Maintaining Compliance for a Successful Wound Care Practice Part 1 Overview

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Disclosures

Paul Kesselman DPM

Receives grant/research support from: POL Tech, Vaporox, EMPO Health Is a member of the Advisory Board for: POL Tech, Vaporox, EMPO Health

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Learning Objectives

- 1. Identify The Top Policies which may affect your wound care practice
- 2. Analyze these policies and recent changes
- 3. Demonstrate successful navigation through these policies
- 4. Incorporate these with Standard of Care to defend your services
- 5. Add cash non-covered services

Why is documentation so important?

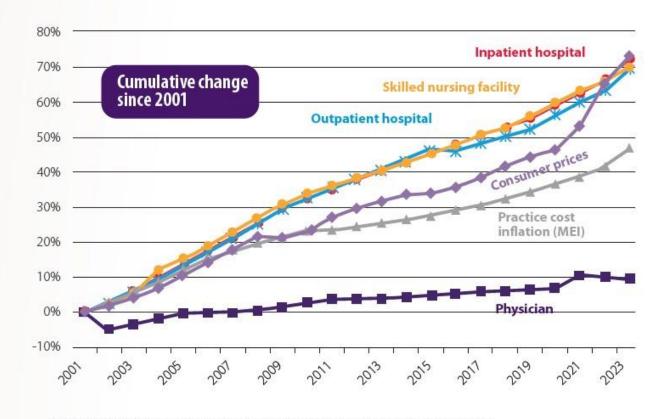
Inflation
Audits
Liability

Medicare physician payment is NOT keeping up with inflation.

Medicare updates compared to inflation (2001–2023)

Adjusted for inflation in practice costs, Medicare physician pay declined 26% from 2001 to 2023.





Sources: Federal Register, Medicare Trustees' Reports, Bureau of Labor Statistics, Congressional Budget Office.

Top Considerations for Compliance in Wound Practice

- Physicians are in the Wound Healing Business Not Wound Product Business
- Document Medical Necessity and Instruments for all Procedures
- If Conservative Care Is Working, Stick With It
- If Conservative Care Isn't Working, Document Rationale for Change
- Failure to Properly Document Will Cost You Revenue & Ability to Heal
- Document Rationale for Specific Product(s), Applied and Wastage
- Surgical Dressings and CTP Don't Always Go Together
- In Office Can Bill for Both Product & Application
- Existence of Product & Application Code ≠ Reimbursement
- Chose Procedures & Product Based on Medical Necessity Not Fee Schedule
- Stay on Top of LCD & Policy Articles

3rd Party Payer Policies

- Local Carrier Determination (LCD) and Local Carrier Articles (LCA) +
- Supplementary Instruction Articles (SIA)
- Where Can I Find These Policies?
- How Can I Obtain Updates?
- Where Can I Find Schedule?

Top Wound Care Policies (LCD) to Understand

- CTP: Effects Application (1527X) + Supply (A or Q) codes
- Pending Overhaul for Mid April. Will it go through?
- E/M Codes (If performed on same DOS as debridement)?
- Wound Debridement (11042-11047) 97597/8 and others
- Non-Invasive Arterial/Venous Vascular Testing (939XX)
- Treatment of VLU
- Compression Wraps, Unna Boot
- Lymphedema Garments
- Surgical Dressings (JA 29% error rate, JC/CERT error rate higher)
- AFO and Therapeutic Shoes (~30-~70% error rate)

Local MAC Website (Novitas)

Contact Us Enrollment Frequently Asked Questions Forms Catalog Join our E-mail Lists Medical Policy / LCDs Medical Review News & Publications Self-Service Tools pecialties / Services











Note: The search bar below only looks for a direct match of what is in the table below; multiple keyword searches are not available. For custom results, try our LCD Search Tool which offers additional search options, including multiple keywords and ICD-10.

Inclusion in this list does not imply coverage or non-coverage. Click on the LCD ID and/or article number for specific information. Prior to viewing the LCD and/or article, you may be prompted to accept a license agreement.

Not all codes have a policy associated with them. Novitas will consider medically reasonable and necessary services for payment in the absence of an LCD, billing and coding article, NCD, or CMS manual instruction that limits coverage.

A national Medicare Administrative Contractors (MACs) workgroup collaborated to develop or revise the LCD titles marked with an *.

Proposed LCDs **Update History**

Title	LCD#	Article # \$	Response to comments article #	CPT/HCPCS codes
4Kscore Test Algorithm	L37792	A56653	uruoio ii	81539
Allergen Immunotherapy	<u>L36240</u>	A56538	A59574	95115, 95117, 95144, 95145, 95146, 95147, 95148, 95149, 95165, 95170, 95180
Allergy Testing	<u>L36241</u>	<u>A56558</u>		0165U, 0178U, 82785, 86001, 86003, 86005, 86008, 95004, 95017, 95018, 95024, 95027, 95028, 95044, 95052, 95056, 95060, 95065, 95070, 95076, 95079
Ambulatory Electrocardiograph (AECG) Monitoring	<u>L39490</u>	<u>A59268</u>	A59366	93224, 93225, 93226, 93227, 93228, 93229, 93241, 93242, 93243, 93244, 93245, 93246, 93247, 93248, 93268, 93270, 93271, 93272, 93297, 93298
Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds	<u>L35041</u>	A54117		15002, 15003, 15004, 15005, 15040, 15050, 15271, 15272, 15273, 15274, 15275, 15276, 15277, 15278, C5271, C5272, C5273, C5274, C5275, C5276, C5277, C5278
Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents		A53049		*** This article is applicable to all drugs and biological CPT and HCPCS codes. *** The following codes are specifically listed in the text of this article: 36593, 96360, 96361, 96365, 96366, 96367, 96375, 96376, 96379, 96411, 96413, 96415, 96417, 96523, 99211, J7999
Assays for Vitamins and Metabolic Function	<u>L34914</u>	A56416		82180, 82306, 82379, 82607, 82652, 82746, 83090, 83698, 84207, 84252, 84425, 84446, 84590, 84597, 85385, 86352
Auricular Peripheral Nerve Stimulation (Electro-Acupuncture Device)		A55240		64555, 64999
Autonomic Function Tests	L35395	A54954		95921, 95922, 95923, 95924, 95999

