

**CDR3: Process measure: Plan of Care Creation for Diabetic Foot Ulcer (DFU) and Venous Leg Ulcer (VLU) not Achieving 30% Closure at 4 Weeks after undergoing treatment with CTP**

**MEASURE STEWARD:**

Alliance of Wound Care Stakeholders and the US Wound Registry

This measure was developed via a consensus process in collaboration with the Alliance of Wound Care Stakeholders Member Organizations, which include 16 wound care related clinical associations.

**DESCRIPTION:**

A plan of care needs to be created for patients that fail to achieve 30% of wound closure within 4 weeks of the application of the first CTP, and will include review of whether appropriate usual care has been implemented as well as whether further CTP applications are indicated.

**NATIONAL QUALITY STRATEGY DOMAIN:** Effective Clinical Care

**MEASURE TYPE:** Process

**MEANINGFUL MEASURE AREA:** Care is Personalized and Aligned with Patient's Goals

**TRADITIONAL MEASURE:** Yes

**PROPORTIONAL MEASURE:** Yes

**RISK ADJUSTED:** No

**NUMERATOR:**

Diabetic foot ulcers or venous leg ulcers among patients aged 18 years or older treated with any cellular and/or tissue based product (CTP) which did not achieve 30% of wound closure (by surface area) within 4 weeks of the first CTP application for which a plan of care was created.

Appropriate Usual Care of DFUs and VLUs:

1. MIPS measure #1 (hemoglobin A1c measure <9)
2. MIPS measure #226 for Tobacco screening and cessation
3. MIPS measure #128 for BMI screening
4. Vascular screening
5. Adequate off-loading documented for each visit
6. Management of possible infection of a DFU
7. Diagnosis of osteomyelitis in a DFU
8. Antibiotics for infected DFU
9. Nutritional Counseling
10. Debridement of necrotic tissue

**DENOMINATOR:**

Diabetic foot ulcers or venous leg ulcers among patients aged 18 years or older treated with any cellular and/or tissue based product (CTP) which did not achieve 30% of wound closure (by surface area) within 4 weeks of the first CTP application.

**DENOMITOR EXCLUSIONS:** NONE

**EXCEPTIONS:** NONE

**RATIONALE:**

Multiple studies show that the percentage of closure of a chronic ulcer after approximately 4 weeks of care (30 days) is predictive of final healing. Sheehan and colleagues looked at the rate of wound closure for DFUs and found that if the wound had not closed by at least 50% over 4 weeks, there was a 91% chance it would not heal in 12 weeks. (Sheehan P, Jones P, Caselli A, Giurini JM, Veves A. Percent change in wound area of diabetic foot ulcers over a 4-week period is a robust predictor of complete healing in a 12-week prospective trial. *Diabetes Care* 2003 June 1;26(6):1879-82). Thus, % closure at 4 weeks can be used as a surrogate for healing likelihood and to trigger an evaluation for more advanced therapeutic interventions. In fact, the majority of local coverage determinations by Medicare Administrative Carriers use the “30 day failure rate” to determine whether more costly interventions are warranted. These policies reflect published evidence and clinical practice guidelines by many wound care societies. USWR data show that many wounds actually get larger after they are first documented, usually due to debridement. Thus, to account for this factor as well as studies which suggest a slower rate of closure among patients with multiple co-morbid diseases, we have suggested creating a “plan of care measure” based on a 30% reduction in wound surface area at 4 weeks. DFUs which fail to achieve this should undergo a re-assessment of the plan of care with consideration being given to the use of an advanced therapeutic.

**GAP IN PRACTICE:**

US Wound Registry data demonstrate that the average time to chronic wound healing is 6 months with 10% of healed patients take more than 8 months to achieve healing. Perhaps as many as one third of chronic wound patients never achieve healing at all even though they are followed for more than one year in a hospital based outpatient setting (*Wound Care Outcomes and Associated Cost Among Patients Treated in U.S. Outpatient Wound Centers: Data from the U.S. Wound Registry, Fife, et al. Wounds* 2012; 24(1) 10-17). These poor outcomes may be due to patient severity, but may also be due to failure to properly supervise and aggressively implement advanced therapeutic interventions. The goal of this measure is to prevent supervised neglect, a type of care in which patients receive regular follow-up, but the treating physician provides therapies that are ineffective. (International Center for Limb Salvage (ICLS), Geneva [www.gfmer.ch/ICLS/Homepage.htm](http://www.gfmer.ch/ICLS/Homepage.htm)).

**EVIDENCE:**

1. Wound Healing Society Guidelines - If an ulcer does not reduce by 40% or more after four weeks of therapy, re-evaluate the patient and consider other treatments. [http://www.woundheal.org/index.php?option=com\\_content&view=article&id=180](http://www.woundheal.org/index.php?option=com_content&view=article&id=180)
2. A reduction in wound area of 10 – 15% per week represents normal healing and does not mandate a change in the current wound-healing strategy. However, if this level of wound area reduction is not met consistently on a weekly basis, then alternative healing interventions should be considered. (Clinical Approach to Wounds: Debridement and wound bed preparations including the use of dressing and Wound-Healing Adjuvants, Attinger, et al, *Plastic and Reconstructive Surgery* April 4, 2006 [www.plasreconsurg.org](http://www.plasreconsurg.org))

3. Medicare coverage policy with WPS states: A wound that shows no improvement after 30 days requires a new approach which may include physician re-assessment of underlying infection, metabolic, nutritional, or vascular problems inhibiting wound healing or a new treatment.
4. Sheehan P, Jones P, Caselli A, Giurini JM, Veves A. Percent change in wound area of diabetic foot ulcers over a 4-week period is a robust predictor of complete healing in a 12-week prospective trial. *Diabetes Care* 2003 June 1;26(6):1879-82.
5. Warriner RA, Snyder RJ, Cardinal MH. Differentiating diabetic foot ulcers that are unlikely to heal by 12 weeks following achieving 50% percent area reduction at 4 weeks. *Int Wound J* 2011;8:632–7.