

CDR8: Appropriate use of hyperbaric oxygen therapy for patients with diabetic foot ulcers

MEASURE STEWARD:

Alliance of Wound Care Stakeholders and the US Wound Registry

This measure was developed via a consensus process in collaboration with the Undersea and Hyperbarics Medicine Society (UHMS) Quality Measure Committee.

DESCRIPTION:

Percentage of visits in which diabetic foot ulcers among patients aged 18 years and older received adequate off-loading during a 12-month reporting period.

NATIONAL QUALITY STRATEGY DOMAIN: Efficiency and Cost Reduction

MEASURE TYPE: Process

MEANINGFUL MEASURE AREA: Appropriate Use of Healthcare

HIGH PRIORITY: Yes

INVERSE MEASURE: No

TRADITIONAL MEASURE: Yes

PROPORTIONAL MEASURE: Yes

RISK ADJUSTED: No

of PERFORMANCE RATES: 1

NUMERATOR:

Diabetic foot ulcers graded stage 3 or higher on the Wagner Grading System for Diabetic Foot Infections that received HBOT appropriately.

Prior to receiving HBOT patients must have met the following criteria –

- Have a diabetic foot ulcer that has not achieved 30% closure after four weeks of treatment
- Adequate offloading of the diabetic foot ulcer at each visit for four weeks of treatment
- Vascular screening performed
- Measurement of BMI with follow-up MIPS #128

DENOMINATOR:

Diabetic foot ulcers receiving HBOT treatment during the reporting period

DENOMINATOR EXCLUSIONS/EXCEPTIONS

NONE

RATIONALE:

The purpose of this measure is to ensure that patients with DFUs who undergo hyperbaric oxygen therapy treatment have undergone the appropriate clinical work up and conservative plan of care beforehand and that the coverage policy established by Medicare for the use of this modality is adhered to. CMS continues to assert that there are too few Appropriate Use measures and has stated in the MACRA final rule that more are needed.

This measure was developed to mirror the key requirements of the LCD for hyperbaric oxygen therapy as it pertains to the coverage of HBOT for diabetic foot ulcers, a condition which CMS has now placed under a "prior authorization" pilot project (see the link to this information on the CMS website below). <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Prior-Authorization-Initiatives/Prior-Authorization-of-Non-emergent-Hyperbaric-Oxygen.html>. The guidance document for prior authorization is also being used for "pre-payment reviews" of HBOT services in many Medicare Administrative Carrier (MAC) jurisdictions.

This measure is a composite of several relevant quality measures including QCDR measures for vascular screening and off-loading, in order to encapsulate the prior authorization requirements for HBOT in a diabetic foot ulcer. EPs may wish to report this measure as a way to prepare for the expansion of prior authorization and/or pre-payment review programs of HBOT.

Gap in Practice:

In 2000, the OIG published a report called, "Hyperbaric Oxygen Therapy, Its Use and Appropriateness," in which it estimated that 32% of payments for HBOT were paid in error (\$14.2 million that year). A major reason for improper payment was failing to perform the appropriate tests or treatments before instituting HBOT (<http://oig.hhs.gov/oei/reports/oei-06-99-00090.pdf>). In 2013, a retrospective analysis of a large hyperbaric and wound care database by Margolis showed that 60% of the DFUs treated with HBOT were Wagner Grade 2, which confirms that Medicare coverage guidelines are still not being followed. Inappropriate use likely contributed to Margolis' findings that HBOT was not effective in healing diabetic foot ulcers or preventing amputation. Adherence to appropriate patient selection and treatment criteria are essential to the effectiveness of HBOT. HBOT is appropriate when the most severe DFUs have failed to improve after 4 weeks of conservative treatment, following appropriate vascular assessment (with revascularization if needed) and off-loading

Hyperbaric Oxygen Therapy has been demonstrated with highest AHA Level 1A evidence to be of benefit as adjunctive therapy for the healing of diabetic foot ulcers (DFUs). HBOT is often included in a comprehensive plan of care for patients with advanced diabetic foot ulcers even though it is not a type of wound care *per se*. HBOT works mechanistically by inducing angiogenesis and vasculogenesis within the microangiopathic wound. Among randomized controlled trials (RCT) performed for various forms of treatment for diabetic foot ulcers, only HBOT trials have included Wagner 3 or higher DFUs, giving it a unique place in the armamentarium of the wound care clinician for the most severe and limb threatening DFUs. However, neovascularization of the wound cannot be achieved if large vessel ischemia has not been assessed and optimally and repaired prior to initiating HBOT. **Thus, vascular assessment and should be done prior to initiating HBOT.** HBOT is also not effective if it is not part of a multidisciplinary approach to therapy with the concomitant use of treatments directed at all the impediments to healing. If optimally revascularized peripheral arterial disease, appropriate debridement, infection management, glycemic control and off-loading the wound are not maintained while HBOT is undertaken, the wound will not heal despite any success of HBOT in inducing good granulation tissue with neovascularization.

CLINICAL RECOMMENDATION STATEMENTS:

- HBOT is indicated for the treatment of Wagner grade 3 and higher DFUs

- HBOT is indicated for DFUs only after appropriate conservative care has failed to show adequate improvement in 30 days, per Medicare LCD
- Appropriate conservative care includes vascular screening (with revascularization if indicated) and off-loading

Evidence:

1. Londahl M, Katzman P, et al. Hyperbaric oxygen therapy facilitates healing of chronic foot ulcers in patients with diabetes. *Diabetes Care*. 2013;33(5):998-1003
2. Abidia A, Laden G, Kuhan G, et al. The role of hyperbaric oxygen therapy in ischaemic diabetic lower extremity ulcers: A double-blind randomised-controlled trial. *Eur J Vasc Endovasc Surg*. 2003;25:513-518.
3. Faglia E, Favales F, Aldeghi A, et al. Adjunctive systematic hyperbaric oxygen therapy in treatment of severe prevalently ischemic diabetic foot ulcer. A randomized study. *Diabetes Care*. 1996;19:1338-1343.
4. Doctor N, Pandya S, Supe A. Hyperbaric oxygen therapy in diabetic foot. *J Postgrad Med*. 1992;38:112-114.
5. Liu R, Li L, Yang M, et al. Systematic Review of the Effectiveness of Hyperbaric Oxygenation Therapy in the Management of Chronic Diabetic Foot Ulcers. *Mayo Clin Pro*. 2013;88(2):166-175.
6. Hopf HW, Kelly M, Shapshak D. (2008). Oxygen and the basic mechanism of wound healing. In: Neuman, T and Thom, S *Physiology and Medicine of Hyperbaric Oxygen Therapy*. Philadelphia: Saunders. 203-228.
7. Thom SR, Milovanova TN, Yang M, et al. Vasculogenic stem cell mobilization and wound recruitment in diabetic patients: increased cell number and intracellular regulatory protein content associated with hyperbaric oxygen therapy. *Wound Rep Regen*. 2011;19(2):149-161.
8. Carter MJ, Fife CE, Bennett M. Effectiveness of hyperbaric oxygen therapy as an adjunct procedure in the treatment of diabetic foot ulcers. *Diabetes Care* [letter]. 2013; (in press)
9. Brem H, Sheehan P, Boulton AJM. Protocol for treatment of diabetic foot ulcers. *Am J Surg*. 2004;187(5A):1S-10S.
10. Margolis DJ, Gupta J, Hoffstad O, et al. Lack of effectiveness of hyperbaric oxygen therapy for the treatment of diabetic foot ulcer and prevention of amputation. *Diabetes Care* 2013 Feb 19. [Epub ahead of print].