COALITION OF

Wound Care Manufacturers

November 18, 2022

Meredith Loveless, MD
Medical Director
Cigna Government Services
Attn: Medical Review
26 Century Blvd.
Ste ST610
Nashville, TN 37214-3685

RE: Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers" (D36690 and DA 56696)

Submitted electronically to cmd.inquiry@cgsadmin.com

Dear Dr. Loveless,

On behalf of the Coalition of Wound Care Manufacturers ("Coalition") I am pleased to submit comments on the draft LCD for Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (DL366901) and the accompanying Local Coverage Article-Billing and Coding: Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (DA56696). Founded in 2000, the Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds. Our members manufacture cellular and or tissue-based products for skin wounds (CTPs) – also referred to as "skin substitutes" – and therefore have a vested interest in ensuring that this policy is clinically sound and based on evidence.

The Coalition has major concerns with the proposed LCD and LCA. To begin, CGS has created an LCD and LCA that is virtually verbatim to what was issued by Novitas and First Coast. With all due respect, the Coalition would have hoped that in mirroring other MAC draft policies, CGS would have done its own due diligence to ensure that the language contained in their draft would be based on the evidence cited and on sound clinical practice. Unfortunately, as with the Novitas and First Coast drafts, the evidence that has been utilized in the draft CGS LCD is either not the most currently available or is used in such a way that is contradictory to the provisions of the LCD. Furthermore, the policy is fraught with clinical inaccuracies that ultimately will be detrimental to patient care. In fact, Novitas and First Coast notified several organizations – including the

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Coalition - that based on our feedback they are making substantive changes to their policy and article. So, provisions in the CGS draft will no longer mirror the policy that this draft sought to emulate.

There is also language contained in the draft stating that the draft policy was written in order to be more uniform with other MAC jurisdictions. However, most of the provisions in this policy are in fact not uniform with other MAC jurisdictions including but not limited to: the application limitation, smoking cessation timeframes, the notion that CTPs are surgical supplies and the definition of what constitutes a chronic non healing wound.

The Coalition recommends that CGS pull this draft, work with stakeholders and its Contractor Advisory Committee (CAC) to craft a more clinically accurate policy that is based on the most currently available evidence so that patient care will not be negatively impacted.

Specific areas in which the Coalition is extremely concerned and believe CGS could have benefitted from CAC and stakeholder involvement include but are certainly not limited to the following:

Application Limitation Over A 12 Week Time Frame

Under the Limitations section in the LCD, CGS allows only 4 applications of a specific product. We submit that this is an arbitrary application limitation that is not based on the evidence in general nor is it based on any evidence cited in the policy itself.

In fact, the evidence cited in this policy either shows the number of applications to be higher than the four applications permitted under this draft policy or is very clear that the number of applications should be based on the labeling instructions for the specific product being used.

More specifically, the number of applications cited in the evidence largely exceeds the application limitation cited in this policy and is based on individual product studies as the number of applications is not located on product labels. Furthermore, the 4 application limitation is also contrary to several provisions stated in the policy in which CGS specifically states that the labeling instructions need to be followed. If the labeling instructions are followed in the 12 weeks cited in this policy, the number of applications would surely exceed the 4 application limitation.

CGS has stated that their intention in creating this draft was so there is consistency in coverage across the MAC jurisdictions. If this is indeed true, there have been some provisions that have consistently been adopted not only by the MACs but private payers that CGS has ignored. Specifically, consistently both Medicare and private payers have held to a 10 application or higher limitation in a 12 week period of time and while not every patient will require the maximum, there are also patients that may require more. [i], [ii]

,[iii] ,[iv] We question the rationale that CGS used to would move away from utilization parameters that are already consistent and used by other payers, to create an arbitrary application limitation that is not based on the evidence.

Not only is there is no clinical evidence that supports the 4 application limitation but the reliance on the median/average number of applications limits access to a successful and medically necessary advanced treatment option for patients who potentially are trying to avoid an amputation.[v] This is extremely problematic. The draft policy is not a scientifically sound policy and not evidence based. If CGS were to finalize the LCD as proposed with the 4 application maximum, a large percentage of Medicare beneficiaries would not receive the additional applications needed for complete wound closure as the evidence suggests.

