**CDR 7: Process measure: Plan of Care for Venous Leg Ulcer Patients not Achieving 30% Closure at 4 Weeks**

**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:**
Percentage of patients aged 18 years or older with a diagnosis of venous leg ulcer for whom a plan of care was not created if they failed to achieve 30% of wound closure within 4 weeks. The plan of care will include a review of whether appropriate usual care has been implemented as well as whether an advanced therapeutic is indicated.

**NUMERATOR**
Those venous leg ulcers not achieving desired closure percentage at 4 weeks for which appropriate usual plan of care was created:

- **Appropriate Usual Care for Venous Leg Ulcers:**
  1) Moist Wound care has been provided
  2) Debridement of Necrotic Tissue
  3) Nutritional Assessment Performed
  4) Nutritional Issues addressed
  5) Optimal Compression documented
  6) Management of Infection
  7) Vascular Status optimized as far as possible

**DENOMINATOR:**
Venous leg ulcers of patients age 18 or older seen during the measurement period that did not achieve 30% closure at 4 weeks of treatment.

**DENOMINATOR EXCLUSIONS/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. 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 a measure based on a 30% reduction in wound surface area at 4 weeks rather than 40% as supported in the literature to provide more time for clinicians and patients to fully engage an initial plan of care. VLUs which fail to achieve 30% closure at 4 weeks this should undergo an assessment regarding the impediments to healing (e.g. whether appropriate conservative care has been properly implemented)
and consideration as to whether an advanced therapeutic intervention is warranted. Advanced therapeutics which can be considered include negative pressure wound therapy (NPWT), bioengineered tissue also referred to as cellular and tissue based products, pneumatic compression, various surgical interventions, and other treatments depending on the ulcer severity, patient co-morbid conditions and patient preferences.

**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](http://www.woundheal.org/index.php?option=com_content&view=article&id=180)). 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](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](http://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. 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.

   Association for the Advancement of Wound Care (AAWC) venous ulcer guideline

4. Leg ulcers that fail to improve within 6 weeks despite consistent evidence-based treatment may not be caused by venous insufficiency. Consider biopsy for histological diagnosis, or other procedures to identify suspected malignancy, vasculitis, pyoderma gangrenosum, mycobacterial or fungal infection or other atypical etiologies ([Combemale et al., 2007; Schnirring-Judge & Belpedio, 2010; Shelling, Federman, & Kirsner, 2010](http://www.woundheal.org/index.php?option=com_content&view=article&id=180)) (Evidence Level = C2)
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.

