



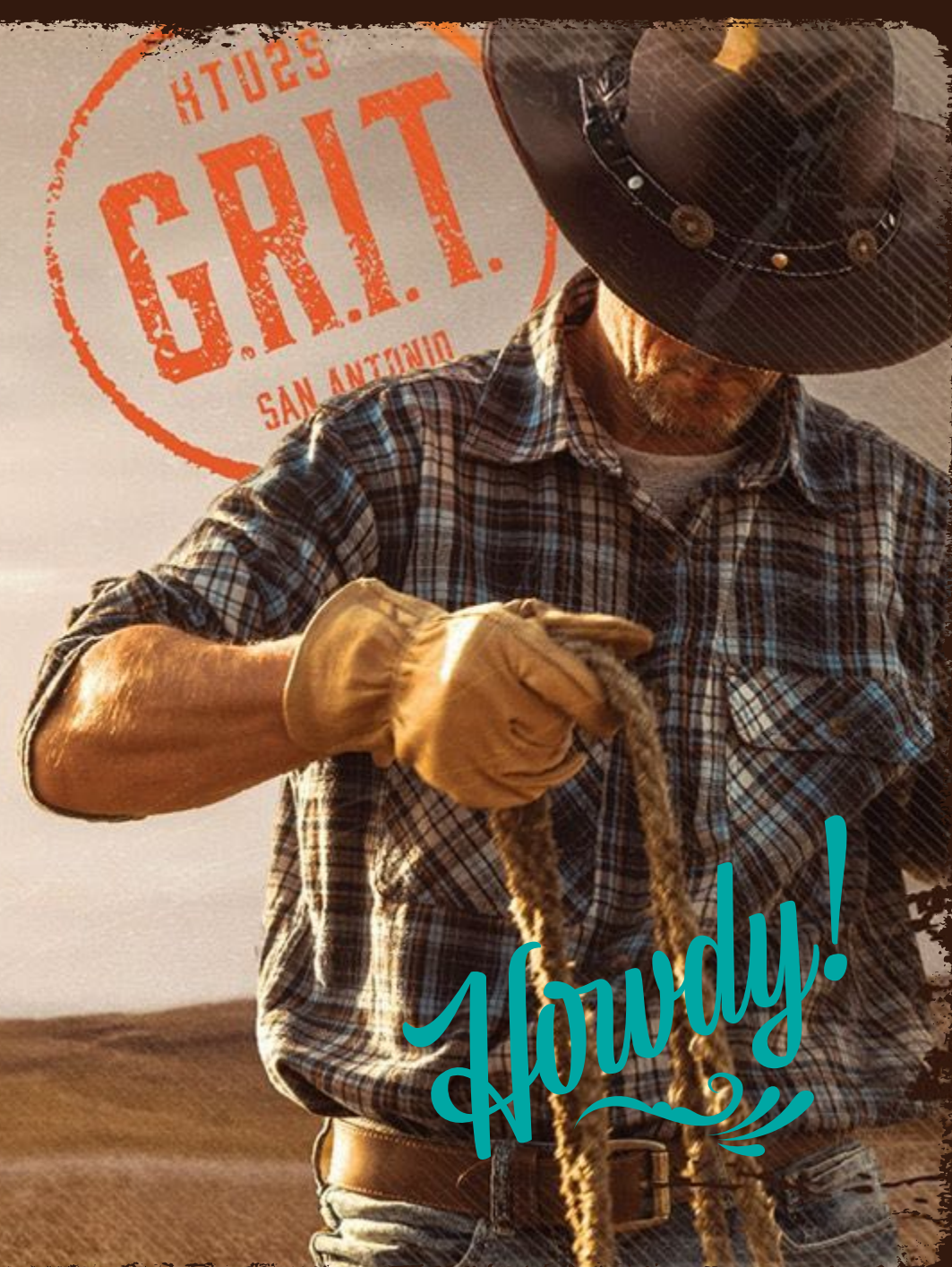
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Wound Care/Regenerative Tissue—Big Changes Impacting Utilization

THIS SESSION IS NOT OPEN TO SUPPLIERS

Applying for CE credit or need a Certificate of Participation?
Be sure to snap a pic of the code shown at the end of this session.

