



November 22, 2015

First Coast Service Options, Inc.
Medical Policy
532 Riverside Ave
ROC 19T
Jacksonville, FL 32202

Submitted electronically to: Medical.Policy@FCSO.com

RE: DRAFT Local Coverage Determination (LCD) for Hyperbaric Oxygen (HBO) Therapy
(DL36504)

Dear Dr. Corcoran:

On behalf of the Alliance of Wound Care Stakeholders (“Alliance”), we are pleased to submit the following comments in response to the draft local coverage determination for Hyperbaric Oxygen Therapy (HBOT) (DL35021). The Alliance is a nonprofit multidisciplinary trade association of physician medical specialty societies and clinical associations whose mission is to promote quality care and access to products and services for people with wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. These comments were written with the advice of Alliance clinical specialty societies and organizations that not only possess expert knowledge in complex chronic wounds, but also in wound care research. Many of our members utilize HBOT in their practices as an adjunctive therapy when treating a patient with a chronic non-healing wound and especially when treating patients with diabetic foot ulcers. As such, we have a vested interest in this policy. A list of our members can be found at www.woundcarestakeholders.org.

GENERAL COMMENTS

The Alliance appreciates that First Coast Service Option (FCSO) has drafted an LCD for HBOT. HBOT is a valuable treatment option for improving wound healing in patients with diabetes, radiation complications, compromised flaps and grafts, and complex non-healing wounds. HBOT has contributed to a decrease in the national amputation rate, as more patients have received advanced wound care, including HBOT, from a multidisciplinary team of providers. We support the need for safe and effective HBOT and the need for policies that minimize administrative burdens while still easy to implement and enforce. However, the draft policy contains confusing, inconsistent and incorrect information. For example, there are several areas in the draft policy in which FCSO

provides specific dose and frequency parameters which are contrary to current standards of practice. In addition, some of the evidence that FCSO has used to substantiate the provisions in this policy is outdated, contradicts existing evidence and is not relied upon by those physicians that perform HBOT for the treatment of covered HBOT indications. As a result, we highly recommend that FCSO revisit this draft LCD and clear up any inconsistencies, confusing language, inaccurate information, and outdated evidence prior to issuing this policy in final.

As a general observation, the Alliance has noticed that FCSO has identified treatment dosing and frequency throughout the draft policy. The treatment and dosing parameters are different throughout the document at not always based on evidence or clinical practice. The Alliance maintains that orders for HBOT are prescribed by the treating physician – who is HBOT credentialed and therefore the decision to treat their patients at a higher or lower pressure for varying treatment times should be determined by the patients condition and their co-morbidities and not arbitrary dosing and frequency parameters. As such, the Alliance recommends that FCSO allow qualified clinicians to determine what is best for their patient. The treating physician is best able to determine the treatment protocol and the pressure and duration of treatment.

SPECIFIC COMMENTS

Coverage Indications, Limitations and/or Medical Necessity

Specific Conditions: Diabetic Wounds

Language in the policy: Adjunctive treatment of an ulcer of the lower extremity deemed to be secondary to the neuropathic effects of diabetes will be allowed no more than 40 treatments (60-90 minutes daily) without documentation of improvement.

Concern: The adjunctive treatment of the diabetic foot ulcer (DFU) is not solely based on the neuropathic effects of diabetes, but also the vascular effects of diabetes. The dysvascular foot is the basis for the Wagner scoring system. The accepted number of treatments identified in this draft policy is based on the standards of practice as well as the evidence which suggests it is more appropriate for there to be 40 treatments. However, oxygen breathing times are not total treatment times. Most clinicians include a 10 minute pressurization time, a 10 minute depressurization time, and 2 5-minute air breaks in the treatment protocol. This results in a total treatment time of 120 – 150 minutes, of which 90 - 120 minutes is breathing 100% oxygen. As such the treatment time identified in the policy, 60-90 minutes daily, is insufficient.

Recommendation: The Alliance recommends deleting the language and instead allow for the clinician to appropriately determine the amount of treatment time their individual patient requires.

Language in the policy: 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.

AND

NOTE: Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days during which there is evidence of “optimization of wound healing” and there is no appreciable change in the wound. .

Concern: Failure to respond to standard wound therapy does not always manifest itself by a LACK of any healing, but by slow or delayed wound healing. The industry standard is to use a 4 week healing percentage to predict which wound will heal with standard care in 12 weeks, and which will not. If the wound area is not reduced by 50% in 4 weeks, there is a 91% probability the wound will not be healed in 12 weeks and therefore, more advanced care such as HBOT would be appropriate.¹ Additionally, the absolute lack of any evidence of improvement, such as reduction in necrotic tissue, some advancement of an epithelial border, or evidence of some granulation tissue is unreasonable, as some improvement is to be expected, although, a lack of significant improvement should be a trigger to the clinician to employ advanced modalities in these patients.

