

Lower Extremity  
Cellular Tissue  
Product Update 2026  
Documentation, Coding  
and Compliance Issues  
for the Health Care  
Provider

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- Dr. Kesselman has been a consultant for many wound care companies, including but not limited to Smith and Nephew, Wright Medical and other graft manufacturers.
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Clinical practice for over 40 years. Board certified by the ABFAS.

Performing NIVT Since 1980.

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Not an employee of CMS or any third- party payer.

Experienced consultant to manufacturers of CTP

Chair APMA DME Workgroup, Member APMA Health Policy Committee, Consultant to PICA, Member NYSPMA Ins. Com. & Medicare Council

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This Lecture  
Assumes You  
Have a Basic  
Knowledge of

Debridement Codes

Selective Debridement Codes

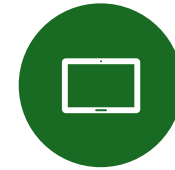
Wound Prep Codes

Cellular Tissue Product Application  
Codes

# CTP 2026 and Beyond



How we got here



WISeR and LCD  
Requirements



Charting  
Requirements



Photos



Pathology



Other Reporting

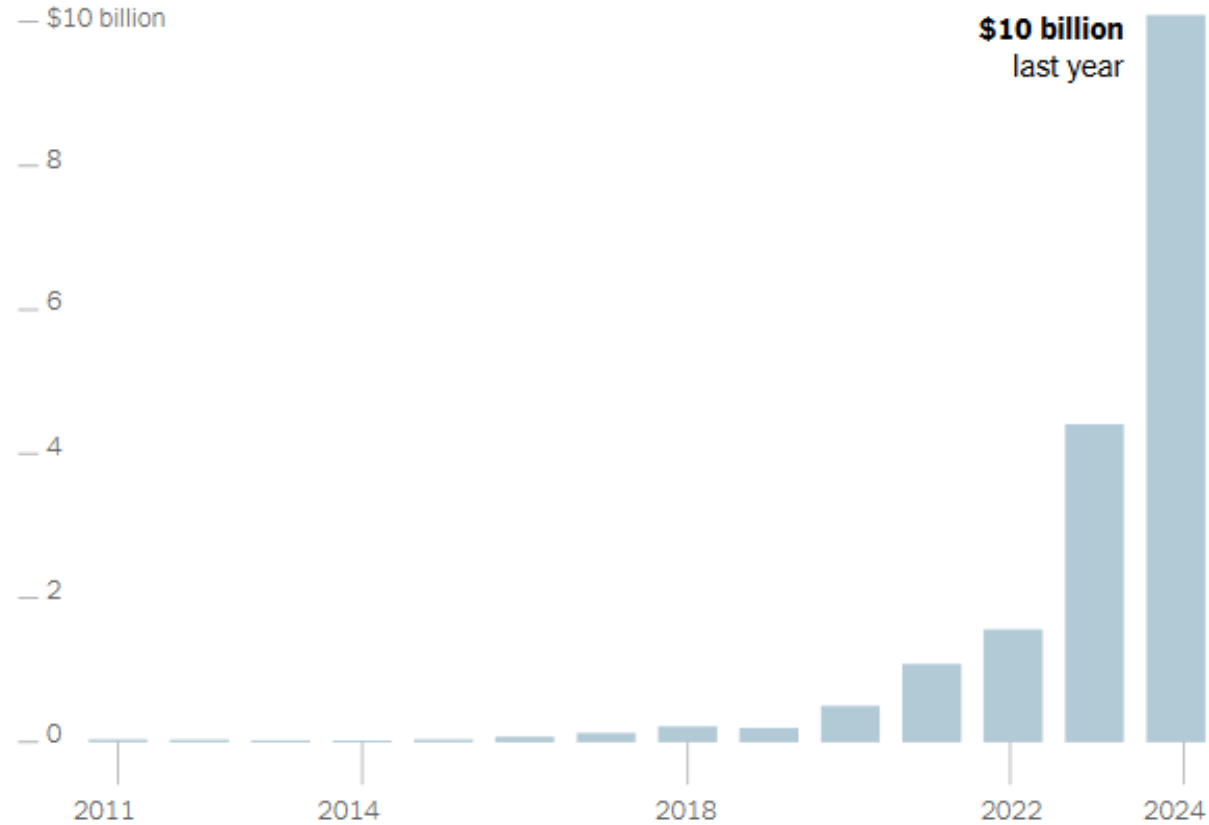


Coding



Consults

## Spending on skin substitutes has soared



Note: Annual spending on skin substitutes includes both Medicare's contribution and expected patient payments, including co-payments, co-insurance and deductibles. The data does not include spending by Medicare Advantage plans Source: Early Read By The New York Times

