Open meeting skin substitute draft LCD speaking points

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Bullet Point List for FCSO/Novitas LCD DL36377-Treatment of Diabetic and Venous leg Ulcers

1. Coverage Guidance

* Stop calling these skin substitutes. Confirm language with ASTM to refer to all products in this category of coverage as CELLULAR TISSUE PRODUCTS for WOUNDS.
* Para 4: “Current Position is that….surgical supplies”.
* Issue: No reference to that being the policy of DMERC or Noridian in their initial determination of HCPCS coding
* Just because there is a surgical application does not necessarily make it a surgical supply (i.e. catheters for arterial angioplasty, shunts for hydrocephalus, etc.)
* Para 8: “Chronic Wounds…”
* Stay consistent with messaging. Chronic wounds may include DFU and VLU, but may also include other wounds of other etiologies.
* 1 to 3 months is too variable. Is it 1 month (industry standard of care) or 3 months? The policy is vague and needs clarification. All of the evidence that has preceded this policy states 30 days of non-healing equivocates chronic DFU/VLU.

1. Covered Indications

* Item 1: Inconsistent with language in policy – stated 4 weeks for DFU but have 1-3 months as coverage guidance.
* Item 2: Inconsistent with language in policy – stated 4 weeks for VLU but have 1-3 months as coverage guidance.
* Item 3: VCSS was developed as a result of the inadequacies of the CEAP classification. The contractor should be specific as to which measurement system they want in the clinical record. It is confusing to providers to have to have 2 separate VLU documentation systems to approve coverage.

1. Limitations

* Item 1: Huge issue. “Greater than 2 applications of a skin substitute….”
* Most of these items approved by the FDA are weekly applications. The clinical severity of minimized applications for specific product indications is harmful to the patient. The increased risk of infection, exudate, contamination and failure of the wound to progress to healing increases. This language is inflammatory to the provider and creates an issue whereby the patient will undergo the following:
* Admission to hospital (increase cost of care)
* Admission to outpatient surgery (increase cost of care)
* Admission for outpatient IV antibiotics (increase cost of care)
* Need for additional specialist interventions (increase cost of care)

1. Excessive wastage

* It is not up to the provider to decide which products are stocked at HOPD departments and what contracted pricing each system/supplier is using. Sometimes it is not feasible to always use the smallest size product because of SKU/stock issues with a hospital’s buying system and storage.

1. Summary of Evidence

* Introduction
* At issue is the use of terminology of “pressure ulcers” and “Wounds” used in the policy language. This is confusing for providers as pressure ulcers have completely different etiology than those of DFU and VLU.
* Evidence-Based Guidelines for SOC
* Para 3: “…ABI is below 0.9”.
* There is no reference for this evaluation. The contractor needs to provide the required reference for this determination.
* The contractor has also stated that “To supplement ankle-brachial studies…” are we to question that this is going to be a case-by-case decisional process that the contractor MAY require SPP, TCOM, Toe Pressures, etc. and in some cases not? This will cause increased confusion with providers.
* Para 4: “…Venous plethysmography is recommended”. This also is unclear as there is no definitive evidence that use of VP in patients with active VLU provides ANY useful diagnostic information to help heal the wound. It is usually not a required diagnostic service for VLU treatment. It is more important to use VP in ARTERIAL vessels when evaluating a DFU vs. PAD.
* Para 7: “…SOC treatment schedule for DFU that includes weekly to monthy…” This is not accurate. SOC treatment schedule should be WEEKLY or twice weekly to maintain SOC.
* Para 7: “…HbA1c < 7%...” this is also problematic as there is no diabetic patient that has routine HbA1c < 7% with a DFU. Also there is significant evidence that there is increased mortality in diabetics with A1C levels < 7.5%.

Sources:

* LeRoith D, Biessels GJ, Braithwaite SS, et al. Treatment of Diabetes in Older Adults: An Endocrine Society\* Clinical Practice Guideline. J Clin Endocrinol Metab 2019; 104:1520.
* International Diabetes Federation. Managing older people with type 2 diabetes, Global Guideline https://www.idf.org/sites/default/files/IDF%20Guideline%20for%20Older%20People.pdf (Accessed on February 24, 2014).
* Riddle MC, Gerstein HC. Comment on Hempe et al. The hemoglobin glycation index identifies subpopulations with harms or benefits from intensive treatment in the ACCORD trial. Diabetes Care 2015;38:1067-1074. Diabetes Care 2015; 38:e170.

1. Technology Assessment

* In all of the assessments, it was painfully clear that real-world evidence and lack of use of the 21st Century Cures Act was utilized. There was no evidence that the contractor used in their technology assessment that reflected Registry data, Claims Data or use of Real-World data studies in their analysis. All studies used were RCT designs, impacted greatly by the specificity of “industry sponsored studies”. Out of all the clinical research available, the contractor only utilized 3 systematic reviews and 22 RCTs of only 16 products. It is evident that the contractor biased its own policy by negating the use of federal law to emphasize its own findings.

It is also evident that the contractor does not accurately understand the wound healing paradigm and the providers that service these beneficiaries. The contractor also has not reached out to stakeholder groups in Florida or individual practitioners they are aware of who are industry experts in these matters to help craft a singular sense-worthy policy. Instead, the contractor has delivered a document that is rife of errors, factually inaccurate and provocative in nature. This policy as a whole determinately will harm patients of these populations and will lead to an increase in the cost of care, not a decrease.