	Tetanus Immunization		<u>A58872</u>	90714, 90715
	Thoracic Aortography and Carotid, Vertebral, and Subclavian Angiography	<u>L35035</u>	<u>A56631</u>	36200, 36215, 36216, 36217, 36218, 36221, 36222, 36223, 36224, 36225, 36226, 36227, 36228, 75600, 75605, 75710, 75716
	Transcranial Magnetic Stimulation (TMS) in the Treatment of Adults with Major Depressive Disorder	<u>L34998</u>	<u>A57072</u>	90867, 90868, 90869
	Transesophageal Echocardiography (TEE)	<u>L35016</u>	<u>A56505</u>	93312, 93313, 93314, 93315, 93316, 93317, 93318, 93320, 93321, 93325, 93355, C8925, C8926, C8927, Q9955, Q9956, Q9957
	Transurethral Waterjet Ablation of the Prostate*	L38712	<u>A58243</u>	C2596, 0421T
	Treatment of Abnormal Uterine Bleeding with Intrauterine Device (Hormone-Eluting)		<u>A59620</u>	58300, 58999
→	Treatment of Chronic Venous Insufficiency of the Lower Extremities	<u>L34924</u>	A55229	29581, 36465, 36466, 36468, 36470, 36471, 36473, 36474, 36475, 36476, 36478, 36479, 36482, 36483, 37241, 37242, 37243, 37244, 37500, 37700, 37718, 37722, 37735, 37760, 37761, 37765, 37766, 37780, 37785
	Trigger Point Injections	<u>L35010</u>	<u>A57751</u>	20552, 20553, M0076
	Upper Gastrointestinal Endoscopy (Diagnostic and Therapeutic)	<u>L35350</u>	<u>A57414</u>	43191, 43192, 43193, 43194, 43195, 43196, 43197, 43198, 43200, 43201, 43202, 43204, 43205, 43206, 43211, 43212, 43213, 43214, 43215, 43216, 43217, 43220, 43226, 43227, 43229, 43231, 43232, 43233, 43235, 43236, 43237, 43238, 43239, 43240, 43241, 43242, 43243, 43244, 43245, 43246, 43247, 43248, 43249, 43250, 43251, 43252, 43253, 43254, 43255, 43257, 43259, 43260, 43261, 43262, 43263, 43264, 43265, 43266, 43270, 43274, 43275, 43276, 43277, 43278
	Urodynamic Services - Non-invasive		A58541	55899
	Vestibular and Audiologic Function Studies	<u>L35007</u>	A57434	92537, 92538, 92540, 92541, 92542, 92544, 92545, 92546, 92547, 92550, 92552, 92553, 92555, 92563, 92567, 92568, 92570, 92562, 92563, 92565, 92577, 92577, 92572, 92575, 92576, 92576, 92579, 92582, 92583, 92584, 92587, 92588, 92601, 92602, 92603, 92604, 92620, 92621, 92651, 92652, 92653
	Wireless Capsule Endoscopy	<u>L35089</u>	<u>A57753</u>	91110, 91111
•	Wound Care	<u>L35125</u>	A53001	11000, 11001, 11004, 11005, 11006, 11008, 11010, 11011, 11012, 11042, 11043, 11044, 11045, 11046, 11047, 11720, 11721, 29580, 29581, 97597, 97598, 97602, 97605, 97606, 97607, 97608, 97610

CTP LCD

Local Coverage Determination (LCD)

Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds

L35041

Expand All | Collapse All







Regulatory Status

US Food and Drug Administration (FDA) Governing Skin Substitute Products

The FDA does not refer to any product or class of products as "skin substitutes." However, products commonly described as "skin substitutes" are regulated by FDA under one of the four categories described below depending on the origin and composition of the product and listed as a "Skin Substitute" with a HCPCS code Q41XX.

- 1. Human Cells, Tissues, and Cellular and Tissue-Based Products Cells and tissues taken from human donors and transplanted to a recipient are regulated under PHS 361 [21 CFR 1270 & 1271]. This regulation describes the rules concerning the use of HCT/Ps for human medical purposes. The final rule, 21 CFR Part 1271, became effective on April 4, 2001, for human tissues intended for transplantation that are regulated under section 361 of the PHS Act and 21 CFR Part 1270. HCT/Ps are regulated by the Center for Biologics Evaluation and Research (CBER). The Center for Biologics Evaluation and Research is responsible for regulating biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies. Establishments producing HCT/Ps must register with FDA and list their HCT/Ps establishments are not required to demonstrate the safety or effectiveness of their products and FDA does not evaluate the safety or effectiveness of these products.
- 2. Premarket Approval Premarket approval (PMA) by FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices. Before Class III devices can be marketed, they must have an approved PMA application. Therefore, wound care products regulated under the PMA process will require evidence that they promote wound healing before they are approved for marketing.
- 3. 510(k) Submissions According to FDA documents a "510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent (SE), to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to PMA." Submitters must compare their device to one or more similar legally marketed devices and make and support their substantial equivalency claims. Unlike PMA, 510(k) confers reasonable assurance of safety and effectiveness via demonstration of substantial equivalence to a legally marketed device that does not require premarket approval. Therefore, wound care products regulated under the 510(k) process will not typically require clinical evidence to establish effectiveness in wound healing, as compared with products regulated under the PMA process in which substantial clinical evidence is always required.
- 4. Humanitarian Device Exemption (HDE) An HDE is similar in both form and content to a premarket approval (PMA) application, but is exempt from the effectiveness requirements of a PMA. An HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. The applicant must demonstrate that no comparable devices are available to treat or diagnose the disease or condition, and that they could not otherwise bring the device to market. Humanitarian Device Exemption approval is based on evidence of probable benefit in a disease population occurring at a frequency of less than 4,000 patients per year in the United States.

Updated designation and approved usage criteria may be found under Medical Devices/Products and Medical Procedures at: http://www.fda.gov/&

Expanded classification criteria and explanation is included in the HHS/AHRS Final Report, December 18, 2012, entitled Skin Substitutes for Treating Chronic Wounds.

CTP LCD for DFU and VLU

- Recent History
- Result: All 7 MAC Drafted New LCD/LCA
- CAC & Industry Are Crafting Responses
- There Are MAC (e.g. NGS) No Current LCD/LCA
- What does one do if there is no LCD/LCA?
- That is no longer as new LCD is for all MACs

Why Need for LCD for CTP?

- Explosion of Available CTP
- Explosion in Utilization of CTP
- Reduced 200 + Products ~17
- With appropriate testing
- Poor Application Technique and Waste of Product Size: Wound Size

Proposed Problems with Future LCD ALL 7 MACS

- Treatment Time Period Being Reduced 12-16 weeks
- Number of Applications Limited (8) per EOC
- > 4 applications will require a KX modifier
- Can't Reopen New EOC for 12 months After EOC Has Closed.
- Pending Lawsuits by Mfg. against CMS.
- Recurrence of Wound in Same Area Subsequent to Closure =
- Failure and possible non-coverage
- What is <u>Substantial</u> improvement for VLU?
- Push Back from APMA & Other Medical/Industry Stakeholders

Billing E/M on Same Date as Wound Care Procedure

 As if buried in shifting sands like a booby trap, Modifier 25 is poised to wreak havoc on claims when it's appended incorrectly to an evaluation and management (E&M) charge – typically to indicate a separate service on the same date of service. So, what's a provider to do? When is it actually appropriate to append Modifier 25? How do providers indicate that there was a significant yet separately identifiable E&M service that went above and beyond the typical preand post-work associated with the applicable procedure? And how can providers avoid a possible audit by the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG)?

