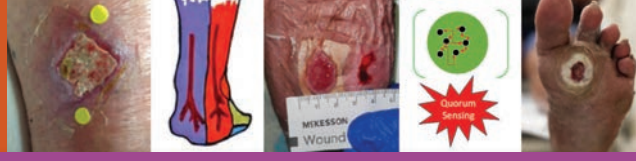


Skin Substitute Policy Changes

Be aware of some recent restrictions on the use of these products.

BY JEFFREY LEHRMAN, DPM

On August 3, 2023 Novitas, First Coast Service Options, and CGS Part B Medicare Administrative Contractors (MAC) finalized skin substitute policies for the treatment of diabetic foot ulcers and venous leg ulcers, effective September 17, 2023. These policies limit the number of applications of a skin substitute graft or cellular tissue product (CTP) considered "medically reasonable and necessary" within an episode of skin replacement surgery. They also list products that meet the Contractors' FDA regulatory requirements for indications covered in these policies and other products that are considered non-covered.

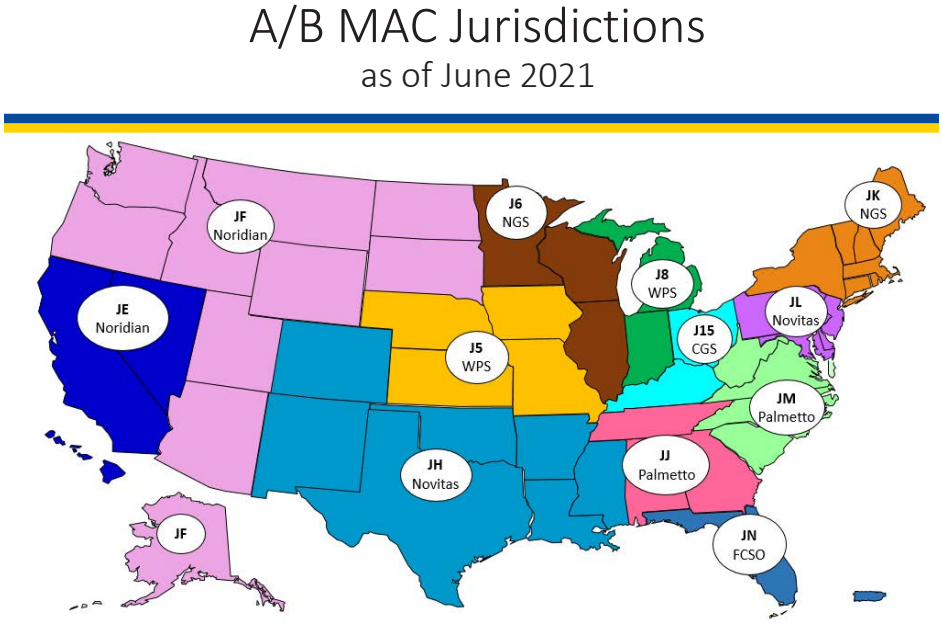


Figure 1: https://www.cms.gov/files/document/ab-jurisdiction-map-jun-2021.pdf

Figure 1 shares the information regarding which Part B MACs have jurisdiction over which states.

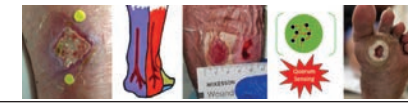
MAC

Medicare is a national program, but it is administered on a local level by Medicare Administrative Contractors (MACs). There are seven Part B MACs in the United States. Some of the Part B MACs have large jurisdictions and some have small jurisdictions. Figure 1 shares the information regarding which Part B MACs have jurisdiction over which states. This article refers to skin substitute policies released by only Novitas, First Coast, and CGS.

Most of the time, when providing Part B services to Medicare beneficiaries, guidance regarding coding, coverage, medical necessity, and documentation requirements comes from the Part B MAC, not from Medicare. Most of the time, the question of, "What are the Medicare guidelines for _____" is the incorrect question and instead that question should be, "What are my MAC's guidelines for _____?" Most of the time, the question of, "How frequently does Medicare allow payment for _____" is the incorrect question and instead that question should be, "How frequently does my MAC allow payment for _____?" Most of the time, the question of, "Does Medicare cover _____" is the incorrect question and instead that question should be, "Does my MAC cover _____?"