CE Deadline: 09/30/25



Moderator & Panelists



Moderator

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Health Sciences Center

Director of Trauma &
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Panelist

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Podiatrist,
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Founder, Conemaugh
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Panelist

Dean Vayser, DPM, FACFAS

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Member, Division of
Orthopedics, Scripps
Clinic
San Diego, CA



Disclosures



- Dr. Carter has a vested interest in or an affiliation with Avita Medical, PolyNovo Medical, Spectral AI and Vericel.
- The other presenters have no real or perceived conflicts of interest related to this presentation.

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Learning Objectives



At the end of this session, participants should be able to:

- Recognize types of regenerative tissue products and common uses in the treatment of chronic wounds.
- Identify contracted regenerative tissue products now covered by Medicare.
- Recall the financial impact for reimbursement of various wound care products at the facility level.



REGENERATIVE TISSUE MARKET OVERVIEW



Chronic Wounds Affect 16% of Medicare Beneficiaries



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- Medicare FFS population affected by chronic wounds: 16%
- Cost estimate: **\$96.8 billion** (4.5% of Medicare spending)
 - Most spending is **OUTPATIENT (49%)**
- Most common wounds: **Venous Leg Ulcers** and **Surgical complications**
- Most *expensive* wound: **Surgical complications**

Sources: 1. An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds. Value Health. 21(1): 27-32, 2017. [https://www.valueinhealthjournal.com/article/S1098-3015\(17\)30329-7/fulltext](https://www.valueinhealthjournal.com/article/S1098-3015(17)30329-7/fulltext). 2. Chronic wound prevalence and the associated cost of treatment in Medicare beneficiaries: changes between 2014 and 2019 [Full article: Chronic wound prevalence and the associated cost of treatment in Medicare beneficiaries: changes between 2014 and 2019](#)

What They Are Made of:

(BRANDS BY COMPONENT MATERIAL IN 2015)

- Human derived products
- Animal derived products
- Synthetic products
- Combinations of human/animal

SYNTHETIC

♦ LYOFOAM EXTRA
♦ SUPRATHEL

BIOSYNTHETIC ± DEAD CELLS

♦ BIOBRANE (B)
♦ EZ-DERM (P)
♦ INTEGRA (B)
♦ JALOSKIN
♦ LASERSKIN
♦ HYALOMATRIX
TALYMED
♦ TRANSCYTE (P)
XELMA

BIOMATERIAL / TISSUE DERIVED ± DEAD CELLS

♦ ALLODERM
♦ ALLOPATCH
♦ ALLOSKIN
♦ ARTHROFLEX
CYMETRA
♦ DERMACELL
DERMASPAN
♦ ENDOFORM (O)
♦ FLEX HD (H)
♦ GAMMAGRAFT
♦ GRAFTJACKET
hMATRIX
INTEGUPLY
♦ INTEXEN (P)
MATRIDERM (B)
♦ MATRISTEM (P)
♦ MATRIX HD
♦ MEDISKIN (P)
♦ MEMODERM
♦ OASIS (P)
♦ PERMACOL (P)
♦ PRIMATRIX (B)
♦ PUROS DERMIS
♦ REPLIFORM
♦ STRATTICE (P)
♦ TISSUEMEND (B)
UNITE BIOMATRIX (E)

What They Are Made of:

(BRANDS BY COMPONENT MATERIAL IN 2015)

- Human derived products
- Animal derived products
- Synthetic products
- Combinations of human/animal

LIVING CELLS BIOLOGICAL

Autologous , not cultured

FULL THICKNESS GRAFT FB KC
SPLIT THICKNESS GRAFT FB KC
RECELL KC

Autologous cultured

BIOSEED-S KC
CELLSPRAY KC
EPIBASE KC
EPISKIN KC
HYALOGRAFT FB KC
◇ KERAGRAF (EPIDEX) KC
LASERSKIN (VIVODERM)FB KC
MYSKIN KC
MYDERM FB KC
PERMADERM FB KC

Autologous cultured & Xenogeneic

◇ EPICEL KC

Allogeneic minimally manipulated

◇ EPI-FIX
GRAFIX
◇ THERASKIN

Allogeneic cultured

CELADERM KC
DERMAGEN FB
ICX-SKN FB

Allogeneic + synthetic

◇ DERMAGRAFT FB

Allogeneic immortal

◇ APLIGRAF (B) FB KC

HOW THEY COME TO MARKET DETERMINES WHAT CLAIMS THE SALES REPS CAN MAKE

FDA classification determines regulatory pathway required for commercialization and promotion (advertising claims)

FDA Classification of Medical devices:

- Premarket approval (PMA)

Only 3 products have come to market this way: Requires prospective, randomized, controlled trials. **These can make claims of healing.**

Lots of products: Requires the manufacturer to say that the product is

Dear Doctor,

This is [name withheld] from [company name redacted]. We understand the unique challenges in caring for elderly patients, and our innovative wound care product, [amniotic product name] is designed to meet their specific needs. It is Medical Part B covered and is made from the inner layer of human placenta, it promotes rapid healing, reduces infection risks and provides exceptional comfort for elderly patients.

