2018 Comprehensive Reimbursement Resource Guide

Prepared by Musculoskeletal Clinical Regulatory Advisers, LLC. Version 01/2018.

DermACELL AWM®

Disclaimer: *This information is for educational/informational purposes only and should not be construed as authoritative. The information presented here is current as of January 2018 and is based upon publicly available source information. Codes and values are subject to frequent change without notice. The entity billing Medicare and/or third party payors is solely responsible for the accuracy of the codes assigned to the services or items in the medical record. When making coding decisions, we encourage you to seek input from the AMA, relevant medical societies, CMS, your local Medicare Administrative Contractor and other health plans to which you submit claims. Items and services that are billed to payors must be medically necessary and supported by appropriate documentation. It is important to remember that while a code may exist describing certain procedures and/or technologies, it does not guarantee payment by payors.*

68-00-059.00 Reimbusement Coding Guide: DermACELL AWM Wound Care Reimbursement Coding Guide (2018)

Comprehensive Reimbursement Resource Guide

1. DermACELL AWM Product Overview

DermACELL AWM is a technologically advanced human acellular dermal matrix. Dermacell AWM is decellularized using Matracell®, a proprietary, patented, and validated processing technology that removes cells and ≥ 97% of donor DNA without compromising the desired biomechanical or biochemical properties of the graft and allowing for rapid cellular infiltration and re-vascularization.

Dermacell AWM is ready to use out of the package and stored at room temperature, eliminating the need for refrigeration and rehydrating processes. As a final step, all Dermacell AWM grafts are terminally sterilized – rendering the graft sterile to medical device-grade standards with a Sterility Assurance Level (SAL) of 10-6, or a 1 in 1 million chance of the presence of a single viable microorganism on the graft.

Dermacell AWM is indicated for Chronic Wounds* including:

- Diabetic foot ulcers (DFUs)
- Venous stasis ulcers (VSUs)
- Arterial ulcers
- Pressure ulcers
- Dehisced surgical wounds
- Traumatic burns

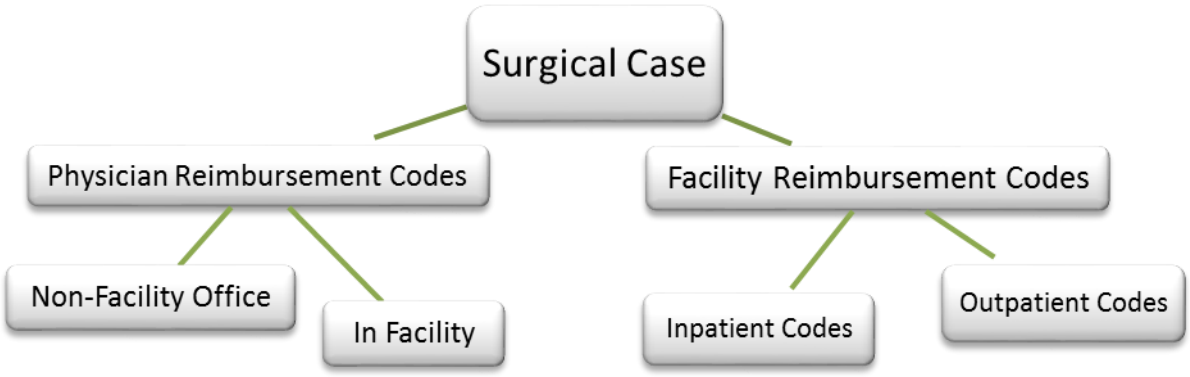
** Dermacell AWM can be used over exposed tendon, bone, joint capsule, and muscle*

Dermacell AWM is regulated by the U.S. Food and Drug Administration (FDA) as a human skin tissue under its Human Cells, Tissues and Tissue-Based Products (HCT/P) guidelines, subject to Section 361 of the Public Health Service Act and 21 CFR 1270 and 1271.

2. Coding Basics

Whenever code assignment is discussed for new or existing procedures or technologies, the different coding and reimbursement pathways and types of code sets used should be reviewed. Distinct code sets are used to report various aspects of procedures and technologies for reimbursement depending on the entity billing the case.

Reimbursement pathways and appropriate code sets take two directions resulting in two separate reimbursements for a single patient encounter when performed in a facility. Physicians report their work separately from the facility where the procedure is performed. This in turn creates unique coding pathways for each side of the equation that results in appropriate reimbursement from third party payors (such as Medicare or private payors).



