2025 Medicare Update Part 2

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Member, Noridian Medicare physician advisory committee

CPMA Medicare & insurance committees

Disclosures

Gabriel Halperin, DPM, FACFAS, DABFAS has no relevant financial interests to disclose.

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

- Identify new programs that CMS is planning
- Analyze the Medicare Carrier's expectations regarding our documentation
- Demonstrate to use the language of the LCD to protect our documentation
- Understand the different audits and appeals
- Introduce potential new services that can enhance, ethically, our office income
- Identify the sources available to us to code correctly for services rendered to our patients

Tracking Sheet

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

DL39760

Important Dates

Proposed LCD Posting Date:	04/25/2024
Public Comment Period:	04/25/2024 - 06/08/2024
Contractor Advisory Committee Meeting Dates:	N/A
Open Meeting Dates:	05/16/2024
Final LCD Notice Period:	11/14/2024 - 04/12/2025
Final LCD Effective Date:	04/13/2025

Contacts

Noridian Healthcare Solutions, LLC JE Part B Contractor Medical Director(s)
Attention: Draft LCD Comments
PO Box 6781

Tracking Sheet

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

DL39760

Issue

Issue Description

This Local Coverage Determination (LCD) has been developed to create a policy consistent with current evidence. This LCD covers skin substitute grafts/cellular and tissue-based products (CTP) for the treatment of diabetic foot ulcers (DFU) and venous leg ulcers (VLU) in the Medicare population. Diabetic foot ulcers and VLU have multifactor etiologies requiring targeted therapy. Both are associated with significant morbidity, including amputations, and diminished quality of life. Numerous remedies including systemic and local treatments have been proposed. Skin substitute grafts/CTP are marketed as purported treatments for these ulcers. Their effectiveness is currently an active area of investigation. Despite lack of definitive improved health outcomes in the Medicare population coverage will be provided for skin substitute grafts/CTP having peer-reviewed, published evidence supporting their use as adjunctive treatment for chronic ulcers shown to have failed established methods to affect healing.

Issue - Explanation of Change Between Proposed LCD and Final LCD

Based on comments and literature submitted during the open comment period the following changes have been made from the proposed to final policy:

- The term 'Failure to respond' has been replaced with the phrase '50% ulcer area reduction.' Clarification of documentation requirements, additional definitions and other clarifying language added as recommended by commenters.
- Ankle-Brachial Index (AB) was replaced with vascular assessment, uncontrolled diabetes removed examples of contraindications and Class III compression requirement removed.
- Language added to clarify that standard of care is expected to be continued throughout the course of treatment.
- Application limit expanded from 4 to 8 and duration increased from 12 to 16 weeks based on submitted literature, comments received,

- Application limit expanded from 4 to 8 and duration increased from 12 to 16 weeks based on submitted literature, comments received, and recommendations from SMEs.
- Use of the KX-modifier is added as an attestation of medical necessity for use over 4 applications.
- Further description of wastage documentation requirements added to the B & C article.
- Clarified use of product over exposed muscle, tendon, or bone when consistent with the labeled indication. The relevant ICD-10-CM codes were added to B & C article.
- Additional references were added to section on product classification and further clarification of porcine dressings were detailed in the LCD.
- Four systematic reviews and a new section entitled "Real World Evidence"(RWE) with summary of previous and newly submitted RWE were added to evidence review section.
- Additional literature was added for to product section for Apis, Derma-Gide, DermaPure, Grafix, Kerecis, NuShield, Phoenix wound Matrix, PuraPly AM, Restrata, Supra SDRM, and TheraGenesis (Pelnac). Derma-Gide, Kerecis and NuShield were added to the DFU covered list.
- The product Oasis Tri-Layer Wound was found to have insufficient evidence for coverage in DFUs and VLUs, therefore, it was removed from tables 1 & 2 and placed in table 3 in the LCD.
- The evidence for DFU and VLU was placed in separate tables and corresponding sections of the B&C article to ensure clarity that coverage is based on evidence for the indication in which has been studied.
- Additional literature added to the Societal Guidance section.
- Analysis of Evidence section expanded and provides further discussion on the limitations of the current body of literature, clarity on the methodology utilized to assess the literature, and explanation for the above changes. Multiple published sources to aid investigators in development of high-quality future studies have been added as requested by Stakeholders.
- Additional ICD-10-CM codes with clarifications were added to Billing and Coding Article.

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2024

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PROPOSED LCD

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Contractor Information

Proposed LCD Information

Document Information

Source LCD ID
L39760

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Jurisdiction A

Durable Medical Equipment, Prosthetics, Orthotics and Supplies

Jurisdiction D

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Current Projects

Local Coverage Determination (LCD)

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Active LCDs

All LCDS are the same for each state within a Jurisdiction and are accessible from the table below.

Access LCD or Article: Select the LCD or Article number in the table below to view the policy or article on the Medicare Coverage Database (MCD).

Access MolDX LCDs and MolDX Articles

Print the LCD or Article: Select the LCD or Article number in the table below to view the policy or article on the Medicare Coverage Database (MCD).

1. Click on the blue download arrow on the right side of page when LCD or Article appears.
2. Click the print when PDF opens.

View the ICD-9 to ICD-10 LCD number crosswalk.

Once you access the LCD, the "Coding Guidelines" can be found under the heading, "LCD Attachments" near the end of the document. Note: All CPT/HCPCS codes listed are mentioned in the LCD, but are not necessarily subject to diagnosis codes or coverage criteria.

Search for an LCD Type here to filter...

Educational Resources

Policy Related Forms

Looking for MolDX?

For easier viewing, all Molecular Diagnostic Services (MolDX) materials have been consolidated into the Molecular Diagnostic Services webpage:

- Active MolDX LCDs
- Active MolDX Billing and Coding Articles and Educational Articles
- Proposed MolDX LCDs
- MolDX Open Public Meetings

Medicare Coverage Database (MCD)

The official LCD version is in CMS Medicare Coverage Database

- California Northern - Contractor ID 01112

LCD Title	LCD Number	Billing and Coding Companion Article	CPT / HCPCS Codes Referenced
Allergy Testing	L34313	A57181	86003, 86005, 95004, 95017, 95018, 95024, 95027, 95028, 95044, 95052, 95056, 95060, 95065, 95070, 95076, 95079
Allogeneic Hematopoietic Cell Transplantation for Primary Refractory or Relapsed Hodgkin's and Non-Hodgkin's Lymphoma with B-cell or T-cell Origin	L39396	A59175	38240
Amniotic and Placental-Derived Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound	L39116	A58865	Q4112, Q4139, Q4145, Q4149, Q4155, Q4162, Q4168, Q4171, Q4174, Q4177, Q4185, Q4189, Q4192, Q4206, Q4212, Q4213, Q4215, Q4230, Q4231, Q4233, Q4240, Q4241, Q4242, Q4244, Q4245, Q4246
Artificial Intelligence Enabled CT Based Quantitative Coronary Topography (AI-QCT)/Coronary Plaque Analysis (AI-CPA)	L39881	A59769	0623T, 0624T, 0625T, 0626T
B-type Natriuretic Peptide (BNP) Testing	L35526	A57083	83880
BDX-XL2	L37054	A57356	0080U
Benign Skin Lesion Removal (Excludes			11200, 11201, 11300, 113 02, 11303, 11305, 11306, 1130 08, 11310, 11311, 11312, 11313, 11400,

FEEDBACK

TOP

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Proposed LCDs

When there are Proposed Local Coverage Determinations (LCDs) that are in the comment period, this webpage will provide a summary of comments received and Noridian's response. This information will remain on this webpage for at least six months.

Status Indicators

D = Proposed under development, not yet released for comment
C = Proposed LCD released for comment
E = Formal comment period has ended; comments now being considered
F = Final new/revised LCD has been issued for notice
A = Active policy: notice period complete and the policy is in effect

Send Proposed LCD Comments to:

Mail:
Noridian Medicare JE Part B
Attention: Proposed LCD Comments
PO Box 6781
Fargo, ND 58108-6781
Email: policydraft@noridian.com

- Nevada - Contractor ID 01312

Micro-Invasive Glaucoma Surgery (MIGS) Billing and Coding: Micro-Invasive Glaucoma Surgery	05/30/2024	07/13/2024	F	View	09/27/24	View
Minimally Invasive Arthrodesis of the Sacroiliac Joint (SIJ) Billing and Coding: Minimally Invasive Arthrodesis of the Sacroiliac Joint (SIJ)	03/28/24	05/11/24	F	View	01/02/25	View
Polysomnography and Other Sleep Studies Billing and Coding: Polysomnography and Other Sleep Studies	07/18/24	09/01/24	E			
Skin Substitutes Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers Billing and Coding: Skin Substitutes Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers	04/25/24	06/08/2024	F	View	11/14/24	View
Urine Drug Testing	09/19/24	11/02/24	C	View	01/02/2	

Last Updated Jan 02 , 2025

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PROPOSED LCD

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Contractor Information

Proposed LCD Information

Expand/Collapse the Proposed LCD Information section

Document Information

Source LCD ID
L39760

DRAFT | LCD Reference Article | Billing and Coding Article

Billing and Coding: Skin Substitutes Grafts/Cellular Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers

DA59626

Expand All | Collapse All

DRAFT ARTICLE

Draft Articles are works in progress and not necessarily a reflection of the current billing and coding practices. Revisions to codes are carefully and thoroughly reviewed and are not intended to change the original intent of the LCD.

Contractor Information

Draft Article Information

Coding Information

Bioengineered Skin Substitutes **or Cellular and Tissue Based Products (CTPs), referred to as** Skin Substitutes **by CMS, The Current Procedural Terminology (CPT) and The Healthcare Common Procedure Coding Manuals**, have been developed in an attempt to circumvent problems inherent with autografts, allografts and xenografts. These constitute biologic covers for refractory wounds with full thickness skin loss secondary to 3rd degree burns or other disease processes such as diabetic neuropathic ulcers and the skin loss of chronic venous stasis or venous hypertension. The production of these biologic skin substitutes or CTPs varies by company and product, but generally involves the creation of immunologically inert biological products containing protein, hormones or enzymes seeded into a matrix which may provide protein or growth factors proposed to stimulate or facilitate healing or promote epithelization. A variety of biosynthetic and tissue-engineered skin substitution products marketed as **Human Skin Equivalents (HSE) or Cellular or Tissue-based Products (CTP)** are manufactured under an array of trade names and marketed for a variety of indications. All are procured, produced, manufactured, processed and promoted in sufficiently different manners to preclude direct product comparison for equivalency or superiority in randomized controlled trials. Sufficient data is available to establish distinct inferiority to human skin autografts and preclude their designation as skin equivalence.

Bioengineered skin substitutes or **CTPs** are classified into the following types:

- **Human skin allografts** derived from donated human skin (cadavers)
- **Allogeneic matrices** derived from human tissue (fibroblasts or membrane)
- **Composite matrices** derived from human keratinocytes, fibroblasts and xenogeneic collagen
- **Acellular matrices** derived from xenogeneic collagen or tissue

Human Skin Allografts are bioengineered from human skin components and human tissue which have had intact cells removed or treated to avoid immunologic rejection. They are available in different forms promoted to allow scaffolding, soft tissue filling, growth factors and other bioavailable hormonal or enzymatic activity.

LCD - Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds (L35041)

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

Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
Novitas Solutions, Inc.	A and B MAC	04111 - MAC A	J - H	Colorado
Novitas Solutions, Inc.	A and B MAC	04112 - MAC B	J - H	Colorado
Novitas Solutions, Inc.	A and B MAC	04211 - MAC A	J - H	New Mexico
Novitas Solutions, Inc.	A and B MAC	04212 - MAC B	J - H	New Mexico
Novitas Solutions, Inc.	A and B MAC	04311 - MAC A	J - H	Oklahoma
Novitas Solutions, Inc.	A and B MAC	04312 - MAC B	J - H	Oklahoma
Novitas Solutions, Inc.	A and B MAC	04411 - MAC A	J - H	Texas
Novitas Solutions, Inc.	A and B MAC	04412 - MAC B	J - H	Texas
Novitas Solutions, Inc.	A and B MAC	04911 - MAC A	J - H	Colorado New Mexico Oklahoma Texas

Autologous skin grafts, also referred to as autografts, are permanent covers that use skin from different parts of the individual's body. These grafts consist of the epidermis and a dermal component of variable thickness. A split-thickness skin graft (STSG) includes the entire epidermis and a portion of the dermis. A full thickness skin graft (FTSG) includes all layers of the skin. Although autografts are the optimal choice for full thickness wound coverage, areas for skin harvesting may be limited, particularly in cases of large burns or venous stasis ulceration. Harvesting procedures are painful, disfiguring and require additional wound care.

Allografts which use skin from another human (e.g., cadaver) and **Xenografts** which use skin from another species (e.g., porcine or bovine) may also be employed as temporary skin replacements, but they must later be replaced by an autograft or the ingrowth of the patient's own skin.

Bioengineered Skin / Cultured Epidermal Autografts (CEA) are autografts derived from the patient's own skin cells grown or cultured from very small amounts of skin or hair follicle. Production time is prolonged. One such product is grown on a layer of irradiated mouse cells, bestowing some elements of a xenograft. Wide spread usage has not been available due to limited availability or access to the technology.

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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. 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.

Standard treatment of chronic lower extremity ulcers or skin loss (e.g., DFU or VLU) primarily includes infection and edema control, mechanical offloading, mechanical compression or limb elevation, debridement of necrotic or infected tissue, and management of concomitant and inciting medical issues (blood glucose control, tobacco use). Maintenance of a therapeutic environment with appropriate dressings to preclude further trauma facilitates development of healthy granulation tissue and encourages re-epithelialization. A wound that fails to show evidence of healing by contraction and advancement of epithelial margins following 4 weeks of optimization, including all aspects of standard therapy, is considered a chronic non-healing wound and falls into the auspices of this LCD. The fundamental basis for non-healing of a wound is of paramount importance and must be corrected prior to consideration of additional therapy.

The depth of skin loss is the determinant of its ability to return. Full thickness skin loss, implying the loss of all elements of the epidermis and dermis, will require re-epithelization of the surface once a clean granular base is established. Both full and partial thickness skin loss may benefit from enhanced products referred to as Skin Substitutes. Though no skin substitutes are capable of replacing the patient's own skin, they have been demonstrated to allow scaffolding for the growth of epithelium, enzymatic cleansing and provision of growth factors beneficial to deficit reduction and re-epithelization.

This document addresses the management of chronic non-healing wounds or skin deficits of the lower extremities with the goal of wound and skin closure when standard or conservative measures have failed. While lower extremity ulcers have numerous causes such as burns, trauma, immobility, ischemia or other neurologic impairment, over 90% of the lesions are related to venous stasis disease and diabetic neuropathy. Therefore, the focus of this policy is the application of bioengineered skin substitute material to diabetic foot ulcers and venous leg ulcers of the lower extremities and the reasonable and necessary (R&N) threshold for utilization of skin substitutes. Particular emphasis is placed on the indications for application of bioengineered skin substitute material for DFU and VLU.

Medicare coverage for wound care on a continuing basis, for a single wound, in an individu
upon evidence documented in the patient's medical record that the wound is improving in
care being provided. Since it is neither reasonable nor medically necessary to continue a g
the absence of wound improvement, it is expected that the wounds response to treatment
medical record at least once every 30 days for each episode of wound treatment and made

Medicare coverage for wound care on a continuing basis, for a single wound, in an individual patient is contingent upon evidence documented in the patient's medical record that the wound is improving in response to the wound care being provided. Since it is neither reasonable nor medically necessary to continue a given type of wound care in the absence of wound improvement, it is expected that the wounds response to treatment will be documented in the medical record at least once every 30 days for each episode of wound treatment and made available to the contractor upon request.

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Documentation of response requires measurements of the initial ulcer, measurements at the completion of at least four weeks of appropriate wound care and measurements immediately prior to placement and with each subsequent placement of the bioengineered skin substitute or CTP.

Covered Indications

2024 DEFINITION

Chronic Wounds are defined as wounds that do not respond to standard wound treatment for at least a 30 day period during organized comprehensive conservative therapy.

For all wounds, documentation (as outlined in the documentation requirements of the policy) and a comprehensive treatment plan, before initiation of a specialized wound therapy product is required.

For purposes of this LCD **Failed Response** is defined as an ulcer or skin deficit that has failed to respond to documented appropriate wound-care measures, has increased in size or depth, or has not changed in baseline size or depth and has no indication that improvement is likely (such as granulation, epithelialization or progress towards closing).

Medicare covers application of skin substitutes to Ulcers or Wounds with **Failed Response** that are:

- Partial- or full-thickness ulcers, not involving tendon, muscle, joint capsule or exhibiting exposed bone or sinus tracts, with a clean granular base;
- Skin deficit at least 1.0 square centimeter (cm) in size;
- Clean and free of necrotic debris or exudate;
- Have adequate circulation/oxygenation to support tissue growth/wound healing as evidenced by physical examination (e.g., Ankle-Brachial Index [ABI] of no less than 0.60, toe pressure greater than 30 millimeters of mercury [mmHg]);
- For diabetic foot ulcers, the patient's medical record reflects a diagnosis of Type 1 or Type 2 Diabetes and also reflects medical management for this condition.

Wound healing is impaired by the systemic use of tobacco. Therefore, ideally patients who have smoked will have ceased smoking or have refrained from systemic tobacco intake for at least 4 weeks during conservative wound care and prior to planned bioengineered skin replacement therapy.

Documentation (in the pre-service record) specifically addressing circumstances as to why the wound has failed to respond to standard wound care treatment of greater than 4 weeks and must reference specific interventions that have failed. Such record should include updated medication history, review of pertinent medical problems that may have occurred since the previous wound evaluation, and explanation of the planned skin replacement surgery with choice of skin substitute graft product. The procedure risks and complications should also be reviewed and documented. Documentation of smoking cessation counseling and cessation measures prescribed, if applicable, must also be documented in the patient's record.

Application of a skin substitute graft for lower extremity chronic wound (DFU and VLU) will be covered when the following conditions are met for the individual patient:

- Presence of neuropathic diabetic foot ulcer(s) having failed to respond to documented conservative wound-care measures of greater than four weeks, during which the patient is compliant with recommendations, and without evidence of underlying osteomyelitis or nidus of infection.
- Presence of a venous stasis ulcer for at least 3 months but unresponsive to appropriate wound care for at least 30 days with documented compliance.
- Presence of a full thickness skin loss ulcer that is the result of abscess, injury or trauma that has failed to respond to appropriate control of infection, foreign body, tumor resection, or other disease process for a period of 4 weeks or longer.

In all wound management the ulcer must be free of infection and underlying osteomyelitis with documentation of the conditions that have been treated and resolved prior to the institution of skin substitute therapy. For purposes of this LCD, appropriate therapy includes, but is not limited to:

- Control of edema, venous hypertension or lymphedema
- Control of any nidus of infection or colonization with bacterial or fungal elements
- Elimination of underlying cellulitis, osteomyelitis, foreign body, or malignant process
- Appropriate debridement of necrotic tissue or foreign body (exposed bone or tendon)
- For diabetic foot ulcers, appropriate non-weight bearing or off-loading pressure
- For venous stasis ulcers, compression therapy provided with documented diligent use of multilayer dressings, compression stockings of greater than 20 mmHg pressure, or pneumatic compression
- Provision of wound environment to promote healing (protection from trauma and contaminants, elimination of inciting or aggravating processes)

Limitations

Due to the propensity for misuse of skin substitute and biological dressing products, reimbursement may be made only when the medical record clearly documents that these products have been used in a comprehensive, organized wound management program. **All listed products, unless they are specifically FDA-labeled or cleared for use in the types of wounds being treated, will be considered to be biologic dressings and part of the relevant Evaluation and Management (E/M) service provided and not separately reimbursed.**

- Partial thickness loss with the retention of epithelial appendages is not a candidate for grafting or replacement, as epithelium will repopulate the deficit from the appendages, negating the benefit of overgrafting.

- Skin substitute grafts will be allowed for the episode of wound care in compliance with FDA guidelines for the specific product (see utilization guidelines) not to exceed 10 applications or treatments. In situations where more than one specific product is used, it is expected that the number of applications or treatments will still not exceed 10.
- Simultaneous use of more than one product for the episode of wound is not covered. Product change within the episode of wound is allowed, not to exceed the 10 application limit per wound per 12 week period of care.
- Treatment of any chronic skin wound will typically last no more than twelve (12) weeks.
- Repeat or alternative applications of skin substitute grafts are not considered medically reasonable and necessary when a previous full course of applications was unsuccessful. Unsuccessful treatment is defined as increase in size or depth of an ulcer or no change in baseline size or depth and no sign of improvement or indication that improvement is likely (such as granulation, epithelialization or progress towards closing) for a period of 4 weeks past start of therapy.
- Retreatment of healed ulcers, those showing greater than 75% size reduction and smaller than 0.5 square cm, is not considered medically reasonable and necessary.
- Skin substitute grafts are contraindicated and are not considered reasonable and necessary in patients with inadequate control of underlying conditions or exacerbating factors (e.g., uncontrolled diabetes, active infection, and active Charcot arthropathy of the ulcer extremity, vasculitis or continued tobacco smoking without physician attempt to affect smoking cessation).
- Skin substitute grafts are contraindicated in patients with known hypersensitivity to any component of the specific skin substitute graft (e.g., allergy to avian, bovine, porcine, equine products).
- Repeat use of surgical preparation services in conjunction with skin substitute application codes will be considered not reasonable and necessary. It is expected that each wound will require the use of appropriate wound preparation code at least once at initiation of care prior to placement of the skin substitute graft.