Audits on E/M on Same DOS as CTP

- Recoupments Have Been Very Successful
- E/M Supports Need for CTP (Included with CTP Application)
- E/M Mostly Due to Same Issues as Med Necessity for CTP
- If E/M Is Separate & Distinct for need for CTP, E/M Level Not Appropriate

Billing E/M on Same Date as Wound Care Procedure

- Circumventing E/M Monday & Sx Procedure on Tuesday Problematic
- All are subject to either pre or post payment review

- Use of 25 on same date or separate E/M on proximate date is problematic
- Many insurance carriers + MCR investigating this practice

 Conclusion: E/M Distinct and separate from sx procedures must be carefully documented and consider implications prior to billing

Reducing Reimbursement on E/M on Same DOS as Sx. CPT

Rationale: Carriers Do Not Want to Pay for Duplicity of Practice Expense

BC BS and Other Carriers

Payment of E/M Same DOS as Sx. CPT: 50% Reduction

• But a 50% reduction in payment really equals a significant reduction in more than just the PE. It actually = reduction in PE, Malpractice, etc.

Billing E/M on Same Date as Other Sx Procedures

- Best Tip:
- Separate Out the Additional Hx. & Management to Support E/M
- Document the additional work required
- Document why the E/M Was Necessary and Separate from Sx CPT

DME LCD from JA

JA DME > Policies > Local Coverage Determination (LCD) > Active LCDs



Policies

▶ Clinicians Corner

Documentation Checklists

▼ Local Coverage Determination (LCD)

Active LCDs

Archived LCDs and Policy Articles

Open Meeting

Proposed LCDs

Medical Director Articles

National Coverage Determination (NCD)

Noridian Medical Directors

Pricing Data Analysis and Coding (PDAC)

L200 Webinars Claim Examples Needed

To provide suppliers with in-depth insight into LCD requirements via claim examples and real life scenarios, Noridian will begin hosting policy specific L200 webinars.

Fax claim examples to 701-433-5957

Attention:

Provider Outreach and Education L200 Claim Example ____ Specialty



Active LCDs

In the table below, select an "LCD Title" link to view the locally hosted LCD PDF. To access the official LCD version, visit the CMS Medicare Coverage Database (MCD) 2.

CMS Medicare Coverage Database

- Current LCDs
- Current Policy Articles ☑

Search for an LCD Type here to filter...

LCD Title -	LCD ID Number and Effective Date	Policy Article and Effective Date	HCPCS
Ankle-Foot/Knee-Ankle- Foot Orthosis	L33686 [2] Effective 01/23/24	A52457 [2] Effective 01/23/24	A4467, A9283, A9285 L1900, L1902, L1904, L1906, L1907, L1910, L1920, L1930, L1932, L1940, L1995, L1951, L1960, L1970, L1971, L1980, L1990, L2000, L2005, L2006, L2010, L2020, L2030, L2034, L2035, L2036, L2037, L2038, L2106, L2108, L2112, L2114, L2116, L2126, L2128, L2132, L2134, L2136, L2180, L2182, L2184, L2192, L220, L2230, L2232, L2240, L2250, L2260, L2265, L2270, L2275, L2280, L2300, L2310, L2320, L2330, L2335, L2340, L2350, L2360, L2370, L2375, L2380, L2385, L2387, L2390, L2395, L2397, L2405, L2415, L2425, L2430, L2492, L2500, L2510, L2520, L2556, L2526, L2530, L2540, L2550, L2750, L2755, L2760, L2768, L2780, L2785, L2795, L2800, L2810, L2820, L2830, L2840, L2850, L2999, L4002, L4010, L4020, L4030, L4040, L4045, L4050, L4055, L4060, L4070, L4080, L4090, L4110, L4130, L4205, L4210, L4330, L4361, L4370, L4386, L4387, L4392, L4394, L4396, L4397, L4398, L4631
	1 22000 53	ACOJEDER	

Suction Pumps	Effective 01/01/24	A52519 ☑ Effective 04/01/23	A4216, A4217, A4605, A4624, A4628, A7000, A7001, A7002, A7047, A9272, E0600, E2000, K0743, K0744, K0745, K0746
Surgical Dressings	L33831 ☐ Effective 01/01/24	A54563 [2] Effective 09/07/23	A4450, A4452, A4461, A4463, A4465, A4490, A4495, A4500, A4510, A4649, A6010, A6011, A6021, A6022, A6023, A6024, A6025, A6154, A6196, A6197, A6198, A6199, A6203, A6204, A6205, A6206, A6207, A6208, A6209, A6210, A6211, A6212, A6213, A6214, A6215, A6216, A6217, A6218, A6219, A6220, A6221, A6222, A6223, A6224, A6228, A6229, A6230, A6231, A6232, A6233, A6234, A6235, A6236, A6237, A6238, A6239, A6240, A6241, A6242, A6243, A6244, A6245, A6246, A6247, A6248, A6250, A6251, A6252, A6253, A6254, A6255, A6256, A6257, A6258, A6259, A6260, A6261, A6262, A6266, A6402, A6403, A6404, A6407, A6410, A6411, A6412, A6413, A6441, A6442, A6443, A6444, A6445, A6446, A6447, A6448, A6449, A6450, A6451, A6452, A6453, A6454, A6455, A6456, A6457, A6501, A6502, A6503, A6504, A6505, A6506, A6507, A6508, A6509, A6510, A6511, A6512, A6513, A6530, A6531, A6532, A6533, A6534, A6535, A6536, A6537, A6538, A6539, A6544, A6545, A6545, A6544, A6545, A6545, A6545, A6545, A6545, A6544, A6545, A6545, A6544, A6545, A6545, A6554, A6555, A6538, A6539, A6540, A6541, A6544, A6545, A6545, A6545, A6546, A6547, A6544, A6545, A6555, A6556, A6537, A6538, A6539, A6540, A6541, A6544, A6545, A6545, A6549, A9270
Therapeutic Shoes for Persons with Diabetes	L33369 ☐ Effective 01/01/20	A52501 [2] Effective 11/05/20	A5500, A5501, A5503, A5504, A5505, A5506, A5507, A5508, A5510, A5512, A5513, A5514, K0903

Surgical Dressings

33831

Expand All | Collapse All







compression treatment items benefit.

Issue - Explanation of Change Between Proposed LCD and Final LCD

No proposed LCD issued.

CMS National Coverage Policy

CMS Manual System, Pub. 100-02, Benefit Policy Manual, Chapter 15, Section 100, 100-03, National Coverage Determinations Manual, Chapter 1, Sections 270.4 & 270.5

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the "reasonable and necessary" criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

Medicare provides reimbursement for surgical dressing under the Surgical Dressings Benefit. This benefit only provides coverage for primary and secondary surgical dressing used on the skin on specified wound types. Refer to the related Policy Article NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES for information about these statutory requirements.

In addition to the statutory requirements, for the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

DRESSINGS

The following are specific guidelines for individual product types.