When procedures indicated for the use of Dermacell AWM are performed within the physician office setting of care the physician may be reimbursed not only for the work performed during the procedure but also for the office expenses and supplies such as Dermacell AWM, that are included in the procedure. The extent of available reimbursement for an in office procedure is dependent on specific payor guidelines and should be reviewed for each case through a pre-authorization or benefits verification.

Physician Codes – Physician services and surgical procedures are reported using Common Procedural Terminology (CPT)[1] codes. These codes are created by the American Medical Association (AMA). These codes are reported across all settings of care including the physician office, outpatient and inpatient facility. Medicare and many private health plans rely primarily on CPT codes to describe procedures performed in the physician office, ambulatory surgery center (ASC) and hospital outpatient department. CPT codes are developed, maintained and annually

[1] AMA/CPT codes and descriptions are copyright of the American Medical Association. All rights reserved.

updated by the AMA. Please note that the assignment of a CPT code to a procedure does not guarantee coverage or payment by a health plan in all cases.

Permanent (Category I) CPT Codes both existing and newly created, for physician procedures and services, have met the qualifications outlined by the AMA/CPT Editorial Panel and typically have established RVU values that can be directly used to determine reimbursement. These RVU values are multiplied by a conversion factor (published yearly by CMS or established per contract by private payors) to provide payment for surgeon services within coverage guidelines. Just because a permanent CPT code exists does not mean that it will be paid. All reimbursement is subject to coverage guidelines and payor policies. Under Medicare's Resource-Based Relative Value Scale (RBRVS) methodology each CPT code is assigned a value, the relative value unit (RVU), which is then converted to a payment amount.

CPT Add-on Codes CPT coding guidelines state that some physician procedures are commonly carried out in addition to the primary procedure performed and may be designated as add-on codes. Add-on codes describe additional intra-service work associated with a primary procedure. CPT typically lists the primary procedures that an add-on code is reported with during the same session. Add-on codes are not reported as stand-alone codes and are exempt from the multiple procedure reduction in payment concept.

Facility Codes – Skin substitute Graft procedures are performed in the office, outpatient or inpatient setting of care, as determined by the physician. Each setting utilizes a different code set to report their services to the payor for reimbursement. When the place of service is other than the physician's office the physician reports his services separately from the facility with CPT codes.

Outpatient APC Codes, are based on the same CPT codes reported by physicians but these are typically mapped to or placed into a second code set called Ambulatory Payment Classification (APC) Codes. APC codes combine CPT procedure services into like groupings that utilize similar resources in the outpatient setting and are paid an established rate for the particular APC. These APC code sets can be reported and reimbursed singularly or in inclusive groupings, as determined by payor guidelines. Government payors and some private payors use this system but reimbursement guidelines can differ considerably depending on the payor and contracted agreements. Medicare reimbursement rates are determined by the Outpatient Prospective Payment System (OPPS) and are published semi-annually.[2]

HCPCS Level II Codes Outpatient reporting also requires that implantable devices and biologics used in procedures be coded separately using the Healthcare Common Procedure Coding System (HCPCS) Level II Codes. This code set allows line item reporting of products used in procedures that are not already included within the reimbursement rate for the reported APC. This system differs for government payors

[2] Centers for Medicare & Medicaid Services Medicare Learning Network. Hospital Outpatient Prospective Payment System. Available at: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/HospitalOutpaysysfctsht.pdf. (Accessed January 2018).

where a pass-through payment code must be adopted and valued by CMS, and private payors, who use the HCPCS code to determine contracted rates with more generalized codes.

ICD-10-CM Codes International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) code set was implemented on October 1, 2015. This change impacts the specificity of diagnosis coding. When reporting procedures after October 1st 2015, care should be taken to include ICD-10-CM diagnosis coding specifics for all procedures. ICD-10-CM diagnosis codes report the patient diagnoses for each patient. These codes are always patient specific and provide this important information to payors when establishing the MS-DRG for inpatient reimbursement. Note that this diagnosis system is also used by physicians to report patient diagnoses and should be consistent with any facility reported diagnosis codes.