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- Skin substitute grafts are contraindicated in patients with known hypersensitivity to any component of the specific skin substitute graft (e.g., allergy to avian, bovine, porcine, equine products).
- Repeat use of surgical preparation services in conjunction with skin substitute application codes will be considered not reasonable and necessary. It is expected that each wound will require the use of appropriate wound preparation code at least once at initiation of care prior to placement of the skin substitute graft.
- Re-treatment within one (1) year of any given course of skin substitute treatment for a venous stasis ulcer or (diabetic) neuropathic foot ulcer is considered treatment failure and does not meet reasonable and necessary criteria for re-treatment of that ulcer with a skin substitute procedure.

Documentation Requirements

1. All documentation must be maintained in the patient's medical record and made available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service[s]). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
3. Medical record documentation must support the medical necessity of the services as stated in this policy.
4. The documentation must support that the service was performed and must be included in the patient's medical record. This information is normally found in the history and physical, office/progress notes, hospital notes, and/or procedure report.
5. The medical record must clearly show that the criteria listed under the Covered Indications and Limitations sections have been met, as well as, the appropriate diagnosis and response to treatment.
6. The documentation must support the need for skin substitute application and the product used.
7. A description of the wound(s) must be documented at baseline (prior to beginning conservative treatment) relative to size, location, stage, duration, and presence of infection, in addition to type of treatment given and response.
    - This information must be updated in the medical record throughout treatment.
    - Wound description must also be documented pre and post treatment with the skin substitute graft being used.
    - If obvious signs of worsening or lack of treatment response is noted, continuing treatment with the skin substitute would not be considered medically reasonable and necessary without documentation of a reasonable rationale for doing so.
8. Documentation of smoking history, and that the patient has received counseling on the effects of smoking on surgical outcomes and treatment for smoking cessation (if applicable) as well as outcome of counselling must be in the medical record.
9. The amount of utilized and wasted skin substitute must be clearly documented in the procedure note with the following minimum information:
    - Date, time and location of ulcer treated;
    - Name of skin substitute and how product supplied;
    - Amount of product unit used;
    - Amount of product unit discarded;
    - Reason for the wastage;
    - Manufacturer's serial/lot/batch or other unit identification number of graft material. When manufacturer does not supply unit identification, record must document such.

    Note: Novitas expects that where multiple sizes of a specific product are available, the size that best fits the wound with the least amount of wastage will be utilized. Please refer to article A54117 for coding/billing instructions regarding drug wastage.

FUTURE | Local Coverage Determination (LCD)

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

L39760 2025

Expand All | Collapse All

FUTURE EFFECTIVE

L39760

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
DL39760

Original Effective Date
For services performed on or after 04/13/2025

Revision Effective Date
N/A

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
11/14/2024

Notice Period End Date
04/12/2025

Tracking Sheet

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

DL39760

Important Dates

Proposed LCD Posting Date:	04/25/2024
Public Comment Period:	04/25/2024 - 06/08/2024
Contractor Advisory Committee Meeting Dates:	N/A
Open Meeting Dates:	05/16/2024
Final LCD Notice Period:	11/14/2024 - 04/12/2025
Final LCD Effective Date:	04/13/2025

Contacts

Noridian Healthcare Solutions, LLC JE Part B Contractor Medical Director(s)
Attention: Draft LCD Comments
PO Box 6781

Tracking Sheet

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

DL39760

Issue

Issue Description

This Local Coverage Determination (LCD) has been developed to create a policy consistent with current evidence. This LCD covers skin substitute grafts/cellular and tissue-based products (CTP) for the treatment of diabetic foot ulcers (DFU) and venous leg ulcers (VLU) in the Medicare population. Diabetic foot ulcers and VLU have multifactor etiologies requiring targeted therapy. Both are associated with significant morbidity, including amputations, and diminished quality of life. Numerous remedies including systemic and local treatments have been proposed. Skin substitute grafts/CTP are marketed as purported treatments for these ulcers. Their effectiveness is currently an active area of investigation. Despite lack of definitive improved health outcomes in the Medicare population coverage will be provided for skin substitute grafts/CTP having peer-reviewed, published evidence supporting their use as adjunctive treatment for chronic ulcers shown to have failed established methods to affect healing.

Issue - Explanation of Change Between Proposed LCD and Final LCD

Based on comments and literature submitted during the open comment period the following changes have been made from the proposed to final policy:

- The term 'Failure to respond' has been replaced with the phrase '50% ulcer area reduction.' Clarification of documentation requirements, additional definitions and other clarifying language added as recommended by commenters.
- Ankle-Brachial Index (AB) was replaced with vascular assessment, uncontrolled diabetes removed examples of contraindications and Class III compression requirement removed.
- Language added to clarify that standard of care is expected to be continued throughout the course of treatment.
- Application limit expanded from 4 to 8 and duration increased from 12 to 16 weeks based on submitted literature, comments received,

- Application limit expanded from 4 to 8 and duration increased from 12 to 16 weeks based on submitted literature, comments received, and recommendations from SMEs.
- Use of the KX-modifier is added as an attestation of medical necessity for use over 4 applications.
- Further description of wastage documentation requirements added to the B & C article.
- Clarified use of product over exposed muscle, tendon, or bone when consistent with the labeled indication. The relevant ICD-10-CM codes were added to B & C article.
- Additional references were added to section on product classification and further clarification of porcine dressings were detailed in the LCD.
- Four systematic reviews and a new section entitled "Real World Evidence"(RWE) with summary of previous and newly submitted RWE were added to evidence review section.
- Additional literature was added for to product section for Apis, Derma-Gide, DermaPure, Grafix, Kerecis, NuShield, Phoenix wound Matrix, PuraPly AM, Restrata, Supra SDRM, and TheraGenesis (Pelnac). Derma-Gide, Kerecis and NuShield were added to the DFU covered list.
- The product Oasis Tri-Layer Wound was found to have insufficient evidence for coverage in DFUs and VLUs, therefore, it was removed from tables 1 & 2 and placed in table 3 in the LCD.
- The evidence for DFU and VLU was placed in separate tables and corresponding sections of the B&C article to ensure clarity that coverage is based on evidence for the indication in which has been studied.
- Additional literature added to the Societal Guidance section.
- Analysis of Evidence section expanded and provides further discussion on the limitations of the current body of literature, clarity on the methodology utilized to assess the literature, and explanation for the above changes. Multiple published sources to aid investigators in development of high-quality future studies have been added as requested by Stakeholders.
- Additional ICD-10-CM codes with clarifications were added to Billing and Coding Article.

LCA –Article: Routine Foot Care

A 57954

Policies

- Local Coverage Determination (LCD)
- **Billing and Coding Articles**
- Clinician's Corner
- Medical Director Articles
- Molecular Diagnostic Services
- National Coverage Determination (NCD)
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Billing and Coding Articles

The term "article" is used to describe any bulletin article, website article, educational handout or any other non-LCD document intended for public release that contains coverage/coding statements or medical review related billing or claims considerations.

Medicare contractors post articles into the Medicare Coverage Database (MCD). Articles address local coverage, coding or medical review related billing and claims considerations, and may include any newly developed educational materials, coding instructions or clarification of existing medical review related billing or claims policy.

View coverage information on topics found outside NCDs and LCDs. As articles are updated in the MCD, they will be published as webpages here as well. Watch the below list continue to expand as updates are made.

Access Article: Select the Article number in the table below to view the policy or article on the Medicare Coverage Database (MCD).

Print the Article: Select the LCD or Article number in the table below to view the policy or article on the Medicare Coverage Database (MCD).

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2. Click the print when PDF opens.

Search for an Article foot care ×

Topic ▲	Article Number	CPT/HCPCS Codes Referenced
Billing and Coding: Routine Foot Care	A57954	11055, 11056, 11057, 11719, 11720, 11721, G0127

To view all the articles on the CMS website, select a link below to be redirected to the MCD.

Contents

Billing and Coding Article

Billing and Coding: Routine Foot Care

A57954

Expand All | Collapse All

NOT AN LCD REFERENCE ARTICLE

This article is not in direct support of an LCD. Learn more

Contractor Information

Article Information

Expand/Collapse the Article Information section

General Information

Article ID

A57954

Article Title

Billing and Coding: Routine Foot Care

Group 1 Paragraph

Note: Providers are reminded to refer to the long descriptors of the CPT codes in their CPT book.

Group 1 Codes

Code	Description
11055	Paring/cutg b9 hyprker les 1
11056	Parng/cutg b9 hyprkr les 2-4
11057	Parng/cutg b9 hyprkr les >4
11719	Trim nail(s) any number
11720	Debride nail 1-5
11721	Debride nail 6 or more
G0127	Trim nail(s)

Group 1 (3 Codes)

Group 1 Paragraph

For purposes of applying presumption of coverage, when the evidence available discloses certain physical and/or clinical findings consistent with the diagnosis and indicative of severe peripheral involvement, the following findings are pertinent:

- Class A Findings:
  - Nontraumatic amputation of foot or integral skeletal portion thereof.
- Class B Findings:
  - Absent posterior tibial pulse;
  - Advanced trophic changes as: hair growth (decrease or absence) nail changes (thickening) pigmentary changes (discoloration) skin texture (thin, shiny) skin color (rubor or redness) (three required); and
  - Absent dorsalis pedis pulse.
- Class C Findings:
  - Claudication;
  - Temperature changes (e.g., cold feet);
  - Edema;
  - Paresthesias (abnormal spontaneous sensations in the feet); and
  - Burning.

The presumption of coverage may be applied when the physician rendering the routine foot care has identified the following by using the modifiers below:

1. A Class A finding (Q7);
2. Two of the Class B findings (Q8); or
3. One Class B and two Class C findings (Q9).

Group 1 Codes

Code	Description
Q7	ONE CLASS A FINDING
Q8	TWO CLASS B FINDINGS
Q9	ONE CLASS B AND TWO CLASS C FINDINGS

Group 1 (19 Codes)

Group 1 Paragraph

The ICD-10-CM codes below represent the PRIMARY diagnoses for all Group 2, Group 3 and Group 4 SECONDARY diagnoses.

(For **treatment of painful mycotic nails, or onychogryphosis, or onychauxis**, see Groups 5 and 6).

For the treatment of painful callouses, please see the Wound and Ulcer Care LCD and associated Billing and Coding article L38902/A58565 effective 11/28/2021.

Group 1 Codes

Code	Description
B35.1	Tinea unguium
L11.0	Acquired keratosis follicularis
L60.1	Onycholysis
L60.2	Onychogryphosis
L60.3	Nail dystrophy

L60.8*	Other nail disorders
L84*	Corns and callosities
L85.0	Acquired ichthyosis
L85.1	Acquired keratosis [keratoderma] palmaris et plantaris
L85.2	Keratosis punctata (palmaris et plantaris)
L86	Keratoderma in diseases classified elsewhere
L87.0	Keratosis follicularis et parafollicularis in cutem penetrans
L87.2	Elastosis perforans serpiginosa
L98.7*	Excessive and redundant skin and subcutaneous tissue
Q81.0	Epidermolysis bullosa simplex

Q81.0	Epidermolysis bullosa simplex
Q81.1	Epidermolysis bullosa letalis
Q81.2	Epidermolysis bullosa dystrophica
Q81.8	Other epidermolysis bullosa
Q82.8	Other specified congenital malformations of skin

Group 1 Medical Necessity ICD-10-CM Codes Asterisk Explanation

*Effective 06/19/2022, L60.8 is to be billed with 11719 - trimming of non-dystrophic nails - only if one of the systemic conditions from Group 2, 3 or 4 below is present AND the patient does NOT have dystrophic nails. G0127 is the appropriate code for the trimming of dystrophic nails.

*Effective 06/19/2022, G0127 is to be billed for dystrophic nails only. It is inappropriate to bill L60.8, L84 and L98.7 with G0127.

Group 2 (167 Codes)

Group 2 Paragraph

The ICD-10-CM codes below represent the diagnoses where the patient has evidence of neuropathy, as demonstrated by methods such as the Semmes-Weinstein filament, but no vascular impairment, for which no class findings modifiers are required.

One of the Group 1 ICD-10-CM codes above **MUST** be billed as the *primary* diagnosis to ensure payment.

Group 2 Codes

Code	Description
A30.4	Borderline lepromatous leprosy
A30.5	Lepromatous leprosy
A50.43	Late congenital syphilitic polyneuropathy
A52.15	Late syphilitic neuropathy
A52.16	Charcot's arthropathy (tabetic)

E10.29*	Type 1 diabetes mellitus with other diabetic kidney complication
E10.40*	Type 1 diabetes mellitus with diabetic neuropathy, unspecified
E10.41*	Type 1 diabetes mellitus with diabetic mononeuropathy
E10.42*	Type 1 diabetes mellitus with diabetic polyneuropathy
E10.43*	Type 1 diabetes mellitus with diabetic autonomic (poly)neuropathy
E10.44*	Type 1 diabetes mellitus with diabetic amyotrophy
E10.49*	Type 1 diabetes mellitus with other diabetic neurological complication
E10.610*	Type 1 diabetes mellitus with diabetic neuropathic arthropathy
E10.618*	Type 1 diabetes mellitus with other diabetic arthropathy
E10.620*	Type 1 diabetes mellitus with diabetic dermatitis

G60.2	Neuropathy in association with hereditary ataxia
G60.3	Idiopathic progressive neuropathy
G60.8	Other hereditary and idiopathic neuropathies
G60.9	Hereditary and idiopathic neuropathy, unspecified
G61.0	Guillain-Barre syndrome
G61.1*	Serum neuropathy
G61.81	Chronic inflammatory demyelinating polyneuritis
G61.89	Other inflammatory polyneuropathies
G61.9	Inflammatory polyneuropathy, unspecified
G62.0*	Drug-induced polyneuropathy

G63*	Polyneuropathy in diseases classified elsewhere
G64	Other disorders of peripheral nervous system
G65.0*	Sequelae of Guillain-Barre syndrome
G65.1*	Sequelae of other inflammatory polyneuropathy
G65.2*	Sequelae of toxic polyneuropathy
G90.09	Other idiopathic peripheral autonomic neuropathy
G99.0	Autonomic neuropathy in diseases classified elsewhere
M05.511	Rheumatoid polyneuropathy with rheumatoid arthritis of right shoulder
M05.512	Rheumatoid polyneuropathy with rheumatoid arthritis of left shoulder
M05.521	Rheumatoid polyneuropathy with rheumatoid arthritis of right elbow

N18.30*	Chronic kidney disease, stage 3 unspecified
N18.31*	Chronic kidney disease, stage 3a
N18.32*	Chronic kidney disease, stage 3b
N18.4*	Chronic kidney disease, stage 4 (severe)
N18.5*	Chronic kidney disease, stage 5
N18.6*	End stage renal disease

Group 2 Medical Necessity ICD-10-CM Codes Asterisk Explanation

When the patient's condition is one of those designated by an asterisk (*), routine procedures are covered only if the patient is under the active care of a Doctor of Medicine or Osteopathy, who documents he/she has seen the patient for treatment and/or evaluation of the complicating disease process during the 6-month period prior to the rendition of the routine-type services per the Benefit Policy Manual, Publication 100-02, Chapter 15, Section 290F-Presumption of Coverage.

Group 3 (392 Codes)

Group 3 Paragraph

The ICD-10-CM codes below represent those diagnoses where the patient has evidence of vascular impairment, for which the class findings modifiers are required.

For purposes of applying presumption of coverage, when the evidence available discloses certain physical and/or clinical findings consistent with the diagnosis and indicative of severe peripheral involvement, the following findings are pertinent:

- Class A Findings:
  - Nontraumatic amputation of foot or integral skeletal portion thereof.
- Class B Findings:
  - Absent posterior tibial pulse;
  - Advanced trophic changes as: hair growth (decrease or absence) nail changes (thickening) pigmentary changes (discoloration) skin texture (thin, shiny) skin color (rubor or redness) (three required); and
  - Absent dorsalis pedis pulse.
- Class C Findings:
  - Claudication;
  - Temperature changes (e.g., cold feet);
  - Edema;
  - Paresthesias (abnormal spontaneous sensations in the feet); and
  - Burning.

The presumption of coverage may be applied when the physician rendering the routine foot care has identified the following by using the modifiers below:

1. A Class A finding (Q7);
2. Two of the Class B findings (Q8); or
3. One Class B and two Class C findings (Q9).

One of the Group 1 ICD-10-CM codes above **MUST** be billed as the *primary* diagnosis to ensure payment.

Group 3 Codes

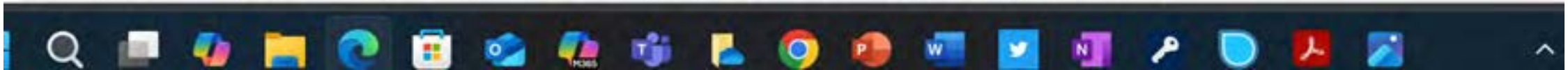
Code	Description
E08.311*	Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy with macular edema
E08.319*	Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy without macular edema
E08.3211*	Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, right eye

I70.201	Unspecified atherosclerosis of native arteries of extremities, right leg
I70.202	Unspecified atherosclerosis of native arteries of extremities, left leg
I70.203	Unspecified atherosclerosis of native arteries of extremities, bilateral legs
I70.211	Atherosclerosis of native arteries of extremities with intermittent claudication, right leg
I70.212	Atherosclerosis of native arteries of extremities with intermittent claudication, left leg
I70.213	Atherosclerosis of native arteries of extremities with intermittent claudication, bilateral legs
I70.218	Atherosclerosis of native arteries of extremities with intermittent claudication, other extremity
I70.221	Atherosclerosis of native arteries of extremities with rest pain, right leg
I70.222	Atherosclerosis of native arteries of extremities with rest pain, left leg
I70.223	Atherosclerosis of native arteries of extremities with rest pain, bilateral legs

I70.263	Atherosclerosis of native arteries of extremities with gangrene, bilateral legs
I70.268	Atherosclerosis of native arteries of extremities with gangrene, other extremity
I70.291	Other atherosclerosis of native arteries of extremities, right leg
I70.292	Other atherosclerosis of native arteries of extremities, left leg
I70.293	Other atherosclerosis of native arteries of extremities, bilateral legs
I70.298	Other atherosclerosis of native arteries of extremities, other extremity
I70.311	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with intermittent claudication, right leg
I70.312	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with intermittent claudication, left leg
I70.313	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with intermittent claudication, bilateral legs

I80.00*	Phlebitis and thrombophlebitis of superficial vessels of unspecified lower extremity
I80.01*	Phlebitis and thrombophlebitis of superficial vessels of right lower extremity
I80.02*	Phlebitis and thrombophlebitis of superficial vessels of left lower extremity
I80.03*	Phlebitis and thrombophlebitis of superficial vessels of lower extremities, bilateral
I80.11*	Phlebitis and thrombophlebitis of right femoral vein
I80.12*	Phlebitis and thrombophlebitis of left femoral vein
I80.13*	Phlebitis and thrombophlebitis of femoral vein, bilateral
I80.201*	Phlebitis and thrombophlebitis of unspecified deep vessels of right lower extremity
I80.202*	Phlebitis and thrombophlebitis of unspecified deep vessels of left lower extremity
I80.203*	Phlebitis and thrombophlebitis of unspecified deep vessels of lower extremities, bilateral

I87.001	Postthrombotic syndrome without complications of right lower extremity
I87.002	Postthrombotic syndrome without complications of left lower extremity
I87.011*	Postthrombotic syndrome with ulcer of right lower extremity
I87.012*	Postthrombotic syndrome with ulcer of left lower extremity
I87.013*	Postthrombotic syndrome with ulcer of bilateral lower extremity
I87.021*	Postthrombotic syndrome with inflammation of right lower extremity
I87.022*	Postthrombotic syndrome with inflammation of left lower extremity
I87.023*	Postthrombotic syndrome with inflammation of bilateral lower extremity
I87.031*	Postthrombotic syndrome with ulcer and inflammation of right lower extremity
I87.032*	Postthrombotic syndrome with ulcer and inflammation of left lower extremity



I82.5Z3*	Chronic embolism and thrombosis of unspecified deep veins of distal lower extremity, bilateral
I87.001	Postthrombotic syndrome without complications of right lower extremity
I87.002	Postthrombotic syndrome without complications of left lower extremity
I87.011*	Postthrombotic syndrome with ulcer of right lower extremity
I87.012*	Postthrombotic syndrome with ulcer of left lower extremity
I87.013*	Postthrombotic syndrome with ulcer of bilateral lower extremity
I87.021*	Postthrombotic syndrome with inflammation of right lower extremity
I87.022*	Postthrombotic syndrome with inflammation of left lower extremity
I87.023*	Postthrombotic syndrome with inflammation of bilateral lower extremity
I87.031*	Postthrombotic syndrome with ulcer and inflammation of right lower extremity

M30.2	Juvenile polyarteritis
M30.8	Other conditions related to polyarteritis nodosa
M35.0B	Sjogren syndrome with vasculitis

Group 3 Medical Necessity ICD-10-CM Codes Asterisk Explanation

When the patient's condition is one of those designated by an asterisk (*), routine procedures are covered only if the patient is under the active care of a Doctor of Medicine or Osteopathy, who documents he/she has seen the patient for treatment and/or evaluation of the complicating disease process during the 6-month period prior to the rendition of the routine-type services per the Benefit Policy Manual, Publication 100-02, Chapter 15, Section 290F-Presumption of Coverage.