Panelist Questions – Round One



1. What is your experience in utilizing regenerative tissue products?
2. How do you select a product?
3. How do you determine the validity of product claims?

Assessment Question #1



Which of the following statements about Biologicals and wound healing is TRUE?

- A. They are all made from human tissue.
- B. Companies marketing amniotic products cannot make claims of improved wound healing.
- C. Products made from human amnion must be cleared by the FDA.
- D. They make wounds heal.

Assessment Question #1: Correct Response



Which of the following statements about Biologicals and wound healing is TRUE?

- A. They are all made from human tissue.
- B. Companies marketing amniotic products cannot make claims of improved wound healing.
- C. Products made from human amnion must be cleared by the FDA.
- D. They make wounds heal.

The GAIT logo is a circular emblem with the word "GAIT" in a bold, sans-serif font. It is positioned in the upper left corner of the slide, partially overlapping the teal background and the wood texture.

CONTRACTED PRODUCTS ON MEDICARE



Outpatient (office/hospital clinic) Payment May Be Determined by Medicare Coverage Policy for Diabetic Foot Ulcers & Venous Leg Ulcers

- Medicare relies on regional (“local”) contractors to establish the specific criteria for coverage policy – called “**Local Coverage Determinations**” (LCDs)
- Recently, all 8 regional Medicare Administrative Contractors (MACs) released identical coverage policies for CTPs/CAMPs around Diabetic Foot Ulcers and Venous Leg Ulcers

The LCD(s) are on hold until 1/1/2026 due to *intense* lobbying by manufacturers.

FUTURE

Local Coverage Determination (LCD)

LCD - Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (L36377)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Future Effective

To see the currently-in-effect version of this document, go to the [Public Versions](#) section.

Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
First Coast Service Options, Inc.	A and B MAC	09101 - MAC A	J - N	Florida
First Coast Service Options, Inc.	A and B MAC	09102 - MAC B	J - N	Florida
First Coast Service Options, Inc.	A and B MAC	09201 - MAC A	J - N	Puerto Rico Virgin Islands
First Coast Service Options, Inc.	A and B MAC	09202 - MAC B	J - N	Puerto Rico
First Coast Service Options, Inc.	A and B MAC	09302 - MAC B	J - N	Virgin Islands

LCD Information

Document Information

LCD ID
L36377

LCD Title
Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers

Proposed LCD in Comment Period
N/A

Source Proposed LCD
[DL36377](#)

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Healthcare Common Procedure Coding System (HCPCS) Codes