# 2026 CTP Issues-How Did We Get Here?

April 2025

# Fraud Allegations involving CTP Applications

- April 2026: California Clinic Accused in \$34M Medicare Fraud Probe
- December 2025: Az \$1.2B – CTP applied to terminally ill patients
- One Law Firm Advertisement

**Podiatrists are Being Investigated for Billing Fraud in Connection with Grafts and Other Wound Treatment Procedures**

# CMS Statement on Improper Spending on CTP

\$252M in 2019 to \$10B in 2024

\$185M in improper payments in 2025

Inappropriate Use on vulnerable patients (e.g., hospice)

Abuse concentration on small number of outliers

Mfgs. ASP inflated pricing

# What is new for 2026?

Pre Payment Arduous Audits in Many MAC

Withdrawal of Most LCD Safety Nets

“Voluntary” Prior Authorization in four states

“Incident to” Replaces ASP for Non BLA

Wastage is on you for Most CTP!

Estimates CMS Will Save 90% on CTP vs 2025

## What Is Incident To?

Supplies used by the provider during the patient encounter

Incident to supplies are typically NOT separately paid

CMS Made an exception and has a flat payment rate for non-BLA



# Charting Requirements

Thorough Wound Care History

What's Worked and What's Failed

Minimum of 4 weeks before "stalled" wound

"Optimization"

For DM: Controlled Renal, Glucose, Weight

For Venous: Leg elevation, edema control

For Both: Smoking cessation, dietary counseling/optimization

# Your chart must prove optimization

**2025**



DIET IS OPTIMIZED



PROPER NUTRITION  
DISCUSSED WITH PT.



FOOTWEAR IN  
GOOD WORKING  
ORDER

**2026**

- Patient is now on weight loss diet of 2500cal/day x 2 months has reduced weight from 250 to 235 (loss of 15 lbs) and continues to go to weight watchers weekly. Albumin wnl on labs from 3/2/26
- ..Footwear and inserts in good working order and off loading of DFU...