Group 4 (27 Codes)

Group 4 Paragraph

The ICD-10 codes below represent those diagnoses where the patient has neither a neurological nor vascular impairment yet are covered services.

One of the Group 1 ICD-10-CM codes above **MUST** be billed as the *primary* diagnosis to ensure payment.

Group 4 Codes

Code	Description
B20	Human immunodeficiency virus [HIV] disease
D68.01*	Von Willebrand disease, type 1
D68.020*	Von Willebrand disease, type 2A
D68.021*	Von Willebrand disease, type 2B
D68.022*	Von Willebrand disease, type 2M

D68.023*	Von Willebrand disease, type 2N
D68.029*	Von Willebrand disease, type 2, unspecified
D68.03*	Von Willebrand disease, type 3
D68.04*	Acquired von Willebrand disease
D68.09*	Other von Willebrand disease
D68.1*	Hereditary factor XI deficiency
D68.2*	Hereditary deficiency of other clotting factors
D68.311*	Acquired hemophilia
D68.312*	Antiphospholipid antibody with hemorrhagic disorder
D68.318*	Other hemorrhagic disorder due to intrinsic circulating anticoagulants, antibodies, or inhibitors

D68.318*	Other hemorrhagic disorder due to intrinsic circulating anticoagulants, antibodies, or inhibitors
D68.32*	Hemorrhagic disorder due to extrinsic circulating anticoagulants
D68.4*	Acquired coagulation factor deficiency
D70.1*	Agranulocytosis secondary to cancer chemotherapy
D70.2*	Other drug-induced agranulocytosis
D81.82	Activated Phosphoinositide 3-kinase Delta Syndrome [APDS]
D82.0	Wiskott-Aldrich syndrome
D82.1	Di George's syndrome
I89.0	Lymphedema, not elsewhere classified
Q82.0	Hereditary lymphedema

I89.0	Lymphedema, not elsewhere classified
Q82.0	Hereditary lymphedema
R60.0	Localized edema
R60.1	Generalized edema
Z79.01*	Long term (current) use of anticoagulants

Group 4 Medical Necessity ICD-10-CM Codes Asterisk Explanation

When the patient's condition is one of those designated by an asterisk (*), routine procedures are covered only if the patient is under the active care of a Doctor of Medicine or Osteopathy, who documents he/she has seen the patient for treatment and/or evaluation of the complicating disease process during the 6-month period prior to the rendition of the routine-type services per the Benefit Policy Manual, Publication 100-02, Chapter 15, Section 290F-Presumption of Coverage.

Painful Mycotic Nails

Group 5 Paragraph:

When billing CPT® codes 11720 or 11721 for the **treatment of painful mycotic nails, or onychogryphosis, or onychauxis**, ICD-10 CM codes listed below must be reported as **primary**.

Note: It is inappropriate to bill the debridement of nails on the leg(s) for which a patient has a prosthetic limb(s).

Group 5 Codes: (5 Codes)

CODE	DESCRIPTION
B35.1	Tinea unguium
L60.1	Onycholysis
L60.2	Onychogryphosis
L60.3	Nail dystrophy

CODE	DESCRIPTION
L60.5	Yellow nail syndrome

Group 5 (5 Codes)

Group 5 Paragraph

When billing CPT® codes 11720 or 11721 for the **treatment of painful mycotic nails, or onychogryphosis, or onychauxis**, ICD-10 CM codes listed below must be reported as **primary**.

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L60.1	Onycholysis
L60.2	Onychogryphosis
L60.3	Nail dystrophy
L60.5	Yellow nail syndrome

Symptoms of the Symptomatic Mycotic Nails

Group 6 Paragraph:

The ICD-10 codes listed below are those diagnoses representing the patient's symptom and reported as the *secondary* to the codes listed in Group 5 above.

Group 6 Codes: (25 Codes)

CODE	DESCRIPTION
L02.611	Cutaneous abscess of right foot
L02.612	Cutaneous abscess of left foot
L03.031	Cellulitis of right toe
L03.032	Cellulitis of left toe
L03.041	Acute lymphangitis of right toe
L03.042	Acute lymphangitis of left toe
L03.115	Cellulitis of right lower limb
L03.116	Cellulitis of left lower limb
L03.119	Cellulitis of unspecified part of limb
L03.125	Acute lymphangitis of right lower limb
L03.126	Acute lymphangitis of left lower limb
L03.129	Acute lymphangitis of unspecified part of limb
L03.90	Cellulitis, unspecified
L03.91	Acute lymphangitis, unspecified
L60.0	Ingrowing nail
L98.3	Eosinophilic cellulitis [Wells]
M79.671	Pain in right foot
M79.672	Pain in left foot
M79.674	Pain in right toe(s)
M79.675	Pain in left toe(s)
R26.0	Ataxic gait
R26.1	Paralytic gait
R26.2	Difficulty in walking, not elsewhere classified
R26.81	Unsteadiness on feet
R26.89	Other abnormalities of gait and mobility

Group 6 (25 Codes)

Group 6 Paragraph

The ICD-10 codes listed below are those diagnoses representing the patient's symptom and reported as the *secondary* to the codes listed in Group 5 above.

Group 6 Codes

Code	Description
L02.611	Cutaneous abscess of right foot
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L03.115	Cellulitis of right lower limb
L03.116	Cellulitis of left lower limb
L03.119	Cellulitis of unspecified part of limb
L03.125	Acute lymphangitis of right lower limb
L03.126	Acute lymphangitis of left lower limb
L03.129	Acute lymphangitis of unspecified part of limb
L03.90	Cellulitis, unspecified
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L60.0	Ingrowing nail
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M79.675	Pain in left toe(s)
R26.0	Ataxic gait
R26.1	Paralytic gait
R26.2	Difficulty in walking, not elsewhere classified
R26.81	Unsteadiness on feet
R26.89	Other abnormalities of gait and mobility

Billing and Coding Article

Billing and Coding: Routine Foot Care

A57954

Expand All | Collapse All

NOT AN LCD REFERENCE ARTICLE

This article is not in direct support of an LCD. Learn more

Revision History Information

Revision History Date	Revision History Number	Revision History Explanation
01/01/2024	R15	Per 2024 CPT/HCPCS Updates: Either the short and/or long code description was changed for the following code(s). **Please Note:** Depending on which descriptor was used, there may not be any changes to the code display in this document: 11055, 11056, 11057 This update is effective 01/01/2024.
10/01/2022	R14	Updated to indicate this article is not an LCD Reference Article.
10/01/2022	R13	Under **Article Text**, replaced the broken link with new link for Part B within the following sentence: "Please refer to the CMS website for instructions for billing Part A and Part B claims."
10/01/2022	R12	Updated the Group 1 Asterisk Section in the ICD-10 Codes That Support Medical Necessity to read:

10/01/2022	R12	Updated the Group 1 Asterisk Section in the ICD-10 Codes That Support Medical Necessity to read: • "*Effective 06/19/2022, L60.8 is to be billed with 11719 - trimming of non-dystrophic nails - only if one of the systemic conditions from Group 2, 3 or 4 below is present AND the patient does NOT have dystrophic nails. G0127 is the appropriate code for the trimming of dystrophic nails." and • "*Effective 06/19/2022, G0127 is to be billed for dystrophic nails only. It is inappropriate to bill L60.8, L84 and L98.7 with G0127." In Group 4 ICD-10 Codes That Support Medical Necessity, added an asterisk (*) to the following codes: D68.01, D68.020, D68.021, D68.022, D68.023, D68.029, D68.03, D68.04, D68.09.
10/01/2022	R11	Per Annual ICD-10 Updates, the following changes were made effective 10/01/2022: • Deleted D68.0 and replaced this code with D68.01, D68.020, D68.021, D68.022, D68.023, D68.029, D68.03, D68.04, D68.09 in Group 4 of the ICD-10 Codes That Support Medical Necessity. • Added D81.82 in Group 4 of the ICD-10 Codes That Support Medical Necessity.

Symptomatic Painful Hyperkeratosis

Article - Billing and Coding: Wound and Ulcer Care (A58565)

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

Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
Noridian Healthcare Solutions, LLC	A and B MAC	01111 - MAC A	J - E	California - Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern

Paring and Cutting for the Management of a Symptomatic Hyperkeratosis - 11055-11057

- Codes 11055-11057 represent paring. The medical record must reflect the symptomatic nature of the lesion that makes this a coverable service, as the treatment of asymptomatic hyperkeratotic lesions are within the scope of Routine Foot Care. Please refer to Groups 2 and 3 in the ICD 10 Codes That Support Medical Necessity section for further information.

Symptomatic (Painful) Hyperkeratosis

Group 2 Paragraph:

Note: If the coverage conditions for the treatment of Symptomatic Hyperkeratoses are not met, the claims will be adjudicated based off Noridian's JEAB Billing & Coding: Routine Foot Care A57954 Local Coverage Article (LCA).

For CPT codes **11055-11057**, the claim **must** have at least **one** of the following nineteen diagnosis codes **and** at least **one** of the diagnosis codes listed in **Group 3.**

Group 2 Codes: (19 Codes)

CODE	DESCRIPTION
E10.621	Type 1 diabetes mellitus with foot ulcer
E11.621	Type 2 diabetes mellitus with foot ulcer
E75.21	Fabry (-Anderson) disease
G60.0	Hereditary motor and sensory neuropathy
G60.1	Refsum's disease
G60.2	Neuropathy in association with hereditary ataxia
G60.3	Idiopathic progressive neuropathy
G60.8	Other hereditary and idiopathic neuropathies
L11.0	Acquired keratosis follicularis
L84	Corns and callosities
L85.0	Acquired ichthyosis
L85.1	Acquired keratosis [keratoderma] palmaris et plantaris
L85.2	Keratosis punctata (palmaris et plantaris)
L85.8	Other specified epidermal thickening
L86	Keratoderma in diseases classified elsewhere
L87.0	Keratosis follicularis et parafollicularis in cutem penetrans
L87.2	Elastosis perforans serpiginosa
Q81.9*	Epidermolysis bullosa, unspecified
Q82.8*	Other specified congenital malformations of skin

Group 2 Medical Necessity ICD-10-CM Codes Asterisk Explanation:

*Use ICD-10-CM code **Q81.9 and Q82.8** only for those hyperkeratotic, symptomatic lesions referable to this diagnosis such as painful porokeratosis or keratoderma.

Group 3 Paragraph:

For CPT codes **11055-11057**, the claim **must** have at least **one** of the diagnosis codes from Group 2 above and at least **one** of the following diagnosis codes:

Group 3 Codes: (6 Codes)

CODE	DESCRIPTION
L03.031	Cellulitis of right toe
L03.032	Cellulitis of left toe
M79.671	Pain in right foot
M79.672	Pain in left foot
M79.674	Pain in right toe(s)
M79.675	Pain in left toe(s)

Noridian Medicare

Noridian CAC Meetings

G2211 Frequently Asked Questions (FAQ)

- CMS published HCPCS G2211 FAQs
  - Complex add-on code only billed with office or outpatient E/Ms
    - CPTs 99202-99205 and 99211-99215
- CMS FAQs_Office and Outpatient E/M Visit Complexity Add-On Code G2211
- Noridian hosted another G2211 webinar on Dec. 5, 2024
  - Register under Schedule of Events

FYI: no-pay Medicare summary notice (MSN) mailings

- CR13627
- Effective date: 10/1/2024
- Implementation date: 10/7/2024
- When MSN mailed to **beneficiaries** notifying of "No-Pay"
  - Frequency changed from every 90 days to every 120 days

Medicare Summary Notice

- The Medicare Summary Notice (MSN) is a report that details any covered healthcare services and items a person on original Medicare receives in a 3-month period, along with the costs. It is not a bill, but rather a summary of services and a breakdown of payments.

Social Determinants of Health Risk Assessment

- CR13486
- Effective date: 1/1/2024
- Implementation date: 10/7/2024
- Annual Wellness Visit (AWV) option for the Social Determinants of Health (SDOH) Risk Assessment
  - Add modifier -33 to G0136 when included with AWV

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From the Noridian medicare contractor medical director

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

We will discuss

- Medical Review (Targeted Probe and Education)
- Appeals
- Documentation
- Telehealth
- Response to Requests for Records
- Changing or Amending a Claim

RE: Notice of Review - Targeted Probe and Education

Dear Medicare Provider:

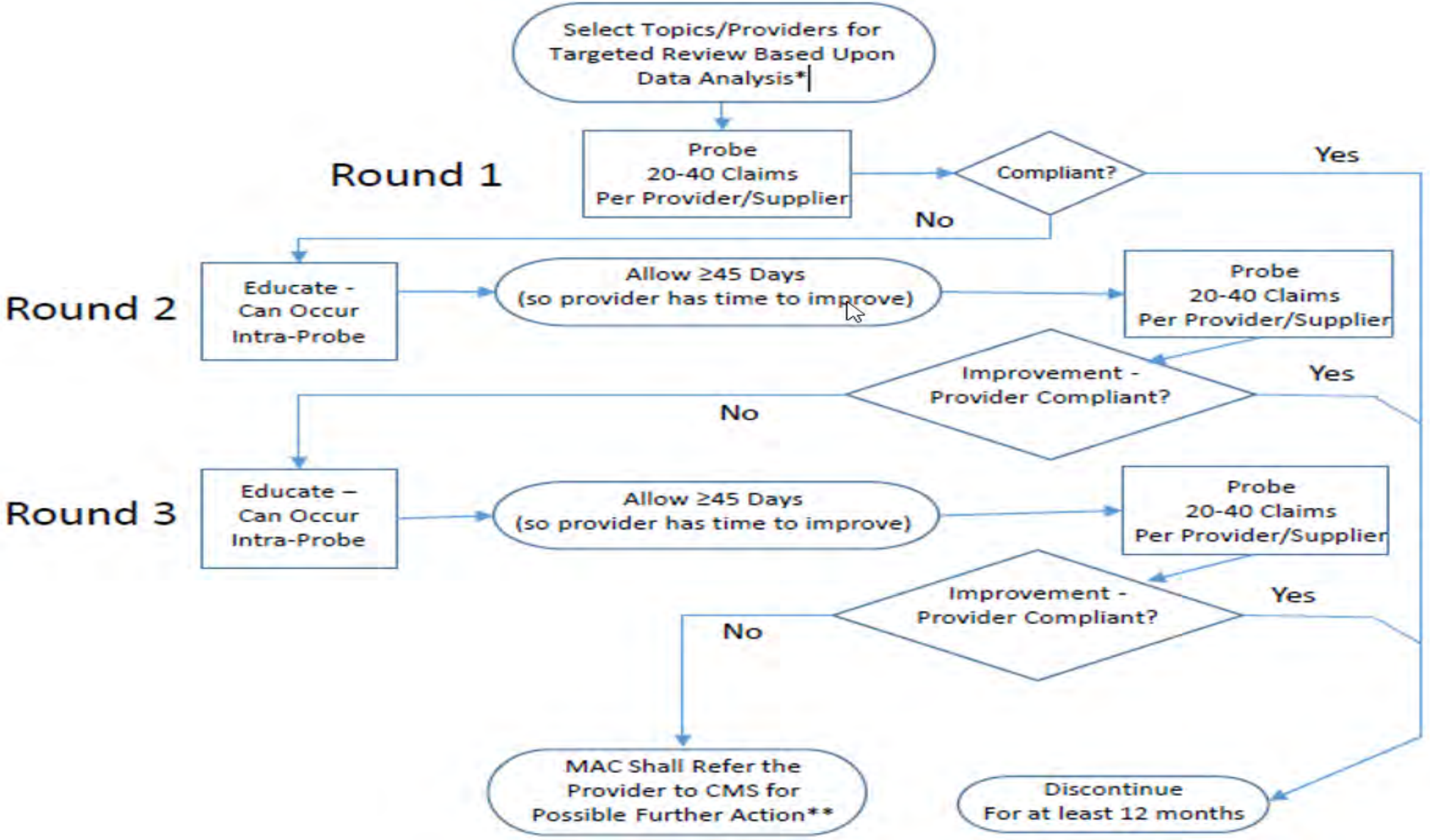
In order to fulfill our contractual obligation with the Centers for Medicare & Medicaid Services (CMS), Noridian Healthcare Solutions, LLC, your Jurisdiction E Medicare Administrative Contractor (MAC), performs reviews in accordance with the CMS instruction. CMS has authorized Jurisdiction E to conduct the Targeted Probe and Educate (TPE) review process. The TPE review process includes three rounds of a prepayment probe review with education. If there are continued high denials after three rounds, Noridian will refer the provider to CMS for additional action, which may include 100% prepay review, extrapolation, referral to a Recovery Auditor, etc. Note, discontinuation of review may occur at any time if appropriate improvement is achieved during the review process.

This letter serves as notification of the TPE process and to notify you of the initiation of the review. The purpose of the claim review is to ensure documentation supports the reasonable and necessary criteria of the services billed and follows Medicare rules and regulations.

Reason for Review

A prepayment review has been initiated to probe a sample of your claims billed with the following code(s):

Healthcare Common Procedure Coding System (HCPCS) code G0277


Select Topics/Providers for Targeted Review Based Upon Data Analysis*
Round 1
Probe 20-40 Claims Per Provider/Supplier
Compliant?
Yes
No
Round 2
Educate - Can Occur Intra-Probe
Allow ≥45 Days (so provider has time to improve)
Probe 20-40 Claims Per Provider/Supplier
Improvement - Provider Compliant?
Yes
No
Round 3
Educate – Can Occur Intra-Probe
Allow ≥45 Days (so provider has time to improve)
Probe 20-40 Claims Per Provider/Supplier
Improvement - Provider Compliant?
Yes
No
MAC Shall Refer the Provider to CMS for Possible Further Action**
Discontinue For at least 12 months

WHAT COMES NEXT

- You will get an e-mail asking for a specific patient, code and date of service-often every 3rd or 4th claim
- How are you and the code selected:
  - Outlier code/s compared to other states, or regions---specific code or groups of codes related
  - Outlier (higher frequency) numbers of claims for that code or series of codes by your office
  - Increased frequency of billing for those codes by your practice compared to prior time period
- You will be told where and when to send the chart information/documentation

REPORT ON RESULTS OF REVIEW

RE: Notice of File Closure - Targeted Probe and Educate

Dear Medicare Provider,

This letter is to inform you of the round 1 findings for the review initiated on January 4, 2022 for Current Procedural Terminology (CPT®) code 96374. This file is now closed.

An e-visit is not required given the low error rate for the round 1 file, however if you determine that one to one education would be beneficial, Noridian encourages your facility to contact me to set up an e-visit.

Claim Review Summary

Your facility had 20 claims selected for pre-payment review from January 4, 2022 through June 3, 2022 with an overall payment error rate of 2.8% and a claim error rate of 5%. The results are based on the documentation requests submitted by your facility. This review does not guarantee coverage and payment as the claims identified may be subject to other claim processing issues or reviews by other CMS contractors.

The formula to calculate the error rate, which is based on pre-payment decisions only, is the dollar amount of charges billed in error (minus any confirmed under-billed charges) divided by the total amount of charges for services medically reviewed. Individual claim correction is not required as the claims were reviewed on a pre-payment basis and processed per medical review determinations.

A summary of the claim determinations is as follows:

- 19 claims were accepted
- 0 claims required correct coding:
  - Documentation Supporting Infusion Units Billed
  - Therapeutic Administration Billing
  - Therapeutic Administration Billing Integral to a Procedure

Refer to the Claim Review Summary at the end of this letter for more detailed information on your individual claim determinations.

