Open meeting skin substitute draft LCD comments

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Introduction

Dr. William Tettelbach is a Wound Care, Hyperbaric Medicine and Infectious Diseases specialist who serves as Medical Director of Wound Care & Infection Prevention for Encompass Health Rehabilitation Hospital of Utah as well as Principal Medical Officer for MIMEDX. He received his medical degree from the University of Tennessee Health Science Center, College of Medicine, has been in practice for more than 25 years and retains academic appointments at Duke University School of Medicine and Western University of Health Sciences. He is an active Noridian CAC member who’s most recent publications focus on the retrospective analysis of Medicare data;

• Observed impact of skin substitutes in lower extremity diabetic ulcers: lessons from the Medicare Database (2015-2018),

• Cost-effectiveness of dehydrated human amnion/chorion membrane allografts in lower extremity diabetic ulcer treatment.

Thank you

I want to open by sincerely thanking Novitas and First Coast for examining the topic of Skin Substitutes by creating the draft LCD. Providers appreciate when MACs are transparent with their coverage guidelines, and this draft definitely takes steps to clarify areas of confusion. For example, this latest revision is more explicit in its focus on diabetic foot ulcer and venous leg ulcers.

Main issues to address

I plan to submit written comments that address multiple aspects of the draft LCD and article, but my oral comments today will focus on two key issues, namely:

1. Evidenced-based coverage of skin substitutes
2. Language throughout the draft LCD specifying an expected limit of 2 applications within 12 weeks

Issue 1: Evidenced-based coverage of skin substitutes

The draft LCD covers any products that meet the necessary FDA regulatory requirements due to a perceived low quality of evidence and likelihood of bias. The exact language from the LCD is as follows:

“Despite the lack of studies, the moderate to low quality of current research and the likelihood of bias, coverage has been provided to increase the chances of improved health outcomes of interest which includes patient quality of life and function. Coverage will be provided for products in the associated billing and coding guidelines meeting the necessary FDA regulatory requirements as of publication.”

In the payor arena there have been several guiding documents, the 21st Century Cures (which requires evidence-based decisions) combined with two Agency for Healthcare Research and Quality's (AHRQ) Technology Assessments (2012 and 2020) which continue to direct providers on the desired path of practicing evidence-based medicine where solid data exists. Yet, MACs continue to cover skin substitutes that have insufficient clinical evidence. Many of the products that meet the necessary FDA regulatory requirements have no Level 1 evidence or even strong lower-level evidence.

The draft LCD notes that AHRQ defines gaps in research. However, the draft LCD fails to see that AHRQ also notes strengths where they occur. Example of a blind spot in draft LCD:

* Draft LCD notes the role in industry funding in a majority of RCTs.
* However, the draft LCD omits that AHRQ also implemented a risk of bias tool to assess study design.
* Even with industry funding, a number of the examined RCTs were assigned a low risk of bias due to strong study design.

As a reminder: AHRQ is part of HHS, and the Technology Assessment states it is meant to be a “guiding document” for payers. Despite the gaps it identified, it also identified products with well-designed clinical trials. I urge First Coast and Novitas to review Table 18 and 19 within the assessment. (https://www.ncbi.nlm.nih.gov/books/NBK554220/pdf/Bookshelf\_NBK554220.pdf)

HHS invested a lot of effort in commissioning this Technology Assessment. Many Manufacturers went to a lot of effort and expense to provide high quality level 1 evidence, which was in fact identified throughout the assessment. Why would the government or the manufacturers go to all this expense and effort if MACs and other payers would just cover based on a very low bar of filing correctly with the FDA?

All national commercial payers provide coverage only for products that have level 1 evidence. The vast majority of commercial payers cover a very short list of products. They are not confused on where to draw the line—they look to products that have studies behind them that show the ability to provide a clinically significant improvement. AHRQ also stipulates that “processing matters” and the results from one study should not be extrapolated to another product.