# Prior to and DOS of CTP Implantation

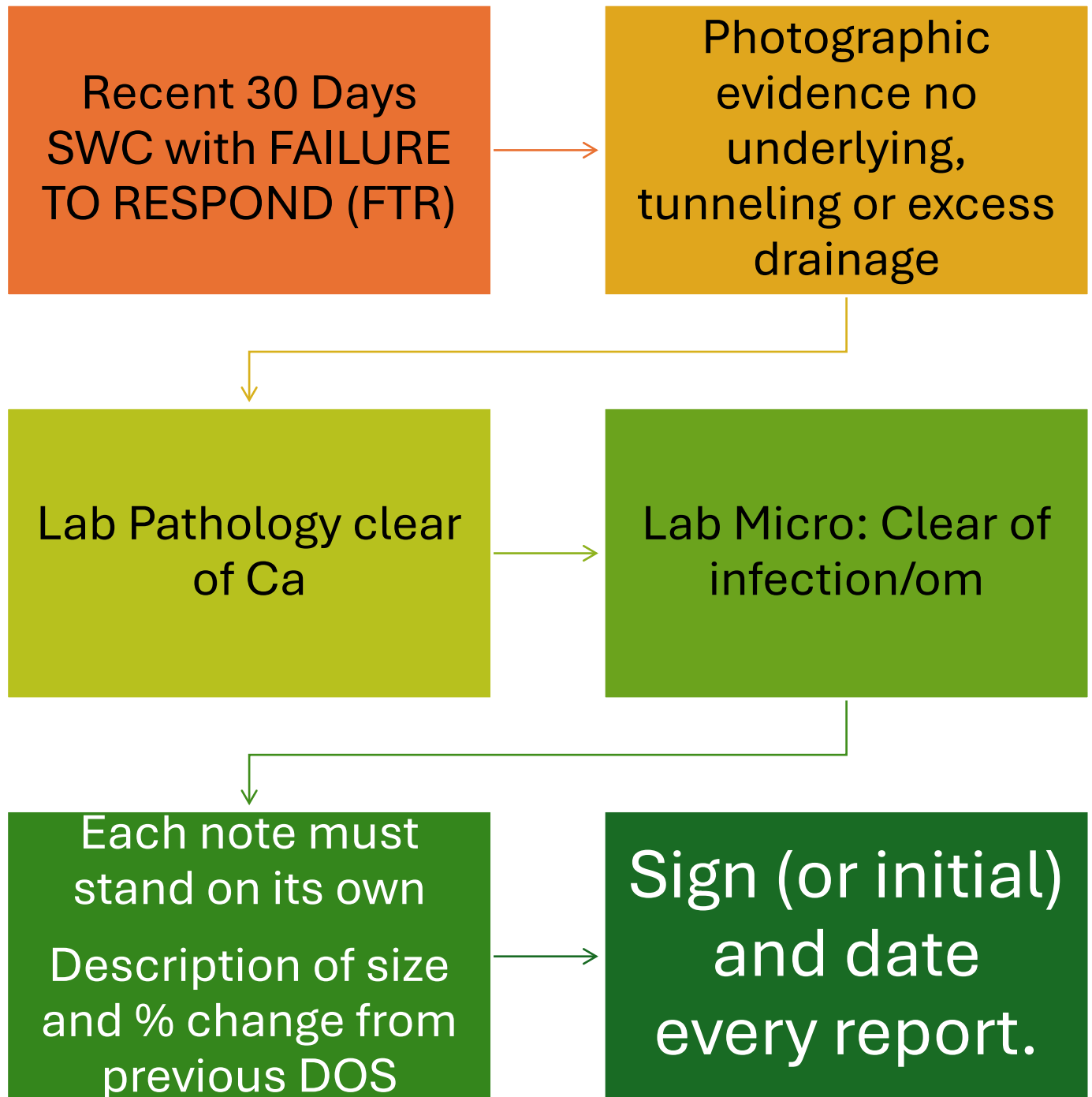
## DFU

- Comprehensive Blood Chemistries: Albumins, GFR, CCl, etc.
- Comprehensive Arterial Testing show optimization of ischemia or lack of severe ischemia ( $ABI > 6.0$ )
- *Proof of Off Loading*
- Proof of Dietary Management (e.g. caloric intake for wt. loss)
- Proof of Optimization of Glycemic Management ( $< 8 A1C$ )

## VLU

- Comprehensive Blood Chemistries: Albumins, GFR, CCl, etc.
- Comprehensive Venous Testing show no evidence of DVT, severe reflux or reverse flow on augmentation optimization
- Proof of Edema Control (Elevation, compression garments, PCD)

For  
Both DFU  
and VLU



CTP  
Implantations  
are Surgical  
Procedures

Get Medical  
Clearance  
from MD/DO  
who is treating  
their DM

CTP  
Application is  
Primarily  
Elective

Wound Care  
is a Team  
Approach

Share the  
Wealth With  
Other  
Providers

# What is Failure to Respond?

- FTR=INCREASE, OR NO CHANGE IN BASELINE SIZE OR NO SIGNS OF IMPROVEMENT OR NO INDICATION THAT IMPROVEMENT IS LIKELY
- (LACK OF GRANULATION, EPITHELIALIZATION OR PROGRESS TOWARDS CLOSING





# Why Pathology or Microbiology Testing?

Most CTP  
contraindicated  
in face of  
infection

CTP are  
contraindicated  
with neoplasm

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# The Importance of Photos

- Photos document & augment the hx of the wound better than words
- Measurements should be parallel to the wound dimension
- Camera should be perpendicular to the wound
- All Three Dimensions Must Be Documented
- Use Patient Chart EMR # and camera with date/time stamp
- Photos at each DOS
- Preference: Prior to and post debridement, pre and post CTP app.
- Prove/Disprove Tissue Depth-



## Consults

If patient had OM which has resolved-Get feedback from ID

Up-to-date imaging, or Bone Biopsy to prove resolved OM

Vascular: Current testing/consult

# BLA vs. Non-BLA

BLA=Biologics License Application

Approved Under Section 351 of Public Health Service

Act

FDA Approval as biologics/gene tx

Go through strict FDA pathway (PMA)