Education

This section provides education on errors found in the claims reviewed from your facility; it does not educate on all of CMS's guidelines required for this service. Furthermore, practitioner orders were not part of Noridian's scope of review and not incorporated in the error rate; however, orders are still required per Medicare

No mistakes or few mistakes and you need have no fear
Our requests for extra charts will stop and disappear
We won’t bother you for this code set for at least a year

WHAT SHOULD YOUR DOCUMENTATION SHOW

- For Laboratory Tests:
  - Signed and dated order exists in hospital and institutional charts
  - That office chart documentation shows that doctor wanted tests and (hopefully) for what reason tests were ordered
- For imaging tests:
  - Signed and dated order exists in hospital and institutional charts
  - Office documented shows that doctor wanted / needed the tests
- Total time and what happened during office visit (E&M), or
- Decision making aspects of office visit (E&M)
  - Potential problems, provider thoughts, rule outs help level of visit
  - What you are thinking at the time also helps…
  - Tests you plan and potential drug interactions also helps…

DOCUMENTING REASONABLE & NECESSARY: NOT CHANGING

- Only the actual physician who is treating the patient knows what is reasonable and necessary for that patient being evaluated and treated at that visit.

•The only way a Noridian reviewer can determine if something is (was) reasonable and necessary on a claim is to review the complete documentation submitted

FIGHTING BACK: RESPONDING TO ANY REQUEST FOR CHART RECORDS / DOCUMENTS

- Have a set office process for dealing with Record Requests (from Medicare or any insurance or agency)
- Have 1 individual responsible for sending all records as part of set office process---experienced office manager or equivalent
- Have a check off sheet that includes:
  - Legibility of document and signature (can add typed / printed addendum to help us decipher)
  - Correct name, date, physician listed in request
  - Signature (signature sheet or attestation if needed)
  - Correct address for records to be sent (other entities may also want records)
  - Timeliness of records being sent
- Know how and where to get hospital /clinic records
- Send by certified mail (or equivalent) so you have proof it arrived

MEDICARE APPEALS PROCESS

- Initial Determination from Noridian ($1)
- Redetermination from Noridian ($1)-120 days/file
- Qualified Independent Contractor (QIC) ($1)-180 days/file
- Administrative Law Judge (ALJ) ($180)-60 days/file
- Department Appeals Board (DAB) ($180)-60 days/file
- Federal Court ($1760)-60 days/file
- There is no penalty for appealing a claim

AMENDED RECORDS

- **Late entries, addendums, or corrections to a medical record are legitimate occurrences in documentation of clinical services. A late entry, addendum or correction to the medical record, bears the current date of that entry and is signed by the person making the addition or change.**
  - **Late Entry: supplies additional information that was omitted from original entry. The late entry bears the current date, is added as soon as possible, is written only if the person documenting has total recall of the omitted information and signs the late entry.**
  - **Addendum: An addendum is used to provide information that was not available at the time of the original entry. The addendum should be timely and bear the current date and reason for the addition or clarification of information being added to the medical record and be signed by the person making the addendum.**
- **When making a correction to the medical record, never write over, or otherwise obliterate the passage when an entry to a medical record is made in error.**
  - **Draw a single line through the erroneous information, keeping the original entry legible. Sign or initial and date the deletion, stating the reason for correction above or in the margin.**
  - **Document correct information on the next line or space with the current date & time, making reference back to the original entry.**

Telehealth

- All current telehealth codes will continue until the end of 2024
- Some may continue until the end of 2025
- Some will be permanent (depending on Congress)

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FROM THE MEDICAL DIRECTOR

October

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Telehealth

- *-Will continue through 2025*
- *-Usually required license in state where patient is being treated*

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Medications

- *-Consider cost of meds*
- *-Consider generic when available*
- *-Consider polypharmacy effect*
- *-Consider Pharmacy Card from manufacturer*
- *-Physician fee structure*

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Documentation tricks
-Time versus decision making
-Symptoms of potential disease

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Split-Shared Services

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october 2024 IMPAC: CERT Information

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Top provider errors

CA/NV Error: Top five Provider Types by dollars

- Clinical Laboratory (Billing Independently)
- Internal Medicine
- Physical Therapist in Private Practice
- Family Practice
- Nephrology

Top Clinical Laboratory (Billing Independently) Errors

- Missing/Inadequate
  - Documentation to support medical necessity
  - Provider's intent to order (for certain services)
  - Order
  - Result of the diagnostic or laboratory test
  - Risk assessment for urine drug screen

Clinical Laboratory (Billing Independently) Example

- Provider Billed 81479
- CERT Received
  - Authenticated order for AlloSure testing dated 07/22/2022 which is one day after the billed date of service 07/21/2022
  - Authenticated progress noted dated 03/18/2020 and 04/08/2020 that documents a beneficiary status post kidney transplant on 11/01/2019 immunosuppressed with Tacrolimus, Myfortic, and Prednisone
  - Laboratory report for AlloSure testing with collection date 07/21/2022
- Missing Documentation
  - Treating provider's authenticated order dated prior to or on 07/21/2022 or clinical documentation to support the plan/intent to order the billed unlisted molecular pathology procedure (AlloSure) for DOS 07/21/2022

Top Internal Medicine Errors

- Missing/Inadequate
  - Documentation supports lower level of E/M service than what was billed
  - Service/item is included in another service/item billed and is not separately payable
  - Time requirement for payment of the code
  - Attestation for unsigned documentation

Internal medicine Example

- Provider Billed 99233
- CERT Received
  - Treating provider's authenticated hospital visit note that does not meet the required 2 of 3 key components (D Hx, D Ex, and HC MDM) for the level of E/M billed for DOS
- CERT Decision
  - Billed Service is Incorrectly Coded: Documentation supports a down code from 99233 to 99232 with an EPF Hx, EPF Exam and HC MDM based on the documentation

Top Physical Therapy in Private Practice Errors

- Missing/Inadequate
  - Physical/Occupational/Speech Therapy - Certification/Recertification
  - Physical/Occupational/Speech Therapy - Plan of care
  - Physical/Occupational/Speech Therapy - Therapy minutes
  - Attestation for unsigned documentation
  - Physical/Occupational/Speech Therapy - Required progress report, performed at least once every 10 treatment days

Physical Therapy in Private Practice Example

- Provider Billed 97140
- CERT Received
  - Authenticated physical therapy plan of care dated 09/06/2022 documenting long-term goals for a beneficiary with diagnosis of unspecified fracture of acetabulum with routine healing; however, lacks certification by the physician
  - Authenticated physical therapy treatment note dated 09/23/2022 (visit #6) documenting the performance of 30 minutes of manual therapy for a beneficiary with healed acetabular fracture and pain in the right hip
  - Prescription for physical therapy dated 08/31/2022 authenticated by physician
  - Incomplete physical therapy recertification note dated 10/12/2022
- Missing Documentation
  - Physician certification of physical therapy plan of care relevant to billed DOS

Top Family Practice Errors

- Missing/Inadequate
  - Chronic Care Management (CCM) - Care Plan provided to the beneficiary or family
  - LCD/LCA requirements, other documentation required for payment
  - Documentation supports lower level of E/M service than what was billed
  - Time requirement for payment of the code
  - Documentation to support the services were provided or other documentation required for payment of the code

Family Practice Example

- Provider Billed 99490
- CERT Received
  - Patient summary dated 06/14/2022 documenting discussion with beneficiary regarding blood pressure; list of beneficiary's problems which includes abnormal blood glucose, hypothyroidism and HTN, and indicates beneficiary is compliant with medications and on track with goals
  - Electronically authenticated call log for June 2022, for 25 minutes, which includes information pertaining to date of service
- Missing Documentation
  - Documentation supporting the chronic care management (CCM) comprehensive care plan was provided to the beneficiary or the beneficiary's caregiver to support CCM services billed on date of service 06/30/2022
  - Documentation of the beneficiary's verbal or written consent for CCM services relevant for DOS 06/30/2022
  - Treating physician's clinical documentation to support the beneficiary has 2 or more chronic conditions expected to last at least 12 months in order to support physician involvement for the CCM service billed for DOS 06/30/2022

Top Nephrology Errors

- Missing/Inadequate
  - Plan of care
  - Provider/supplier indicates that a medical record could not be found for the specified date of service
  - Documentation of time is missing and supports a lower level of service
  - Documentation supports lower level of E/M service than what was billed
  - A separate and identifiable service is not supported as billed (i.e., removal of a modifier as a coding error)

Nephrology Example

- Provider Billed 90966
- CERT Received
  - Authenticated PD Dialysis visit note dated 10/18/2022 documenting a history of diabetes and CKD
- Missing Documentation
  - Plan of Care for home dialysis relative to the DOS developed and must be signed by at least one team member and the beneficiary or their designee; or, if the beneficiary chooses not to sign, the reason the signature was not provided must be documented on the plan of care
  - Comprehensive assessment or reassessment of the beneficiary relative to the DOS developed by an Interdisciplinary team to support the billed end-stage renal disease (ESRD) related services for home dialysis per full month, for patients 20 years of age and older for DOS

What providers need to do

Provider requirements

- Promptly respond to requested information
  - Within 45 days of the initial request
- Non-responders receive an error
- Once a claim has been pulled for a CERT review, do not adjust the claim.

Error prevention

Overall prevention

- Document orders and intent
- Identify patient information on each page of medical record
- Legibly sign records
  - Utilize Signature logs if needed
- Collaborate with the ordering/referring physician to ensure your practice has all the necessary records to support the claim billed (as necessary).

Overall prevention2

- Code and bill for only the level of service/procedure specified in medical records
- Implement an internal control to ensure your practice has the necessary documentation to support services prior to rendering/billing
- Validate contact information is accurate
- Authenticate certifications/recertification's, plan of care, etc.
- Utilize Clinicians Corner and Checklists

Contractual obligation

- Respond to all CERT requests timely
- Common inappropriate responses
  - Patient was seen at facility “A”, not our office
  - Check with “Said” facility as we have no record of this patient
- Billing provider responsible to support claim
- Social Security Act §1862(a)(1)(A) provisions

Medical request cooperation

October 2024

- Cooperation is essential for medical record requests between:
  - Physicians' offices
  - Labs
  - Hospitals
  - Skilled Nursing Facilities (SNF)
- All entities must work together to obtain records for patients

Cert resources

CERT Inquiry look up tool

- Available on the Noridian Medicare Portal (NMP)
- Claim Status- CERT Inquiry
- Status and Error Details
- Reviewer Comments
- Contact Information

October 2024

Utilize your mac

October 2024

- We are here to support you!
  - Unsure what next step is?
  - Not sure who to contact?
  - Didn’t receive a request?
  - Want to check the status of your claim?
  - Want to identify any pending requests?
- Contact us!

Contact us

- Use CERT questions email addresses
  - Part A – CERTPartAQuestion@noridian.com
  - Part B – certquestion@noridian.com
  - DME JA – jadmecert@noridian.com
  - DME JD – jddmecert@noridian.com

October 2024

Provider Inquiries

- Email should include:
  - CERT Claim Identifier (CID) in subject line
  - Provider/supplier name and address
  - Contact person
  - Telephone number if requesting a phone call
  - Explanation of the issue, concern, or question
- Do not include any PHI/PII

CERT Contractor Contact Information

- CERT Documentation Center
  - 8701 Park Central Drive, Suite 400-A, Richmond, VA 23227
- Fax: 804-261-8100
- Customer Service: 443-663-2699
- Toll Free: 888-779-7477
- Email:
  - CertMail@empower.ai
  - CertProvider@empower.ai
- Website: https://c3hub.certrc.cms.gov/

WOUND CARE GUIDELINES

Local Carrier Determination – Wound Care

DL38902

SUMMARY OF EVIDENCE

- Chronic wound
  - Defined as a wound that has failed to progress through normal healing in a timely manner (30 days failure of Standard of Care)
  - Generally occur in patients with co-morbidities such as diabetes or vascular disease
  - Older adults are more likely to have chronic ulcers and to have the quality of their lives affected by these ulcers
- Chronic ulcers include but are not limited to:
  - Diabetic ulcers
  - Venous ulcers
  - Pressure ulcers

EVIDENCE-BASED CLINICAL GUIDELINES SUPPORT

- Removal of necrotic tissue with debridement
- Maintaining moisture balance
- Selecting appropriate wound dressings to control excessive moisture or add additional moisture, depending on wound type
- Infection prevention and treatment when needed
- Evaluation and improvement of circulation to the wound area
- Frequent monitoring, evaluation and measurement of wounds to determine wound progress
- Offload Diabetic foot ulcers
- Appropriate positioning and support surfaces for pressure ulcers
- Compression for venous leg ulcers

ANALYSIS OF EVIDENCE: FREQUENCY OF DEBRIDEMENT

- The appropriate interval & frequency of debridement depends on the individual clinical characteristics of the patient and the extent of the wound.
- The extent and number of services should be medically necessary and reasonable based on the documented medical evaluation of the patient's condition, diagnosis and plan
- Given the varied nature and diversity of options available to the clinician, this **LCD does not strictly impose defined frequency limitations as such on wound care debridements, palliative wound treatments and other wound care services**
- **Opinion: It is generally understood that the frequency should not be more frequent than every few days (twice a week). Document the reason for frequency.**
  - **New necrosis, continued infection, undermining, worsening wound**
- **Note: the frequency of debridement is covered in several sections, limiting surgical debridement to 4. however that can be increased with proper documentation and medical necessity, as to why the debridement is necessary**

LCD COVERAGE DEFINITION (CHRONIC WOUNDS)

- Wounds/ulcers refractory to healing or complicated healing cycles due to:
  - Nature of the wound
  - Complicating metabolic / physiological factors
- Excludes:
  - Acute wounds passing through healing cycle
  - Wounds healing by primary intention
  - Surgical wounds with primary closure
  - Post-op wound care not separately covered during the global period
  - Methods unproven by scientific literature / not reasonable & necessary

WOUND CARE

- Evaluation and treatment of a wound
- Identification of potential causes delayed healing & modification of the treatment
- Wound evaluation leads to Plan of Care (POC) (Monthly)
  - Comprehensive medical evaluation
  - Vascular assessment
  - Metabolic
  - Nutritional evaluation
  - Plan to reduce pressure
  - Plan to control infection

POC SUGGESTIONS THAT NEED TO BE NOTED

- Functional evaluations by different specialties may be of value
- Integration of PT may be of value
- Mention these in documentation. Whether needed or not necessary

DEVELOPMENT OF ULCERS

- Ischemia
- Infection
- Abscess
- Trauma
- Prolonged pressure
- Repetitive stress
- Venous / Arterial insufficiency
- Edema
- Loss of sensation

MANAGEMENT OF ULCERS INCLUDE:

- Overall medical and surgical treatment of the cause
- Meticulous care of the ulcerated skin & other associated soft tissue with applications of medicines and dressings
- When reasonable and necessary, debridement of the **necrotic and devitalized tissue**
- Offloading of the external pressure source(s)

WOUND CARE ON A CONTINUING BASIS

- Evidence in med record that the wound healing being maintained in response to the wound care being provided.

- Consistent measurements:
  - Length x width x depth. Volume?
  - Measure longest segment as "length"
  - Measure longest segment at 90° from length as width
  - Personal: Never measure depth as '0'

DOCUMENTATION OF WOUND HEALING

- Undermining
  - Clock technique with the head at 12 o'clock. Depth via swab
- Tunneling
  - Clock technique with the head at 12 o'clock. Depth via swab
- Severe contractures
- Infection reported by describing exudate:
  - Amount
  - Turbidity
  - Color
  - Odor
  - And signs of infection (cellulitis) in the tissue surrounding the wound
- Necrosis: ultimate loss of tissue vitality. Presence impedes healing

GOALS OF ACUTE WOUND & CHRONIC ULCER CARE
PRIMARY GOALS – ACUTE WOUND

Primary Goals:

- Eventual wound closure
  - With or without grafts, cellular or tissue products, or other surgery
  - Surgery: amputation, wound excision, etc.

- In the case of severe underlying debility or other factors of operability, in the outpatient setting, the goals may only be to:
  - prevent progression of the wound and,
  - prevention of prolonged hospitalization

GOALS OF ACUTE WOUND & CHRONIC ULCER CARE
SECONDARY GOAL

Secondary Goal:

- With appropriate management, wound may reach a state at which its care may be performed primarily by the patient/caregiver with **periodic** physician assessment and supervision

GOALS OF ACUTE WOUND & CHRONIC ULCER CARE
PRIMARY GOAL – CHRONIC WOUNDS

Primary Goal:

- Eventual wound closure

STANDARD WOUND CARE MEASURES INCLUDE BUT NOT LIMITED TO:

- Appropriate control of:
  - Pressure (offloading, padding, appropriate footwear)
  - Infection
  - Vascular insufficiency (venous and arterial)
  - Metabolic derangement
  - Nutritional deficiency

WOUND DEBRIDEMENT

- Active Wound Care procedures
  - Non-Selective debridement
  - Selective debridement

- Surgical debridement

WOUND CARE

- Active wound care management
  - Selective (97597)
  - Non-Selective (97602)
- Surgical debridement
  - Most surgical specialists fall into this category
  - 11042 series

- Different coding in each category
- Different documentation is each category

ACTIVE WOUND CARE MANAGEMENT

- The 97597 series
  - 97597 (selective debridement)
  - 97598
  - 97602 (non-selective) (w/o anesthesia)
  - 97605 (Neg Pressure Wound Therapy DME </= 50 sq cm)
  - 97606 (Neg Pressure Wound Therapy DME > 50 sq cm)
  - 97607 (Neg Pressure Wound Therapy non-DME </= 50 sq cm)
  - 97608 (Neg Pressure Wound Therapy non-DME > 50 sq cm)

- The 11400 series is not used in Active Wound Care Management

ACTIVE WOUND CARE MANAGEMENT 97597, 97598, 97602

- **Active Wound Care Management is separate from Surgical Debridement**
- Code 97602 is a Status B (Bundled) code for physician services; therefor separate payment is not allowed for this service
- Code 97602 (non-selective debridement of non-viable tissue from wound without anesthesia, ie: wet-to-dry
- Debridement should be coded with either selective or non-selective CPT codes unless medical record supports a surgical debridement has been performed.
- Dressings applied to the wound on the day of the service are part of the service and can not be billed separately
- CPT 97602 can not be billed same day as 97597/97598

97597 VS. 11043

- Codes 97597/97598/97602 can not be reported in conjunction with the 11043-11047 code series for the **same** wound
- Wound depth and depth of the debridement determines the code
- If only biofilm is debrided on the surface of a muscular ulceration, then use codes 97597/97598
- If the muscle substance is debrided, use codes 11043-11046
- Slough is devitalized tissue. Describe where it is originated.
  - Debriding slough of a muscle layer is debriding muscle
  - Debriding periosteum is **not** debriding bone

CODES 97602 / 97605 / 97606 / 97608

- Includes application of, and removal of, any protective devices or bulk dressings
- If dressing change is performed without any active wound procedure, then do not code with these CPT codes
  - E/M would be appropriate

ACTIVE WOUND CARE PROCEDURES

- Debridement techniques
- Performed to remove devitalized tissue and promote healing
- Provider with "one-on-one" patient contact
- Interval and frequency of debridement
  - Extent of the wound
  - Clinical characteristics of the patient
- Frequent debridement
  - Reassess and re-examine treatment plan
  - Address all facets of care

RE-EVALUATION: ISSUES TO ADDRESS FOR FREQUENT REPEATED DEBRIDEMENT

- Regular Frequency – Monthly POC

- Determine whether the treatment goals are being met
  - Pressure reduction
  - Nutritional status
  - Vascular insufficiency (arterial and venous)
  - Infection control
  - Metabolic disease (diabetes, etc)

DEFINITION OF TERMS

- Dressing changes:
  - Wet dressings: water and meds applied to skin with dressings (cotton or gauze). Wet compresses w frequent changes provide gentle debridement.
  - Dry dressings: gentle debridement, protect skin, hold medicines against skin, keep clothing and sheets from rubbing, keep dirt and air away, avoid scratching and rubbing the wound
  - Advanced dressings: acute wounds, chronic venous wounds, diabetic and pressure ulcers. Used for gentle debridement, moisture control, prevent bacterial overgrowth, thermal insulation and physical protection.

- Dressing changes alone are not procedures by themselves; are included in the debridement or in the E/M visit.