A54563

Surgical Dressings - Policy Article

Expand All | Collapse All







Article Text

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary").

Surgical Dressings are covered under the Surgical Dressings Benefit (Social Security Act §1861(s)(5)). The CMS Benefit Policy Manual (IOM 100-02), CH 15, §100 provides interpretive guidance to contractors for the implementation of this provision. The relevant part of the manual section establishes two separate benefit criteria:

- . The necessity for and definition of a qualifying wound; and,
- . The requirements necessary for any product to be classified as a surgical dressing for purposes of coverage under this benefit.

In order for a beneficiary's item(s) to be eligible for reimbursement, all benefit requirements discussed below and the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met.

OUALIFYING WOUND

Surgical dressings are covered when a qualifying wound is present. A qualifying wound is defined as either of the following:

- · A wound caused by, or treated by, a surgical procedure; or,
- · After debridement of the wound, regardless of the debridement technique.

The surgical procedure or debridement must be performed by a treating practitioner or other healthcare professional to the extent permissible under State law. Debridement of a wound may be any type of debridement (examples given are not all-inclusive):

- · Surgical (e.g., sharp instrument or laser)
- · Mechanical (e.g., irrigation or wet-to-dry dressings)
- · Chemical (e.g., topical application of enzymes) or
- Autolytic (e.g., application of occlusive dressings to an open wound).

Dressings used for mechanical debridement, to cover chemical debriding agents, or to cover wounds to allow for autolytic debridement are covered although the debridement agents themselves are noncovered.

Examples (not all-inclusive) of clinical situations in which dressings are noncovered under the Surgical Dressings benefit are:

- . Drainage from a cutaneous fistula which has not been caused by or treated by a surgical procedure; or,
- · A Stage 1 pressure ulcer; or,
- · A first degree burn; or,



Surgical Dressings and Therapeutic Shoe Audits

- Have High Failure Rates in DME
- TPE, Post Pay, RAC, Cert, Etc.
- Accessibility To Care Becoming Big Issue for T Shoes

How Do I Stay Up to Date on Policy?

- Visit Both Your Local and DME MAC
- Enroll In List Serves
- Assign "one" Individual In Your Practice to Review Any LCD Updates
- Have an "electronic binder" with all the updates.
- It is Your Responsibility to Stay Up To Date!!
- Hold Monthly Staff Meetings to Discuss Updates

What Does the LCD & LCA Provide?

- Framework for coverage
- The LCD May or May Not Provide CPT/HCPCS Coding
- The LCA Always Provides CPT or HCPCS and ICD10 Coding
- LCA May be Product Specific LCD is Not Product Specific
- Frequency & Medical Requirements (e.g. "Optimization")
- Minimal Number Requirements ? (e.g. A1C > 9 non-covered?)
- Prior Authorization Requirements for MCR Part C/MCD/Others

Other Differences Between LCD and LCA

- Revisions of LCA May Be Unilateral by MAC
- Revisions of LCD Must Adhere to 21st Cent. Cures Act
- LCD Changes Very Complex Process
- Current Example: CTP LCD Revision Process
- Past Example: LCD Revision:
- Removed Specific Q or A CTP Products from LCA
- CTP Products Most Often in LCA

Identify Non-Covered Services

- Wound Wash Provided for At Home Use
- Other Products For Wound Cleansing (Gauze)
- AFO strictly for Off Loading
- Footwear for Non-Diabetics

Identify Covered HCPCS Services & Where to Bill?

- Surgical Dressings to DME MAC
- CTP, Wound Debridement, STSG to Local MAC
- How Do non-FFS MCR Pay for DME (e.g., Surgical Dressings, etc.)?
- Addition of Product Category May Require Change in DMEPOS Status

Diagnostic Testing & Procedures

- Adhere To The Requirements of the LCD
- Meet the Litmus Test of Provision
- No Matter Specialty Providing Service
- Separate Report from E/M May Be Required

Diagnostic and Procedural Examples:

- Was the Testing Equipment Compliant with the Standards of the LCD?
- Do The Objective Findings Accurately Reflect the Conclusions and DX?
- Is Your Report Compliant with the LCD?
- Will it stand up to medical standards of other medical professionals?
- Does Your Procedure Meet the Requirements of the LCD?
- Does the Claim ICD10 Match the Chart's Narrative Dx?

Diagnostic Test Compliance Issues

- Bidirectional Doppler Mandatory for Vascular Testing
- ABI cannot be Indirectly Inferred From other Modalities
- Document the ABI/TBI Report Referred to on the CTP DOS
- Standard of Care for Tissue Perfusion: Micro/Macro Circ.

Examples of Procedural Compliant Issues

- Sx Dressings: Document the "Amount of Drainage", Tunneling, Shape
- Sx Dressings: Match Drainage Amount to Type of Dressing
- CTP By FDA Single Use Only
- Document The Lot #/Expiration of CTP Applied
- Document The Level of Tissue Debrided & The Depth
- Match Size of Wound to Size Of Graft ("Q" Code) to Minimize Wastage
- Amount CTP Applied (JC) & Wastage (JW) Separately
- JZ: No Wastage

Measurements

- Pre and Post Wound Debridement
- Photographs Must Accurately Capture L X W X D
- Photographs Must Capture Date, Site & MR#

Lymphedema CVI Garments and PCD

- Are the Lymphedema Garments Registered Medical Devices?
- Has Your Patient Maxed Out on Garments?
- Exhausted Conservative Care Prior to Rx and Receiving PCD
- Does Your State Limit Rx PCD to MD/DO Only?
- Which Type of PCD Devices Are Reimbursable?

Can I Trust My Vendor for Coding Advice?

Never Explicitly Trust Vendors on Coding & Compliance Issues

- Best Sources:
- State and National Medical Association and CAC Reps
- MAC & Independent Wound Source Advocates (APWCA APWH SAWC)

Is Medicare All I Need to Worry About?

5/15/2024

Dear Provider:

In our notification on 5/15/2024, we advised of our continuing efforts to achieve greater payment accuracy. To assist us in that effort, we are announcing our partnership with Cotiviti, Inc for periodic prepayment reviews of paid medical claims, beginning on 6/17/2024. The payment review to be conducted is: Clinical Claim Validation (CCV).

What you can expect:

- Pre-payment CCV reviews are conducted to ensure proper billing. These require a copy of the medical records, which may be requested, if Oscar Health has not already received the medical records.
- If a claim is identified for review, you will receive a letter identifying the claim(s) selected and provide detailed information related to guidelines and timeframes to follow.

Cotiviti, Inc's staff includes registered nurses, medical and claims experts with expertise including, but not limited to, coding, claims operations and quality. They work collaboratively with their clients and medical providers to help create effective strategies, plans and activities to prevent both future payment errors and help improve the reimbursement process. You may already be familiar with Cotiviti, Inc as a leader in the industry with health plans across the United States.