COVERED CTPs/skin subs

HCPCS codes/products covered for Diabetic Foot Ulcers (DFU) ONLY

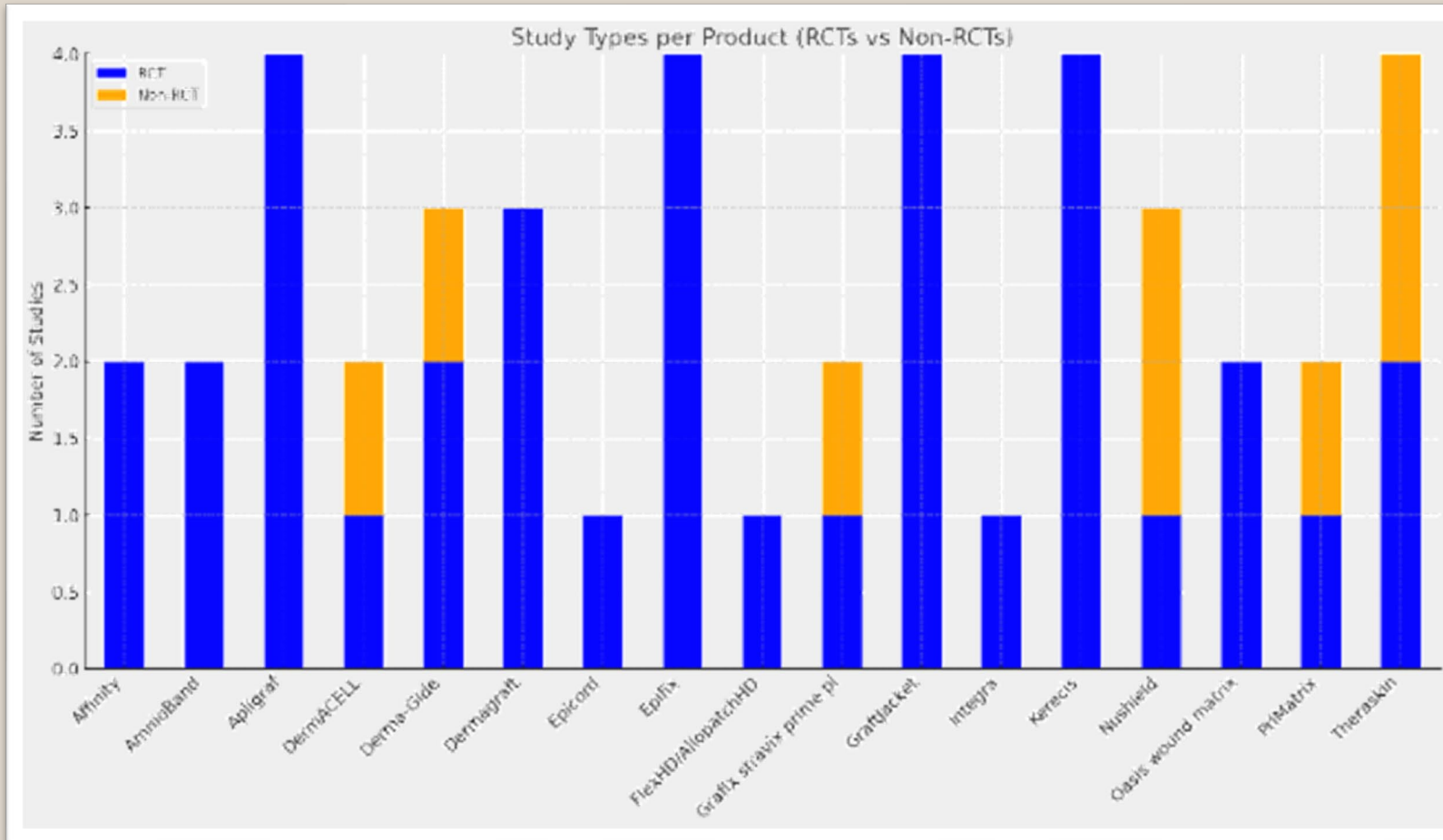
Code	Description
A2019	KERECIS OMEGA3 MARIGEN SHIELD, PER SQUARE CENTIMETER
Q4105	INTEGRA DERMAL REGENERATION TEMPLATE (DRT) OR INTEGRA OMNIGRAFT DERMAL REGENERATION MATRIX, PER SQUARE CENTIMETER
Q4107	GRAFTJACKET, PER SQUARE CENTIMETER
Q4110	PRIMATRIX, PER SQUARE CENTIMETER
Q4121	THERASKIN, PER SQUARE CENTIMETER
Q4122	DERMACELL, DERMACELL AWM OR DERMACELL AWM POROUS, PER SQUARE CENTIMETER
Q4128	FLEX HD, OR ALLOPATCH HD, PER SQUARE CENTIMETER
Q4133	GRAFIX PRIME, GRAFIXPL PRIME, STRAVIX AND STRAVIXPL, PER SQUARE CENTIMETER
Q4158	KERECIS OMEGA3, PER SQUARE CENTIMETER
Q4159	AFFINITY, PER SQUARE CENTIMETER
Q4160	NUSHIELD, PER SQUARE CENTIMETER
Q4187	EPICORD, PER SQUARE CENTIMETER
Q4203	DERMA-GIDE, PER SQUARE CENTIMETER

HCPCS codes/products covered for BOTH DFUs and Venous Leg Ulcers (VLU)

Code	Description
Q4101	APLIGRAF, PER SQUARE CENTIMETER
Q4102	OASIS WOUND MATRIX, PER SQUARE CENTIMETER
Q4106	DERMAGRAFT, PER SQUARE CENTIMETER
Q4151	AMNIOBAND OR GUARDIAN, PER SQUARE CENTIMETER
Q4186	EPIFIX, PER SQUARE CENTIMETER

Source: LCD - Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (L36377)

Products Covered in the LCD for DFUs & VLUs Are Likely to Change by January 2026



- The (on hold) Local Coverage Determination (LCD) around CTPs created a “Medicare covered” list of skin subs for DFUs and VLUs – based on whether the product had prospective clinical trials for those conditions.
- Manufacturers have until November 1, 2025, to provide research data to the MACs in hopes of getting on the list.
- The list of covered products is expected to grow.
- It is possible that the LCD(s) will never be implemented.