Inpatient ICD-10-PCS Codes International Classifications of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS) code set reporting inpatient procedures performed on the patient during the hospital stay, was implemented on October 1, 2015. These hospital inpatient procedure codes are more specific in reporting the procedure performed as to approach used and anatomic level than the previous ICD-9 code set. Specific diagnoses and detailed procedure coding is important to ensure correct assignment of the MS-DRG code that determines the total inpatient reimbursement. It is important that all ICD-10-PCS procedure codes be reported to capture the use of a product or device and map to the appropriate MS-DRG reported.

MS-DRG Codes Medicare Severity, Diagnosis Related Grouping (MS-DRG) codes are used to report hospital inpatient stays for reimbursement. These codes are groupings that represent the entire patient stay at the inpatient facility, inclusive of all services, costs and devices utilized during the episode of care. There are typically no line item reimbursements for biologics or devices as in the outpatient setting of care.

CPT/HCPCS Code Modifiers In specific cases it is sometimes necessary to submit a CPT or HCPCS code with a modifier. Modifiers indicate that a reported service has been altered by a specific circumstance but that the code description has not changed. Modifiers enable healthcare professionals to report services more accurately and to provide detail and clarity to the third party payor per required guidelines and policies. The following table provides a list of some common CPT code modifiers. Complete lists are available in the AMA/CPT book and online on the Medicare website. Use of modifiers is subject to payor guidelines.

Sample CPT/HCPCS Modifiers

Modifier	Description
-JC	**Skin Substitute Used as Graft.**
-JW	**Drug Amount Discarded/Not Administered to Any Patient.** Used to report wastage when payor guidelines require separate reporting.
-22	**Increased Procedural Services.** When the work required to provide a service is significantly increased beyond the typical work required a modifier -22 may be appended. The documentation must support the increased services and the reasoning. (Examples include; increased time, technical difficulty, severity of patient condition, increased effort.)

-50	**Bilateral Procedure.** When CPT codes are not identified as bilateral in the code description or parenthetical a modifier -50 may be appended when the procedure is performed bilaterally.
-51	**Multiple Procedures.** When more than one procedure is performed at the same session a modifier -51 is appended to additional procedures. It is not appended to codes listed as "add-on" codes.
-59	**Distinct Procedural Service.** Modifier -59 is used to report separate services that are distinct or independent and not normally reported together. Documentation must support the distinct service (Example; separate area of injury in extensive injuries)

3. Coding Pathway Options by Place of Service

Physician, hospital outpatient and hospital inpatient coding is provided in this guide, along with key considerations for addressing the status of the code options provided. The 2018 Medicare national average reimbursement rates have also been included.

The coding pathways provided within this document address the use of Dermacell AWM in wound care procedures and the reporting of the skin substitute graft material. Medicare place of service guidelines and reimbursement rates are provided as benchmarks for the applicable procedures. Private insurer reimbursement rates and guidelines are carrier and plan specific and may differ significantly from the benchmark rates. Actual private payor reimbursement guidelines and rates are contracted agreements.

The following information is intended for provider guidance and allows the physician to consider coding pathways on a case by case basis. Final decision-making regarding coding guidelines for specific third party payors remains in the hands of the provider. Ultimately, the provider has a better understanding of the coding pathways available and how to use them appropriately in the office setting of care as well as in the outpatient and inpatient facility settings of care.

Physician Coding

Physicians bill Medicare and other payors separately for services performed, regardless of whether the service takes place in the physician's office, a hospital or other outpatient facility. Procedure codes identify the specific treatment that is performed on the patient. It is possible to report more than one procedure code on a claim form, and the type of payor and setting of care often dictate whether the services are paid independently or as a single bundled payment.

The following tables illustrate potential CPT codes that can be used to denote surgical skin procedures and the application of Dermacell AWM for the treatment of wounds. Medicare RVUs and national average payment rates have been included for both the facility setting and the physician's office. When services are provided in the physician's office (non-facility) RVUs are higher to reflect the increased costs that the practice must absorb.