Cotiviti, Inc is a Business Associate of Oscar Health as defined in 45 CFR 160.103 of the regulations implementing the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and will perform its responsibilities on behalf of Oscar Health in full compliance with HIPAA requirements.

Consistent with this business relationship, please provide Cotiviti's staff access to medical and/or financial information necessary to complete these reviews to the same extent Oscar Health's staff would be authorized to access such records.

Thank You

Dr Paul Kesselman DPM CEO Park DPM Consulting, LLC drkesselman@parkdpm.com 516 632-9944

Maintaining Compliance for a Successful Wound Care Practice Part 2 Overview

Paul Kesselman DPM DAPFAS DABMSP CEO Park DPM Consulting, LLC DrKesselman@parkdpm.com

Disclosures

Paul Kesselman DPM

Receives grant/research support from: POL Tech, Vaporox, EMPO Health Is a member of the Advisory Board for: POL Tech, Vaporox, EMPO Health

Disclosure will be made when a product is discussed for an unapproved use.

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Commercial support was not received for this activity.

Learning Objectives

- 1. Clinical Examples of Proper Documentation of Compliance
- Analyze How To Streamline Documentation and policies without LCD Regurgitation
- 3. Demonstrate successful or non successful treatment to your advantage
- 4. How Documentation Works with Standard of Care to Defend Your Services
- 5. Add cash non-covered services



Medicare JL Providers in DC, DE, MD, NJ & PA

Novitasphere | Policy Search | 👤 📨

JL Home

Medicare Part B [Change to A]



Schedules

Flu, Pneumonia, and Hep B Fees **Local Contractor Pricing**

Forms Catalog

Join our E-mail Lists Medical Policy / LCDs

Medical Review News & Publications Self-Service Tools

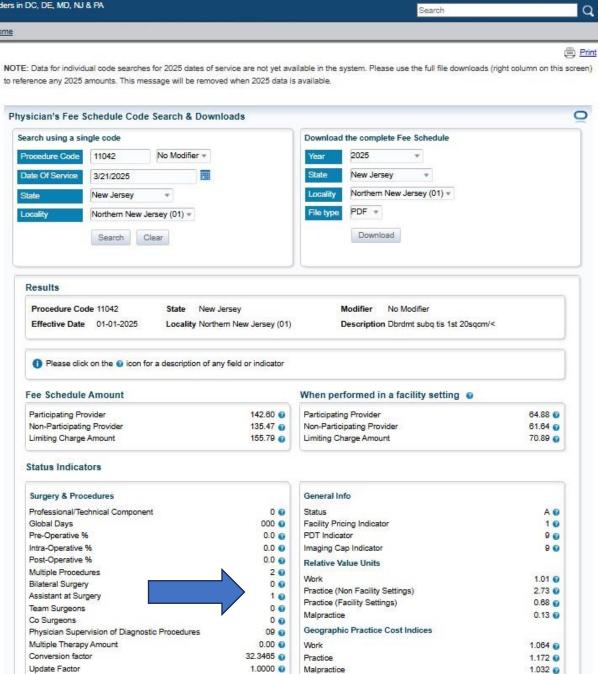
Specialties / Services



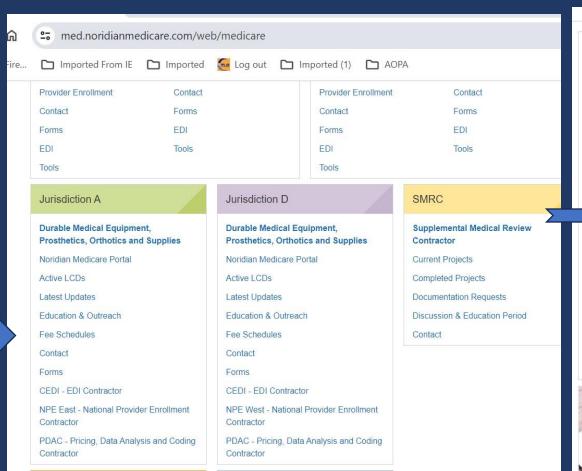




ISO 9001:2015 CERTIFIED COMPANY



Fee Schedule DME



Fees and News

Alerts

Bulletins

CMS MLN Connects

Email List Sign Up

▼ Fee Schedules

DMEPOS

Drug, Pharmacy Supply and Dispensing

Fee Schedule Lookup Tool

Labor Payment Rates

Oral Anti-Cancer Drugs

Parenteral and Enteral Nutrition

Pricing

Frequently Asked Questions (FAQs)

Latest Updates

Program Manager Collaboration

Fee Schedules

A fee schedule is a complete listing of fees used by Medicare to pay suppliers. This comprehensive listing of fee maximums is used to reimburse a supplier for an item or service. To access the most current fee schedules, select the appropriate Noridian or CMS link(s) below.

DMEPOS Fees - View Medicare DMEPOS Fee Schedules

- Seguestration
- Seguestration History
- Rural Zip Code File ☑

Drug, Pharmacy Supply and Dispensing Fees - View ASP, pharmacy supply and dispensing fees

Fee Schedule Lookup Tool - Find DMEPOS, Drug or PEN fees. Select applicable state and enter HCPCS to view

Former Competitive Bidding Area (CBA) Fee Schedule

Adjusted fees for former Competitive Bidding Areas (CBAs) during a gap period in the DMEPOS Competitive Bidding Program (CBP) are determined by CMS. These items have been paid based on the Former CBA Fee Schedules since 2019 (see MM11064 27).

To view the Former CBA Fee Schedule, visit the CMS DMEPOS Fee Schedule page [2]

- · Select the applicable file for the date of service
 - Under "File Name." Download that ZIP file, and you can open the files for CBA information, which are labeled
 - Former CBA Fee schedule
 - Former CBA National Mail Order diabetic testing supply fee schedule
 - Former CBA ZIP Code

Round 2 Zip Code Tool

Utilize the downlo
CBA and Zip tab
Competitive Bidd
to determine if a :
a Competitive Bid

Capped Monthly Calculat

Calculate
HCPCS Code of

Fee Schedule An

Rental Month:

Months 1

O Months 4

Fee Schedule Category: Prosthetics and Orthotics

Short Description for L5000: Sho insert w arch toe filler

Long Description for L5000: PARTIAL FOOT, SHOE INSERT WITH LONGITUDINAL

ARCH, TOE FILLER

Show 10 v entries

Showing 31 to 40 of 53 entries

Export As CSV

Export As PDF

Print

Filter Results

Check ZIP Code

Previous

2

6

Next

Beneficiary State of Residence	Modifier ↑	Modifier 11	Rural Fee 📗	Non-Rural Fee 📗	Effective From 📗	Effective To 📭
NJ				\$606.43	01/01/2025	03/31/2025
NM				\$808.58	01/01/2025	03/31/2025
NY				\$606.43	01/01/2025	03/31/2025
NC				\$635.20	01/01/2025	03/31/2025

Surgical Dressings Review

Have High Failure Rate and Narrow Profit Margin:

- Clinical Documentation of:
- Etiology, Location, Measurements
- Drainage, Infection, Tunneling, Undermining
- Stay Within Policy Lane Regarding Drainage
- Don't Forget WPOD

Surgical Dressing Compliance

- DFU of 3 sq cms. exhibits moderate to significant drainage & Rx bid hydrogel dressing changes. Covered or non covered?
- Policy Stipulates that Hydrogels are only covered to absent to mild drainage.
- Foam/alginate dressings covered for moderate-significant drainage
- Documentation of correct drainage may also support frequency of dressing changes and need for secondary dressing.