COVERED INDICATIONS

TYPES OF WOUNDS NEEDING WOUND CARE

- Surgical wounds left open to heal via secondary intention
- Trauma wounds, open and infected
- Surgical wounds, open and infected
- Wounds with biofilm
- Wounds associated with complicating autoimmune, metabolic, vascular and/or pressure factors
- Wounds complicated by necrotic tissue and/or eschar

ACTIVE WOUND CARE MANAGEMENT

- Debridement indicated:
  - To keep wound in active state of healing
  - To remove necrotic tissue, cellular debris, proteinaceous debris
  - To address abnormal wound healing or repair

- Routine application of local or topical anesthetic will not elevate wound care management to surgical debridement.
- Debridement under Active Wound Care is either selective or non-selective

ACTIVE WOUND CARE MANAGEMENT SELECTIVE DEBRIDEMENT:

- Removal of specific, targeted areas of devitalized or necrotic tissue from a wound along the margin of viable tissue by sharp dissection.
- Utilizing: scissors, scalpel, curette, and/or tweezers/forceps
- Typically requires no anesthesia
- Generally minimal or no bleeding

ACTIVE WOUND CARE MANAGEMENT NON-SELECTIVE DEBRIDEMENT

- Mechanical
  - Removal of necrotic tissue by cleansing or appropriate dressings
  - Removal of debris and dressing changes are not considered a skilled or separate service
- Enzymatic
  - Debridement with topical enzymes used for protein, fiber and collagen.
  - Clinician to comply with packet insert, manufacturer's guidelines
- Autolytic
  - Indicated when manageable amount to necrotic tissue present and no infection.
  - Occurs when enzymes naturally found in wound fluids are sequestered under synthetic, non-permeable dressings
- Maggot / larvae
  - Debridement with medical grade maggots in wounds

WOUND CARE SURGICAL DEBRIDEMENTS

- Conditions that may require surgical debridement of large amounts of skin may include, but are not limited to:
  - Rapidly spreading necrotizing process
  - Severe eczema
  - Extensive skin trauma (including large abraded areas with ground-in dirt)!!
  - Autoimmune skin disease

WOUND CARE SURGICAL DEBRIDEMENTS

- Surgical debridement occurs when
  - Material has been excised
  - Reported for the treatment of a wound to clear and maintain the site free of devitalized tissue, including:
    - Necrosis
    - Eschar
    - Slough
    - Infected tissue
    - Biofilm
    - Abnormal granulation tissue
  - Should be accomplished to the margins of the viable tissue
  - These procedures can be very effective, but represent extensive debridement. May be complex and may require use of anesthesia

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
01/01/2024	R5	Per 2024 CPT/HCPCS Updates: Either the short and/or long code description was changed for the following code(s). **Please Note:** Depending on which descriptor was used, there may not be any changes to the code display in this document: 11000, 11001, 11004, 11005, 11006, 11008, 11042, 11043, 11044, 11045, 11046, 11047, 11055, 11056, 11057, 97597, 97598, 97605, 97606, 97607, 97608. This update is effective 01/01/2024.
02/03/2022	R4	Updated to indicate this article is an LCD Reference Article.
02/03/2022	R3	Under Revision History Number 2: Correcting the sentence, "This section of the NCCI

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Wound Assessment©

Page 1 Of ___

Patient: _____ ☐ New Patient PMD: _____ Date: _____

Facility: Room/Bed: D.O.B.: ☐ Established Patient Length of visit: minutes Provider:

Wound Type:
☐ Pressure ☐ Diabetic ☐ Venous ☐ Arterial ☐ Neuropathic ☐ Trauma/Surgical ☐ Mixed ☐ Other:

Factors Effecting Healing: ☐ Obesity ☐ Failure to Thrive ☐ Limited Mobility ☐ Hypoalbuminemia
☐ Diabetes ☐ Neuropathy ☐ Contracture ☐ CVA ☐ HTN ☐ CKD ☐ CHF ☐ Respiratory Failure ☐ PAD ☐ Hospice Status ☐ Medications ☐ Weakness
☐ Patient non-compliant behavior _____ ☐ Other:

Discussion/Relevant Interim History: The wound measure will increase in depth until the true wound bed is revealed. Last Exam Date:

☐ No report of Nausea, Vomiting, Fever, or Chills ☐ Medication List reviewed in patient chart; no action needed **Is this wound healable:** ☐ Yes ☐ No

Labs & Studies

Protein: Albumin: Pre-albumin:
HgbA1C: Sed Rate: CRP:
Last Blood Draw: _____ Last RD Evaluation: _____
Has there been a significant change in labs since last visit:
☐ Yes ☐ No
Other studies: (include results and comments)

Healing Factors

Controllable?	Y	N		Y	N
Pressure Reduction	☐	☐	Infection Control	☐	☐
Hydration Status	☐	☐	Vascular Disease	☐	☐
Nutritional Status	☐		followed with RD		
Metabolic Status	☐		followed with PMD		

Rationale:

Infection Control

☐ Wound Prophylaxis
Are there signs of possible infection ☐ Yes ☐ No
Studies: ☐ Culture & Sensitivity ☐ PCR
Intervention: ☐ Topical _____
Systemic antibiotics: ☐ PO ☐ IV

Peripheral Edema: ☐ Localized ☐ Generalized ☐ None
☐ Left ☐ Right ☐ Bilateral and Symmetrical
☐ Pitting ☐ Non-pitting ☐ Mild ☐ Moderate ☐ Severe
Stasis Changes?

Pulses: DP – L 0 1 2 3 4 R 0 1 2 3 4
PT – L 0 1 2 3 4 R 0 1 2 3 4

Adequate Extremity Arterial Perfusion? ☐ YES ☐ NO
Evidence: ☐ Diminished Pedal Pulses
Capillary Refill Time: Right: sec Left: sec
Color: ☐ pink/normal ☐ erythematous ☐ pallor ☐ cyanotic
Distal Temp: ☐ warm ☐ cool ☐ cold ☐ ice-cold ☐ B/L and sym
Vascular Testing Performed: ☐ ABI ☐ Arterial Doppler
☐ $TcPO_2$ (digital O_2 perfusion) ☐ Toe-Brachial Index ☐ Angiogram
☐ Venous Doppler ☐ Venous Duplex ☐ Venography
Is vascular intervention planned? ☐ YES ☐ NO
Vascular specialist's opinion: ☐ patient healable
☐ candidate for surgical intervention and healable
☐ not a candidate for surgery, but healable
☐ not a candidate for revascularization surgery/not healable
Comments: See note of _____

Nutritional Status

Current factors of concern:
☐ Decreasing BMI ☐ Increasing Risk of Pressure Injury
☐ Delay in Healing ☐ Increasing Loss of Weight
Interventions currently employed:
☐ Protein Supplement ☐ Protein Additive 3 6 8 gm/day
☐ MVI/Mineral supplement Add'l Vitamins: A C D_3
Add'l Mineral: Cu^{++} Fe^{++} Zn^{++}

Wound #: Location:

Pre-/Post- L / W / D /

Assessed Stage of Wound: 1 2 3 4 US DTI Non-Pressure

Wound Type (this wound):

Debridement: ☐ Selective ☐ Surgical ☐ Serial/Surgical

Prognosis

Healable: Goals
☐ Eventual Closure ☐ Convert to Self-care or Home Health (if patient's general health, medical issues, continuing adequate mental status, and home environment allow this change)
Non-healable: Goal – Palliation
Minimize the risk of the following:
☐ Additional Loss of Activity ☐ Psycho-social issues for the patient and their family
☐ Negative Progression of Wound ☐ Additional Devitalized Tissue ☐ Frequency of Hospitalization
☐ Hospital Length of Stay ☐ Infection ☐ Amputation ☐ Sepsis ☐ Death

Tissue Involvement/Uncovered: ☐ Superficial ☐ Fascia ☐ Fat ☐ Muscle/Tendon ☐ Periosteum ☐ Bone ☐ Other:_____
Undermining: Superior 9 3 Inferior
Drainage: ☐ None ☐ Scant ☐ Light ☐ Moderate ☐ Heavy ☐ Copious
Type: ☐ Serous ☐ Serosanguinous ☐ Seropurulent ☐ Purulent
Odor: ☐ None ☐ Increasing ☐ Decreasing ☐ Malodor ☐ Sweet ☐ Fecal ☐ Other_____

Wound Bed:
Pink % Yellow/White % Eschar % Slough %
Necrotic % Other: _____% Boney prominence ☐ Yes ☐ No
Sinus /Tunneling ☐ Yes ☐ No
Wound Margins & Periwound: (circle)
Intact Smooth Regular Macerated Hypergranular Epiboly Erythema Atrophic
Slough Thickened Irregular Friable Keratotic Indurated Ecchymosis Necrotic
Treatment: Topical & Dressing

Debridement Report: **Probe to Bone** ☐ **Yes** ☐ **No**
Debridement Level: **I** **II** **III** **IV** **$AgNO_3$ Cautery**
Instrument: 10/15 Blade Curette Scissors Nippers Forceps/Tweezers
Tissue Removed: Skin Full thickness Fat Capsule Slough/Eschar/Necrosis
Hypergranulation Fascia/Muscle/Tendon Bone
Hemostasis: EBL cc ☐ None ☐ Minimal
☐ Pressure ☐ Gelfoam ☐ Thrombin
Pain: pre- /10 during Tx- /10 post- /10
Anesthesia: Pre-medicated Topical Injection None

Continue Debridement? ☐ Yes ☐ No ☐ Wound Closed
Rationale for Continued Debridement of *this* wound
Healable:
☐ Maintain the wound in the active/acute phase of healing
☐ Clinically, the wound is improving with continuing care, including regular surgical debridements.
☐ The wound is not amenable to self-care or homecare.
Non-healable:
☐ Continuing care with palliation goals (see above)
☐ Remove necrotic, non-vital and infected tissue from the wound

Hydration Consider Additional Hydration ☐ PO ☐ IV

Today's Treatment Plan

☐ Serial/Surgical Debridement performed today by the provider, with removal of biofilm, non-viable tissue, ☐ infected tissue ☐ excessive granulation
☐ Surgical debridement will continue as needed, performed by the provider, while non-selective active wound care continues by staff between visits
☐ Selective debridement will continue as needed, performed by the provider, while non-selective active wound care continues by staff between visits
☐ Pressure reduction and offloading continue: _____
☐ Healing factors addressed: ☐ Recommend Comprehensive RD Evaluation
☐ No New Orders

Continues →

Provider Signature: **Supervising Physician:** ☐ Kimberly Conley, MD ☐ James E Burrows, MD ☐ Herbert Marshak, MD

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Wound Assessment©

Page 1 Of ___

Patient: _____ ☐ New Patient PMD: _____ Date: _____

Facility: Room/Bed: D.O.B.: ☐ Established Patient Length of visit: minutes Provider:

Wound Type:

☐ Pressure ☐ Neuropathic:
☐ Diabetic: ☐ Trauma/Surgical
☐ Venous ☐ Mixed
☐ Arterial ☐ Other:

Factors Effecting Healing: ☐ Obesity ☐ Failure to Thrive ☐ Limited Mobility ☐ Hypoalbuminemia

☐ Diabetes ☐ CVA ☐ Respiratory Failure ☐ Hospice Status ☐ Weakness
☐ Neuropathy ☐ HTN ☐ PAD ☐ Medications _____
☐ Contracture ☐ CKD ☐ Patient non-compliant behavior _____
☐ CHF ☐ Other:

Discussion/Relevant Interim History: This wound measure will increase in depth until the true wound bed is revealed Last Exam Date:

☐ No report of Nausea, Vomiting, Fever, or Chills ☐ Medication List reviewed in patient chart; no action needed **Is this wound healable:** ☐ Yes ☐ No

Labs & Studies

Protein: Albumin: Pre-albumin:
HgbA1C: Sed Rate: CRP:
Last Blood Draw: _____ Last RD Evaluation: _____
Has there been a significant change in labs since last visit:
☐ Yes ☐ No
Other studies: (Include results and comments)

Healing Factors

Controllable?	Y	N		Y	N
Pressure Reduction	☐	☐	Infection Control	☐	☐
Hydration Status	☐	☐	Vascular Disease	☐	☐
Nutritional Status	☐		followed with RD		
Metabolic Status	☐		followed with PMD		

Rationale:

Infection Control

☐ Wound Prophylaxis

Are there signs of possible infection ☐ Yes ☐ No
Studies: ☐ Culture & Sensitivity ☐ PCR
Intervention: ☐ Topical _____
Systemic antibiotics: ☐ PO ☐ IV

Wound #: **Location:**

Pre- / Post- L / W / D

Assessed Stage of Wound: 1 2 3 4 US DTI Non-Pressure

Wound Type (this wound):

Debridement: ☐ Selective ☐ Surgical ☐ Serial/Surgical

Prognosis

Healable: Goals:
☐ Eventual Closure ☐ Convert to Self-care or Home Health (if patient's general health, medical issues, continuing adequate mental status, and home environment allow this change)

Non-healable: Goal – Palliation
Minimize the risk of the following:
☐ Additional Loss of Activity ☐ Psycho-social issues for the patient and their family
☐ Negative Progression of Wound ☐ Additional Devitalized Tissue ☐ Frequency of Hospitalization
☐ Hospital Length of Stay ☐ Infection ☐ Amputation ☐ Sepsis ☐ Death

Tissue Involvement/Uncovered: **Undermining:** Superior 9 3 Inferior

☐ Superficial ☐ Fascia ☐ Fat ☐ Muscle/Tendon
☐ Periosteum ☐ Bone ☐ Other: _____

Drainage:
☐ None ☐ Scant ☐ Light ☐ Moderate ☐ Heavy ☐ Copious
Type: ☐ Serous ☐ Serosanguinous ☐ Seropurulent ☐ Purulent
Odor: ☐ None ☐ Increasing ☐ Decreasing

Peripheral Edema: ☐ Localized ☐ Generalized ☐ None
☐ Left ☐ Right ☐ Bilateral and Symmetrical
☐ Pitting ☐ Non-pitting ☐ Mild ☐ Moderate ☐ Severe
Stasis Changes?

Pulses: DP – L 0 1 2 3 4 R 0 1 2 3 4
PT – L 0 1 2 3 4 R 0 1 2 3 4

Adequate Extremity Arterial Perfusion? ☐ **YES** ☐ **NO**
Evidence: ☐ Diminished Pedal Pulses
Capillary Refill Time: Right: sec Left: sec
Color: ☐ pink/normal ☐ erythematous ☐ pallor ☐ cyanotic
Distal Temp: ☐ warm ☐ cool ☐ cold ☐ ice-cold ☐ B/L and sym
Vascular Testing Performed: ☐ ABI ☐ Arterial Doppler
☐ $TcPO_2$ (digital O_2 perfusion) ☐ Toe-Brachial Index ☐ Angiogram
☐ Venous Doppler ☐ Venous Duplex ☐ Venography

Is vascular intervention planned? ☐ **YES** ☐ **NO**
Vascular specialist's opinion: ☐ patient healable
☐ candidate for surgical intervention and healable
☐ not a candidate for surgery, but healable
☐ not a candidate for revascularization surgery/not healable
Comments: See note of _____

Nutritional Status
Current factors of concern:
☐ Decreasing BMI ☐ Increasing Risk of Pressure Injury
☐ Delay in Healing ☐ Increasing Loss of Weight
Interventions currently employed:
☐ Protein Supplement ☐ Protein Additive 3 6 8 gm/day
☐ MVI/Mineral supplement Add't Vitamins: A C D_3
Add't Mineral: Cu^{++} Fe^{++} Zn^{++}

☐ Maldor ☐ Sweet ☐ Fecal ☐ Other: _____

Wound Bed:
Pink % Yellow/White % Eschar % Slough %
Necrotic % Other: _____ % Boney prominence ☐ Yes ☐ No
Sinus /Tunneling ☐ Yes ☐ No
Wound Margins & Periwound: (circle)
Intact Smooth Regular Macerated Hypergranular Epiboly Erythema Atrophic
Slough Thickened Irregular Friable Keratotic Indurated Ecchymosis Necrotic
Treatment: Topical & Dressing

Debridement Report: **Probe to Bone** ☐ **Yes** ☐ **No**
Debridement Level: **I** **II** **III** **IV** **$AgNO_3$ Cautery**
Instrument: 10/15 Blade Curette Scissors Nippers Forceps/Tweezers
Tissue Removed: Skin Full thickness Fat Capsule Slough/Eschar/Necrosis
Hypergranulation Fascia/Muscle/Tendon Bone
Hemostasis: EBL _____ cc ☐ None ☐ Minimal
☐ Pressure ☐ Gelfoam ☐ Thrombin
Pain: pre- /10 during Tx- /10 post- /10
Anesthesia: Pre-medicated Topical Injection None

Continue Debridement? ☐ Yes ☐ No ☐ Wound Closed
Rationale for Continued Debridement of *this* wound
Healable:
☐ Maintain the wound in the active/acute phase of healing
☐ Clinically, the wound is improving with continuing care, including regular surgical debridements.
☐ The wound is not amenable to self-care or homecare.
Non-healable:
☐ Continuing care with palliation goals (see above)
☐ Remove necrotic, non-vital and infected tissue from the wound

Hydration Consider Additional Hydration ☐ PO ☐ IV

Today's Treatment Plan
☐ Serial/Surgical Debridement performed today by the provider, with removal of biofilm, non-viable tissue, ☐ Infected tissue ☐ excessive granulation
☐ Surgical debridement will continue as needed, performed by the provider, while non-selective active wound care continues by staff between visits
☐ Selective debridement will continue as needed, performed by the provider, while non-selective active wound care continues by staff between visits
☐ Pressure reduction and offloading continue: _____
☐ Healing factors addressed: ☐ Recommend Comprehensive RD Evaluation
☐ No New Orders

Continues →

Provider Signature: **Supervising Physician:** ☐ Kimberly Conley, MD ☐ James E Burrows, MD ☐ Herbert Marshik, MD

Amnionic Membrane Skin Substitutes - HCT Biologics

Code	Description
Q4139	Amnio or biodmatrix, inj 1cc
Q4145	Epifix, inj, 1mg
Q4155	Neoxflo or clarixflo 1 mg
Q4162	Wndex flw, bioskn flw, 0.5cc
Q4168	Amnioband, 1 mg
Q4171	Interfyl, 1 mg
Q4174	Palingen or promatrx
Q4177	Floweramnioflo, 0.1 cc
Q4185	Cellesta flowab amnion 0.5cc
Q4189	Artacent ac, 1 mg
Q4192	Restorigin, 1 cc
Q4206	Fluid flow or fluid gf 1 cc
Q4212	Allogen, per cc
Q4213	Ascent, 0.5 mg
Q4215	Axolotl ambient, cryo 0.1 mg
Q4230	Cogenex flow amnion 0.5 cc
Q4231	Corplex p, per cc
Q4233	Surfactor /nudyn per 0.5 cc
Q4240	Corecyte topical only 0.5 cc
Q4241	Polycyte, topical only 0.5cc
Q4242	Amniocyte plus, per 0.5 cc
Q4244	Procenta, per 200 mg
Q4245	Amniotext, per cc
Q4246	Coretext or protext, per cc

Centers for Medicare & Medicaid Services
https://www.cms.gov/medicare/payment/all-fee...

ASP Pricing Files | CMS - Centers for Medicare

Web **Medicare**. Payment. All Fee-For-Service-Providers. **Medicare** Part B **Drug** Average Sales Price. **ASP** Pricing Files. **ASP** Pricing Files. View the quarterly **drug** pricing files to see the Average Sales Price (**ASP**) of some Part B-covered **drugs** and biologicals: 2024 **ASP Drug** ...

Missing: ~~HTG~~ | Must include: HTC

Tags: Medicare Asp | Medicare Part B | Drug Pricing | Part B Drugs

EXPLORE FURTHER

Drug Pricing Lookup | National Drug Codes List	ndclist.com
NDC - HCPCS Crosswalk - **NDC** List 2024	ndclist.com
2024 **NDC - HCPCS Crosswalk**	hcpcs.codes
Addendum A and Addendum B Updates | CMS	cms.gov
ASP Drug Pricing - January 2023 Medicare Part B Drugs	hcpcs.codes

Recommended to you based on what's popular • Feedback

Centers for Medicare & Medicaid Services
https://www.cms.gov/medicare/payment/fee-for...

Medicare Part B Drug Average Sales Price | CMS

Web View the 2024 Average Sales Price (**ASP**) drug pricing files. **Medicare** pays for some separately payable **Medicare** Part B-covered drugs and biologics using the average sales ...

Missing: ~~HTG~~ | Must include: HTC

All Fee-For-Service-Providers

- Home Health Agency (HHA) Center
- Hospice Center
- Shared Savings Program (SSP) / ACOs
- Hospital-Acquired Conditions (HAC)
- Physician bonuses in Health Professional Shortage Areas (HPSAs)
- Medicare Fee-for-Service 5010 - D0

ASP Pricing Files

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

2024 ASP Drug Pricing

January 2024 ASP Pricing File (ZIP) - 12/20/2023 – final file

January 2024 NOC Pricing File (ZIP) - 12/20/2023 – final file

January 2024 ASP NDC-HCPCS Crosswalks (ZIP) - 12/20/2023 – final file

2023 ASP Drug Pricing

2022 ASP Drug Pricing

2021 ASP Drug Pricing

2005-2020 ASP Drug Pricing

Payment Allowance Limits for Medicare Part B Drugs

Effective January 1, 2024 through March 31, 2024

Note 1: Payment allowance limits subject to the ASP methodology are based on 3Q23 ASP data.
Note 2: The absence or presence of a HCPCS code and the payment allowance limits in this table does not indicate whether Mec
local Medicare contractor processing the claim.