Will the LCD(s) change anything?



- The LCDs only cover diabetic foot ulcers and venous leg ulcers.
- **Common wounds are surgical complications, “generic” chronic ulcers, and pressure ulcers which are covered for biologicals now.**
- Limiting coverage for ONLY DFUs and VLUs may have little impact when the majority of use is in other wound types.
- There will eventually be some change in payment policy to get control of spending.

Panelist Questions – Round Two



1. How are the new LCD coverage determinations going to affect your **selection**?
2. How are the new LCD coverage determinations going to affect your **patients**?

Assessment Question #2



What statements about the contracted regenerative tissue products currently covered by Medicare are TRUE?

- A. The list of products covered for diabetic foot ulcers and venous leg ulcers will likely be expanded before January 2026 to include more HCPCS codes.
- B. The regenerative products not on the “DFU/VLU covered lists” can still be used in the operating room and in other wound types.
- C. Until new policies are created or implemented, Medicare is covering all contracted biological products.
- D. All of the above are true.

Assessment Question #2: Correct Response



What statements about the contracted regenerative tissue products currently covered by Medicare are TRUE?

- A. The list of products covered for diabetic foot ulcers and venous leg ulcers will likely be expanded before January 2026 to include more HCPCS codes.
- B. The regenerative products not on the “DFU/VLU covered lists” can still be used in the operating room and in other wound types.
- C. Until new policies are created or implemented, Medicare is covering all contracted biological products.
- D. All of the above are true.



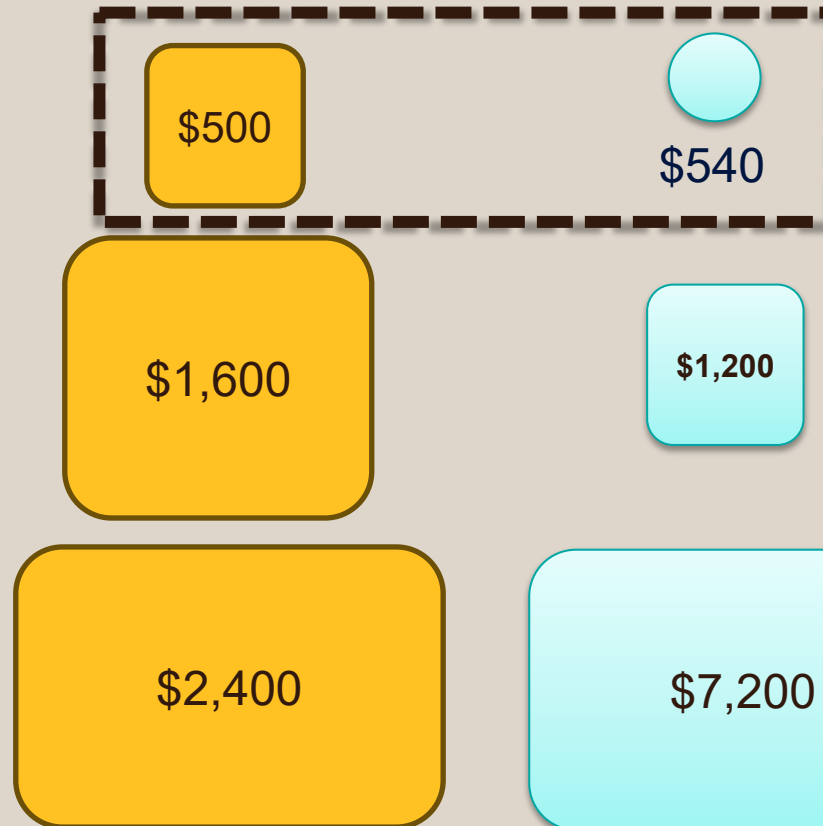
FINANCIAL CONSIDERATIONS & OPPORTUNITIES



Priced by the cm^2 – Sold by the PIECE!