Any other NCD and LCD focused on drugs, services and products would look to existing studies. For this LCD not to rely on level 1 RCTs would deviate from 21st Century Cures and evidence-based coverage.

Lastly, the draft LCD explicitly pertains to DFUs and VLUs. AHRQ directly acknowledges that most of research is for DFUs, and tables 18 and 19 identify primarily DFU and VLU research. These tables highlight the results and statistical significance and assign a Risk of Bias.

Rather than focusing on gaps all throughout wound care research, Novitas and First Coast should be focused on the high-quality evidence that exists for the disease states addressed in the LCD. Again, this evidence was identified by an agency within the United States Department of Health and Human Services; more specifically, the Agency for Healthcare Research and Quality whose mission is to advance excellence in healthcare by producing evidence to make healthcare safer, higher quality, more accessible, equitable, and affordable.

Issue 2: Two applications within 12 weeks

As I’m sure a lot of fellow commenters are, I am confused by language throughout allowing only 2 applications within 12 weeks.

This is at odds with data and precedent:

* There is no clinical data supporting the clinical efficacy of only 2 applications.
* The majority clinical research involving skin substitutes is typically based on weekly or biweekly applications over 12-16 weeks.
* All currently active LCDs allow 10 applications within 12 weeks or 12 weekly applications. Of course, medical necessity must be met.
* Any commercial plans.
* The longer a chronic DFU remains open the higher the risk of hospitalization, amputation and even death.1
* Recently published analyses of Medicare data demonstrated the use of skin substitutes in treating chronic lower extremity diabetic ulcers reduced amputations rates, emergency department visits, readmissions, and the number of clinic visits.2 Furthermore, over the 1-5 years from the initiation of treatment with a skin substitute, there is a realized cost saving superior to not utilizing a skin substitute.3

As an example, EPIFIX RCTs showed that 81% of the DFUs (Per Protocol) within the largest DFU trial closed at 12 weeks and that 60% of the VLUs (Per Protocol) within the VLU trial closed. Even with these strong results of clinical efficacy, one takeaway will be that a significant portion of patients with chronic wounds will need more than 12 weekly/biweekly applications of a given skin substitute.

If the goal is to prevent overutilization, that can be addressed through other mechanisms within the LCD. Skin substitute applications can be guided by signs of improvement with the wound bed, as assessed through 30-day reevaluations. (Evaluations should assess reduced surface area, reduced depth, increased granulation tissue in the wound base, or reduced drainage.) Continued use of weekly/biweekly applications should be predicated on evidence of improvement.

Conversely, if there are no significant signs of improvement in the wound bed at 30-day evaluations (or after a set number of applications), then the skin substitute should be discontinued and a secondary work up should be considered to navigate a possible underlying condition that may be impeding progression to closure.

Conclusion

In conclusion, LCD decisions should be made around evidence, in line with 21st Century Cures, which mandates evidence in LCD coverage decisions. I urge Novitas and First Coast to reexamine the areas of the AHRQ Tech Assessment that identify those products that do provide strong clinical evidence related to the disease state in question (DFUs and VLUs)

Moreover, the vast majority of guidelines and research indicate the appropriateness of weekly or biweekly applications to closure. New HECON data confirms the advisability of starting skin substitutes early and treating weekly or biweekly to closure. Across MACs, current and retired LCDs predicated the number of applications on a consensus of research protocols. The current draft LCD from Novitas and First Coast does not provide an evidentiary justification for the movement to 2 applications only.

Lastly, I want to reiterate my intention to file written comments that examine other parts of the LCD. Specifically, surrounding use of the label “surgical supplies,” the definition of failed response to conservative measures, smoking cessation at 6 weeks, as well as some of the limitations within the diagnoses code list within the article, and potentially others. However, I really do appreciate Novitas and First Coast examining the issue of skin substitute coverage and providing the draft LCD that brings us here for discussion today. Thank you.

References

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