High standards for efficacy and safety

Strictest GMP

Batch to Batch potency and functional testing

Proven Effectiveness via Multiple RCT's

Very few CTP are BLA


- Non-BLA=Non- Biologics License Application
- Submitted as medical devices under Section 361 HCT/P
- FDA Registered via 510(k) process
- 510(k)=modification or equivalent to existing
- Limited Evidence of Effectiveness
- Vast Majority of CTP are Non-BLA

CMS: WISeR model targets both BLA and Non BLA CTP

## BLA or Non BLA?

| CY 2025 HCPCS Code | CY 2025 Short Descriptor                                   | FDA Regulatory Category |
|--------------------|--|-------------------------|
| A2001              | Innovamatrix ac, per square centimeter                     | 510(k)                  |
| A2002              | Mirrugen advanced wound matrix, per square centimeter      | 510(k)                  |
| A2005              | Microlyte matrix, per square centimeter                    | 510(k)                  |
| A2006              | Novosorb synpath dermal matrix, per square centimeter      | 510(k)                  |
| A2007              | Restrata, per square centimeter                            | 510(k)                  |
| A2008              | Theragenesis, per square centimeter                        | 510(k)                  |
| A2009              | Symphony, per square centimeter                            | 510(k)                  |
| A2010              | Apis, per square centimeter                                | 510(k)                  |
| A2011              | Supra sdrm, per square centimeter                          | 510(k)                  |
| A2012              | Suprathel, per square centimeter                           | 510(k)                  |
| A2013              | Innovamatrix fs, per square centimeter                     | 510(k)                  |
| A2015              | Phoenix wound matrix, per square centimeter                | 510(k)                  |
| A2016              | Permeaderm b, per square centimeter                        | 510(k)                  |
| A2018              | Permeaderm c, per square centimeter                        | 510(k)                  |
| A2019              | Kerecis omega3 marigen shield, per square centimeter       | 510(k)                  |
| A2021              | Neomatrix, per square centimeter                           | 510(k)                  |
| A2022              | Innovabum or innovamatrix xl, per square centimeter        | 510(k)                  |
| A2024              | Resolve matrix, per square centimeter                      | 510(k)                  |
| A2027              | Matriderm, per square centimeter                           | 510(k)                  |
| Q4101              | Apligraf, per square centimeter                            | PMA                     |
| Q4102              | Oasis wound matrix, per square centimeter                  | 510(k)                  |
| Q4103              | Oasis burn matrix, per square centimeter                   | 510(k)                  |
| Q4104              | Integra bilayer matrix wound dressing (bmwd), per square   | 510(k)                  |
| Q4105              | Integra demal regeneration template (drt) or integra omnig | PMA                     |
| Q4106              | Demagraft, per square centimeter                           | PMA                     |
| Q4107              | Graftjacket, per square centimeter                         | 510(k)                  |
| Q4108              | Integra matrix, per square centimeter                      | PMA                     |
| Q4110              | Primatrix, per square centimeter                           | 510(k)                  |
| Q4111              | Gammagraft, per square centimeter                          | 510(k)                  |

- <https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices/cms-1832-f>



# 2026 Reimbursement Implications for BLA vs Non BLA

Currently non BLA (510(K) 365 HCT/P paid same

Current National Rate is \$127.14/sq cms.

BLA under 351 Continue at ASP +6%

Several Legal Actions to Reverse

Payment policy applies to offices and facilities

Unbundling of application and product in facilities

2027 and  
Beyond Reimbursement for CTP?