Product X = **\$100/ cm^2** Average Sales Price (ASP)

- 2 x 2 cm = \$500
(small pieces increase cost/ cm^2)
- 4 x 4 cm = \$1,600
- 4 x 6 cm = \$2,400



Product Y = **\$300/ cm^2** ASP

- 1.8 mm disc = \$540
- 2 x 2 cm = \$1,200
- 4 x 6 = \$7,200



BREAKING NEWS! MEDICARE PLANS TO CHANGE PAYMENT STRUCTURE!

CMS is proposing to use a single payment amount for all these products (PMA, 510(k) and 361 HCT/P) of **\$125.38 per sq cm**

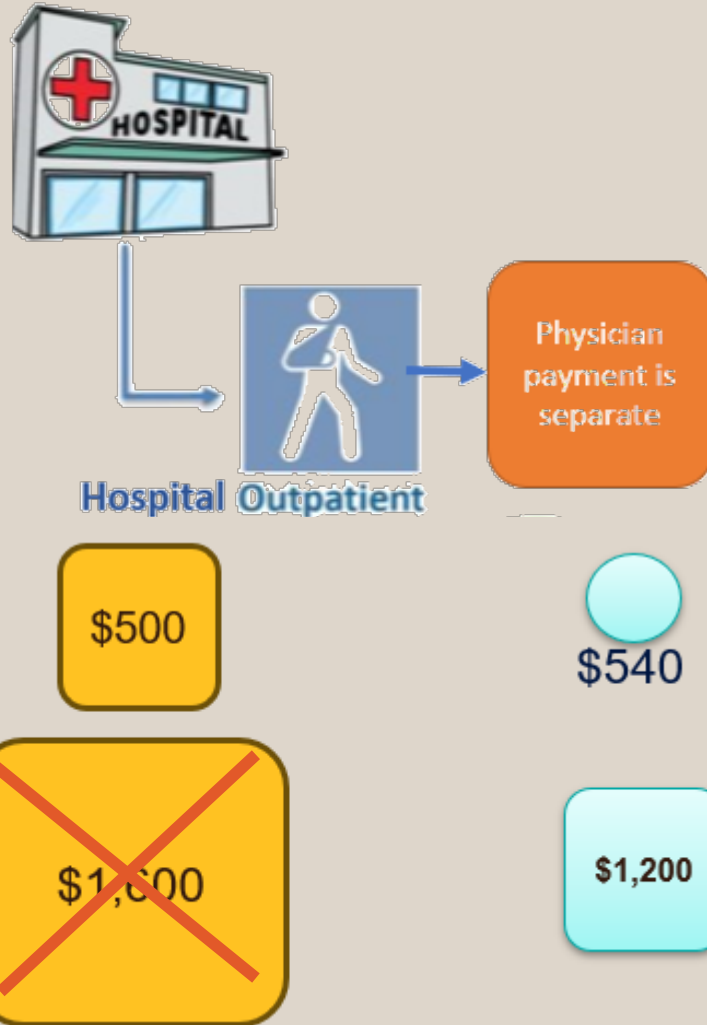
- Medicare payment will not be based on ASP
- If the product costs less than the fixed payment rate per cm², the hospital will experience a net gain
- “Final rule” (with final price amount) is typically released in mid-November
- Effective date for the new pricing is expected to be January 1, 2026

(CMS is proposing to continue to pay for products that have a biologic license agreement [BLA] using ASP +6%.)

Sources: [2025-13271.pdf](#);

Fact sheet: <https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2026-medicare-physician-fee-schedule-pfs-proposed-rule-cms-1832-p>