Surgical Dressing Compliance

- Secondary Dressing Must Be Additive and Supportive of 1° Dressing
- Don't Mix Between Hydrating (Hydrogel) and Absorptive (Alginates)
- (1) Wound= Single 1° Dressing + Single 2° Dressing

Extra Non-Covered Supplies = Gauze to clean wound + Wound Wash

Get Bulk Contract & Deal Directly With Mfg.

Surgical Dressing Compliance Size Matters

• DFU 2" x 2" wound

What Size Dressing Allowing for Some Minor Overlap?

• Is a 6" x 6" dressing supportive?

- Size of wound to size of dressing does matter
- Fee schedule not necessarily keep up with size differential

AFOs For Patients With Wounds?

DFU With Charcot Foot and Wound

- If AFO is solely needed for off loading
- Not covered

- AFO Is Needed to Tx MSK, or Neuro Dx
- Yes Covered

Always Offer Non-Covered Services

- Wound Wash Provided for At Home Use
- Other Products For Wound Cleansing (Gauze)
- Nutraceuticals are often non-covered but often medically necessary
- Footwear for Non-Diabetics
- Foot Orthotics Not Covered By FFS MCR or Others

Despite Non-Coverage: Document Their Medical Necessity

Therapeutic Shoes For Patients With Diabetes

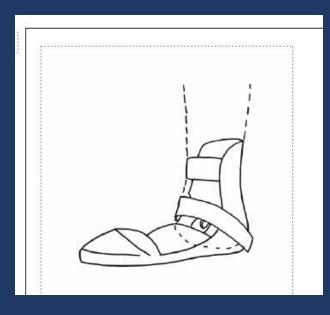
- FFS Medicare Audits Very High Failure Rate
- Rules are Clear in LCD But the Auditors Frequently Abuse and Misinterpret
- Created Patient Inaccessibility To Care Issue In Some Areas
- Result: Anticipated Higher Frequency of DFU in Certain Patient Populations
- FFS Medicare If Done Right: Profitable >\$250 p/pair of shoes +3 Pairs Inserts

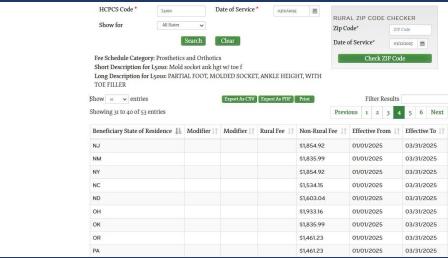
- Third-Party Medicare & Third-Party Issues:
- ROI is Low But Auditing and Compliance Issues Have Much Lower Bar

Lower Limb Prosthesis

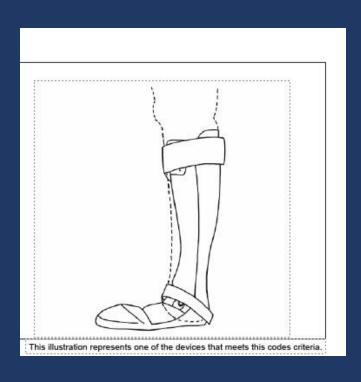


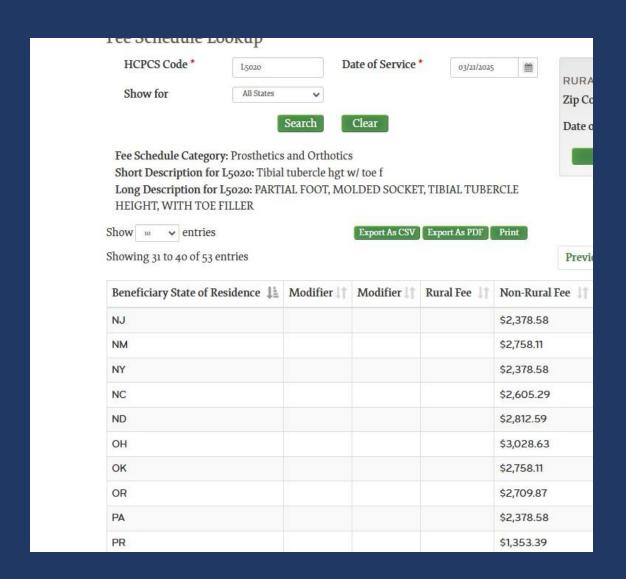






L5020: Toe Filler with AFO to Tibial Tubercle



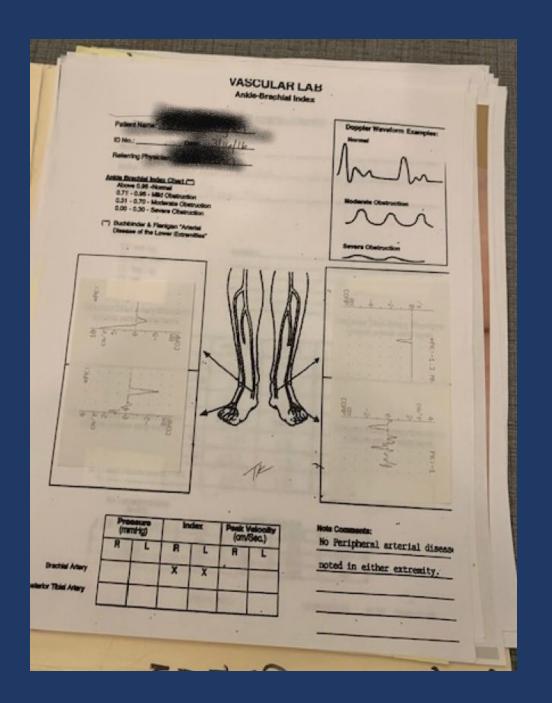


Requirements for L5000/L5010/L5020

- Post TMA + Equinus/Varus or Drop Foot
- Replaces A551X Inserts on the amputated limb
- LLP are not subject to the limits of the TSPD
- Frequency: Based on Medical Necessity

Vascular Testing Needs to Be Accurate & Complete

- Rationale For Testing
- Thorough Testing
- Bi-Directional Doppler
- Wave form analysis of all testing (Doppler, PVR, PPG)
- Under the Radar Billing for 2 Level Testing Is Problematic
- Impression
- Referrals and Treatment



This was read as normal
No Pressures or ABI Calculated
Wave Form Analysis Not Conducted
Not Signed nor dated by provider
No mention of bidirectional doppler
No indication of why testing performed

Date: 2012/05/07 Time: 4:38:12 PM

Ankle Brachial Index(ABI) Report

Sex: FEMALE Age: 65

Left



1sec/div.