361 HCT/P

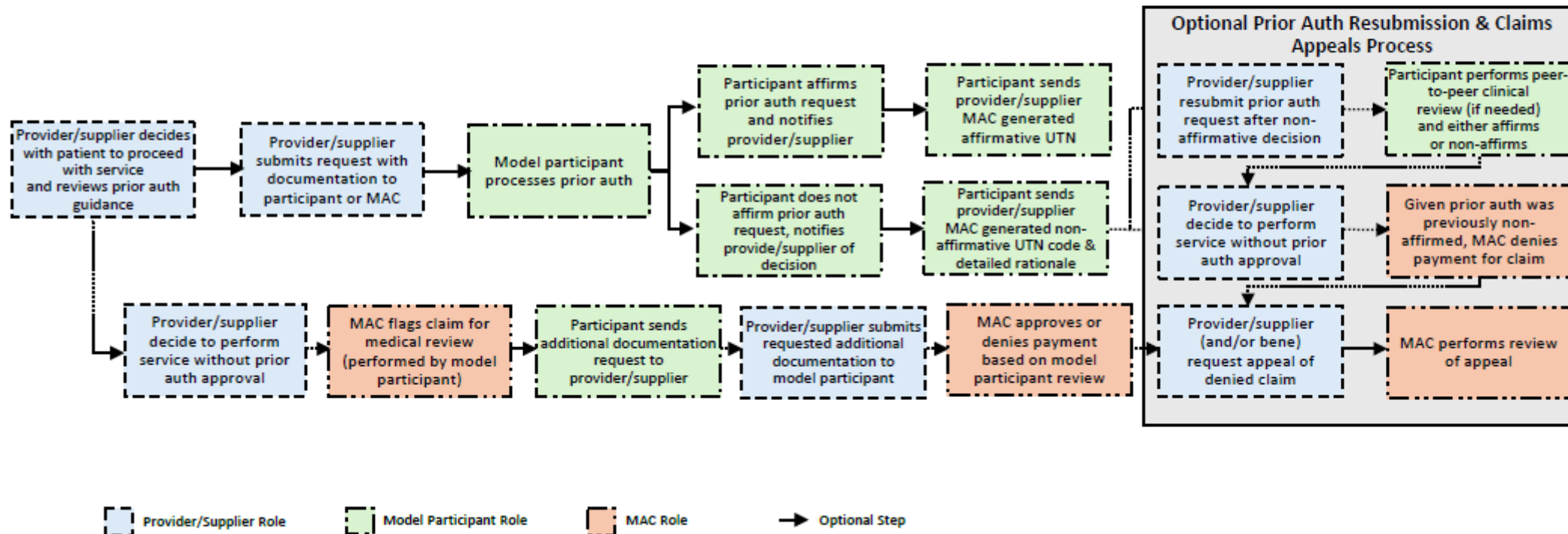
510K

PMA (Similar to BLA)

These three will be paid under separate  
payment rates


Rates will be updated during rulemaking  
(summer or early fall)

Figure 1. WISeR Model workflow



## What Does CTP Reimbursement Look Like?

- Perform Service
  - Submit for Pre Payment Review
  - Risk Claim Rejection
  - Potential Denial-
  - Loss of what you paid for product
  - Potential Loss of fee for product
  - Potential Denial of application fee
- Obtain Prior Authorization 2-3 day
  - Obtain UTN
  - Submit UTN to MAC
  - No Pre-Payment Review
  - Guaranteed Payment
- Submit Enough P/A and approvals
  - Obtain Gold Card
  - Opt out of future P/A?



# What Is the WISeR Program?

WISeR=Wasteful Inappropriate and Service Reduction

“Voluntary” Program in Six States

NJ, ~~Arizona~~, Ohio, Oklahoma, Texas and ~~Washington~~

Does not change Medicare coverage of payment

Supports NCD or LCD

Jan 15,2026-Dec 31, 2031

Currently:14 Targeted items/services w/more added on qtrly basis

CTP Is currently the Only DPM Provided service

WISeR Limited to MAC where there is an LCD for Service

# How Do I Opt Into WISeR?

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WISeR is a voluntary

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WISeR program operator in NJ is Genzeon

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Fax Materials to Genzeon (484) 200-2155 or

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Mail Materials to Genzeon

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Register for Genzeon Portal : <https://portal.hip.one/>

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Contact Info:

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WISeR helpdesk email  
(preferred): [wiserhelpdesk@genzeon.com](mailto:wiserhelpdesk@genzeon.com)

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WISeR helpdesk phone: 484-713-9291

# Where does WISeR Apply/Not Apply?

## **Applies**

- Physician's Office (11)
- Patient Home (12)
- ASC (24)
- Hosp Out-Patient 19, 22
- MSP
- Novitas: NJ, Oklahoma, Texas,
- CGS: Ohio

## **Does Not Apply**

- Indian Health Service
- MCR Advantage
- Nursing Home (32)
- Part A Billing (In-Patient Hosp).
- V.A.
- Hospital ER