Physician Coding Pathway Options					
CPT[3] Code	**CPT Description**	**Medicare National Average Payment & RVUs[4]**			
		Office		**Facility**	
		RVUs	**2018 Payment**	**RVUs**	**2018 Payment**

[3] CPT 2018 Professional Edition, 2018, American Medical Association

[4] CMS 2018 PFS Final Rule, www.cms.gov

Physician Coding Pathway Options					
CPT[3] Code	CPT Description	Medicare National Average Payment & RVUs[4]			
		Office		Facility	
		RVUs	2018 Payment	RVUs	2018 Payment
15002	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, legs; first 100 sq. cm or 1% of body area of infants and children	9.93	$357.48	6.53	$235.08
+15003	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, legs; each additional 100 sq. cm, or part thereof, or each additional 1% of body area of infants and children (List separately in addition to code for primary procedure)	2.16	$77.76	1.33	$47.88
15004	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet and/or multiple digits; first 100 sq. cm or 1% of body area of infants and children	11.38	$409.68	7.73	$278.28
+15005	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet and/or multiple digits; each additional 100 sq. cm, or part thereof, or each additional 1% of body area of infants and children (List separately in addition to code for primary procedure)	3.56	$128.16	2.63	$94.68
15271	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq. cm; first 25 sq. cm or less wound surface area	4.03	$145.08	2.43	$87.48
+15272	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq. cm; each additional 25 sq. cm wound surface area, or part thereof (List separately in addition to code for primary	.78	$28.08	.51	$18.36
15273	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq. cm; first 100 sq. cm wound surface area, or 1% of body area of	8.59	$309.24	5.88	$211.68

Physician Coding Pathway Options					
CPT[3] Code	CPT Description	Medicare National Average Payment & RVUs[4]			
		Office		Facility	
		RVUs	2018 Payment	RVUs	2018 Payment
	infants and children				
+15274	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq. cm; each additional 100 sq. cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)	2.03	$73.08	1.33	$47.88
15275	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq. cm; first 25 sq. cm or less wound surface area	4.26	$153.36	2.75	$99.00
+15276	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq. cm; each additional 25 sq. cm wound surface area, or part thereof (List separately in addition to code for primary procedure)	.99	$35.64	.73	$26.28
15277	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq. cm; first 100 sq. cm wound surface area, or 1% of body area of infants and children	9.40	$338.40	6.63	$238.68
+15278	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq. cm; each additional 100 sq. cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)	2.43	$87.48	1.67	$60.12

When reporting office based (non-facility) skin substitute graft procedures that are not performed in the hospital outpatient or ASC setting of care, the product utilized in the procedure should be reported on the claim form using the appropriate HCPCS Level II "Q" code. The third party payor determines the coverage and reimbursement guidelines for graft material reimbursement. One common payment methodology uses Average Sales Price (ASP) plus a percentage. This is determined by the third party payor dependent on coverage guidelines and is not standardized across all carriers. Each administrative contractor, insurance carrier and case specific coverage plan should be queried for reporting guidelines and available remuneration.

HCPCS Coding Pathway Options	
HCPCS Code[5]	**HCPCS Code Description**
Q4122	DermACELL®, per square centimeter

CMS has not included, at this time (January 2018), Dermacell on their published list of Part B Average Sales Price (ASP). The ASP list is updated quarterly by CMS. Medicare pricing for products not included on this list is determined by the Medicare Administrative Contractor (MAC) and often based on invoice cost.[6]

Hospital Outpatient & Ambulatory Surgery Center Coding Pathways

DermACELL - Q4122 – CMS High Cost Group – January1, 2018

As part of Medicare's OPPS/ASC 2014 policy of packaging of skin substitutes the high cost/ low cost grouping was adopted to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures. Medicare reimburses hospital outpatient visits based on the APC to which a particular CPT code is assigned.

Dermacell is assigned to the high-cost skin substitute group as of January 1, 2018 by CMS.

The assignment to the high cost or low cost group determines the CPT coding pathways reportable and APC assignments for the hospital outpatient (OPPS) and ambulatory surgery center (ASC) skin substitute graft procedures. The high cost CPT and APC coding pathways are provided in the tables below and are applicable for DermACELL skin substitute graft procedures performed in the outpatient settings of care.

The tables below depict potential hospital outpatient APC assignments and Medicare national average payment amounts for hospital outpatient and ASC procedures for the application of skin

[5] 2018 HCPCS, www.cms.gov
[6] CMS Physician Services Fee Schedule: https://www.gpo.gov/fdsys/pkg/FR-2016-11-15/pdf/2016-26668.pdf , CMS Hospital Outpatient Prospective Payment System (PPS): https://www.gpo.gov/fdsys/pkg/FR-2016-11-14/pdf/2016-26515.pdf, page105.

substitute grafts for the treatment of chronic and acute wounds. Medicare national average reimbursements have been provided as a benchmark where applicable. Commercial payors will have established fee schedules for the application of skin substitutes utilizing CPT coding or a combination of APC coding and/or CPT coding. This methodology is not standardized and can vary with each provider-payor contract.