HCPCS Code	Short Description	HCPCS Code Dosage	Payment Limit	Co-insurance Percentage	Vaccine AWP%	Vaccine Limit	
Q4101	Apligraf	1 SQ CM	30.401	20.000			
Q4102	Oasis wound matrix	1 SQ CM	13.407	20.000			
Q4103	Oasis burn matrix	1 SQ CM	12.989	20.000			
Q4104	Integra bmwd	1 SQ CM	49.534	20.000			
Q4105	Integra drt or omnigraft	1 SQ CM	25.344	20.000			
Q4106	Dermagraft	1 SQ CM	44.944	20.000			
Q4108	Integra matrix	1 SQ CM	44.360	20.000			
Q4110	Primatrix	1 SQ CM	39.055	20.000			
Q4111	Gammagraft	1 SQ CM	7.437	20.000			
Q4114	Integra flowable wound matri	1 CC	1507.000	20.000			
Q4115	Alloskin	1 SQ CM	12.130	20.000			
Q4117	Hyalomatrix	1 SQ CM	16.913	20.000			
Q4118	Matristem micromatrix	1 MG	2.548	20.000			
Q4121	Theraskin	1 SQ CM	45.000	20.000			
Q4123	Alloskin	1 SQ CM	37.602	20.000			
Q4124	Oasis tri-layer wound matrix	1 SQ CM	9.284	20.000			
Q4126	Memoderm/derma/tranz/integup	1 SQ CM	78.343	20.000			
Q4127	Talymed	1 SQ CM	68.487	20.000			
Q4128	Flexhd/allopatchhd/sq cm	1 SQ CM	30.732	20.000			
Q4132	Grafix core, grafixpl core	1 SQ CM	158.237	20.000			
Q4133	Grafix stravix prime pl sqcm	1 SQ CM	136.324	20.000			
Q4137	Amnioexcel biodexcel 1sq cm	1 SQ CM	113.678	20.000			
Q4141	Alloskin ac, 1 cm	1 SQ CM	39.449	20.000			
Q4143	Repriza, 1cm	1 SQ CM	29.680	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	77.655	20.000			
Q4151	Amnioband, guardian 1 sq cm	1 SQ CM	132.875	20.000			
Q4152	Dermapure 1 square cm	1 SQ CM	50.416	20.000			
Q4153	Dermavest, plurivest sq cm	1 SQ CM	116.257	20.000			
Q4154	Biovance 1 square cm	1 SQ CM	148.462	20.000			
Q4159	Affinity1 square cm	1 SQ CM	359.662	20.000			
Q4160	Nushield 1 square cm	1 SQ CM	97.987	20.000			
Q4161	Bio-connekt per square cm	1 SQ CM	138.294	20.000			
Q4163	Woundex, bioskin, per sq cm	1 SQ CM	168.638	20.000			
Q4164	Helicoll, per square cm	1 SQ CM	1335.383	20.000			
Q4166	Cytal, per square centimeter	1 SQ CM	18.554	20.000			
Q4169	Artacent wound, per sq cm	1 SQ CM	176.057	20.000			
Q4170	Cygnus, per sq cm	1 SQ CM	46.156	20.000			

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Q4124	Oasis tri-layer wound matrix	1 SQ CM	9.284	20.000		
Q4126	Memoderm/derma/tranz/integup	1 SQ CM	78.343	20.000		

Provider Screening Tool

Patient Name:

Date of Birth:

Date:

Facility:

Wound type:

1. ☐ At least 1cm² in dimension
2. ☐"Failed to adequately respond" to **last 4 weeks** of conservative treatment measures?
   a. Wound is worsening / stable / improving very slowly or less then expected?
   b. Currently trying and failing pressure-reducing intervention (eg. frequent turning, foam, footwear)
   c. has received treatment of Application of dressings (last 30 days)
   d. had received Debridement of necrotic tissue was performed
3. ☐ Obtain Face Sheet and Active Medication list
4. ☐ Note the duration of ulcer – in weeks (will need it later)
5. ☐ Need Labs (last 30 days): CMP, CBC, Pre-alb. If DM, HbA1C.
6. ☐ Smoking Status (Smoker, Previous Smoker, Non-Smoker). If current smoker, counsel to stop (6 weeks prior)
7. ☐ X-Ray (if foot/ankle)
8. ☐ Arterial Duplex Doppler with ABI and Venous Doppler – (if foot/ankle)
9. ☐ ABI
10. ☐ Venous Doppler
11. ☐ Test sensation with a sharp end of an applicator snapped in two – if DFU

EXCLUSIONS to remember:

- ☐ **No h/o Biologic used for this wound in past 1 year!**
- ☐ *No Evidence of active infection or osteomyelitis?*
- ☐ *No Evidence of necrotic tissue that cannot be debrided?*
- ☐ *No Active Charcot deformity or major structural abnormality (Chronic is ok)?*
- ☐ *No known or suspected malignancy of ulceration (other malignancy is ok, except see below...)?*
- ☐ *Not actively receiving radiation therapy or chemotherapy?*
- ☐ *Not taking medications considered to be immune system modulators/suppressants?*
- ☐ *No autoimmune connective tissue disease diagnosis?*
- ☐ *If the DFU patient has no loss of sensation or atrophy (peripheral neuropathy), they could be enrolled with PAD if they have those findings*

If Ulcer located on Leg/ankle/foot:
Circulation must be Adequate with Diagnostic Testing:

- ☐ **Arterial Doppler (last 30 days)**
- ☐ Note ABI **MUST BE ≥ 0.6 and ≤ 1.4)** Result:
- ☐ Note Doppler arterial waveforms (Triphasic, Biphasic at the ankle of the affected leg)
- ☐ Pedal pulses: Result: Date:
- ☐ CFT: Result Date:
- ☐ **Venous Doppler** (last 30 days)
- ☐ **X-Ray of the foot/ankle with a negative finding of osteomyelitis**

If Diabetic Ulcer:

Note if Type 1 ☐ , or Type 2 ☐

- ☐ **MUST have diabetic neuropathy** to qualify for biologic with a Diagnosis of Diabetes
  - Identify if peripheral neuropathy present: Paresthesia ☐ , Numbness on foot ☐
  - Need one for Dx: Insensate ☐ / reduced sensation to touch ☐ / reduced sensation to filament ☐ / atrophy of intrinsic musculature ☐ / atrophy of skin & sub Q ☐ / weakness of musculature ☐ / contracture of joints ☐
  - *EXCEPTION if: diagnosis of PAD*
- ☐ Note if under Medical Management (Y or N):
- ☐ Note name of Primary Provider (PMD):
- ☐ Note HbA1C result (last 30 days)

If Venous Stasis Ulcer:

- ☐ **Venous Doppler** (Last 30 days)
- ☐ Failed 30 day Compression Tx (eg. ace wrap, unaboot)

Also

1. ☐ **Obtain consent**
2. ☐ **Pre-Application documentation** (+/- debridement form)

Office needs:

1. ☐ Pre-Application documentation +/- debridement form
2. ☐ Face sheet for IVR
3. ☐ 3-4 weeks of prior documentation if not available in the system
4. ☐ **Preferred shipping location (option 1: office, 2: FEDEX location near you)**

Provider Screening Tool

Patient Name:

Date of Birth:

Date:

Facility:

Wound type:

---

1. ☐ At least 1cm² in dimension
2. ☐ "Failed to adequately respond" to last 4 weeks of conservative treatment measures?
   a. Wound is worsening / stable / improving very slowly or less then expected?
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   d. had received Debridement of necrotic tissue was performed
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5. ☐ Need Labs (last 30 days): CMP, CBC, Pre-alb. If DM, HbA1C.
6. ☐ Smoking Status (Smoker, Previous Smoker, Non-Smoker). If current smoker, counsel to stop (6 weeks prior)
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  - Need one for Dx: Insensate ☐ / reduced sensation to touch ☐ / reduced sensation to filament ☐ / atrophy of intrinsic musculature ☐ / atrophy of skin & sub Q ☐ / weakness of musculature ☐ / contracture of joints ☐
  - *EXCEPTION if: diagnosis of PAD*
- ☐ Note if under Medical Management (Y or N):
- ☐ Note name of Primary Provider (PMD):
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INITIAL CMN – Pre-Treatment

Product Requested (XCellerate)

- ☐ 2cm x 2cm
- ☐ 4cm x 4cm
- ☐ 2cm x 4cm
- ☐ 4cm x 7cm

Date:

Pt Name:

Location / Facility:

Room:

31 – Skilled

32 – LTC / NH / Non-Skilled / Domicile

Wound Type:
pressure / non-pressure / diabetic / neuropathic / venous / arterial / ischemic / vasculitic / traumatic / s/p burn / s/p surgical

Baseline Measurements: L_____cm x W_____cm x D_____cm
AREA: _____ SQ cm [Including Undermining]

Stage / Grade:
Full Thickness

- The ulcer extends through the dermis ☐
- without tendon, muscle, capsule, or bone exposure. ☐
- with tendon, muscle, capsule, or bone exposure. ☐

- Stage or Grade: _____

Location: _____
Right / left
Toe / foot / ankle / leg
Dorsal / plantar

Duration of the ulcer: _____ weeks

WAGNER CLASSIFICATION SYSTEM
for diabetic foot ulcers (DFU's)

Grade	Description of Ulcer
0	No ulcer, but high risk foot
1	Superficial ulcer
2	Deep ulcer; No bony involvement or abscess
3	Abscess with bony involvement (X-Ray)
4	Localized gangrene (e.g. toe, heel, etc.)
5	Extensive gangrene involving whole foot

Arterial Perfusion
Pulses:

DP – L 0 1 2 3 4 R 0 1 2 3 4
PT – L 0 1 2 3 4 R 0 1 2 3 4
Non-palpable

CFT <= 3 sec is normal

- CFT: _____ seconds

Must have adequate circulation/oxygenation to support tissue growth/wound healing (ABI >= 0.60, TBI > 30mmHg)

- ABI or TBI value _____
- **Arterial Doppler** Wave Pattern: Triphasic ☐ Biphasic ☐ Monophasic ☐
- **Venous Duplex Doppler:** Results: Normal ☐ Venous reflux ☐ Incompetent Perforator ☐ Venous Thrombosis ☐

For Diabetic ulcers:

- Current medical management of diabetes (description):

_____

- Type 1 ☐ or Type 2 ☐
- Presence of neuropathic disease? Yes ☐
- Controlled ☐ or not controlled ☐

Neuropathic Changes (circle all that apply): *Must be noted for DFU*

Insensate / reduced sensation to touch / reduced sensation to filament / atrophy of intrinsic musculature / atrophy of skin & sub Q / weakness of musculature / contracture of joints

Venous Ulcers - VLU:

Compression: Class 3 High Compression Garment ☐ Unna Boot ☐ Compression Stockings ☐ Multilayered Elastic compression ☐
Mixed Venous / Arterial Disease / CHF Disease needing modifications / Loosened Compression ☐

INITIAL CMN – Pre-Treatment

Product Requested (XCellerate)

☐ 2cm x 2cm ☐ 4cm x 4cm

☐ 2cm x 4cm ☐ 4cm x 7cm

Date:

Pt Name:

Location / Facility:

Room:

31 – Skilled

32 – LTC / NH / Non-Skilled / Domicile

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AREA: _____ SQ cm [Including Undermining]

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Location: _____
Right / left
Toe / foot / ankle / leg
Dorsal / plantar

Duration of the ulcer: _____ weeks

Arterial Perfusion
Pulses: **DP – L 0 1 2 3 4 R 0 1 2 3 4**
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For Diabetic ulcers:

- Current medical management of diabetes (description):

_____

- Type 1 ☐ or Type 2 ☐
- Presence of neuropathic disease? Yes ☐
- Controlled ☐ or not controlled ☐

CEAP Classification: Ulcer # 1 2 3 Ulcer Duration: 0-None; 1-Mild- <3 mo; 2-Moderate-3-12 mo; 3-Severe->12 mo
Active ulcer size: 0-None; 1-Mild- <2cm; 2-Mod- 2-6cm; 3-severe- >6cm

Venous Duplex Scan: Results: Normal ☐ Venous reflux ☐ Incompetent Perforator ☐ Venous Thrombosis ☐

Chronic Wound: This wound has met the conditions (see below) of a Chronic Wound? Yes ☐

- Wounds not responding to standard/conservative wound care treatment for >= **30 days** by means of closure; Has r
  open despite appropriate standard/conservative advanced care; ☐

& / OR • Has remained the same size or depth or has increased in size or depth; ☐

AND • Has no indication that improvement is likely ☐

A Failed Response is defined as an ulcer or skin deficit that has failed to respond to appropriate wound-care measures, has not closed, has increased in size or depth, or has not changed in baseline size or depth with no indication that improvement is likely (such as increasing granulation, increasing epithelialization, or progress towards closing).

Was there a pervious failed response to amniotic skin substitute(s)? Yes ☐ No ☐. If yes, date(s): _____

Has the wound previously been healed using Amniotic skin substitute(s)? Yes ☐ No ☐. If yes, date(s): _____
[Greater than 1 year] Yes ☐ No ☐. If yes, date(s): _____

Description of all failed previous treatments & why failed >=4 weeks:

Debridement ☐ Advanced Wound Dressings ☐

_____

_____

Pertinent Medical Conditions: DM ☐ CHF ☐ HTN ☐ CAD ☐ PAD ☐ Dementia ☐ Contracture ☐ See Attachment ☐

_____

_____

Are condition(s) listed above controlled? Yes ☐

If **SMOKER**: Smoking cessation counseling was performed? Yes ☐

If currently smoking, to the best of my knowledge patient ceased smoking 4 weeks prior to treatment. Yes ☐

Current Medication(s): See Attached Medication Sheet ☐

_____

_____

Location of Grafting [circle]: Domiciliary LTC NF Bed / Skilled SNF Part A Bed / Home / Board & Care / Hospice / Acute Hospital / Wound Center – Acute Care / Office

Name of Skin Substitute / Amniotic Membrane: _____ is being used as part of a comprehensive and organized WOUND MANAGEMENT PROGRAM.

Rational for amniotic membrane:

This is a human amniotic membrane, stemmed collagen drive from the placenta during which the human fetus grows and develops in the mother's uterus. The human amniotic membrane consists of multiple layers, some of them were manipulated, dehydrated, nonviable cellular amniotic membrane allograft, there is multiple extracellular matrix proteins. Growth factor cytokines and other specialty proteins present in the amniotic tissue to provide a barrier of membrane and enhance the healing.

The closure of the wound is necessary to avoid sepsis, hospitalization and amputation/death. The failure of the progression towards closure necessitates the use of amniotic membrane. All the other reasons for the failure of active aggressive conservative care have been ruled out. The patient has adequate arterial and venous perfusion. Diet and caloric intake is sufficient. There is no sign of dehydration. There is no sign of active, acute infection. The wound base is simply not responding to an environment conducive to wound closure. As such, as noted above, I find that the amniotic membrane serial application is necessary to further wound closure. There may not be significant signs of healing within the first 4 applications, but this is not an indication of failure of this treatment.

Description of the treatment plan: Rational for this membrane
Application of amniotic membrane: Weekly ×10 applications, if less than anticipated 50% take is identified, but as long as there is positive signs of healing after 4 weeks.

Physical Exam Findings pertinent to Skin Subs Grafting:

The use of amniotic membrane on Partial-orfull-thickness ulcers, not involving tendon, muscle, joint, capsule or exhibiting exposed boneor sinus tracts, with a clean granularbase, unless theCTP package label indicates the CTP is approved for use involving tendon, muscle, joint, capsule or exhibiting exposed boneor sinustracts,with a clean granular base.

The manufacturer allows for the use of the amniotic membrane on exposed bone, tendon, muscle, joint, capsule, sinus tract: Yes ☐

Wound Description:

- **Significant** Progress towards closing Yes No ☐
- **Insignificant** Progress towards closing Yes ☐ No ☐
- Involvement tendon, muscle, joint capsule, exposed bone, exposed sinus tracts Yes ☐ No ☐
- Epithelial tissue without improvement _____ % Yes ☐ No ☐
- Granulation without improvement _____ % Yes ☐ No ☐
- Skin deficit of wound/ulcer >= 1.0 cm^2 Yes ☐
- Must be clean and free of necrotic debris or exudate [after debridement] Yes ☐
- Must have a clean, granular base [after debridement] Yes ☐
- Free of surrounding callus tissue and devitalized tissue [after debridement] Yes ☐
- Must be free of infection and underlying osteomyelitis Yes ☐
- Advanced wound dressings creating moist environment (for last 30 days) Yes ☐

The wound is with EITHER (select one):

Full thickness tissue loss ☐

Partial Thickness Tissue Loss ***without*** retention of epithelial appendages ☐

Note: Partial thickness loss with the retention of epithelial appendages is NOT a candidate for grafting or replacement, as epithelium will repopulate the deficit from the appendages, negating the benefit of grafting.

Describe the treatment of the underlying disease process contributing to the ulcer:

Off-loading ☐ Turning/repositioning ☐ Air Loss Surface ☐ Encourage food intake ☐ Protein Supplement ☐ Debridement ☐ Moist Healing ☐ Hydration ☐

_____

_____

Adequate control of exacerbating factor, including but not limited to those listed below? Yes ☐

- uncontrolled blood pressure
- uncontrolled diabetes,
- uncontrolled nutrition / hydration factors
- active infection,
- active Charcot
- arthropathy of the ulcer extremity,
- vasculitis,
- smoking w/o physician attempt to affect smoking cessation

Anticipated Outcomes (circle all that apply): complete closure / partial closure / potential reopening / amputation avoidance / increased function & activities / Need to close to reduce chance of serious infection, sepsis, hospitalization, amputation or death

NON-Coverage

- *NOT covered if previous course of skin sub applications was unsuccessful.*
- *Retreatment of healed ulcers are NOT covered. (> 75% size reduction and < 0.5 cm^2)*
- *Simultaneous use of more than one product is NOT covered, nor is Combination Therapy with any skin substitute product.*

- *Contraindicated if known hypersensitivity to component of the skin substitute (i.e. allergy to any of the contents). SEE IFU*
- *Billing CPT codes for surgical wound preparation is ONLY COVERED at the initial application of skin substitute graft.*
- *Non-graft wound dressings or injected skin substitute codes are NOT covered.*
- *When billing for Skin Subs, active wound care management (i.e. CPT code 97602) procedures are NOT covered.*
- *Removal of current graft and/or simple cleansing of wound are NOT Billable along with skin replacement treatment*
- *When billing for Skin Subs, active wound care management (i.e. CPT code 97602) procedures are NOT covered. Removal of current graft and/or simple cleansing of wound are NOT COVERED along with skin replacement treatment.*
- *Max 10 applications PER WOUND – even if more than one product is used.*
- *Max 12 weeks total treatment period PER WOUND*
- *Min 12 months since last treatment period PER WOUND*

nformed Consent: Document if the patient is competent, and/or has the support services necessary to participate in follow-on care (check those that apply).