## If I am being paid a flat rate/sq.cm what is the ROI?

Table 1. Sample List Of Skin Substitutes With Their Respective Average Sales Price (ASP) As Reported By Manufacturers

| HCPCS | CAMPS/ CTP/ Skin Substitute Name, per 1 square centimeter | ASP price | FDA Category  |
|-------|---|-----------|---|
| A2019 | Kerecis marigen shld                                      | \$67.27   | 510(k)  |
| Q4105 | Integra drt or omnigraft                                  | \$26.94   | Class III Medical Device premarket approval (PMA)   |
| Q4107 | Graftjacket   | n/a       | 21 CFR Part 1271 Part 361 Human Cells, Tissues, and Cellular and Tissue-based Products (HCT/Ps) |
| Q4110 | Primatrix   | \$65.40   | 510(k)  |
| Q4121 | Theraskin   | \$52.75   | 21 CFR Part 1271 Part 361 Human Cells, Tissues, and Cellular and Tissue-based Products (HCT/Ps) |
| Q4122 | Dermacell, awm, porous                                    | n/a       | 21 CFR Part 1271 Part 361 Human Cells, Tissues, and Cellular and Tissue-based Products (HCT/Ps) |
| Q4128 | Flexhd / allopatchhd                                      | \$29.91   | 21 CFR Part 1271 Part 361 Human Cells, Tissues, and Cellular and Tissue-based Products (HCT/Ps) |
| Q4133 | Grafix stravax prime pl                                   | \$138.74  | 21 CFR Part 1271 Part 361 Human Cells, Tissues, and Cellular and Tissue-based Products (HCT/Ps) |
| Q4158 | Kerecis omega3  | \$67.27   | 510(k)  |
| Q4159 | Affinity  | \$204.96  | 21 CFR Part 1271 Part 361 Human Cells, Tissues, and Cellular and Tissue-based Products (HCT/Ps) |
| Q4160 | Nushield  | \$2784.38 | CFR Part 1271 Part 361 Human Cells, Tissues, and Cellular and Tissue-based Products (HCT/Ps)    |
| Q4187 | Epicord   | \$245.30  | 1 CFR Part 1271 Part 361 Human Cells, Tissues, and Cellular and Tissue-based Products (HCT/Ps)  |
| Q4203 | Derma-gide  | \$1052.89 | 510(k)  |
| Q4101 | Apligraf  | \$30.23   | Class III Medical Device premarket approval (PMA)   |
| Q4102 | Oasis wound matrix  | \$11.89   | 510(k)  |
| Q4106 | Dermagraft  | n/a       | Class III Medical Device premarket approval (PMA)   |
| Q4151 | Amnioband, guardian                                       | \$134.89  | 21 CFR Part 1271 Part 361 Human Cells, Tissues, and Cellular and Tissue-based Products (HCT/Ps) |
| Q4186 | Epifix  | \$151.17  | 21 CFR Part 1271 Part 361 Human Cells, Tissues, and Cellular and Tissue-based Products (HCT/Ps) |

Fees are per sq. cm

Fees are presented based on mfg. data and published in WoundReference.com

National fee is \$127.14 sq.cm

Minimize Wastage

Choose product closest to wound size

Document How Much Was Applied + Wasted

Bill Amount Applied in Single Layer

Can I Submit  
Multiple Dates  
of Service Under  
A Single P/A?

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UTN is good for 120 Days

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Designate in your request that  
the service is for on-going tx

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Provide reasonable estimate  
for # of units over 120 Days



# Fun Facts from Novitas LCD

- Episode of Care (EOC) =12 weeks
- Maximum of 10 CTP Applications Per Episode of Care
- Product Change Within episode of care is allowed
- Retreatment of ulcers are not allowed if:
  - >75% closure from baseline, or <0.5sqcm, healed ulcers, or
  - Previous EOC was unsuccessful.
  - Re Tx Within One Year of EOC is Not Covered
  - Repeat Use of Wound Prep Codes Not Allowed
- CTP Not Covered if Uncontrolled Systemic Factors (e.g., DM, lack of Tob, active Charcot arthropathy, vasculitis).

Does WISeR  
Model Apply  
to Non  
DFU/VLU?

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WISeR Model Only  
Applies to DFU or VLU

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Other applications not  
covered by DFU/VLU LCD

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\$127.14 applies to all  
applications

# Can I Appeal an Adverse WISeR Determination?



YES



THERE ARE NO LIMITS TO THE  
NUMBER OF SUBMISSIONS



PROVIDERS CAN REQUEST A  
PEER-TO-PEER POST ADVERSE  
DECISIONS

# Can I Use an ABN with CTP?

If a WISeR prior authorization request is denied, or if a service is likely to be denied, the provider should issue an ABN and, in many cases, append a GX modifier.

