
*Adequate Off-loading of Diabetic Foot Ulcers performed at each visit,
appropriate to location of ulcer*

MEASURE ID: USWR 29

MEASURE DESCRIPTION:

Percentage of visits in which diabetic foot ulcers among patients aged 18 years and received adequate off-loading during a 12-month reporting period, stratified by location of the ulcer. Off-loading is not a simple documentation process but may include performing a procedure such as Total Contact Casting or providing appropriate footwear. The location of the diabetic foot ulcer on the foot (e.g., heel/midfoot vs. toes) determines the type of off-loading device that is appropriate, the patient's risk of falling, the probability of successful off-loading and thus the likelihood of major amputation. The clinician needs to evaluate these factors and then provide the most appropriate off-loading option.

DENOMINATOR:

All visits of diabetic foot ulcers among patients aged 18 years and older

NUMERATOR:

Visits in which diabetic foot ulcers receive adequate off-loading at each visit during the 12-month reporting period

DENOMINATOR EXCLUSIONS:

Palliative care, hospice

DENOMINATOR EXCEPTIONS:

Adequate off-loading not prescribed for Medical, Patient or System Reasons such as the affected extremity has been amputated or the patient is in palliative care.

NUMERATOR EXCLUSIONS:

None

HIGH PRIORITY MEASURE:

No

MEASURE TYPE:

Process

NQS DOMAIN:

Effective Clinical Care

SUBMISSION PATHWAY:

Traditional MIPS

PUBLISHED SPECIALTY:

Plastic & Reconstructive Surgery; Podiatry; Wound Care

PUBLISHED CLINICAL CATEGORY:

Wound Care

CARE SETTING:

Hospital Outpatient; Ambulatory Care: Hospital; Ambulatory Care: Clinician Office/Clinic

INCLUDES TELEHEALTH:

No

MEANINGFUL MEASURE AREA:

Management of Chronic Conditions

MEANINGFUL MEASURE AREA RATIONALE:

Diabetic foot ulcers are a chronic medical condition affecting perhaps 50% of diabetics and when incorrectly managed are the second most common cause of amputation in the USA. Off-loading of diabetic foot ulcers is the standard of care for treatment of these problems.

MEASURE CALCULATION TYPE:

Proportional Measure

NUMBER OF PERFORMANCE RATES:

3

PERFORMANCE RATE DESCRIPTION:

There are three rates reported for this measure. The three rates will be risk stratified into two anatomical location groupings based on ICD-10 codes and a combined group which are the following: Rate 1: Midfoot/heel Rate 2: Toes Rate 3: The average of the two risk stratified buckets which will be the performance rate in the JSON or XML file submitted.

INDICATE OVERALL PERFORMANCE RATE:

3rd Performance Rate

RISK ADJUSTED STATUS:

No

CLINICIAN TESTED QCDR MEASURE:

Yes

FEASIBILITY TESTING SUMMARY:

In 2012, the USWR piloted a per visit DFU off-loading measure in 6 hospital-based outpatient wound centers as part of the USWR “Do the Right Thing™” initiative. The impact on patient care was dramatic. In an article published in 2013, within these 6 clinics, DFU off-loading at each visit increased from 11.7% to 69.2%. None of these projects had funding from any source, including the pilot testing of the “per visit” measure. The small size of off-loading studies continues to prevent them from being eligible for NQF endorsement, but since wound care lacks the funding of pharmaceutical trials, larger studies will not be forthcoming. Fife CE. Measuring Quality in Wound Care. Today’s Wound Clinic. Volume 7 Issue 1 - January/February 2013; 9-12. <http://www.todayswoundclinic.com/articles/measuring-quality-wound-care> Carey D. Proving Your Quality-of-Care Compliance. Today’s Wound Clinic. January/February 2013: 12-18. <http://www.todayswoundclinic.com/articles/proving-your-quality-care-compliance-case-study>

CLINICAL RECOMMENDATION STATEMENT:

- Adequate off-loading increases the likelihood of DFU healing.
- There currently exists a “gap” between the evidence supporting the efficacy of DFU off-loading and what is performed in clinical practice.

- Evidence consistently shows that when off-loading is integrated into the patient encounter process and provided at each visit, the likelihood of DFU healing increases and the chance of complications decreases. (off- loading consensus guidelines, JAPMA Vol. 104.(6) 2014.)