Pressure: 122 mmHq

HR: 53 BPM

Posterior Tibial

8M

8M

Separation

ABI Test Results

Noncompressible 0.91-1.30

Compound

Dorsalis Pedis

cm/s

Requesting Physician: Paul Kesselman

Right



11.7 cm/s Peak Velocity:



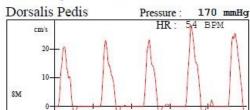
Pressure: 130 mmHg

HR: 61 BPM



8M





22.2 cm/s

Normal

0.00-0.69

Abnormal

TBI Test Results

8.4 cm/s

Peak Velocity: 9.1 cm/s

Deaconcac(men Ua)

Р	ressures(mmiri	8)
	Site	Left
	Arm	118
10.0	1000000	C. C

Compound

Peak Velocity:

Normal	130	Ankle	170
0.41-0.90 Mild to Moderate P.A.D.	82	Great Toe	122
0.00-0.40	1.11	ABI	1.45
Severe P.A.D.	0.69	TBI	1.03

Hirsch et al. 2005 ACC/AHA Practice Guidelines

Right	Site	Left	
118	Arm	118	
130	Ankle	170	
82	Great Toe	122	
1.11	ABI	1.45	
0.69	TBI	1.03	

Notes: Adequate perfusion to predict wound healing.

Continue w/present local wound care and off loading. Additional copies of documents for endo.to fabricate

new shoe order



Lower Extremity Report Date: 2012/05/07 Time: 4:38:12 PM Facility: Paul Kesselman Requesting Physician: Paul Kesselman



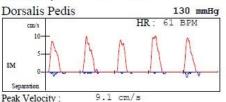
Right Left 1sec/div. Femoral mmHg Femoral mmHcr HR: *** BPM HR: *** BPM ***. * cm/s Peak Velocity ***. * cm/s Peak Velocity:

AK mmHg BK 140 mmHg Popliteal HR: 60 BPM cm/s SM Separation 10.7 cm/s Peak Velocity:

Posterior Tibial HR: *** BPM 8M Compound

11.7 cm/s

Peak Velocity

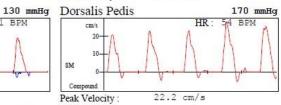


AK mmHg Popliteal HR: 60 BPM 9.9 cm/s Peak Velocity:

Sex: FEMALE

Age: 65

Posterior Tibial 122 mmHg HR: 53 BPM Compound Peak Velocity 8.4 cm/s



Site Left Arm 118 170 Ankle

1.45

Pressures(mmHg)

ABI

Right

118

130

1.11

Diagnostic Testing & Procedures

- Which test adheres to the LCD
- Which meets the standard of care?
- Which provides a prediction for future care of patient?

Examples of Procedural Compliant Issues

- Sx Dressings: Document the "Amount of Drainage", Tunneling, Shape
- Sx Dressings: Match Drainage Amount to Type of Dressing
- Document The Lot #/Expiration of CTP Applied
- Document The Level of Tissue Debrided & The Depth
- Match Size of Wound to Size Of Graft to Minimize Wastage
- Document Wastage of CTP on Separate Claim Line

Wound Care Measurements

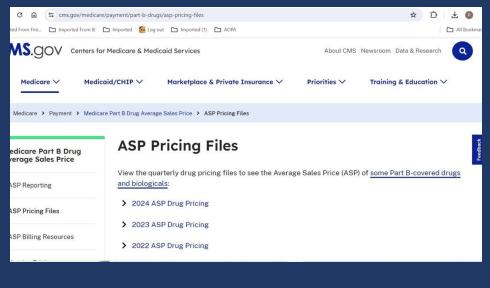






Which one(s) are good or bad and which can be used to substantiate CTP?

Where Can One Find the Fee Schedule for CTP?



Name	Date modified	Туре	Size
April 2024 ASP Pricing File 032124.xls	3/21/2024 5:00 PM	Microsoft Excel 97-2	169 KB
April_2024_ASP_Pricing_File_032124Final_File	4/10/2024 4:57 PM	WinZip File	65 KB
section 508 version of April 2024 ASP Pricing Fi	3/21/2024 5:15 PM	Microsoft Excel Com	53 KB

ASP Pricing Files

View the quarterly drug pricing files to see the Average Sales Price (ASP) of some Part B-covered drugs and biologicals:

April 2024 ASP Pricing File (ZIP) -03/21/2024-final file

 ✓ 2024 ASP Drug Pricing

PCS Code	Short Description	HCPCS Code Dosage	Payment Limit	Co-insurance Percentage
Q4104	Integra bmwd	1 SQ CM	48.875	20.000
Q4105	Integra drt or omnigraft	1 SQ CM	24.599	20.000
Q4108	Integra matrix	1 SQ CM	49.681	20.000
Q4111	Gammagraft	1 SQ CM	7.216	20.000
Q4114	Integra flowable wound matri	1 CC	1497.923	20.000
Q4118	Matristem micromatrix	1 MG	2.561	20.000
Q4121	Theraskin	1 SQ CM	46.134	20.000
Q4124	Oasis tri-layer wound matrix	1 SQ CM	8.968	20.000
Q4126	Memoderm/derma/tranz/integup	1 SQ CM	89.110	20.000
Q4128	Flexhd/allopatchhd/sq cm	1 SQ CM	30.689	20.000
Q4132	Grafix core, grafixpl core	1 SQ CM	110.441	20.000
Q4133	Grafix stravix prime pl sqcm	1 SQ CM	143,226	20.000
Q4137	Amnioexcel biodexcel 1sq cm	1 SQ CM	104.907	20.000
Q4141	Alloskin ac, 1 cm	1 SQ CM	41.351	20.000
Q4143	Repriza, 1cm	1 SQ CM	29.149	20.000
Q4147	Architect ecm px fx 1 sq cm	1 SQ CM	147.222	20.000
Q4150	Allowrap ds or dry 1 sq cm	1 SQ CM	78.273	20.000
Q4151	Amnioband, guardian 1 sq cm	1 SQ CM	132.875	20.000
Q4152	Dermapure 1 square cm	1 SQ CM	44.903	20.000
Q4153	Dermavest, plurivest sq cm	1 SQ CM	125.556	20.000
Q4154	Biovance 1 square cm	1 SQ CM	155.454	20.000
Q4159	Affinity1 square cm	1 SQ CM	309.578	20.000
Q4160	Nushield 1 square cm	1 SQ CM	94.918	20.000
Q4163	Woundex, bioskin, per sq cm	1 SQ CM	171.450	20.000
Q4164	Helicoll, per square cm	1 SQ CM	1571.962	20.000
Q4166	Cytal, per square centimeter	1 SQ CM	19.205	20.000
Q4168	Amnioband, 1 mg	1 MG	17.052	20.000
0.1470	O	1.00.011	50.700	

CTP and Wound Preparation/Debridement

- CTP sites are considered ready to receive CTP
- Require only minimal preparation on DOS of application
- Debridement and Prep CTP are included with RVU for CTP application

April 13 New Requirements? For DFU Each Note Must Document

- Failure to achieve 50% reduction and calculate size % reduction
- Photos over 4 weeks to prove failure to achieve 50% reduction
- Eval of Neuropathy and Vascularity
- Metabolic Factors Optimized (e.g., A1C, glucose, albumin, renal, hep.)
- Tobacco/Nutritional/Diet Issues Documented
- Off Loading, footwear and activity
- Why did you use a specific product?
- Absence of Infection including O/M
- Wound and Skin Assessment (e.g. granulation tissue, etc.)

