CDR 17: Outcome measure: Minor amputation (with preservation of prior ambulatory function) among patients with Wagner Grade 3, 4, or 5 Diabetic Foot Ulcers (DFUs) Treated with HBOT

MEASURE STEWARD:
US Wound Registry and the Undersea and Hyperbaric Medical Society (UHMS)

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

DESCRIPTION:
Percentage of diabetic foot ulcers among patients aged 18 years or older with the outcome of minor amputation within 12 months of completing a course of HBOT, stratified by the Wound Healing Index (WHI). Ulcers must be diagnosed as a Wagner Grade 3, 4, or 5 to quality for HBOT under current Medicare guidelines. Minor amputation preserves ambulatory function.

NUMERATOR:
Wagner Grade 3, 4 or 5 diabetic foot ulcers (DFUs) with an ulcer outcome of minor amputation after completing a course of HBOT, stratified by the DFU WHI, allowing the patient to retain their prior level of ambulatory function

Definition: Minor amputation is defined as an amputation on the toes or foot (no requirement to wear a prosthesis for ambulation).

DENOMINATOR:
DFUs among patients aged 18 years or older treated with 10 or more HBOT treatments during the reporting period. Ulcers must be diagnosed as a Wagner Grade 3, 4, or 5 to quality for HBOT under current Medicare guidelines.

DENOMINATOR EXCLUSIONS / EXCEPTIONS
EXCLUSIONS: Death within 12 months of completing a course of HBOT, Palliative care patients, patients with a major amputation, DFU patients with 10 or fewer HBOT treatments in a 30 day time frame.
EXCEPTIONS: NONE

RATIONALE:
The CDC estimates that 25.8 million people, or roughly 8.3% of the US population, are affected by diabetes. More than 60% of non-traumatic amputations occur in people with diabetes, and a foot ulcer precedes 85% of lower-limb amputations in patients with diabetes. Contralateral leg amputation follows for 56% of patients within 3-5 years, and the 5-year mortality rate for diabetic patients who have had a single-leg amputation is 60%. This figure is higher than the overall 5-year mortality rate of breast cancer (10%), bladder cancer (19%), colorectal cancer (33%), and all cancers combined (32%).

Examination of the evidence provides eight (8) randomized controlled trials (RCTs), over a dozen observational (OBS) studies, and several meta-analyses. These studies show that HBOT increases wound healing, decreases major amputation rates, increases healthcare related quality of life, and improves outcomes of DFUs. The systematic review and analysis of the HBOT literature regarding the treatment of DFUs using the GRADE methodology showed that HBOT is helpful in preventing major amputations and
promoting complete healing in patients with Wagner ≥3 diabetic foot ulcers who have undergone surgical debridement of the foot as well as in patients with Wagner ≥3 diabetic foot ulcers that have not healed after 30 days of conservative treatment. Data indicate that HBOT may reduce major amputations in exchange for an increase in minor amputations. However, minor amputations which preserve the patient’s current level of ambulatory function should be considered a successful outcome given the morbidity and mortality associated with both below the knee and above the knee amputations.

A recent study by Margolis raised questions as to the effectiveness of HBOT in the treatment of diabetic foot ulcers. However, a major criticism of this study was the challenge of stratifying such complicated patients by disease severity. In addition, this study was not able to distinguish between life changing major and minor amputations which preserved the patients’ ambulatory function. We realize that the value of HBOT to Medicare beneficiaries will be determined in large part by whether it improves quality of life years among patients with DFUs.

In order to assess the value of HBOT among diabetic foot ulcers, it is necessary to risk stratify DFUs. This will be accomplished using a validated tool called the Wound Healing Index for Diabetic foot ulcers. The predictive factors in the Diabetic Foot Ulcer Wound Healing Index can be obtained by answering the following questions:

**Diabetes WHI Components:**

1. Patient age in years (calculated from date of birth) at first treatment
2. Wound age (duration) in days (calculated from wound onset) at first encounter
3. Wound area in cm² (calculated from length x width) at first encounter
4. What is the patient’s primary ambulatory method? (walks unaided, cane, crutches, walker, roll about, scooter, wheelchair bound, bed bound)
5. Was the patient admitted to the hospital or the emergency department on the date of service?
6. How many total wounds or ulcers of any type does the patient have?
7. Does this wound have evidence of infection or bioburden? (evidenced by: purulent, green, malodorous drainage, peri-wound induration, tenderness to palpation, warmth)
8. Is the patient on dialysis or status post renal transplant?
9. What is the Wagner Grade of the ulcer (1-5)?
10. Does the patient have peripheral vascular disease (claudication, rest pain, abnormal arterial vascular studies, loss of pulses)?

The DFU HBOT outcome data reported by clinicians each quarter will be stratified using the WHI which contains both patient and wound factors. The goal is to understand the outcome of minor amputation among DFUs treated with HBOT, given the wounds’ predicted likelihood of healing. This knowledge will foster a better understanding of the effect of HBOT treatment number on minor amputation among patients with similar risk stratification, and whether there are risk categories of patients for whom HBOT is either not likely to be beneficial or should be prioritized.

**CLINICAL RECOMMENDATION STATEMENTS:**

The 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. Urgent HBOT should be added to the standard of care for patients with Wagner ≥3 diabetic foot ulcers who have had surgical debridement of an infected foot (e.g., partial toe or foot amputation, I&D of deep space abscess, necrotizing soft tissue infection) to reduce the risk of major amputation and incomplete healing.

REFERENCES: