AdvaMed
Advanced Medical Technology Association

701 Pennsylvania Avenue, NW
Suite 800
Washington, D.C. 20004–2654
P :: 202.783.8700
F :: 202.783.8750
W:: AdvaMed.org

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Marge Watchorn
Director, Division of Coding & Diagnosis Related Groups

David Rice
Acting Director, Division of Outpatient Care

Sarah Shirey-Losso
Director, Division of Ambulatory Services

Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Ms. Watchorn, Mr. Rice, and Ms. Shirey-Losso,

On behalf of the Advanced Medical Technology Association (AdvaMed), we are writing to urge the Centers for Medicare and Medicaid Services (CMS) to consider its policies on skin substitutes for the calendar year (CY) 2023 Outpatient Prospective Payment (OPPS) and Physician Fee Schedule (PFS) proposed rules.

AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring patient access to lifesaving and life-enhancing devices and other advanced medical technologies in the most appropriate settings.

AdvaMed has several concerns about CMS' policy with respect to skin substitutes. These concerns are in the following three categories:

- Coding of Synthetic Skin Substitutes
- Payment of Skin Substitutes under the OPPS
- Payment of Skin Substitutes in physician offices

Due to the complex and cross-cutting nature of this issue, we are submitting these comments to the Hospital and Ambulatory Policy Group (HAPG) and the Technology, Coding and Policy Group (TCPG) as the issues cross coding and payment policy. In the 2022 PFS rule, CMS indicated "We also plan to further …address payment policies for all skin substitutes across settings in a consistent manner…"[1] AdvaMed shares this same goal and hopes our letter can be helpful towards CMS having a consistent payment policy that applies to all skin substitutes across settings. We look forward to your response.

Coding of Synthetic Skin Substitutes

Historically, CMS has established product-specific Q-codes for skin substitutes. CMS pays for skin substitutes as biologicals.[2] However, more recently, CMS assigned A-codes to 13 skin substitute products that are similarly situated to products with Q-codes. These new products assigned A-codes are applied to wounds to aid healing through various mechanisms of action that stimulate the host to regenerate lost tissue consistent with how CMS recognizes skin substitute products that are assigned Q-codes.[3]

A-codes are often used for surgical dressings that may be covered by Medicare under section 1861(s)(5) of the Social Security Act (the Act). CMS specifically distinguished skin substitutes from surgical dressings in the CY 2014 OPPS/ASC final rule, noting the difference in coding between these product categories.[4]

The following skin substitute products have been assigned A-codes inconsistent with CMS policy:

Code	Descriptor
A2001	Innovamatrix ac, per square centimeter
A2002	Mirragen advanced wound matrix, per square centimeter
A2003	Bio-Connekt, wound matrix
A2004	Xcellistem, per square centimeter
A2005	Microlyte matrix, per square centimeter
A2006	Novosorb synpath dermal matrix, per square centimeter
A2007	Restrata, per square centimeter
A2008	Theragenesis, per square centimeter
A2009	Symphony, per square centimeter

[1] 86 FR 65123
[2] See 86 FR 63563, "The CY 2014 OPPS/ASC final rule with comment period also described skin substitutes as ". . . a class of products that we treat as biologicals . . ." and mentioned that prior to CY 2014, skin substitutes were separately paid in the OPPS as if they were biologicals according to the ASP methodology (78 FR 74930 through 74931).
[3] 78 FR 74930 through 74931.
[4] See 78 FR 74932, stating, "We are not conflating these two product categories…we assign HCPCS A-codes to surgical dressings; HCPCS Q-codes are typically assigned to drugs and biologicals and are used to describe skin substitutes, unless a HCPCS C-code has been assigned to a skin substitute with pass-through payment status."

A2010	Apis, per square centimeter
A2011	Supra sdrm, per square centimeter
A2012	Suprathel, per square centimeter
A2013	Innovamatrix fs, per square centimeter

AdvaMed requests that, consistent with prior policy, CMS provide all skin substitutes with product specific Q-codes.

Payment of Synthetic Skin Substitutes under the OPPS

CMS has been packaging skin substitutes as drugs and biologicals that function as supplies when used in a surgical procedure since 2014. The packaging methodology also divides skin substitutes into high- and low-cost groups in order to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures. CMS assigns a skin substitute to a high or low-cost group based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold ($48 per CM^2 for 2022) or the product's per day cost (PDC) exceeding the PDC threshold ($949 for 2022).

These calculations have been done on a code-by-code basis[5] for *non-synthetic* skin substitute products but through an averaging process for *synthetic* skin substitute products mapped to HCPCS code C1849[6]—a generic synthetic skin substitute code. The result is HCPCS code C1849 being assigned to the high-cost skin substitute group, even though CMS' default policy is to assign any skin substitute product to the low-cost group absent data on its MUC or PDC from the OPPS data, or pricing information for products without such data.

Synthetic skin substitutes are being assigned to high-cost group rather than based on their individual product costs, inconsistent with CMS policy. The averaging process means that an individual synthetic skin substitute product could be incorrectly assigned to the high-cost group even if the individual product's MUC or PDC would result in it being assigned to the low-cost group.

It is unclear why CMS is treating synthetic skin substitute products differently than non-synthetic skin substitute products under the OPPS. These products are resorbable and meet CMS' definition of a skin substitute as they are "applied to wounds to aid wound healing and through various mechanisms of action…[and] stimulate the host to regenerate lost tissue."[7] CMS itself indicates "we now believe that both biological and synthetic products could be considered to be skin

[5] It should be noted some HCPCS codes represent multiple products within one code, such as Q4133 (Grafix prime and Stravix) and Q4126 (Memoderm, Dermaspan, Tranzgraft, and Integuply).
[6] CMS assigned codes A6460 and A6461 to synthetic skin substitutes but then recognized that these codes could not be assigned to the high and low-cost skin substitute groups and instructed use of code C1849 for these products when billing under the OPPS.
[7] 85 FR 86067

substitutes for Medicare payment purposes." The preamble language that follows supports this statement with reference to an Agency for Healthcare Research and Quality (AHRQ).[8]

Another example of how this inconsistent coding policy results in an incorrect assignment involves the synthetic product Xcellistem. Xcellistem is sold in a powder form but is assigned to the high-cost skin substitute group based HCPCS code C1849 exceeding the MUC of $48 per CM^2, which is not an applicable measurement for this product. No payment has been made for powders in the past and there are no CPT application codes for application of these products.

AdvaMed requests CMS:

- Assign product-specific Q-codes to all skin substitute products, including synthetic skin substitutes; and
- Assign each product-specific Q-code to either the high-cost or low-cost skin substitute group based on each product's MUC or PDC defaulting to the low-cost group absent information on MUC, PDC, or pricing information.

Pricing of Skin Substitutes in Physician Offices

Unlike the OPPS where skin substitutes are packaged, CMS pays for skin substitutes separate from the application procedure in physician offices using the drugs and biologicals payment methodology under section 1847A of the Act (generally average sales price (ASP)+6 percent). However, CMS is assigning A-codes to more recently marketed skin substitute products and deferring pricing to the Medicare Administrative Contractors (MACs).

On the CMS website (2021-12-16-MLNC | CMS), CMS instructs that physicians and non-physician practitioners:

- …may bill separately for skin substitute codes A2001-A2010 when applied in a non-facility setting
- Report the appropriate application of skin substitute CPT code(s) 15271 – 15278 and the appropriate charge on the same claim with the skin substitute "A" code
- [Medicare] will pay for skin substitutes assigned "A" codes separately from the physician's office for the application procedure, similar to skin substitutes with "Q" code and their application.
- Codes A2001 – A2010 will be priced by your Medicare Administrative Contractor when billed with CPT codes 15271 – 15278

[8] 86 FR 63562. ARHQ states "Whether natural or synthetic, the biomaterial provides an extracellular matrix that allows for infiltration of surrounding cells." CMS then states "The paper by Dieckmann et al. indicates that skin substitute products may be synthetic products as well as biological products."

These instructions are problematic. CMS is instructing that the MACs price some skin substitutes inconsistently with how CMS develops pricing for other skin substitutes. Many skin substitutes are priced using the methodologies that apply under section 1847A of the Act to drug and biologicals. This instruction leaves pricing to the MACs without providing any direction on the methodology to be used. It has the same effect as CMS not establishing an ASP rate for a skin substitute product with a Q-code – payment is left to the MAC, which pays based on wholesale acquisition cost or invoice. Meanwhile, CMS will use ASP pricing for other skin substitutes when ASP is reported.

In addition, the Consolidated Appropriations Act (CAA), 2021 requires that manufacturers of products that are paid as Medicare Part B drugs and biologicals report ASP information to CMS effective January 1, 2022.[9] CMS should be requiring ASP reporting for all skin substitutes and pricing them according to ASP+6 percent rather than instructing each MAC to develop their own pricing. ASP pricing information for each skin substitute product should also be published on the Drug/Biological Part B List in order to make this information available for both providers and the MACs.

AdvaMed requests CMS:

- Assign product-specific Q-codes to all skin substitute products, including synthetic skin substitutes;
- For product-specific skin substitute Q-codes, make clear that CMS treats these products as biologicals and pays for them using the methodologies specified in section 1847A of the Act.[10]
- Make clear that ASP reporting is mandatory for all products paid as drug/biologicals.
- Report ASP pricing for skin substitutes in the Part B Drug file for provider and MAC transparency.

We appreciate this opportunity to share our recommendations for your consideration in preparation for the CY 2023 OPPS/ASC and PFS proposed rules. If you have any questions, please contact Kirsten Tullia (ktullia@advamed.org).

[9] Section 401 of Division CC, Title IV Consolidated Appropriations Act (CAA) (Pub.L. 116-260), *December 27, 2020*. Prior to enactment of this law, only manufacturers of drugs and biologicals with a Medicaid rebate agreement were required to report ASP to CMS.

[10] This payment methodology includes HCT/P skin substitutes under the PFS. As specified by CMS in their November 2021 physician final rule, when a physician or NPP furnishes a surgical service to apply a (HCT/P) skin substitute in a non-facility setting, they may bill Medicare for the surgical service (as described by CPT codes 15271 through 15278), and separately bill for the (HCT/P) skin substitute.

Sincerely,

Chandra N. Branham, J.D.

Senior Vice President and Head of Payment & Healthcare Delivery Policy