

CDR 9: Appropriate use of Cellular and/or Tissue Based Product (CTP) in diabetic foot ulcers (DFUs) or venous leg ulcer (VLUs)

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 derived products appropriately as demonstrated by meeting all of the numerator targets of this problem and patient level composite measure: venous ulcer or diabetic foot ulcer did not achieve 30% closure within 4 weeks, patient underwent vascular screening, wound bed preparation with debridement of necrotic tissue, venous ulcer had adequate compression at each visit and diabetic foot ulcer had adequate off-loading at each visit.

NUMERATOR:

Those ulcers that have received treatment with CTP appropriately:

Prior to receiving treatment with CTP diagnosed VLUs and DFUs must have met the following criteria –

- Not achieved 30% closure after four weeks of treatment
- Wound bed preparation with debridement of necrotic material
- VLU: Adequate compression therapy at each visit for four weeks of treatment
- DFU: Adequate offloading of the diabetic foot ulcer at each visit for four weeks of treatment
- Vascular screening performed

DENOMINATOR:

Venous Leg Ulcers or Diabetic Foot Ulcers of patients age 18 or older that have received treatment with CTP.

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 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.

EVIDENCE:

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