When navigating to their Part B MAC's website, providers can find a list of coverage policies, Local Coverage Determinations (LCDs). LCDs normally provide guidance regarding coverage, medical necessity, limitations, documentation requirements, and more. In many cases, an LCD is accompa-

Continued on page 56



Skin Substitute Policy *(from page 55)*

nied by a Local Coverage Article (LCA) that offers guidance regarding coding. Part B MACs choose to issue LCDs for certain services. An important point that is often misunderstood is that different Part B MACs issue LCDs for different services. Perhaps even more important to understand is that two different Part B MACs' LCDs for the same service may have different guidance. This is why it is so important for providers to look for guidance from their own Part B MAC rather than from national forums in many cases.

New Policies

All three of these new policies are Part B MAC policies. The Novitas Part B Jurisdiction includes AR, CO, DE, LA, MD, MS, NJ, NM, OK, PA, TX, and Washington, DC.

The First Coast Service Options Part B Jurisdiction includes FL, Puerto Rico, and the Virgin Islands. The CGS Part B Jurisdiction includes KY and OH. Each MAC's policy applies to the states and territories in its jurisdiction.

The lists of 58 products that meet the "necessary FDA regulatory requirements for indications covered in the policies" and 130 products that are considered non-covered are published in the Local Coverage Articles.

All three of these policies state "greater than four applications of a skin substitute graft or CTP within the episode of skin replacement surgery (defined as 12 weeks from the first application of a skin substitute graft or CTP)" are "not medically reasonable and necessary." Furthermore, all three of these policies list 58 skin substitute products that meet the "necessary FDA regulatory requirements for indications covered in the policies" and 130 products that are considered non-covered.

Products

The lists of 58 products that meet the "necessary FDA regulatory requirements for indications covered in the policies" and 130 products that are considered non-covered are published in the Local Coverage Articles. The policies list the following as the criteria that was used to create these product lists:

- A copy of the FDA letter to the drug's manufacturer approving the new drug application.
- A listing of the drug or biological in the FDA's "Approved Drug Products" or "FDA Drug and Device Product Approvals".
- A copy of the manufacturer's package insert approved by the FDA as part of the labeling of the drug, containing its recommended uses and dosage, as well as possible adverse reactions and recommended precautions in using it.
- A Tissue Reference Group (TRG) letter from the FDA or information from the FDA's website regarding intended use of the product as approved/regulated by the FDA.

The policy also states that a letter from the FDA indicating that the human cells or tissues (HCT/P) has met regulatory guidance is acceptable evidence of the FDA regulatory compliance for HCT/Ps regulated under section 361 of the Public Health Service Act and/or the Federal Food, Drug, and Cosmetic Act for skin substitute graft/CTP products classified as human cells, tissues, and cellular and tissue-based products (HCT/Ps).

Process

These changes were initially proposed by Novitas and First Coast in April, 2022 and by CGS Medicare in October, 2022. Novitas and First Coast initially proposed to limit the number of applications of a skin substitute graft or CTP within the episode of skin replacement surgery to only two. When these proposals were released, comment periods ensued where any stakeholder could submit comments and/or participate in public meetings. Many stakeholders resisted these changes and argued against the limit on the number of applications. This comment period was also an opportunity to challenge or defend which products were considered to have met the "necessary FDA regulatory requirements for indications covered in the policies" and which products were considered non-covered. Those comments and feedback were considered and these are now final policies.

Other Jurisdictions

None of the other four Part B MACs have taken any similar action regarding the provision of skin substitute services. None of the other four Part B MACs currently have public policies that govern the provision of skin substitute services. In the absence of a public policy, their coverage of both the service and the products is based on what they deem to be "medically necessary and reasonable." **PM**

References

Novitas LCD: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=35041&ver=120

Novitas LCA: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=54117&ver=104

First Coast LCD: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=36377&ver=11

First Coast LCA: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=57680&ver=15

CGS LCD: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=36690&ver=42

CGS LCA: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=56696&ver=36

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