Surgical Biologics in the Hospital Outpatient Wound Center – Package Pricing

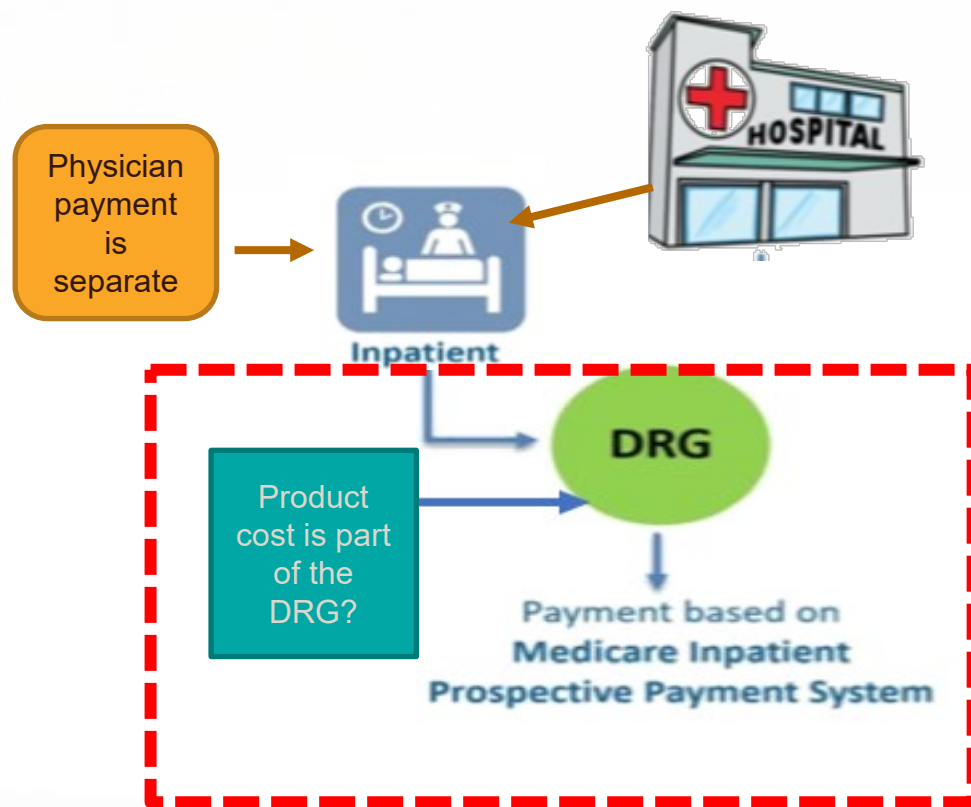


Product is part of the outpatient procedural fee-capped at ~\$1,700

What is “Package Pricing?”

- The hospital overhead and application fees are included in the cost of the CTP.
- All CTPs are divided into “high tier” and “low tier” cost buckets.
- High Tier payment is ~\$1,700
 - **Products that cost more than ~\$1,500 (for the entire piece) result in a net loss to the hospital**
 - Only relatively small wounds can be treated because of the size of products compared to the cost

Surgical Biologics in the Operating Room – Part of the DRG?



Source: Illustrations by C. Fife, M.D.

Pricing Under DRG?

- In the operating room, every procedure has an allowable reimbursement
 - Used for many reasons:
 - Breast reconstruction
 - Tendon repair
 - Others
- However, biologics may be charged separately depending on insurance.

How do surgeons (or hospitals) decide what or *why* to use them in the OR?

Panelist Questions – Round Three



1. How is this financial impact being handled by your facility?
2. How might you suggest partnering with your colleagues and facility leaders on evaluating opportunities in this space?

Recap



- Medicare covers biologicals for all wound types right now
- The LCDs if implemented will not impact wound types other than DFUs and VLUs
- Reimbursement for skin subs varies by site of care (hospital outpatient clinic, doctor's office, operating room)
 - **The HOPD is under “package pricing” – any product over ~\$1,500 is unaffordable**
 - **Operating room use – cost may be passed on to the patient, depending on insurance**
 - **Office-based use is ASP +6% (but substantial discounts can increase profit to the clinician)**
 - **Note: There is a lot of fine print here (“middle-man” vs. direct distributors)**

Assessment Question #3



Which of the following statements is FALSE about the use of biologicals for wound healing?

- A. The wide variation in price (>10,000%) is justified by published evidence based on clinical outcomes.
- B. Medicare is about to dramatically change the pricing structure for these products effective January 2026.
- C. LCDs (still on hold) impact Medicare coverage policy only for DFUs and VLUs.
- D. The clinician's decision about which product to use is often determined by factors other than effectiveness data.

Assessment Question #3: Correct Response



Which of the following statements is FALSE about the use of biologicals for wound healing?

- A. The wide variation in price (>10,000%) is justified by published evidence based on clinical outcomes.
- B. Medicare is about to dramatically change the pricing structure for these products effective January 2026.
- C. LCDs (still on hold) impact Medicare coverage policy only for DFUs and VLUs.
- D. The clinician's decision about which product to use is often determined by factors other than effectiveness data.



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Thanks y'all!



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