***CDR9: Appropriate use of Cellular and/or Tissue Based Product (CTP) in diabetic foot ulcers (DFUs) or venous leg ulcer (VLUs) among patients 18 years or older***

**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 Organization, which include 16 wound care related clinical associations.

**DESCRIPTION:**
Percent of patients 18 or older with venous or diabetic foot ulcer who receive cellular and/or tissue based products (CTPs) appropriately. Appropriate Use of CTPs for a DFU or VLU is defined as use that adheres to Medicare coverage policy regarding the total number of applications over a specific time frame. While various Medicare policies indicate that a typical episode of care for a wound is 12 weeks, US Wound Registry data indicate this time frame is much too short. Additionally, the majority of patients have more than one wound. Coverage policies do not provide the guidance necessary to address all of these issues in our measure. Therefore, we will use a per wound basis, and assume the episode is the reporting period.

**NATIONAL QUALITY STRATEGY DOMAIN:** Effective Clinical Care
**MEASURE TYPE:** Process
**MEANINGFUL MEASURE AREA:** Appropriate Use of Healthcare

**TRADITIONAL MEASURE:** Yes
**PROPORTIONAL MEASURE:** Yes
**RISK ADJUSTED**: No

**NUMERATOR:**
Those ulcers that have received treatment with CTP appropriately. Regional Medicare Administrative Carrier (MAC) policies differ but using the most restrictive Local Coverage Determination (LCD), approrpriate use is defined as:

- No more than 10 applications per wound
- CTP applications do not continue if the wound is unchanged in size or larger in size after 4 weeks have elapsed from the first application
- CTP applications do not continue once the wound is 0.5 cm2 or smaller.

**DENOMINATOR:**
Venous Leg Ulcers or Diabetic Foot Ulcers of patients age 18 or older that have received treatment with at least one CTP application.

**RATIONALE:**
A variety of terms have been used to describe cellular and/or tissue based products in the past including “Allografts,” “Skin Substitutes,” “biologic products,” and “bioengineered tissue. CTP has been accepted by the ASTM (American Section of the International Association for Testing Materials). The products referred to in this measure contain viable or non-viable cells and/or are derived from biological tissue. CTPs are considered medically necessary when wounds, for myriad reasons, fail to close or fail to

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progress through healing stages in a timely fashion, increasing complications and costs. These products stimulate or support healing through incorporation in whole or part into the regenerating tissue by stimulating and augmenting the wound's intrinsic healing pathways. CTPs are distinguished from "dressings" which must be physically removed periodically and which function primarily to help shield the wound against the environment without exerting any direct biological effect.

Prior to the application of a CTP, patients should undergo vascular assessment to exclude ischemia, control bioburden, and debride necrotic material, as well as provide other appropriate basic interventions such as compression of a venous ulcer or off-loading of a diabetic foot ulcer. Excellent consensus guidelines support the above approach as a way to appropriately use these advanced therapeutics and thus ensure that they are provided in a cost effective manner.

**Gap in Practice:**
Data from the USWR suggest that patients with VLUs receive cellular and/or tissue based products but may not undergo adequate compression. Similarly patients with DFUs may undergo treatment with these products without undergoing adequate off-loading. Unpublished data from the USWR suggests that only about 10% of DFU patients undergo any type of vascular assessment with ABI, transcutaneous oximetry or skin perfusion pressure although as a result of the USWR vascular screening quality measure, the percentage of patients with leg ulcers undergoing vascular screening is improving.

Currently the benchmark rate is only 23% which is what would be expected given the variability in both vascular screening and off-loading. We believe that this measure will increase in popularity due to Medicare audits of appropriate use of CTPs. We encourage providers to utilize this measure as part of clinical practice improvement activities.

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