- Patient is competent & has been given informed consent, with risks and complications explained completely, by the provider who will be performing the procedure. ☐
- Patient is incompetent. The patient's _____ has been given informed consent, with risks and complications explained completely, by the provider who will be performing the procedure. ☐
- Decision-maker can not be contacted or does not respond. The facility consent for treatment is in effect and will allow for the use of the biologics. The primary doctor and the wound consultant agree on its use and are aware of the risks and complications. If when the decision maker responds, they will be made aware of the application, risks and complications. ☐
- The orders for the post application treatment will be communicated to the treatment nurse and documented in the patient's chart. ☐
- The nurses have been adequately trained in the post application care of the wound. ☐

Must include 3-4 week of prior notes

Date:

Pt Name:

Facility:

Room:

31 – Skilled

32 – LTC / Non-skilled / Domicile

Product Requested (XCellerate)

☐ 2cm x 2cm ☐ 4cm x 4cm

☐ 2cm x 4cm ☐ 4cm x 7cm

Treatment #1

Has the patient changed location / room since the Pre-Treatment Visit / IVR? Yes ☐ No ☐

The patient is in a LTC / Domiciliary bed? Yes ☐ No ☐

The patient has not been hospitalized in the intervening time from the pre-Treatment visit Yes ☐

Has the patient failed to show sufficient improvement in the wound, with Advanced wound care, >= 30 days? Yes ☐

Ulcer Dimension: L_____cm x W_____cm x D_____cm

[Include Undermining]

AREA: _____ SQ cm

Stage / Grade:

Full Thickness

- The ulcer extends through the dermis ☐
- without tendon, muscle, capsule, or bone exposure. ☐
- with tendon, muscle, capsule, or bone exposure. ☐

- Stage or Grade: _____

Location (circle): _____

Right / left

Toe / foot / ankle / leg

Dorsal / plantar

Duration of the ulcer: _____ weeks

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for diabetic foot ulcers (DFU's)

Grade	Description of Ulcer
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At the time of this examination, prior to the debridement in preparation for amniotic membrane (check all present):

a. Infection ☐
b. Erythema ☐
c. Cellulitis ☐
d. Lymphangitis ☐

---

e. Necrosis ☐
f. Sinus tract, undermining ☐
g. Presence of biofilm ☐
h. Slough ☐
i. Granular, fibrotic tissue ☐
j. Drainage / Exudate ☐
k. Color change on peri-wound ☐
l. Exposed tendon / muscle / capsule / bone / joint [CIRCLE] ☐

If k. checked above, does skin substitute manufacturer allow for the application of their product on exposed tendon, muscle, capsule, bone, joint. Yes ☐

Describe any changes in the wound since Baseline Visit dated _____.

a. Reduction of dimension Yes ☐ Insignificant ☐ No ☐
b. Reduction of depth Yes ☐ Insignificant ☐ No ☐
c. Increased granulation Yes ☐ Insignificant ☐ No ☐
d. Increased epithelium growth Yes ☐ Insignificant ☐ No ☐

There has been no change to the following **Factors of Non-Healing**, from the Pre-Treatment visit:

a. Arterial perfusion to the lower extremity – Controlled ☐
b. Venous perfusion to the lower extremity – Controlled ☐
c. Diabetes coverage – Controlled ☐
d. Nutritional status – Controlled ☐
e. Hydration status – Controlled ☐
f. Pressure issues – Control ☐
g. Other metabolic issues – Controlled ☐
h. Infection & Colonization – Controlled ☐

Rational for graft has been discussed in the Pre-Treatment note? Yes ☐
Underlying disease processes contributing to failure of closure discussed in baseline visit? Yes ☐

Medical Necessity:

Advanced wound care treatment has failed to result in the closure of this wound? Yes ☐
All conservative therapies previously used in the failed response of the current wound:
Debridement ☐ *Alginate* ☐ *Hydrogel* ☐ *Collagen* ☐ *Foam* ☐ *Silvadene* ☐ *Santyl* ☐ *Medihoney* ☐

Provider treating the patient's systemic disease: _____

Review of pertinent medical problems: How treated / monitored. Reviewed at baseline visit? Yes ☐ No ☐

_____

Change of patient medication since the Pre-Treatment visit: _____ Yes ☐ No ☐

_____

If diabetic ulcer, have identified presence of neuropathy? Yes ☐

If venous insufficiency ulcer, have identified definitive presence of venous insufficiency? Yes ☐

The patient's arterial supply is sufficient. ABI >= 0.6 and/or TBI > 30mmHg? Yes ☐

Hx of smoking? Yes ☐ No ☐
Is patient presently a smoker? Yes ☐ No ☐
If currently smoking, have smoking cessation counseling and cessation measures prescribed? Yes ☐ No ☐
Has smoking ceased during last 4 weeks? Yes ☐ No ☐

Informed consent has been given, including risk and complications? Yes ☐ No ☐

Facility General Consent for Treatment to be used; & obtained Yes ☐ No ☐

Treatment alternatives have been discussed with the patient and/or decision maker? Yes ☐ No ☐

Patient is competent, and/or has support services necessary to participate in follow-on care? Yes ☐ No ☐

Anticipated patient outcomes from the serial applications using the Amniotic Skin Sub membrane (circle all that apply):

Graft take >= 50% / Return to an appropriate rate of healing / Eventual Closure of wound / Increase in activity

Reduced possibility of infection, sepsis, hospitalization, amputation of extremity, death

Application # 1

This is the initial application of the Human Amniotic Skin Substitute

Date: _____

Time: _____

Location of wound _____

Product name: _____

Ulcer Dimension: Length____cm x Width_____cm x Depth____cm on application **[include undermining]**

Ulcer Dimension in sq cm: _____

Stage or Grade: _____

Graft Size: _____

Graft Area in sq cm: _____

Amount of graft used (%) _____

Amount of graft discarded (%) _____

Reason for wastage: _____

How product supplied ☐ Dehydrated / ☐ Packaged

Place all stickers used below, or write by hand:

Manufacturer Serial Number _____ Lot/ Batch _____ Expiration Date _____	Manufacturer Serial Number _____ Lot/ Batch _____ Expiration Date _____
Manufacturer Serial Number _____ Lot/ Batch _____ Expiration Date _____	Manufacturer Serial Number _____ Lot/ Batch _____ Expiration Date _____

Note: Where multiple sizes of a specific product are available, use the size that best fits the wound with the least amount of wastage.

Op Note:

Wound was examined and found to be free of infection, purulent exudate or drainage. The wound and surrounding skin was prepped with Betadine. The procedure was performed under sterile conditions, with sterile field. The surgical debridement and preparation for the graft involved several instruments, scissors, scalpel, and curettes. The edges of the wound were debrided of devitalized tissue and small areas of undermining. A sterile curet was utilized for this portion of the debridement. The base of the wound was similarly debrided using a combination of curettes, scissor, and scalpel. Slough, devitalized tissue, and areas of necrosis were debrided. Bleeding was noted, there were no perforating veins or artery. Bleeding was mild oozing. Hemostasis was accomplished with pressure.

Based on the dimensions of the wound, the appropriate amniotic membrane graft was applied. This is speaking of the dehydrated human amnion/chorion membrane allograft. We are using the amniotic membrane allograft in the treatment of chronic wound to reduce scarring, modulate inflammation, provide a barrier, initiate stem cell recruitment, and initiate signaling of the progenitor cells to reverse the stalling of formation of healing tissue. The graft was oriented correctly.

The graft fit well and the edges of the graft were manipulated to fit the wound precisely; including the walls of the edges of the wound, and any undermining. There was no need to trim the graft, and there was no wastage. 2 ampules of adhesive liquid were applied to the periwound, with care to avoid any application to the graft itself. Steri-Strips were then applied to anchor the graft to the surrounding periwound. Xeroform and a nonstick gauze was then applied and Steri-Strips were also used in a crisscross application to hold that portion of the dressing. Gauze and loosened gauze were placed over the interior dressing, with fluff, Kling, and Coban as the exterior dressing. The nursing staff will remove the exterior dressing and reapply the exterior dressing on an every other day basis or as needed for drainage.

Throughout the procedure the patient maintained adequate perfusion. There was no pain nor did the patient react to the procedure.

The patient was off-loaded. Postoperative orders were written and verbally explained to the nursing staff in detail. Orders included the previously explained dressing changes, avoidance of weightbearing with offloading. Dressings can be removed will be the clean, and fluff. The interior dressing is not to be removed. The area is to be kept dry, the patient receiving sponge baths rather than showers. If the patient should develop any fever, chills, bleeding, severe pain I am to be contacted immediately 24/7

Tylenol for pain. I will return in 1 week for dressing change, debridement if necessary, and reapplication of the graft if appropriate. The application of the amniotic membrane graft in 1 week will be considered graft #2.

Depth of the debridement: Muscle / Tendon / Bone / Fascia

Exposed Structures: Fascia / Fat / Muscle / Tendon / Capsule / Bone / Joint / Ligament

Blood loss: Negligible / ____cc

Hemostasis: Pressure / SilverCel / Hemopatch / Silver nitrate

Anesthesia: None / Native Peripheral Neuropathy / Topical Lidocaine / Prilocaine / Injectable 2% Lidocaine

Premedication: None / Tylenol / Oral Pain Medication: _____

Pain: Pre-operative _____/ 10 Intra-operative _____/ 10 Post-operative _____ / 10

Signature: _____ **Date:** _____

Informed Consent for Placental Derived Allograft

Patient Name: _____ Date: _____

Area(s) to be treated: _____

The purpose of this consent is to inform you about Placental Derived Allograft referred to as a structural extracellular matrix derived from placental connective tissue and the potential side effects or risks. It is important that you read this information carefully and completely. If any part of this content is not clear, please ask for clarification before signing this document.

A Placental Derived Allograft is a minimally manipulated acellular, highly hydrophilic, structural extracellular matrix derived from placental connective tissue intended for homologous use to supplement tissue. The allograft is sterilized and pre- packaged in a syringe ready for use in one patient on a single occasion. It is a natural product that contains growth factors including cytokines, peptides, hyaluronic acid and other powerful anti-inflammatory and healing properties. placental derived allograft allograft is intended for use during soft tissue and local inflammation of any joint or spinal condition.

All policies and procedures for donor screening, serologic and microbiologic testing meet current regulations established by the FDA and other State and local governing bodies. Communicable disease testing has been performed by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on specimens in accordance with Clinical Laboratory Improvement Amendments (CLIA) and 42 CFR Part 493. placental derived allograft allograft is registered with the FDA.

Benefits: No downtime, very little discomfort, minimal preparation and restrictions, suitable for most soft tissue injuries and joints. You may receive relief of pain and swelling immediately following the implantation. Achieving optimal change and improvements may require more than one procedure. The number of procedures and the frequency of the procedures will depend on the medical judgement of your physician.

Risks: There have been no reported adverse reactions associated with placental derived allograft allograft, however general risks and complications of implantations may include, but are not limited to infection, bleeding, injury to nerves, etc. Any adverse reactions that may be related to the use of placental derived allograft allograft should be reported immediately to your physician.

Complications: No complications have been reported with placental derived allograft allograft implantations.

California Wound Healing Medical Group (323)264-7796 **Wound Assessment©** Page 1 Of ____

Patient: _____ ☐ New Patient PMD: _____ Date: _____

Facility: Room/Bed: D.O.B.: ☐ Established Patient Length of visit: minutes Provider:

Wound Type:
☐ Pressure ☐ Neuropathic
☐ Diabetic ☐ Trauma/Surgical
☐ Venous ☐ Mixed
☐ Arterial ☐ Other:

Factors Effecting Healing: ☐ Obesity ☐ Failure to Thrive ☐ Limited Mobility ☐ Hypoalbuminemia
☐ Diabetes ☐ CVA ☐ Respiratory Failure ☐ Hospice Status ☐ Weakness
☐ Neuropathy ☐ HTN ☐ PAD ☐ Medications _____
☐ Contracture ☐ CKD ☐ Patient non-compliant behavior _____
☐ CHF ☐ Other:

Discussion/Relevant Interim History: The wound measure will increase in depth until the true wound bed is revealed Last Exam Date:

☐ No report of Nausea, Vomiting, Fever, or Chills ☐ Medication List reviewed in patient chart, no action needed Is this wound healable: ☐ Yes ☐ No

Labs & Studies

Protein: Albumin: Pre-albumin:
HgbA1C: Sed Rate: CRP:
Last Blood Draw: _____ Last RD Evaluation: _____
Has there been a significant change in labs since last visit:
☐ Yes ☐ No
Other studies: (include results and comments)

Healing Factors

Controllable?	Y	N		Y	N
Pressure Reduction	☐	☐	Infection Control	☐	☐
Hydration Status	☐	☐	Vascular Disease	☐	☐
Nutritional Status	☐		followed with RD		
Metabolic Status	☐		followed with PMD		

Rationale:

Infection Control ☐ Wound Prophylaxis
Are there signs of possible infection ☐ Yes ☐ No
Studies: ☐ Culture & Sensitivity ☐ PCR
Intervention: ☐ Topical _____
Systemic antibiotics: ☐ PO ☐ IV

Peripheral Edema: ☐ Localized ☐ Generalized ☐ None
☐ Left ☐ Right ☐ Bilateral and Symmetrical
☐ Pitting ☐ Non-pitting ☐ Mild ☐ Moderate ☐ Severe
Stasis Changes?

Pulses: DP – L 0 1 2 3 4 R 0 1 2 3 4
PT – L 0 1 2 3 4 R 0 1 2 3 4

Adequate Extremity Arterial Perfusion? ☐ **YES** ☐ **NO**
Evidence: ☐ Diminished Pedal Pulses
Capillary Refill Time: Right sec Left sec
Color: ☐ pink/normal ☐ erythematous ☐ pallor ☐ cyanotic
Distal Temp: ☐ warm ☐ cool ☐ cold ☐ ice-cold ☐ B/L and sym
Vascular Testing Performed: ☐ ABI ☐ Arterial Doppler
☐ TcPO2 (digital/ft perfusion) ☐ Toe-Brachial Index ☐ Angiogram
☐ Venous Doppler ☐ Venous Duplex ☐ Venography
Is vascular intervention planned? ☐ **YES** ☐ **NO**
Vascular specialist's opinion: ☐ patient healable
☐ candidate for surgical intervention and healable
☐ not a candidate for surgery, but healable
☐ not a candidate for revascularization surgery/not healable
Comments See note of _____

Nutritional Status

Current factors of concern:
☐ Decreasing BMI ☐ Increasing Risk of Pressure Injury
☐ Delay in Healing ☐ Increasing Loss of Weight
Interventions currently employed:
☐ Protein Supplement ☐ Protein Additive 3 6 8 gm/day
☐ MVI/Mineral supplement Add'l Vitamins: A C D3
Add'l Mineral: Cu** Fe** Zn**

Wound #: **Location:**
Pre- / Post- L / W / D /
Assessed Stage of Wound: 1 2 3 4
US DTI Non-Pressure
Wound Type (this wound):
Debridement: ☐ Selective ☐ Surgical ☐ Serial/Surgical

Prognosis
Healable: Goals
☐ Eventual Closure ☐ Convert to Self-care or Home Health (if patient's general health, medical issues, continuing adequate mental status, and home environment allow this change)
Non-healable: Goal – Palliation
Minimize the risk of the following:
☐ Additional Loss of Activity ☐ Psycho-social issues for the patient and their family
☐ Negative Progression of Wound ☐ Additional Devitalized Tissue ☐ Frequency of Hospitalization
☐ Hospital Length of Stay ☐ Infection ☐ Amputation ☐ Sepsis ☐ Death

Tissue Involvement/Uncovered: **Undermining:** Superior 9 3 Inferior
☐ Superficial ☐ Fascia ☐ Fat ☐ Muscle/Tendon
☐ Periosteum ☐ Bone ☐ Other: _____
Drainage:
☐ None ☐ Scant ☐ Light ☐ Moderate ☐ Heavy ☐ Copious
Type: ☐ Serous ☐ Serosanguinous ☐ Seropurulent ☐ Purulent
Odor: ☐ None ☐ Increasing ☐ Decreasing
☐ Malodor ☐ Sweet ☐ Fecal ☐ Other _____
Wound Bed:
Pink % Yellow/White % Eschar % Slough %
Necrotic % Other: _____ % Bonwy prominence ☐ Yes ☐ No
Sinus /Tunneling ☐ Yes ☐ No
Wound Margins & Periwound: (circle)
Intact Smooth Regular Macerated Hypergranular Epiboly Erythema Atrophic
Slough Thickened Irregular Friable Keratotic Indurated Ecchymosis Necrotic
Treatment: Topical & Dressing

Debridement Report: **Probe to Bone** ☐ **Yes** ☐ **No**
Debridement Level: **I** **II** **III** **IV** **$AgNO_3$ Cautery**
Instrument: 10/15 Blade Curette Scissors Nippers Forceps/Tweezers
Tissue Removed: Skin Full tickness Fat Capsule Slough/Eschar/Necrosis
Hypergranulation Fascia/Muscle/Tendon Bone
Hemostasis: EBL _____ cc ☐ None ☐ Minimal
☐ Pressure ☐ Gelfoam ☐ Thrombin
Pain: pre- /10 during Tx- /10 post- /10
Anesthesia: Pre-medicated Topical Injection None

Continue Debridement? ☐ Yes ☐ No ☐ Wound Closed
Rationale for Continued Debridement of this wound
Healable:
☐ Maintain the wound in the active/acute phase of healing
☐ Clinically, the wound is improving with continuing care, including regular surgical debridements
☐ The wound is not amenable to self-care or homecare
Non-healable:
☐ Continuing care with palliation goals (see above)
☐ Remove necrotic, non-vital and infected tissue from the wound

Hydration Consider Additional Hydration ☐ PO ☐ IV

Today's Treatment Plan
☐ Serial/Surgical Debridement performed today by the provider, with removal of biofilm, non-viable tissue, ☐ infected tissue ☐ excessive granulation
☐ Surgical debridement will continue as needed, performed by the provider, while non-selective active wound care continues by staff between visits
☐ Selective debridement will continue as needed, performed by the provider, while non-selective active wound care continues by staff between visits
☐ Pressure reduction and offloading continue: _____ ☐ Recommend Comprehensive RD Evaluation
☐ Healing factors addressed
☐ No New Orders

Continues →

Provider Signature: **Supervising Physician:** ☐ Kimberly Conley, MD ☐ James E Burrows, MD ☐ Herbert Marshall, MD

California Wound Healing Medical Group (323)264-7796 — Wound Assessment© Page 1 Of ____

Patient: _____ ☐ New Patient PMD: _____ Date: _____

Facility: Room/Bed: D.O.B.: ☐ Established Patient Length of visit: minutes Provider:

Wound Type:
☐ Pressure ☐ Neuropathic
☐ Diabetic ☐ Trauma/Surgical
☐ Venous ☐ Mixed
☐ Arterial ☐ Other:

Factors Effecting Healing: ☐ Obesity ☐ Failure to Thrive ☐ Limited Mobility ☐ Hypoalbuminemia
☐ Diabetes ☐ CVA ☐ Respiratory Failure ☐ Hospice Status ☐ Weakness
☐ Neuropathy ☐ HTN ☐ PAD ☐ Medications _____
☐ Contracture ☐ CKD ☐ Patient non-compliant behavior _____
☐ CHF ☐ Other:

Discussion/Relevant Interim History: The wound measure will increase in depth until the true wound bed is revealed Last Exam Date:

☐ No report of Nausea, Vomiting, Fever, or Chills ☐ Medication List reviewed in patient chart; no action needed **Is this wound healable: ☐ Yes ☐ No**

Labs & Studies

Protein: Albumin: Pre-albumin:
$HgbA_1C$: Sed Rate: CRP:
Last Blood Draw: _____ Last RD Evaluation: _____
Has there been a significant change in labs since last visit:
☐ Yes ☐ No
Other studies: (include results and comments)

Healing Factors

Controllable?	Y	N		Y	N
Pressure Reduction	☐	☐	Infection Control	☐	☐
Hydration Status	☐	☐	Vascular Disease	☐	☐
Nutritional Status	☐		followed with RD		
Metabolic Status	☐		followed with PMD		

Rationale:

Infection Control

☐ Wound Prophylaxis
Are there signs of possible infection ☐ Yes ☐ No
Studies: ☐ Culture & Sensitivity ☐ PCR
Intervention: ☐ Topical _____
Systemic antibiotics: ☐ PO ☐ IV

Peripheral Edema:

☐ Localized ☐ Generalized ☐ None
☐ Left ☐ Right ☐ Bilateral and Symmetrical
☐ Pitting ☐ Non-pitting ☐ Mild ☐ Moderate ☐ Severe
Stasis Changes?

Wound #: Location:

Pre-/Post- L/W/D

Assessed Stage of Wound: 1 US 2 DTI 3 4 Non-Pressure

Wound Type (this wound):

Debridement: ☐ Selective ☐ Surgical ☐ Serial/Surgical

Prognosis

Healable: Goals
☐ Eventual Closure ☐ Convert to Self-care or Home Health (if patient's general health, medical issues, continuing adequate mental status, and home environment allow this change)

Non-healable: Goal – Palliation
Minimize the risk of the following:
☐ Additional Loss of Activity ☐ Psycho-social issues for the patient and their family
☐ Negative Progression of Wound ☐ Additional Devitalized Tissue ☐ Frequency of Hospitalizaton
☐ Hospital Length of Stay ☐ Infection ☐ Amputation ☐ Sepsis ☐ Death

Tissue Involvement/Uncovered: **Undermining:** Superior 9 3 Inferior
☐ Superficial ☐ Fascia ☐ Fat ☐ Muscle/Tendon
☐ Periosteum ☐ Bone ☐ Other: _____

Drainage:
☐ None ☐ Scant ☐ Light ☐ Moderate ☐ Heavy ☐ Copious
Type: ☐ Serous ☐ Serosanguinous ☐ Seropurulent ☐ Purulent
Odor: ☐ None ☐ Increasing ☐ Decreasing
☐ Malodor ☐ Sweet ☐ Fecal ☐ Other _____

Wound Bed:
Pink % Yellow/White % Eschar % Slough %
Necrotic % Other: _____% Boney prominence ☐ Yes ☐ No
Sinus /Tunneling ☐ Yes ☐ No

Peripheral Edema: ☐ Localized ☐ Generalized ☐ None
☐ Left ☐ Right ☐ Bilateral and Symmetrical
☐ Pitting ☐ Non-pitting ☐ Mild ☐ Moderate ☐ Severe
Stasis Changes?