As such, the Coalition recommends that CGS maintain – for consistency sake - the 10 application limitation in a 12 week period of time. This recommendation is consistent with, and a continuation of, the language in the currently active CGS LCD. Furthermore, there should be allowances for patients that require additional applications of CTPs to achieve wound closure. Should a minority of patients be required to go over this limitation then CGS could require providers to utilize the KX modifier on the claim form and provide documentation as to why they believe it is medically necessary and reasonable for the patient to obtain additional applications. Additionally, language should be stated in the policy – as is the case in other policies including CGS – that not every patient will require the maximum number of applications.

Tissue Reference Group

The Coalition has serious concerns that in addition to the complete and total disregard to what the evidence cited in these draft policies actually states, CGS has failed to accurately understand the regulatory requirements put forward by CMS. It appears that manufacturers must provide evidence of regulatory compliance and it appears that CGS believes this includes the submission of a TRG letter. However, the language in the current regulations only require that NEW HCT/Ps coming into the marketplace obtain a TRG to be included in their HCPCS application in order to receive a code. [vi]This requirement is not being applied to ALL HCT/Ps at this point in time. Therefore, CGS cannot base their non-coverage of products on this requirement. Should CGS determine that this is going to be a new requirement for coverage (which CMS currently does not even require), then this policy would have to be finalized and afford manufacturers a reasonable amount of time to obtain these letters BEFORE non-coverage is considered. At this point in time the TRG is taking close to a year to issue letters. So, CGS is making policy decisions based on language they are incorrectly interpreting to mean that currently all HCT/Ps require a TRG OR on language contained in a CMS proposal that has not yet been implemented.[vii] This is a violation of the Administrative Procedures Act and is a due process violation. Manufacturers cannot be responsible for providing information based on a proposal and at the same time CGS cannot be making coverage

determinations based on receiving information based on a draft until the draft becomes finalized.

Finally, should CGS require TRG letters, as it appears in the current draft, there will be a disruption in care as many manufacturers do not currently have TRG letters (as they are not required as stated multiple times) and will not be able to obtain one for at least a year. As a result, products that are currently being utilized on patients will become non-covered as soon as this policy is finalized.

Additionally, the LCD requires that providers maintain a copy of a TRG letter in their files in order to use any given product. Providers will not have those letters and should not be required to obtain them from the manufacturer in order to use their product and be covered. This is an undue burden on providers and quite simply if CGS imposes this requirement it is up to the MAC to obtain these letters and not the providers.

It is imperative that CGS not implement any final LCD language regarding TRGs until CMS finalizes its position on this topic or at the very least until this policy actually is finalized.

Evidentiary Requirements

It is also concerning that CGS does not identify in the LCA or in the LCD the specific evidence that they are requiring of manufacturers in order for their products to be placed in the Group 2 covered product listing. CGS cannot make general statements about regulatory compliance without providing the specific requirements that need to be met. There needs to be information contained in this policy to identify what regulatory compliance manufacturers are being required to adhere to. HCT/P manufacturers of minimally manipulated products used for homologous use are currently required to follow requirements and adhere to tissue bank compliance.[viii] So it is unclear what other regulatory compliance CGS is expecting manufactures to meet. As mentioned, nothing is identified in the draft policy or article which again is contrary to the 21st Century Cures Act.

Coverage Decisions Cannot Be Made In An Article

Local coverage determinations (LCDS) are defined in Section 1869(f)(2)(B) of the Social Security Act (the Act). This section states: “For purposes of this section, the term ‘local coverage determination' means a determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered in accordance with section 1862(a)(1)(A)”. Local Coverage Articles (LCAs) however are typically published by a local Medicare Administrative Contractor to provide coding and billing guidance or provider education that is complementary to an existing LCD. However, CGS has made coverage decisions in the policy article by non-

covering products that are currently being covered without new evidence, any rationale as to why these products are now going to be non-covered, and without providing the evidentiary threshold for coverage. By moving these products from the covered to the non-covered category, CGS has violated the very nature of what can be done in an Article versus an LCD.

As stated, CGS must withdraw this policy and work with stakeholders to ensure a clinically accurate policy – that is not arbitrary and capricious – and is not only based on evidence but created following the rules of law.