The GX modifier may be used if the claim is expected to be denied by Medicare based on Medical Necessity or frequency limits.

# What Happened to the JW and JZ Modifiers?

JW: Wastage

JZ: Entire Product Applied

These modifiers are no longer to be used on non BLA products

Only used for billing single use drugs and BLA

# What Do I Submit to WISeR?

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Detailed Patient Info (Full Name, MBI, DOB, Address)

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Facility & Provider Details (Name, address, NPI, PTAN Contact inf)

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Specific HCPCS Codes, POS, Units of Service over 120 Days

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Initial or Resubmission, Regular (3 day) or urgent (2 day)

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If urgent-document why?

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WISeR Approval is Product Specific

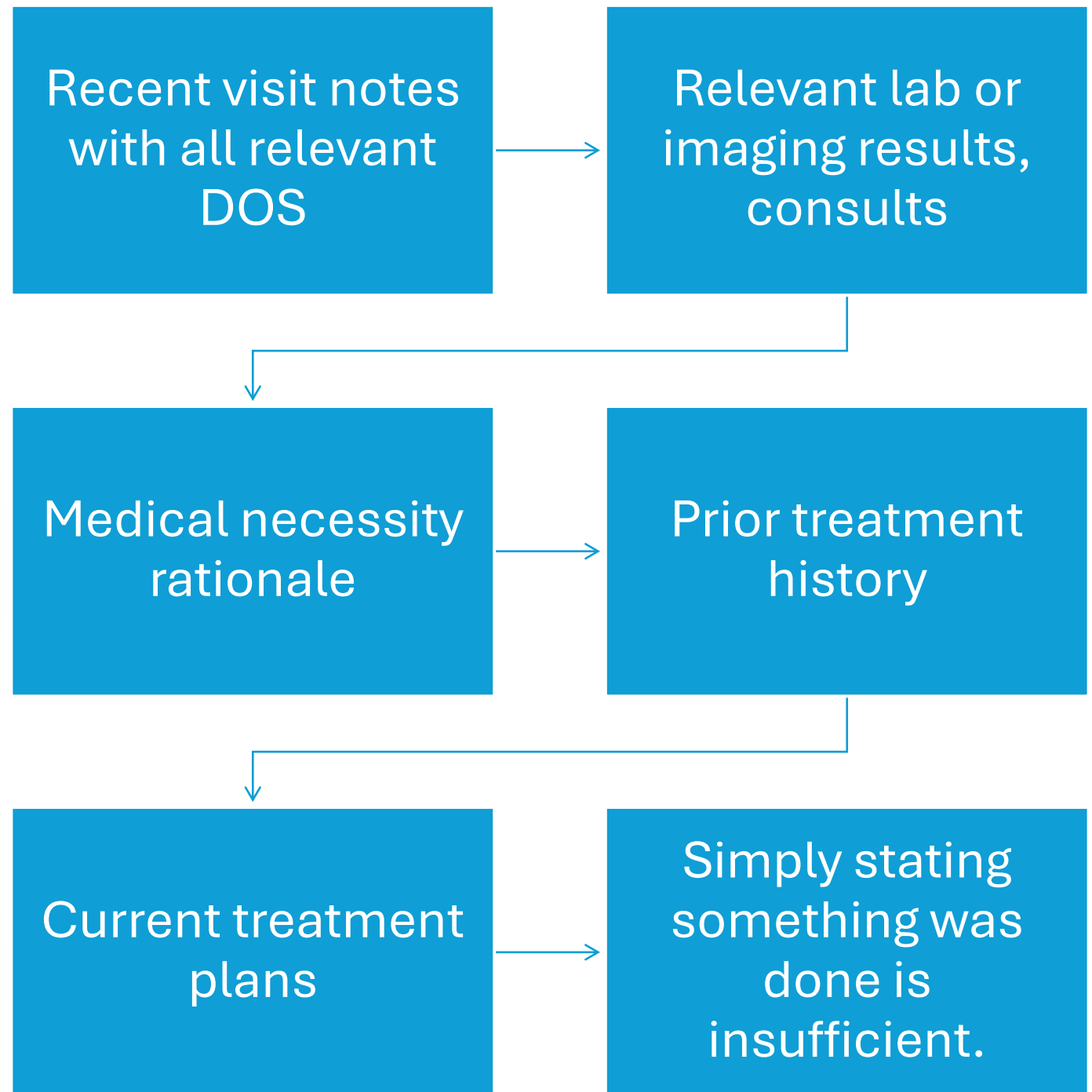
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WISeR Approval is Provider Specific

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Comprehensive Documentation =?

