ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

Alliance of Wound Care Stakeholders Written Comments
Agenda item #2 on December 2, 2021
Request: InnovaMatrix™ FS HCP2109145U5NH

The Alliance of Wound Care Stakeholders is a nonprofit multidisciplinary trade association representing physician specialty societies, clinical and patient associations whose mission is to promote quality care and access to products and services for people with wounds and lymphedema. We are providing written comments on the preliminary coding decision for InnovaMatrix™ FS which is to establish a new HCPCS code Axxx with descriptor "InnovaMatrix fs, per square centimeter."

While the Alliance does not receive any financial compensation from the applicant of this request, other companies who manufacture skin substitutes or cellular and/or tissue based products for skin wounds are members of the Alliance of Wound Care Stakeholders and pay a membership fee.

The Alliance agrees with the HCPCS Workgroup to establish a new HCPCS code but believe that it should be assigned a "Q" code rather than an "A" code.

CMS released its CY2022 Medicare Physician Fee Schedule creating "A" codes for "synthetic" skin substitute products and then the Agency placed this information of ten 510 (k) cleared wound care products in its 2021 HCPCS application summary for supplemental coding cycle as well as issuing "A" codes for skin substitute products in its 2nd biannual 2021 coding cycle. We have the following comments:

- It appears that CMS issued "A" codes for CTPs/skin substitutes that have 510K clearance without any notice as to why these codes are being issued other than the information that was contained in the Physician Fee Schedule which discusses synthetic CTPs/skin substitutes. However, not all CTPs/skin substitutes that are cleared through the 510(k) process are synthetic. We question why the Agency is making this generalization and issuing "A" codes to all CTPs/skin substitutes which have 510(k) clearance since they are not necessarily synthetics?
- InnovaMatrix FS, and other CTPs/skin substitutes which are not synthetics, should not be issued "A" codes since their predicate devices (which also have 510K clearance) were issued Q codes and are not considered synthetic CTPs/skin substitutes.
- The Alliance agrees with the primary speaker that CMS has not provided any definition of what is a synthetic skin substitute/CTP. If the HCPCS Workgroup is issuing HCPCS codes for a product category, there should be a definition issued as to what constitutes a synthetic CTP vs. other CTPs/skin substitutes that obtain 510(k) clearance. ASTM, an independent standard setting organization, does have a definition of "synthetic" in its CTP standard guide (F3163) which can serve as a starting point for discussion of defining it.

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- The Alliance does not agree that synthetic CTPs/skin substitutes should be issued "A" codes or "C" codes as has been repeatedly stated in our comments to the Agency. However, if CMS believes that synthetic CTPs/skin substitutes should be issued "A" codes, then as stated above, the Agency needs to be more transparent. The Agency needs to issue a definition of what constitutes a synthetic CTP, instead of issuing "A" codes to ALL products with 510K clearance. Furthermore, the Agency should review what constitutes the product to make that determination.

  In order to have an even playing field, if these products are assigned "A" codes, we would request that they have the same payment structure as "Q" codes. We also request that the Agency issue a MLN Connects newsletter to provide instruction to providers, billers and the MACs so that they understand how the A code for skin substitutes should be billed and reimbursed. This type of guidance is necessary for clarification as "A" codes are typically supply codes and bundled.

- Finally and most importantly, CMS should be transparent in publicly publishing any guidance in their issuing of coding changes for CTPs/skin substitutes/skin substitutes. For instance, the Agency should publish instructions or guidance so that companies who will be submitting HCPCS code applications for CTP/skin substitute products in the future will know which coding cycle they will need to submit the application. This could be done when there are instructions for submitting applications through the new MEARIS system. It seems that CMS now believes that skin substitutes who go through the BLA pathway or is a HCT/P that goes through FDA's TRG and obtains a letter from them are classified as biologics—and manufacturers can submit HCPCS applications on a quarterly basis for them and CMS releases a drug/biologic summary four times a year. On the other hand, it seems now that CMS believes that skin substitutes that go through the 510k process are now classified in the non-drug/non-biologic category—and manufacturers can only submit HCPCS code applications for them twice a year.

  If this information is correct, it has not been stated publicly and manufacturers should know this information so that they can plan accordingly to submit the application in the right coding cycle.

We appreciate the opportunity to submit these comments and would be pleased to speak with you to provide more detail or if you have questions. Please contact Marcia Nusgart, executive director, at 301530-7846 or marcia@woundcarestakeholders.org