The inconsistency is highlighted by this analysis:

If patients do not have osteomyelitis, they must have a Wagner 3 or greater ulcer. That means that they are likely to have necrotic or gangrenous tissue. According to the LCD, gangrenous tissue must be debrided. The definition of “no measureable sign of healing” includes that there has NOT been a reduction in necrotic tissue. This means that debridement of gangrenous tissue would constitute a measureable improvement which mean that HBOT is not indicated. However, because necrotic tissue must be debrided, if you don’t do that, then the patient is not a candidate for HBOT. Therefore, according to the LCD they must have gangrenous tissue but must undergo debridement after which they no longer meet the requirement for HBOT.

Similarly, according to the draft LCD, there must be documentation of “maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings.” However, patients with gangrene or active osteomyelitis, do not, by definition, HAVE granulation tissue because if they did then the patient would not meet the definition of a Wagner 3, 4 or 5 DFU. Yet, if they do NOT have granulation tissue they are not a candidate for HBOT. If they develop granulation tissue this would be

¹ Sheehan P, Jones P, Caselli A, Giurini JM, Veves A. “Percent change in wound area of diabetic foot ulcers over a 4-week period is a robust predictor of complete healing in a 12-week prospective trial”. Diabetes Care 2003; 26:1879-1882

a measurable sign of healing which would mean HBOT is not needed. Therefore, they must both NOT have granulation tissue and must HAVE granulation tissue to justify HBOT.

Recommendation: The Alliance recommends replacing the language with:

Note: Failure to respond to standard wound care occurs when the wound area has not reduced by 50% or greater over 4 weeks of standard care. We also recommend deleting any reference to no measureable signs of healing. The Alliance further recommends that FCSO delete the language that “there must be documentation of a “moist bed of granulation tissue” for the reason identified above.

Language in the Policy: NOTE: An ankle brachial index of not less than .6 is considered the standard required for healing of a lesion on a diabetic’s foot. Alternative measurements of toe pressures, plethysmography or similar demonstration of small vessel perfusion may be considered if viable results can be obtained in the situation of calcified or non-compressible vessels of the foot and ankle. Transcutaneous oxygen measurements cannot predict whether a patient will respond to HBOT but may provide insight into the response to HBOT or revascularization. HBOT should not be used as a substitute for revascularization. Transcutaneous oxygen measurements consistent with inadequate local blood flow/tissue oxygenation expected to affect improvement, when treating diabetic wounds of the lower extremities, may establish lack of medical necessity to review.

Comment: We strongly support the intent of this policy to ensure proper vascular screening and to ensure that hyperbaric oxygen is not used as a substitute for appropriate revascularization. Guidelines published by the Wound Healing Society (WHS) state that all patients with lower extremity ulcers should be assessed for arterial disease. Thus, the Alliance agrees that vascular screening of patients with Diabetic Foot Ulcers (DFU) is imperative in order to identify patients who are candidates for revascularization. Current evidence shows that the ankle brachial index (ABI) is less reliable in predicting healing than transcutaneous oximetry, toe pressure or skin perfusion pressure due to the high likelihood of incompressible vessels. It is, unfortunately, the most commonly available screening tool. We support your statement that transcutaneous oxygen measurements alone cannot predict the response to HBOT but can predict response to revascularization. If patients have undergone revascularization and their transcutaneous oxygen values have increased to normal levels, they do not require HBOT because they are likely to heal spontaneously.² We are providing a paper which summarizes the use of TCOM in wound healing.³

Furthermore, the wording of this LCD does not follow the recommended use of TcOM.

Transcutaneous oximetry measures the oxygen partial pressure in the skin (TcPO₂). Fifteen studies (1137 patients) have demonstrated that TcPO₂ provides better overall predictive capability than Doppler studies or ABI at predicting whether a DFU will heal spontaneously. If TcPO₂ values are below approximately 40 mmHg, invasive vascular assessment is recommended. Once revascularization has been performed, if TcPO₂ increases by at least 30 mmHg, spontaneous healing

² Hanna GP, Fujise K, Kjellgren O, Field S, Fife CE, Schroth G, Clanton T, Anderson V, Smalling RW. Infrapopliteal Transcatheter Interventions for Limb Salvage in Diabetic Patients: Importance of Aggressive Interventional Approach and Role of Transcutaneous Oximetry. J Am Cardiol. 30:664-9, 1997.

is likely and HBOT is not needed.³

HBOT is reserved for patients whose vasculature has been optimized and whose baseline TcPO₂ is still below 40 mmHg. Among those patients, the best way to predict who will benefit from HBOT is to perform a TcPO₂ during the first hyperbaric oxygen therapy treatment. During HBOT, if the TcPO₂ is >200 mmHg, HBOT is likely to be of benefit. If TcPO₂ is <50 mmHg, HBOT is NOT likely to be of benefit.⁴

Recommendation: The Alliance recommends that a vascular evaluation on all non healing wounds should be part of the clinical algorithm and if possible, compromised blood supply to the area should be corrected prior to starting HBOT. However, TcOMs should not be utilized to predict whether patients will or will not respond to HBOT.