Hospital Outpatient/ASC Coding Pathway Options						
			Hospital Outpatient[7]		ASC[8]	
CPT Code	CPT Description	APC	SI	Medicare Payment 2018	PI	Medicare Payment 2018
15002	Surgical Prep	5054	T	$1,568.43	A2	$817.02
+15003	Each Additional Area	N/A	N	inclusive	N1	inclusive
15004	Surgical Prep	5053	T	$488.20	A2	$254.31
+15005	Each Additional Area	N/A	N	inclusive	N1	inclusive
15271	Application of Skin Substitute Graft	5054	T	$1,568.43	G2	$817.02
+15272	Each Additional Area	N/A	N	inclusive	N1	inclusive
15273	Application of Skin Substitute Graft	5055	T	$2,710.48	G2	$1,411.94
+15274	Each Additional Area	N/A	N	inclusive	N1	inclusive
15275	Application of Skin Substitute Graft	5054	T	$1,568.43	G2	$817.02
+15276	Each Additional Area	N/A	N	inclusive	N1	inclusive
15277	Application of Skin Substitute Graft	5054	T	$1,568.43	G2	$817.02
+15278	Each Additional Area	N/A	N	inclusive	N1	inclusive

Status/Payment Indicators SI/PI

- **T = Multiple procedure reductions apply**
- **A2, G2 = Payment based on OPPS relative payment rate**
- **N, N1 = Payment included in APC rate**

Medicare requires that the graft material used in skin substitute procedures be reported using the appropriate HCPCS Level II Q code. Dermacell was assigned the brand specific Q code (Q4122) for purposes of identifying the graft material utilized in the skin substitute procedure reported with the CPT and APC codes above.

While there is no Medicare line item reimbursement for the graft material in the OP/ASC settings of care, the cost of the product is included in the CPT and APC assignment through an all-inclusive reimbursement. The Q code is reported to drive coverage determinations and allow for data collection and cost analysis of specific skin substitute products.

HCPCS Coding Pathway Options	
HCPCS Code[9]	HCPCS Code Description
Q4122	DermACELL®, per square centimeter

[7] 2018 Medicare Outpatient Prospective Payment System, www.cms.gov
[8] 2018 Medicare ASC Payment Rates, www.cms.gov
[9] 2018 HCPCS, www.cms.gov

Hospital Inpatient Coding Pathways

Medicare reimburses hospital inpatient stays based on the Medicare Severity Diagnosis Related Group (MS-DRG) system. MS-DRGs represent a consolidated prospective payment for all services provided by the hospital during the patient's hospitalization, based on submitted claims data. With limited exceptions, the MS-DRG payment is inclusive of all services, products, and resources, regardless of the final cost to the hospital. Medicare and many private payors use the MS-DRG based system to reimburse facilities for inpatient services.

Distinct hospital procedure coding exists for wound care and skin substitute grafts and the application of Dermacell. The chart below provides a small sample of applicable ICD-10-PCS procedure codes implemented October 1, 2015. The ICD-10-PCS code set is specific as to anatomy, depth of the procedure, laterality, and the type of tissue graft. The list is exhaustive in detail.

A broader list of possible ICD-10-CM/PCS diagnosis and inpatient procedure codes is provided in section 4 of this document. The following examples show the typical detail required to code procedures correctly. Note that Dermacell is considered a non-autologous tissue substitute graft.

ICD-10-PCS Hospital Procedure Coding Pathways (not a complete list - see Section 4)

Hospital Procedure Coding Pathways	
ICD-10-PCS Code[10]	**ICD-10-PCS Description**
0JBR0ZZ	Excision of Left Foot Subcutaneous Tissue and Fascia, Open Approach
0HBNXZZ	Excision of Left Foot Skin, External Approach
0HRNXK4	Replacement of Left Foot Skin with Nonautologous Tissue Substitute, Partial Thickness, External Approach

Medicare establishes MS-DRG groupings depending on the procedure performed, the individual's diagnosis, and the patient condition in order to provide a single reimbursement value for the entire inpatient stay. Certain MS-DRGs account for the possibility of complications and comorbidities present on arrival to the facility or arising during the case, which complicate the case and increase the hospital payment.