Pulses: DP – L 0 1 2 3 4 R 0 1 2 3 4
PT – L 0 1 2 3 4 R 0 1 2 3 4

Adequate Extremity Arterial Perfusion? ☐ **YES** ☐ **NO**

Evidence: ☐ Diminished Pedal Pulses
Capillary Refill Time: Right sec Left sec

Color: ☐pink/normal ☐erythematous ☐pallor ☐cyanotic

Distal Temp: ☐warm ☐cool ☐cold ☐ice-cold ☐B/L and sym

Vascular Testing Performed: ☐ABI ☐ Arterial Doppler
☐$TcPO_2$ (digital O_2 perfusion) ☐ Toe-Brachial Index ☐Angiogram
☐Venous Doppler ☐ Venous Duplex ☐ Venography

Is vascular intervention planned? ☐ **YES** ☐ **NO**

Vascular specialist's opinion: ☐patient healable
☐ candidate for surgical intervention and healable
☐ not a candidate for surgery, but healable
☐ not a candidate for revascularization surgery/not healable

Comments See note of _____

Nutritional Status

Current factors of concern:
☐Decreasing BMI ☐Increasing Risk of Pressure Injury
☐Delay in Healing ☐Increasing Loss of Weight

Interventions currently employed:
☐Protein Supplement ☐Protein Additive 3 6 8 gm/day
☐MVI/Mineral supplement Add't Vitamins: A C D_3
Add't Mineral: Cu^{++} Fe^{++} Zn^{++}

☐ Malodor ☐ Sweet ☐Fecal ☐ Other_____

Wound Bed:
Pink % Yellow/White % Eschar % Slough %
Necrotic % Other:_____% Boney prominence ☐ Yes ☐ No
Sinus /Tunneling ☐ Yes ☐ No

Wound Margins & Periwound: (circle)
Intact Smooth Regular Macerated Hypergranular Epiboly Erythema Atrophic
Slough Thickened Irregular Friable Keratotic Indurated Ecchymosis Necrotic

Treatment: Topical & Dressing

Debridement Report: **Probe to Bone** ☐ **Yes** ☐ **No**

Debridement Level: **I** **II** **III** **IV** **$AgNO_3$ Cautery**
Instrument: 10/15 Blade Curette Scissors Nippers Forceps/Tweezers
Tissue Removed: Skin Full tickness Fat Capsule Slough/Eschar/Necrosis
Hypergranulation Fascia/Muscle/Tendon Bone
Hemostasis: EBL _____cc ☐ None ☐ Minimal
☐ Pressure ☐ Gelfoam ☐ Thrombin
Pain: pre- /10 during Tx- /10 post- /10
Anesthesia: Pre-medicated Topical Injection None

Continue Debridement? ☐ Yes ☐ No ☐ Wound Closed
Rationale for Continued Debridement of *this* wound

Healable:
☐ Maintain the wound in the active/acute phase of healing
☐ Clinically, the wound is improving with continuing care, including regular surgical debridements.
☐ The wound is not amenable to self-care or homecare.

Non-healable:
☐ Continuing care with palliation goals (see above)
☐ Remove necrotic, non-vital and infected tissue from the wound

Hydration Consider Additional Hydration ☐PO ☐ IV

Today's Treatment Plan
☐ Serial/Surgical Debridement performed today by the provider, with removal of biofilm, non-viable tissue, ☐ infected tissue ☐ excessive granulation
☐ Surgical debridement will continue as needed, performed by the provider, while non-selective active wound care continues by staff between visits
☐ Selective debridement will continue as needed, performed by the provider, while non-selective active wound care continues by staff between visits
☐ Pressure reduction and offloading continue: _____
☐ Healing factors addressed: ☐ Recommend Comprehensive RD Evaluation
☐ No New Orders

Continues →

Provider Signature: **Supervising Physician:** ☐ Kimberly Conley, MD ☐ James E Burrows, MD ☐ Herbert Marshak, MD

HOW MUCH GRAFT DO WE ORDER?

- Cover the base of the wound
  - Length X Width

- The shape of the wound
  - Flat
  - Bowel
  - Cylinder

- If deep, make sure the edges are covered
  - Several extra 2x2 to cover the edges if needed

- Return the unopened grafts with the boxes and contents

EXAMPLE OF OPEN ELLIPTICAL CYLINDER TYPE WOUND

- Typical measurement: L x W x D
  - 5cm x 4cm x 2cm
  - Area = 20 Sq cm
  - That accounts for 20 units of graft to cover the base
  - Does not leave enough to cover the lateral walls

U.S. Department of Health and Human Services

Office of Inspector General

Some Skin Substitute Manufacturers Did Not Comply with New ASP Reporting Requirements

Reporting Requirements

Key Results

- CMS calculated ASP-based payment amounts for 38 of the 68 skin substitutes included in our review.
- CMS was unable to calculate ASP-based payment amounts for the remaining 30 skin substitutes because manufacturers did not report the required ASP data.
- These 30 skin substitutes represent a disproportionate share of Part B spending.
- Transitioning skin substitutes to ASP-based payments has the potential to substantially reduce Part B expenditures.
- CMS faces hurdles in setting ASP-based payments for skin substitutes.

Why OIG Did This Review

Ensuring the appropriate reporting of average sales prices (ASPs) is vital because the Centers for Medicare & Medicaid Services (CMS) uses them to directly calculate payments under Medicare Part B. Federal law requires manufacturers to provide CMS with the ASP for each of their Part B drugs and biologicals on a quarterly basis.[1, 2] Prior to 2022, ASP reporting requirements did not generally apply to manufacturers of certain Part B drugs and biologicals, including skin substitutes, although some manufacturers voluntarily reported these data. Congress addressed the reporting gap through the Consolidation Appropriations Act, 2021 (CAA), which required manufacturers of skin substitutes (and the other Part B-covered products referenced above) to begin reporting ASPs to CMS for the first quarter of 2022.[3]

What OIG Found

Despite the new legislative requirements, CMS was unable to calculate ASP-based payment amounts in the first quarter of 2023 for 30 of 68 skin substitute billing codes because their manufacturers did not report the required ASP data. According to our analysis, Part B payment amounts would be reduced substantially if ASPs were consistently reported and used, potentially leading to tens of millions of dollars in savings each quarter. However, CMS faces several unique hurdles in implementing ASP-based reimbursement for skin substitutes. For example, because skin substitutes are not actually prescription drugs, CMS cannot employ its usual methods and data sources to corroborate manufacturer-reported data on pricing and packaging. CMS is actively considering changes to the payment methodology for skin substitutes and, in January 2023, conducted a skin substitutes Town Hall to address stakeholder concerns and discuss potential payment approaches.[4]

Despite the new legislative requirements, manufacturers are not consistently reporting the ASPs needed to set payment amounts for skin substitutes

In the third quarter of 2022 (i.e., the initial quarter in which payment amounts would have been affected by CAA reporting requirements), Medicare Part B and its enrollees paid almost $400 million for 68 unique skin substitute billing codes.[5] CMS used ASPs to set payment for only 16 of the 68. Prior to the new legislative requirements, manufacturers already had been voluntarily reporting ASPs for each of these 16 products and CMS had subsequently calculated the appropriate payment amounts using those ASP data. In other words, no additional skin substitutes (i.e., those beyond the 16 products for which manufacturers had previously reported on a voluntary basis) were paid for on the basis of ASPs in the quarter in which the new requirements took effect. CMS informed OIG that it did not add additional skin substitutes to the payment file (even in the case of several codes for which manufacturers reported ASPs) as CMS was closely evaluating the impact of doing so and determining the appropriate next steps relative to the CAA requirements.

As of the first quarter of 2023, approximately half of skin substitutes (38 of 68 billing codes) are being paid for on the basis of manufacturer-reported ASPs

The number of skin substitutes for which CMS published an ASP-based payment amount increased dramatically in the first quarter of 2023. In total, 24 manufacturers (6 more than in the initial quarter) reported the required pricing data for 38 of the 68 codes included in our review, and CMS subsequently published an ASP-based payment amount for each of them.

Manufacturers did not report ASPs for the remaining 30 skin substitute billing codes

CMS was unable to calculate ASP-based payment amounts in the first quarter of 2023 for the remaining 30 skin substitute billing codes because their manufacturers (26 in

Figure 1. Skin substitutes for which manufacturers did not report ASPs represented a disproportionate share of payments.

Source: OIG analysis of Third-Quarter 2022 Part B Expenditures and First-Quarter 2023 ASP Payment Amount Files.

Transitioning all skin substitutes to ASP-based payments has the potential to substantially reduce Medicare expenditures

Transitioning all skin substitutes to ASP-based payments has the potential to substantially reduce Medicare expenditures

If CMS does not publish an ASP-based payment amount for a skin substitute billing code in a given quarter, the agency instructs its contractors to determine payment using either Wholesale Acquisition Costs (WACs) or actual invoices.[6] Because WACs represent manufacturers' list prices and do not include any discounts, they are generally higher than ASPs. Similarly, to the extent invoices do not reflect post-purchase rebates that may be offered for skin substitutes, the resulting Medicare payments are likely to exceed ASPs as well if providers do not account for these discounts when submitting their claims.

In 2021, prior to the new requirements, Medicare payment amounts for four skin substitutes decreased dramatically when ASPs were voluntarily reported and used to set payment

To gain a sense of how WAC- or invoice-based payment amounts compared to ASP-based payments, OIG identified four skin substitutes for which Part B payments were determined using WAC/invoice prices in the first quarter of 2021 and then set using ASPs in a subsequent quarter later that year. (These are skin substitutes for which

ASP-based payment amounts for skin substitutes were one-third below their WACs

For the 38 skin substitutes with payments set using ASPs in the third quarter of 2022, their ASP-based payment amounts (i.e., ASP plus 6 percent) were 33 percent below published WACs (i.e., one of the potential benchmarks contractors may use to set payment in the absence of ASPs) at the median. If we use this median difference to estimate potential savings, we find that Medicare Part B and its enrollees could save $84 million per quarter if all such products are paid for on the basis of ASPs. Twenty percent of that total (almost $17 million) would stem from reductions in the amounts owed through enrollee coinsurance. Actual savings may be higher or lower than this estimate, given the specific differences between ASP and WAC or actual invoices for each product.

The inconsistent reporting and use of ASPs for skin substitutes has implications in addition to higher payments

Current reimbursement practices could create incentives for providers to prefer skin substitutes that are paid for on the basis of WACs/invoices rather than those paid for using ASPs, exacerbating the missed savings for Medicare and its enrollees. Because ASPs are calculated using actual sales data (including discounts), they presumably reflect provider acquisition costs. However, as described earlier, WACs/invoices for skin substitutes often significantly exceed their ASPs. As a result, providers can typically capture a much larger spread (i.e., the difference between what they pay for a product and the amount they are reimbursed by Medicare) when payment is set using WACs/invoices. This effectively penalizes manufacturers who comply with the law by potentially making their products less attractive to providers. The overall dynamic could therefore unintentionally discourage all manufacturers of skin substitutes from complying with ASP reporting requirements, further increasing the risks of higher payments by the program and enrollees.

CMS faces numerous hurdles in implementing ASP-based payments for skin substitutes

Skin substitutes present unique challenges for CMS to overcome when implementing the new reporting requirements, as these products differ significantly from most items covered under the Part B prescription drug benefit. For example, in its written response to OIG questions, CMS noted that:

- there is not a single database that lists all manufacturers of skin substitutes;
- many of these products are regulated as Human Cellular and Tissue-Based products for which the manufacturer is registered but the products do not receive individual FDA approval; and

First Coast
Novitas

Proposed LCD - Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (DL36377)

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Proposed LCD
Proposed LCDs are works in progress that are available on the Medicare Coverage Database site for public review.
Proposed LCDs are not necessarily a reflection of the current policies or practices of the contractor.

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

Proposed LCD Information

Document Information

Source LCD ID
L36377

Proposed LCD ID
DL36377

Proposed LCD Title
Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
Novitas Solutions, Inc.	A and B MAC	12502 - MAC B	J - L	Pennsylvania
Novitas Solutions, Inc.	A and B MAC	12901 - MAC A	J - L	Delaware District of Columbia Maryland New Jersey Pennsylvania

Article Information

General Information

Article ID
A54117

Article Title
Billing and Coding: Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds

Article Type
Billing and Coding

Original Effective Date
10/01/2015

Revision Effective Date
08/13/2020

Revision Ending Date
09/16/2023

Retirement Date
N/A

CMS National Coverage Policy

Social Security Act (Title XVIII) Standard References:

Coding Guidance:

Notice: It is not appropriate to bill Medicare for services that are not covered (as described by the entire LCD) as if they are covered. When billing for non-covered services, use the appropriate modifier.

Per the Current Procedural Terminology (CPT) definition, skin substitute grafts include non-autologous skin (dermal or epidermal, cellular and acellular) grafts (e.g., homograft, allograft), non-human skin substitute grafts (i.e., xenograft), and biological products that form a sheet scaffolding for skin growth. Skin substitute graft codes are not to be reported for application of non-graft wound dressings (e.g., gel, powder, ointment, foam, liquid) or injected skin substitutes.

Non-graft wound dressings or injected skin substitue codes are not used with skin replacement surgery application codes and are considered incorrect coding. Such products are bundled into other standard management procedures if medically necessary and not separately payable.

Claims reporting skin substitute grafts must contain the presence of an appropriate application CPT code.

If the service for the application code is denied, the service for the skin substitute will also be denied.

Effective 01/01/2017, per CR 9603, when billing for Part B drugs and biologicals (except those provided under Competitive Acquisition Program [CAP] for Part B drugs and biologicals), the use of the JW modifier to identify unused drugs or biologicals from single use vials or single use packages that are appropriately discarded is required.

The discarded amount shall be billed on a separate claim line using the JW modifier. Providers are required to document the discarded drug or biological in the patient's medical record.

Novitas expects that where multiple sizes of a specific product are available, the size that best fits the wound with the least amount of wastage will be utilized.

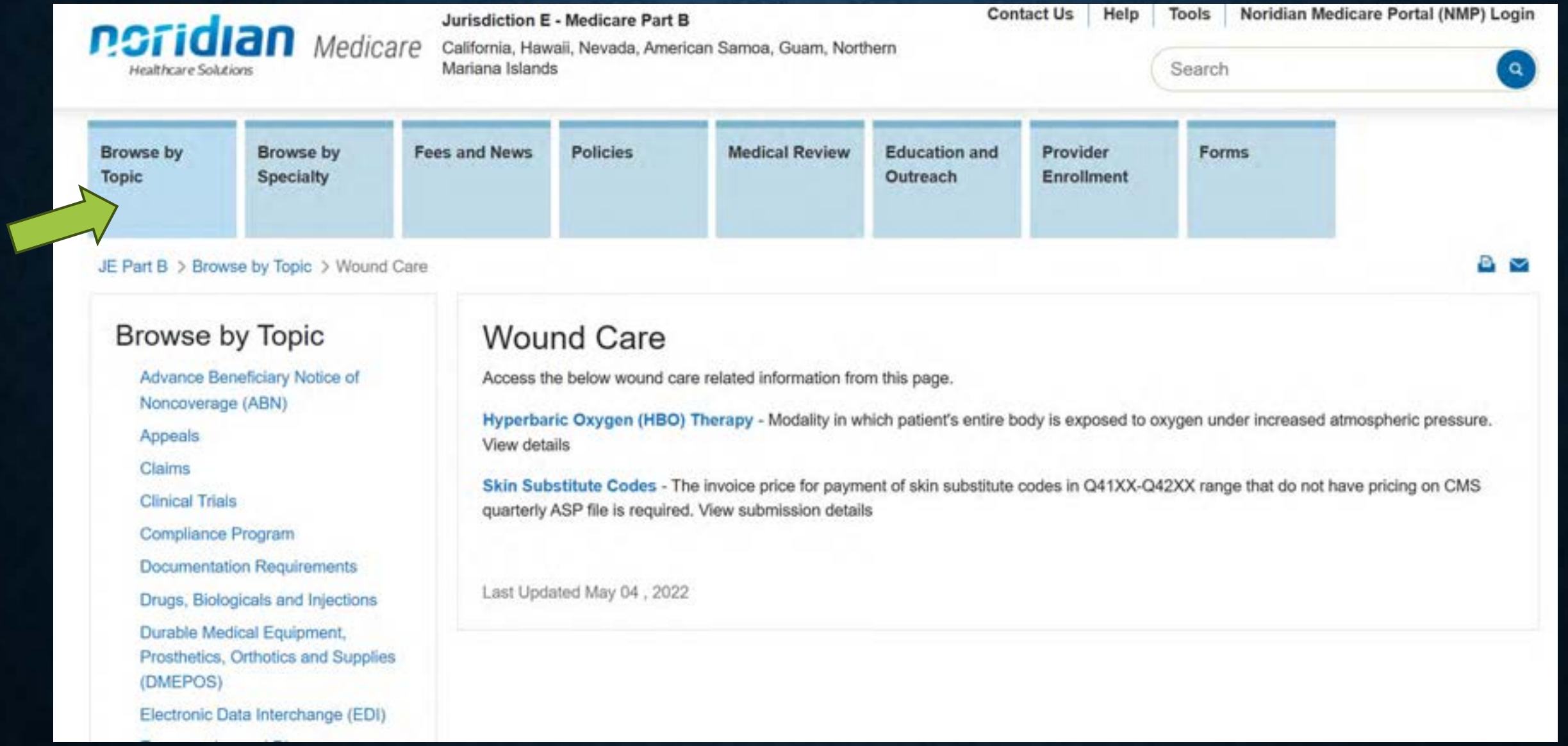
When a portion of a drug/biological is discarded, the medical record must clearly document the amount administered and the amount wasted. The documentation must include the date, time, amount of medication wasted, and the reason for the wastage.

In situations where a portion of a **single use package** must be discarded, payment will be made for the portion discarded along with the amount applied up to the amount of the product on the package label. Medical record documentation must clearly indicate the information noted above.

Note: The unused portion must actually be discarded and may not be used for another patient.

Documentation Requirements

1. All documentation must be maintained in the patient's medical record and made available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service[s]). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
3. The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed.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Browse by Topic
Advance Beneficiary Notice of Noncoverage (ABN)
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Claims
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Compliance Program
Documentation Requirements
Drugs, Biologicals and Injections
Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)
Electronic Data Interchange (EDI)
Wound Care
Access the below wound care related information from this page.
Hyperbaric Oxygen (HBO) Therapy - Modality in which patient's entire body is exposed to oxygen under increased atmospheric pressure. View details
Skin Substitute Codes - The invoice price for payment of skin substitute codes in Q41XX-Q42XX range that do not have pricing on CMS quarterly ASP file is required. View submission details
Last Updated May 04 , 2022

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- Remittance Advice (RA)
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Skin Substitute Codes

If the CMS quarterly ASP file does not contain pricing for a skin substitute code that is within the Q41XX-Q42XX range, the claim must include the total invoice price (amount physician paid, per invoice, for patient's specific item).

We may reimburse for the total invoice price plus shipping but no additional fees (tax, handling fees, delivery fees, administrative fees).

Total invoice price is the net amount a provider pays for an item/service, taking into account ALL discounts, rebates, refunds, or other adjustments. *

ASP File Contains Code

- Enter number of units in Item 24G of CMS-1500 claim form or Loop 2400/SV104 for EMC

ASP File Does Not Contain Code

- Enter procedure code and total invoice price in Item 19 of CMS-1500 claim form or Loop 2400/SV101-7 for EMC
  - 'Invoice' or 'Inv' followed by the price in a currency format using a decimal
    - Examples:
      - Invoice $130 - claim priced at $1.30
      - Invoice $130.00 - claim priced at $130.00
      - Invoice 13000 - claim priced at $130.00
      - Invoice $13000 - claim priced at $130.00
      - Invoice $1,300 - claim priced at $1,300.00

A provider may bill wastage using the JW modifier. However, it is Noridian's expectation where there are multiple sizes of a specific product available, the size that best fits the wound with the least amount of wastage will be utilized by the provider. JW modifier is for single use only packaging and remnants billed as wastage may not be utilized on other patients.

If a provider intends to bill for wastage and total invoice price, please bill invoice price of the portion administered separately from invoice price of the portion discarded along with the JW modifier.

Example: Q41XX Invoice $XXX, Q41XX-**JW** Invoice $XXX

Any use of skin substitute codes must be accompanied **on the same claim** by a CPT/application procedure code consistent with use of the product. For example, CPT 15271-15278.

Products billed with Q4100 (skin substitute, not otherwise specified) must be at a minimum accompanied by the actual name of the product, number of units used, and total invoice price. In addition, Q4100 must be accompanied **on the same claim** by a CPT procedure/application code consistent with use of the product.

If the claim does not include the required information, the item will deny as unprocessable.

Providers must maintain an invoice copy within the patient's file, and it must be made available to Noridian upon request

Note: CMS ASP pricing does not equate to coverage, as provision of any item or service must also meet all Medicare statutory requirements.

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