Why does this not support the use of CTP?

Kenneth is here for follow on bilateral venous leg ulcers. He has a hist of type 2 diabetes and peripheral venous insufficiency. The pati reports burning pain and rates 6/10 today. Decrease in pain since the l visit. Active venous ulcers are at ulcers was noted at the bilateral Erythema is noted. Bilateral venous ulcers noted are at the lateral asp of the right leg and anterior shin of the left leg. The patient is tak doxycycline BID. We reviewed and revealed the wound culture with patient and he is on the correct antibiotic. Moderate drainage was no after the removal of the dressings. New ulceration was noticed at dorsal aspect of the 3rd and 4th MPJ left foot. Topical lidocaine v applied over the ulceration to get it numb. Ulceration debridement v performed to healthy tissue followed by application of 2 of 6 x 8 96UNITS Revita human placental membrane graft at bilateral foot.

April 13 New Requirements? For DFU Each Note Must Document

- Each application should be in an Operative Report Format
- Patient's Name MR# Date.....
- Time In: Time Out:
- Patient was placed on the Operative Table in supine position. A time out was performed and the Operative site confirmed to be.....
- List instruments, supplies and amounts used or wasted & why.
- Pre-operative and post operative photos.
- Post operative instructions

Appropriate for CTP?

- Patient is Type II DM w/plantar DFU Lt Foot sub 5th metatarsal head 4 sq cms 0.5cms deep w/minimal drainage, good granulation tissue to superficial fascia with minimal necrosis.
- IDSA grade 1 with minimal erythema. Last C/S negative. A1C one month ago 7.2. ABI .0.85 and good wave forms doppler/pcr (see report).
 - Patient is non-smoker all their life and is on 2gmNa 2500 Cal Meal Daily
 - BMI: 24.4 Normal
- Albumin and other signs of adequate nutrition.
- Permanent LOPS noted previously. Has been off loading with T Shoe to minimize trauma to wound
- Patient has had multiple debridements over past 4 weeks with only 25% in size reduction (was 4cm 30+ days ago and now 3cms). All photos documented.
- Medical clearance and optimization by PCP last week (see attached).

CTP Application

is still noted. Ulcers are much and decrease in size. Topical lidocaine was applied over the ulceration to get it numb. Ulceration debridement was performed to healthy tissue followed by application of 6 x 6 cm 36 UNITS and 4x4 cm 16UNITS total of 52 Revita human placental membrane graft at bilateral foot. The ulcers were then dressed with adaptic, silver dressings, ABD pads, Xtrasorb, Kerlix, and Coban. Lastly, a UNNA boot at the bilateral foot was performed. All of the procedures were performed today using standard techniques and were well tolerated by the patient. A new wound culture is taken today and will be sent to BAKO diagnostics

Ulcers have not decreased in size in last four weeks despite proper debridement and optimization of DM with A1 C of 7.1 FBS this AM 98. CMP and Medical clearance from Dr. Smith were reviewed and all are optimized and h/she has been cleared for surgery.(see attached) No evidence of infection was noted. Vascularity as per Dr. Jones NIVT (3/1/25) was noted to be optimized and noted to predict healing. Wound is measured as 4x4 cms. which is only 30% reduced from initial visit of >30 days ago when SWC was started (see note of Feb 1 2025.

Using sterile technique and FDA approved application preparation and application guidelines a 6 x 6 piece of Revita was applied. Lot # 123456 exp 4/2/25. There was approximately 2x 2cms of wastage which was trimmed and discarded. The graft was secured with steri-strips. A DSD was applied and the patient was educated to continue with Dr. Smith's Rx/orders for glucose control. PT to continue w/off loading with therapeutic shoes and custom inserts.

Which is appropriate?

CTP For VLU

- Failure of SWC after 4 weeks
- Absence of Infection & Measurement throughout SOC
- Measurements throughout SOC + Each CTP Application
- Clinical Hx including any previous VLU:
- BMI, PE, SVT or DVT, # pregnancies
- Activity Level
- NIVT: Eval of Venous reflux, perforator incompetence
- Compression garments (>20mmHg) and Elevation
- Documentation of improvement with each CTP application
- This includes decrease in wound size, evidence of granulation tissue

Prior Authorization Process for CTP

- Many CTP Mfg. Will Do This
- Be Sure BAA
- Be Careful of POS
- Be Careful of Consolidated Billing Issues

CTP Limits

- Limited to 12-16 weeks episode of care
- Expect 4 to be usual number of applications
- Starting with > 4 applications need KX Modifier
- >4 Will need to document why >4 is needed
- What plan of care is if CTP does not work?

Consider Alternatives to CTP

- Low Frequency Non-Contact Non-Thermal Ultrasound
- Frequency and use are usually located in LCD & PA
- Bottom Line Requirements-
- SWC x 30 days failed to achieve significant progress
- 2-3 Times per week
- Document Improvement after 6 weeks (reduction in wound size, etc.)
- Metabolic Optimization (A1C/glucose, RBC, RFT, Albumin, etc.)
- Compression (VLU) DM (Off loading)
- Infection controlled or (-) no o/m.
- Adequate perfusion
- Photograph Documentation

Top Considerations for Compliance in Wound Practice

- Physicians Are in the Wound Healing Business Not Wound Product Business
- Document Medical Necessity and Instruments for all Procedures
- Use Operative Report Format
- If Conservative Care Is Working, Stick With It
- If Conservative Care Isn't Working, Document Rationale for Change
- Failure to Properly Document Will Cost You Revenue & Ability to Heal
- Document Rationale for Specific Product(s), Applied and Wastage
- Surgical Dressings and CTP Don't Always Go Together
- In Office Can Bill for Both Product & Application
- Existence of Product & Application Code ≠ Reimbursement
- Chose Procedures & Product Based on Medical Necessity Not Fee Schedule
- Don't Simply Regurgitate LCD and Policy Article Requirements
- Stay on Top of LCD & Policy Articles

Thank You

Dr Paul Kesselman DPM CEO Park DPM Consulting, LLC drkesselman@parkdpm.com 516 632-9944