The table below provides potential MS-DRGs assignments for hospitals when applying skin substitutes for the treatment of wounds in the inpatient setting of care. 2018 Medicare average rates are provided as a benchmark.

Hospital Inpatient MS-DRG		
MS-DRG	**MS-DRG Description**	**Medicare National Average Payment 2018[11]**

[10] 2017 ICD-10-PCS www.cms.gov

Hospital Inpatient MS-DRG		
MS-DRG	**MS-DRG Description**	**Medicare National Average Payment 2018[11]**
573	Skin Graft for Skin Ulcer or Cellulitis with MCC	$24,488.60
574	Skin Graft for Skin Ulcer or Cellulitis with CC	$17,834.76
575	Skin Graft for Skin Ulcer or Cellulitis without CC/MCC	$10,497.53
576	Skin Graft Except for Skin Ulcer or Cellulitis with MCC	$27,317.43
577	Skin Graft Except for Skin Ulcer or Cellulitis with CC	$14,719.68
578	Skin Graft Except for Skin Ulcer or Cellulitis without CC/MCC	$8,974.63
622	Skin Grafts and Wound Debridement for Endocrine, Nutritional and Metabolic Disorders with MCC	$21,764.63
623	Skin Grafts and Wound Debridement for Endocrine, Nutritional and Metabolic Disorders with CC	$11,434.04
624	Skin Grafts and Wound Debridement for Endocrine, Nutritional and Metabolic Disorders without CC/MCC	$7,166.09

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[11] 2018 MS-DRG relative weight multiplied by 2018 rate per IPPS Final Rule CMS-1677, as calculated by MCRA, payment rates will vary by facility. Calculation includes labor related, non-labor related and capital payment rates.

4. ICD-10 Code Reference

ICD-10- PCS Inpatient Procedure Code Reference

The following ICD-10-CM code set options are more detailed and provide specifics that were not available in the former ICD-9 code set. Not all options are presented here and the provider is always responsible for the assignment of the actual codes as documented in the medical record. Not intended to be a complete listing of all applicable ICD-10-PCS codes.

Common Skin Substitute Graft Procedures

ICD-10-PCS Code[12]	ICD-10-PCS Description
0HRNXK4	Replacement of Left Foot Skin with Nonautologous Tissue Substitute, Partial Thickness, External Approach
0HRNXK3	Replacement of Left Foot Skin with Nonautologous Tissue Substitute, Full Thickness, External Approach
0HRMXK4	Replacement of Right Foot Skin with Nonautologous Tissue Substitute, Partial Thickness, External Approach
0HRMXK3	Replacement of Right Foot Skin with Nonautologous Tissue Substitute, Full Thickness, External Approach
0HRLXK4	Replacement of Left Lower Leg Skin with Nonautologous Tissue Substitute, Partial Thickness, External Approach
0HRLXK3	Replacement of Left Lower Leg Skin with Nonautologous Tissue Substitute, Full Thickness, External Approach
0HRKXK4	Replacement of Right Lower Leg Skin with Nonautologous Tissue Substitute, Partial Thickness, External Approach
0HRKXK3	Replacement of Right Lower Leg Skin with Nonautologous Tissue Substitute, Full Thickness, External Approach
0HRJXK4	Replacement of Left Upper Leg Skin with Nonautologous Tissue Substitute, Partial Thickness, External Approach
0HRJXK3	Replacement of Left Upper Leg Skin with Nonautologous Tissue Substitute, Full Thickness, External Approach
0HRHXK4	Replacement of Right Upper Leg Skin with Nonautologous Tissue Substitute, Partial Thickness, External Approach
0HRHXK3	Replacement of Right Upper Leg Skin with Nonautologous Tissue Substitute, Full Thickness, External Approach
0HRGXK4	Replacement of Left Hand Skin with Nonautologous Tissue Substitute, Partial Thickness, External Approach
0HRGXK3	Replacement of Left Hand Skin with Nonautologous Tissue Substitute, Full Thickness, External Approach
0HRFXK4	Replacement of Right Hand Skin with Nonautologous Tissue Substitute, Partial Thickness, External Approach