# CTP and Comprehensive Documentation?



# Which is proof of performance?

Smoking cessation counseling was performed on .....

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Smoking cessation counseling was provided on .... at which time the patient was provided with written information on smoking cessation, adverse effects of smoking on their health including delayed wound healing were discussed. The patient was referred back to their PCP for medication to assist with smoking cessation.

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The patient was counseled on wt. loss..... Or

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The patient was informed that their BMI >30 and wider abdominal girth is creating issues with venous blood flow return. The need to lose wt was discussed in detail and the patient was referred to both Dr. Jones a bariatric specialist and Wt. Watchers to assist them with their goal to lose wt.

## More Proof of Performance

The patient had NIVT for a DFU RT Hallux and this was WNL.....

The patient had NIVT done on ..... and the results are as follows:

ABI: RT: .90 LT .80 TBI Hallux: LT 0.8 RT 0.7

Doppler, PPG PCR Wave forms illustrate biphasic flow w/loss of dichrotic notch.

# More proof of performance

AM FBS today 85  
on 500 Metformin  
bid. Other meds...

AM FBS today 85,  
A1C last week 7.2  
3 months ago 8.5

Diary reviewed  
AM and FBS  
copied to chart

Diabetes meds  
reviewed are  
500mg metformin  
bid. Other meds..

# More Proof of Performance

Patient is wearing acceptable footwear which is in good working order... Their foot orthotics are in good working order.

Patient is wearing... shoes provided by this office which is PDAC validated under the Therapeutic Shoe Program for Beneficiaries with diabetes and has a rocker sole. Their diabetic inserts are also PDAC validated. Both were inspected and are in good working order. The second rt metatarsal head ulcer is adequately off loaded.

# Proof of Performance Failure to Respond

03/15/26 DU was initially treated on 02/01/26 and was 2.1 sq cms and is now 2.0 sq. cms and 0.1 cms deep

04/15/26: The wound was initially treated on 02/01/26 and was 2.1 sq cms and 0.1 cms deep. On 03/01 it was 1.75sq cms and 0.1 cms deep. That is a 17% reduction but there is an increase in the biofilm and there is a lack of granulation tissue, this despite weekly sharp debridement (last one 4/8/26) .....



# Billing Wound Debridement and CTP Application on Same DOS

11042-11047 and  
97597-97598  
Why Yes or No?

15002-15005  
Why Yes or No?

## What Else Can I Bill & Support CTP Implantation?

- Let's Not Forget E/M Coding
- Base On Time
- Easy to Predict 99214 or 99215
- 99214 = 30-39 minutes \$136.28
- 99215= 40 + minutes \$193.25
- 11042= \$133.26
- 97597= \$102.25
  
- Time ≠ Time with Patient
- Time = PtF2F +family, reviewing labs & images, past hx, Speaking with and coordinating care w/family, HHA, other qhcp, etc. from 12:00Midnight to 11:59:59 on same DOS as face-to-face time with patient

# Billing of CTP in POS 11

- Bill CTP Application Codes (15271-15278)
- Both BLA and Non BLA Bill # Units
- BLA: Use ASP +6% x # Units
- BLA: Wastage JW Modifiers Billed Separately from that applied
- Non BLA: \$127.14x # Units No payment for wastage

For both BLA and Non BLA=

Amount discarded must be clearly documented in chart

# Billing for CTP in Facilities



HCP Bills for Application 1527X



Facility Bills for CTP

# Forewarning!

All CTP are single use

FDA strictly prohibits sharing  
between patients or

Saving product from one date of  
application for use in future on same  
patient

# Summary

- Extensive Documentation Requirements for both BLA and Non-BLA CTP
- Currently There Are **NO** BLA CTP Approved
- All CTP are under high audit scrutiny
- Obtain prior authorization when possible (WISeR)
- For non MCR obtain pre-determination of benefits
- Be sure and use good SWC x 4 weeks
- Consider alternative treatments (e.g., HBO, Hyperoxyic, US Saline Tx, etc.)