

USWR26: Patient Reported Outcome of late effects of radiation symptoms following treatment with Hyperbaric Oxygen Therapy (HBOT)

MEASURE STEWARD:

US Wound Registry

DESCRIPTION:

The percentage of patients 18 or older undergoing 10 or more treatments with HBOT for late effects of radiation whose self-reported symptoms improve by at least 2 categories on the appropriate questionnaire (e.g. the Hematuria classification scale, the Chandler grade, the Cystitis questionnaire, the Bowel questionnaire, the head and neck questionnaire).

NATIONAL QUALITY STRATEGY DOMAIN: Person and Caregiver Centered Experience and Outcomes

MEASURE TYPE: Outcome, High Priority

MEANINGFUL MEASURE AREA: Functional Outcomes

CARE SETTING: Outpatient Services

TRADITIONAL MEASURE: Yes

PROPORTIONAL MEASURE: Yes

RISK ADJUSTED: No

HIGH PRIORITY: Yes

INVERSE MEASURE: No

of PERFORMANCE RATES: 1

NUMERATOR:

The percentage of patients 18 or older undergoing 10 or more treatments with HBOT for late effects of radiation whose self-reported symptoms improve by at least 2 categories on the appropriate questionnaire.

DENOMINATOR:

All patients age 18 or older treated for late effects of radiation with at least 10 treatments of HBOT

DENOMINATOR EXCLUSIONS / EXCEPTIONS

EXCLUSIONS: Patients who receive fewer than 10 treatments

EXCEPTIONS: NONE

RATIONALE:

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