement?

**Answer:** Documentation for diabetic wounds will need to include the criteria per NCD 20.29. If vascular status is available i.e. vascular studies, then that documentation should be included. People with diabetes may be eligible to receive HBO services if the following conditions are met:

- The patient is a Type I or Type II diabetic
- The patient has a lower extremity wound
- The patient has a wound that is Wagner, grade III or greater
- Documentation that the patient has not responded to standard wound care for the past 30 days.
- Standard wound care in patients with diabetic wounds includes: assessment of a patient’s vascular status and correction of any vascular problems in the affected limb if possible, optimization of nutritional status, optimization of glucose control, debridement by any means to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, appropriate off-loading, and necessary treatment to resolve any infection that might be present. Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days.

10. How does Palmetto define “no measurable signs of healing” in a diabetic wound of the lower extremity?

**Answer:** For a diabetic, no measurable signs and symptoms of healing would be reflected in the wound measurements, description of the wound (% of non-viable tissue, purulent drainage). If a wound was recently debrided between HBO sessions, then the wound bed may larger than the initial wound measurements. For open or diabetic wounds, documentation should include a description of the wound i.e. measurements, drainage (is it copious, is there a small amount of serous drainage, purulent drainage, does the wound contain any non-viable tissue, if it is stageable, then indicate the stage, the wound care being done i.e. wet to dry, aquacel, wound vac, etc.). You want to paint a picture of the beneficiary’s condition so the reviewer can have an idea of what is going on with the
beneficiary. Wounds must be evaluated at least every 30 days during administration of HBO therapy. Continued treatment with HBO therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

11. Is radiation proctitis covered under STRN?

**Answer:** No, HBO is not a reasonable and necessary treatment for radiation proctitis, especially if the patient did not manifest “soft tissue radionecrosis.” According to Up-to-Date, there have been a few small studies conducted that have shown some promise for the use of HBO for this condition. There are flaws in the studies and as such, do not constitute sufficient data to recommend this treatment. In fact, Up-to-Date publishes an extensive list of treatment recommendations for this condition and HBO is not among those Up-to-Date treatment recommendations. In addition, if the patient is not experiencing bleeding or pain and is responding well to other recognized treatments, i.e. hydrocortisone suppositories, radiofrequency ablation, sucralfate, etc. then HBO is not warranted. The primary reason for employing HBO if it were a recommended treatment for this condition; would be if the patient were refractory to all other treatments and had major symptoms such as significant pain and chronic blood loss.