MEASURE PERFORMANCE DATA:

In 2020, the average performance rate of DFU off-loading at each visit for the entire group was 56% with performance ranging from 33% to 100% over the 12-month calendar year.

QCDR MEASURE RATIONALE:

CMS is seeking measures which may help decrease amputation rate among diabetics. Offloading the pressure from a diabetic foot ulcer reduces amputation rate by allowing the wound to heal by secondary intention because pressure is a causal factor for neuropathic foot ulcers. The gold standard is total contact casting (TCC) in which the entire foot is enclosed in a solid structure that is retained until the wound is healed. This is a procedure which is performed during the patient’s visit. However, for many valid medical and patient centered reasons, TCC may not be feasible or appropriate. In those cases, the foot may be padded with felt and foam in the clinic (a “football wrap”) or the patient’s own shoe may be modified by the practitioner. If the wound is on the non-weight bearing surface of the foot, other methods of protection may be more superior to a TCC including something as simple as a cast shoe for lesions on the top of the toe. These are typically provided by the practitioner during the visit.

Principle: In a review of 9 randomized controlled trials of total contact casting (TCC), TCC healed 89% of DFUs on an average of 43 days. Thus, the process of off-loading has been directly linked to the outcome of DFU healing from multiple RCTs. Furthermore, patients treated with TCC experienced a higher percentage of healed ulcers in a shorter period of time than with other advanced therapeutics based on RCTs for other interventions, although direct comparisons with other advanced therapeutics have not been performed since no advanced therapeutic should be used in the absence of appropriate off-loading. When the patient has moderate or severe ischemia, TCC is contraindicated. Additionally, for foot ulcers on the dorsal foot or toes, other protective devices may be superior. An alternative to total contact casting is a removable device such as a CROW walker which still maintains ankle immobility. For patients who are able to use them properly, crutches may be effective. For patients who do not ambulate, the use of a wheelchair may provide effective offloading. Evidence Based Off-Loading Devices

A 2014 consensus statement with a systematic review of the literature ranked the overall strength of evidence for diabetic foot ulcer off-loading as moderate. However, off-loading is widely considered the single most important intervention necessary to accomplish wound healing in the management of the diabetic foot ulcers (1-13). Offloading methods with published studies to support their effectiveness include the options listed below, depending on the location of the ulcer. Generally, a cast shoe will only be acceptable off-loading for ulcers on the dorsal toes. Reverse IPOS, L’NARD splints, and patella tendon-bearing braces will useful only for posterior heel ulcers. Total Contact Casts are placed whenever possible. Some devices require fitting by a prosthetist. The following options may work for ulcers on any area of the foot with certain restrictions known to foot experts: • Total contact cast (any brand) • CROW (Charcot Restraint Orthotic Walker) • DH walker • CAM boot • Air cast • Half wedge shoe • Diabetic shoe • Shoe modification (customized temporary footwear) • Felt and foam • Prefabricated walker • Healing sandal • MBAL shoe

The panel was deeply concerned that the 5-year mortality rate of diabetics after an amputation is 45%, and 85% of lower extremity amputations are preceded by a diabetic foot ulcer. Because DFUs are a major and costly complication of diabetes that can reduce quality of life and result in amputations and death, and because published data clearly demonstrated the gap between evidence and practice with regard to the use of off-loading in the treatment of DFUs, a consensus on the use of off-loading was

needed. The panel developed the following evidence-based recommendations which were published in the Journal of the American Podiatric Medical Association.

STUDY CITATION:

- Fife CE, et al. Diabetic foot ulcer off-loading: The gap between evidence and practice. Data from the US Wound Registry.” *Adv Skin Wound Care*. 2014 Jul; 27(7):310-6.
- Fife CE, et al. Why Is it So Hard to Do the Right Thing in Wound Care? *Wound Rep Reg* (2010) 18 154–158.
- Snyder RJ, et al. The Management of Diabetic Foot Ulcers through Optimal Off-loading. Building Consensus Guidelines and Practical Recommendations to Improve Outcomes. *Journal of the American Podiatric Medical Association*. Vol 104. No. 6. Nov/Dec 2014.