[12] 2018 ICD-10-PCS GEMs www.cms.gov

ICD-10-PCS Code[12]	ICD-10-PCS Description
0HRFXK3	Replacement of Right Hand Skin with Nonautologous Tissue Substitute, Full Thickness, External Approach
0HREXK4	Replacement of Left Lower Arm Skin with Nonautologous Tissue Substitute, Partial Thickness, External Approach
0HREXK3	Replacement of Left Lower Arm Skin with Nonautologous Tissue Substitute, Full Thickness, External Approach
0HRDXK4	Replacement of Right Lower Arm Skin with Nonautologous Tissue Substitute, Partial Thickness, External Approach
0HRDXK3	Replacement of Right Lower Arm Skin with Nonautologous Tissue Substitute, Full Thickness, External Approach
0HRCXK4	Replacement of Left Upper Arm Skin with Nonautologous Tissue Substitute, Partial Thickness, External Approach
0HRCXK3	Replacement of Left Upper Arm Skin with Nonautologous Tissue Substitute, Full Thickness, External Approach
0HRBXK4	Replacement of Right Upper Arm Skin with Nonautologous Tissue Substitute, Partial Thickness, External Approach
0HRBXK3	Replacement of Right Upper Arm Skin with Nonautologous Tissue Substitute, Full Thickness, External Approach
0HR8XK4	Replacement of Buttock Skin with Nonautologous Tissue Substitute, Partial Thickness, External Approach
0HR8XK3	Replacement of Buttock Skin with Nonautologous Tissue Substitute, Full Thickness, External Approach
0HR7XK4	Replacement of Abdomen Skin with Nonautologous Tissue Substitute, Partial Thickness, External Approach
0HR7XK3	Replacement of Abdomen Skin with Nonautologous Tissue Substitute, Full Thickness, External Approach
0HR6XK4	Replacement of Back Skin with Nonautologous Tissue Substitute, Partial Thickness, External Approach
0HR6XK3	Replacement of Back Skin with Nonautologous Tissue Substitute, Full Thickness, External Approach
0HR5XK4	Replacement of Chest Skin with Nonautologous Tissue Substitute, Partial Thickness, External Approach
0HR5XK3	Replacement of Chest Skin with Nonautologous Tissue Substitute, Full Thickness, External Approach
0HR4XK4	Replacement of Neck Skin with Nonautologous Tissue Substitute, Partial Thickness, External Approach
0HR4XK3	Replacement of Neck Skin with Nonautologous Tissue Substitute, Full Thickness, External Approach
0HR1XK4	Replacement of Face Skin with Nonautologous Tissue Substitute, Partial Thickness, External Approach
0HR1XK3	Replacement of Face Skin with Nonautologous Tissue Substitute, Full Thickness, External Approach
0HR0XK4	Replacement of Scalp Skin with Nonautologous Tissue Substitute, Partial Thickness, External Approach

ICD-10-PCS Code[12]	ICD-10-PCS Description
0HR0XK3	Replacement of Scalp Skin with Nonautologous Tissue Substitute, Full Thickness, External Approach
0HBNXZZ	Excision of Left Foot Skin, External Approach
0HBMXZZ	Excision of Right Foot Skin, External Approach
0HBLXZZ	Excision of Left Lower Leg Skin, External Approach
0HBKXZZ	Excision of Right Lower Leg Skin, External Approach
0HBJXZZ	Excision of Left Upper Leg Skin, External Approach
0HBHXZZ	Excision of Right Upper Leg Skin, External Approach
0HBGXZZ	Excision of Left Hand Skin, External Approach
0HBFXZZ	Excision of Right Hand Skin, External Approach
0HBEXZZ	Excision of Left Lower Arm Skin, External Approach
0HBDXZZ	Excision of Right Lower Arm Skin, External Approach
0HBCXZZ	Excision of Left Upper Arm Skin, External Approach
0HBBXZZ	Excision of Right Upper Arm Skin, External Approach
0HB8XZZ	Excision of Buttock Skin, External Approach
0HB7XZZ	Excision of Abdomen Skin, External Approach
0HB6XZZ	Excision of Back Skin, External Approach
0HB5XZZ	Excision of Chest Skin, External Approach
0HB4XZZ	Excision of Neck Skin, External Approach
0HB1XZZ	Excision of Face Skin, External Approach
0HB0XZZ	Excision of Scalp Skin, External Approach