Finally, one of the Alliance member organizations, the Undersea and Hyperbaric Medical Society (UHMS), has provided comments in which it identified clinical inaccuracies within this draft LCD. We have reviewed their comments and agree with them. We urge FCSO to review and implement their recommendations.

Osteomyelitis

Language in the policy: Hyperbaric oxygen therapy is not considered medically necessary or appropriate treatment of osteomyelitis of small or non-weight-bearing bones of the forefoot and fingers (metatarsal bones, phalanges) which are more effectively treated with debridement.

Concerns: The Alliance is concerned that the above description is not anatomically or functionally correct. All of the bones of the toes and metatarsals are weight bearing and none of the bones in the fingers are weight bearing. The Alliance can not find a single reference that states that HBOT is less effective for the phalanges or metatarsals. These bones are necessary for the foot to function as a single unit. The LCD seems to “sacrifice” some bones deemed less important by FCSO, but not by any evidence. Osteomyelitis of any bone should be treated aggressively and HBOT is an adjunctive treatment, meaning that pharmaceuticals and surgical methods should be employed in addition to HBOT.

Recommendation: The Alliance recommends deleting the statement outlining which bones should or should not receive HBOT for osteomyelitis and instead state that “HBOT is an adjunctive treatment for osteomyelitis, which is a complex disease that requires a medical and/or surgical approach.”

³ Fife CE, Smart DR, Sheffield PJ, Hopf HW, Hawkins G, Clarke D. Transcutaneous Oximetry in Clinical Practice: Consensus Statements from an Expert Panel Based on Evidence. *Undersea Hyperb Med.* 36(1):43-53, 2009

⁴ Fife CE, Buyukcakilir C, Otto GH, Sheffield PJ, Warriner RA, Love TL, Mader J. The Predictive Value of Transcutaneous Oxygen Tension Measurement in Diabetic Lower Extremity Ulcers Treated with Hyperbaric Oxygen Therapy; a Retrospective Analysis of 1144 Patients. *Wound Rep Regen.* 10:198-207, 2002

Provider Qualifications /Certification

Language in the policy – the Scope of Practice for a physician supervising HBOT must include all components of patient evaluation necessary to evaluate the potential HBOT recipient and to ensure that there is no relative contraindication to treatment. The physician supervising HBOT should be both cognizant of the potential hazards of the therapy and have the capability of immediate and appropriate treatment of the complication should it arise. The Supervising Physician’s Scope of Practice shall include the training and expertise necessary to diagnose and treat the established complications of HBOT occurring while the patient is in the facility under his care.

Those entities include tension pneumothorax, respiratory decompensation secondary to aspiration, seizures, acute tympanic membrane injury, signs of oxygen toxicity and hypoxia as well as differentiation of these problems from anxiety or claustrophobia. All potential treatment of medical and surgical emergencies arising in the patient receiving HBOT must be within the scope of practice of the physician providing direct supervision who is immediately available throughout the HBOT session.

AND

Qualified Providers may supervise HBOT services, if such service including definitive evaluation of the patient is included within their State Scope of Practice, or if their required supervision or collaborative agreement is with a physician qualified to provide HBOT services who remains immediately available and if the provider meets the educational requirements identified herein

AND

Limited licensed providers performing hyperbaric medicine services must have an unlimited licensed physician who is also credentialed in hyperbaric medicine readily available to render assistance if needed

Concerns: 42 C.F.R. § 410.27(a)(1)(iv), expressly allows *non-physician practitioners* to supervise services that they may personally furnish in accordance with state laws and other requirements. CMS defines a “non-physician practitioner” to include, in pertinent part, physician assistants, nurse practitioners and clinical nurse specialists. Accordingly, under CMS regulations, non-physician practitioners, such as physician assistants, nurse practitioners and clinical nurse specialists, are permitted to supervise HBOT services in clinics, provided such services are within the non-physician practitioner’s scope of practice as defined in applicable state and other requirements.

Furthermore, podiatrists would be categorized as limited licensed physicians under this draft policy. We do not agree that these physicians need to have an unlimited licensed physician available in order to perform HBOT. Podiatrists currently supervise HBOT safely. The two certifying boards in podiatry, the American Board of Podiatric Medicine (ABPM) and the American Board of Foot and Ankle Surgery (ABFAS), include items on the board exam to evaluate a podiatrist’s knowledge on the indications of HBOT and emergency management, including complications of HBOT. Based on their training and their state practice act, podiatrists should be permitted to supervise HBOT services.

Recommendation: The Alliance recommends the following language be added to the draft LCD: Podiatrists as well as nurse practitioners, physician assistants and clinical nurse specialists may administer and/or supervise HBOT provided such services are within the purview of their state practice act as defined in state law.

Conclusion

On behalf of the Alliance of Wound Care Stakeholders, we appreciate the opportunity to submit these comments. If you have any questions or would like further information, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink that reads "Marcia Nusgart R.Ph." in a cursive script.

Marcia Nusgart R.Ph.
Executive Director