Appropriate Use of hyperbaric oxygen therapy for patients with diabetic foot ulcers

### MEASURE ID:CDR8

### **MEASURE DESCRIPTION:**

Percentage of patient with a diagnosis of a diabetic foot ulcer graded stage 3 or higher on the Wagner Grading System for Diabetic Foot Ulcers that received hyperbaric oxygen therapy (HBOT) appropriately, based on Medicare coverage criteria.

# **DENOMINATOR:**

Diabetic foot ulcers receiving at least one HBOT treatment during the reporting period

### NUMERATOR:

Diabetic foot ulcers graded stage 3 or higher on the Wagner Grading System for Diabetic Foot Ulcers that received HBOT appropriately. Appropriate use is defined as patients who, prior to receiving HBOT have met the following criteria:

• Have a Wagner Grade 3 diabetic foot ulcer that has not achieved 30% closure after four weeks of treatment

• Have been provided with adequate offloading of the diabetic foot ulcer at each visit for four weeks of treatment (USWR29)

• Have undergone an arterial assessment to evaluate the likelihood of healing (USWR30)

• HgbA1C control (MIPS Measure #001)

DENOMINATOR EXCLUSIONS: None DENOMINATOR EXCEPTIONS: None

NUMERATOR EXCLUSIONS: None

HIGH PRIORITY MEASURE: Yes

MEASURE TYPE: Outcome

NQS DOMAIN: Effective Clinical Care

SUBMISSION PATHWAY: Traditional MIPS **CARE SETTING:** Ambulatory Care: Clinician Office/Clinic; Ambulatory Care: Hospital

**PUBLISHED SPECIALTIES:** Podiatry; Wound Care; Other: Undersea and Hyperbaric Medicine

**PUBLISHED CLINICAL CATEGORY:** Undersea and Hyperbaric Medicine

INCLUDES TELEHEALTH: No

MEANINGFUL MEASURE AREA: Appropriate use of Healthcare

### MEANINGFUL MEASURE AREA RATIONALE:

An OIG report determined that a high percentage of HBOT treatments were given improperly. Currently there is nationwide implementation of Targeted Probe and Educate (TPE) and Recovery Audit Contractor (RAC) audits focused on whether Medicare coverage policy for HBOT is followed. HBOT is not used appropriately if provided to patients whose wounds were likely to heal without it or who have not been properly assessed for adequate vascular flow or undergone appropriate conservative treatment first.

**MEASURE CALCULATION TYPE:** Proportional Measure

NUMBER OF PERFORMANCE RATES: 1

**PERFORMANCE RATE DESCRIPTION:** Not provided

**INDICATE OVERALL PERFORMANCE RATE:** 1st Performance Rate

RISK ADJUSTED STATUS: No

CLINICIAN TESTED QCDR MEASURE: Yes

# **CLINICAL RECOMMENDATION STATEMENT:**

The Undersea and Hyperbaric Medical Society (UHMS) Guidelines Committee recommends patients with Wagner 3 diabetic foot ulcers that have not healed for 30 days have Hyperbaric Oxygen Therapy added to the Standard of Care to reduce the risk of major amputation and incomplete healing. 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 NCD (National Coverage Determination). Appropriate conservative care includes vascular screening (with revascularization if indicated) and off-loading.

**QCDR MEASURE RATIONALE:** 

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). In comparison to prospective trials of skin substitutes and Becaplermin, only prospective 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, arterial 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.

Although HBOT can be beneficial for DFUs, it is not always used appropriately. 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 (<u>http://oig.hhs.gov/oei/reports/oei-06-99-00090.pdf</u>). 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. (Lack of effectiveness of hyperbaric oxygen therapy for the treatment of diabetic foot ulcer and the prevention of amputation: a cohort study. Margolis et al. Diabetes Care. 2013 Jul;36(7):1961-6. doi: 10.2337/dc12-2160.)

Adherence to appropriate patient selection and treatment criteria are essential to the effectiveness of HBOT. 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. 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.

# **MEASURE PERFORMANCE DATA:**

Performance on this measure is generally poor, although the requirements involve the standard of care. Since 2018, the average performance rate has been 10% or less.