Other Areas of Concern

The Coalition is including below additional areas of concern with this policy including but not limited to the following:

- The use of the clinically inaccurate term "skin substitute" rather than the more clinically accurate term "cellular and or tissue-based products for skin wounds" or CTPs. The Coalition applauded CGS when it previously titled this policy "Cellular and/or Tissue based substitutes for the treatment of diabetic foot ulcers and venous stasis ulcers." We believe that CGS should revert back to this title but use the words "products" instead of "substitutes" and use the term CTPs throughout the LCD and LCA
- The lack of a consistent and accurate definition of what is a chronic non healing wound – which should be 30 days or 4 weeks as it is already standardized and used by CMS and other A/B MACs. In the policy, there are multiple definitions cited such as: the range of 1-3 months, greater than 4 weeks, no less then 4 weeks or other ranges of time.
- Incorrectly describing the application of CTPs as an adjunct therapy rather than an advanced therapy.
- The use of the terms pressure ulcer, decubitus ulcer, burns, and trauma throughout this policy which again specifically states it only addresses DFUs and VLUs.
- An Omission of a significant number of ICD-10 codes from the LCA that should have been included. As an example - it is concerning that CGS only identified codes with the .621 suffix – which is for the foot only - and has excluded any patients with a diabetic ulcer even when just above the ankle.
- The Increase in the smoking cessation timeframe prior to the use of a CTP to 6 weeks is not only problematic it is not based on any evidence cited by CGS in this policy.
- The inability to switch products is very problematic. CGS is interested in using the smallest product available as is stated in the policy. However, as the wound begins to heal it gets smaller. The product that a provider may have started a patient on may not be the product they finish with as there may be a smaller product available and thus not as much waste. Furthermore, a patient may have

different responses to different products. If a provider believes that a patient could benefit from a product that they did not start on, they should be able to switch as this is in the best interest of the patient.

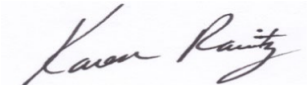
- The Reference to synthetic occlusive dressings throughout the policy is confusing. – a synthetic CTP is not a dressing. Synthetic products should be treated like all other CTPs and not singled out as CMS has included them in the definition of what is a skin substitute in recent rulemaking.
- And finally – The requirement that clinicians utilize the smallest package size available for purchase from the manufacturer - is not appropriate. the clinician does not control what is purchased or is on hand at their facilities. They simply use the best product to treat their patient that is either on their formulary or on the shelf at their clinic.

Conclusion

For all the reasons and issues identified above, the Coalition strongly recommends that CGS withdraw this policy and work with stakeholders to craft a clinically accurate LCD and LCA based on evidence and the rules of law so that patient care is not negatively impacted.

The Coalition appreciates the opportunity to provide our written comments. Should you have any questions or need additional information, please do not hesitate to contact me.

Sincerely,



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[i] *Novitas Solutions. L35041: Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds. Effective 10/01/2015. Latest Revision 09/26/2019.*

ii iiFirst Coast Service Options, Inc. L36377: Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities. Effective 10/01/2015. Latest Revision 01/08/2019.

iii CGS Administrators, LLC. L36690: Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities. Effective 10/10/2016. Latest Revision 02/03/2022.

iv Palmetto GBA. L36466: Application of Skin Substitutes (Retired). Effective 05/17/2016. Retired 01/03/2019.
v David G Armstrong MD, PhD, DPM, MS; William H Tettelbach MD, FACP, FIDSA, FUHM, FAPWCS, CWS; Thomas J Chang DPM; Julie L De Jong MS; Paul M Glat MD, FACS; Jeffrey H Hsu MD, FACS; Martha R Kelso RN, LNC, HBOT; Jeffrey A Niezgoda MD, FACHM, MAPWCA, CHWS; Travis L Tucker MA, MBA; Jonathan M Labovitz DPM, FACFAS, CHCQM, "Observed impact of

CTPs in lower extremity diabetic ulcers-lessons from the Medicare Database (2015-2018)", Journal of Wound Care, North American Supplement Vol 30, No. 7, July 2021

vi 87 FR 46251

vii 87 FR 46251-2

viii 21 CFR part 1271 and 361 Public Health Services Act