Disclaimer: *This information is for educational/informational purposes only and should not be construed as authoritative. The information presented here is current as of January 2018 and is based upon publicly available source information. Codes and values are subject to frequent change without notice. The entity billing Medicare and/or third party payors is solely responsible for the accuracy of the codes assigned to the services or items in the medical record. When making coding decisions, we encourage you to seek input from the AMA, relevant medical societies, CMS, your local Medicare Administrative Contractor and other health plans to which you submit claims. Items and services that are billed to payors must be medically necessary and supported by appropriate documentation. It is important to remember that while a code may exist describing certain procedures and/or technologies, it does not guarantee payment by payors.*

Common ICD-10-CM Diagnosis Code Reference

The following chart provides some of the common diagnoses and ICD-10-CM codes that may require skin substitute grafts as a treatment option. This partial list is provided only for reference and does not represent any particular case or suggested treatment. Not all options are presented here and the provider is always responsible for the assignment of the actual diagnosis codes as documented in the medical record.

Common Diagnoses - Skin Substitute Graft Procedures

ICD-10-CM Code[13]	ICD-10-CM Description	ICD-10-CM Code	ICD-10-CM Description
L97.901	Non-pressure chronic ulcer of unspecified part of unspecified lower leg limited to breakdown of skin	I70.334	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of heel and midfoot
L97.902	Non-pressure chronic ulcer of unspecified part of unspecified lower leg with fat layer exposed	I70.344	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of heel and midfoot
L97.903	Non-pressure chronic ulcer of unspecified part of unspecified lower leg with necrosis of muscle	I70.434	Atherosclerosis of autologous vein bypass graft(s) of the right leg with ulceration of heel and midfoot
L97.904	Non-pressure chronic ulcer of unspecified part of unspecified lower leg with necrosis of bone	I70.444	Atherosclerosis of autologous vein bypass graft(s) of the left leg with ulceration of heel and midfoot
L97.909	Non-pressure chronic ulcer of unspecified part of unspecified lower leg with unspecified severity	I70.534	Atherosclerosis of nonautologous biological bypass graft(s) of the right leg with ulceration of heel and midfoot
L97.911	Non-pressure chronic ulcer of unspecified part of right lower leg limited to breakdown of skin	I70.544	Atherosclerosis of nonautologous biological bypass graft(s) of the left leg with ulceration of heel and midfoot
L97.912	Non-pressure chronic ulcer of unspecified part of right lower leg with fat layer exposed	I70.634	Atherosclerosis of nonbiological bypass graft(s) of the right leg with ulceration of heel and midfoot

[13] 2018 ICD-10-CM GEMs www.cms.gov

ICD-10-CM Code[13]	ICD-10-CM Description	ICD-10-CM Code	ICD-10-CM Description
L97.913	Non-pressure chronic ulcer of unspecified part of right lower leg with necrosis of muscle	I70.644	Atherosclerosis of nonbiological bypass graft(s) of the left leg with ulceration of heel and midfoot
L97.914	Non-pressure chronic ulcer of unspecified part of right lower leg with necrosis of bone	I70.734	Atherosclerosis of other type of bypass graft(s) of the right leg with ulceration of heel and midfoot
L97.919	Non-pressure chronic ulcer of unspecified part of right lower leg with unspecified severity	I70.744	Atherosclerosis of other type of bypass graft(s) of the left leg with ulceration of heel and midfoot
L97.921	Non-pressure chronic ulcer of unspecified part of left lower leg limited to breakdown of skin	L97.401	Non-pressure chronic ulcer of unspecified heel and midfoot limited to breakdown of skin
L97.922	Non-pressure chronic ulcer of unspecified part of left lower leg with fat layer exposed	L97.402	Non-pressure chronic ulcer of unspecified heel and midfoot with fat layer exposed
L97.923	Non-pressure chronic ulcer of unspecified part of left lower leg with necrosis of muscle	L97.403	Non-pressure chronic ulcer of unspecified heel and midfoot with necrosis of muscle
L97.924	Non-pressure chronic ulcer of unspecified part of left lower leg with necrosis of bone	L97.404	Non-pressure chronic ulcer of unspecified heel and midfoot with necrosis of bone
L97.929	Non-pressure chronic ulcer of unspecified part of left lower leg with unspecified severity	L97.409	Non-pressure chronic ulcer of unspecified heel and midfoot with unspecified severity
I70.231	Atherosclerosis of native arteries of right leg with ulceration of thigh	L97.411	Non-pressure chronic ulcer of right heel and midfoot limited to breakdown of skin
I70.241	Atherosclerosis of native arteries of left leg with ulceration of thigh	L97.412	Non-pressure chronic ulcer of right heel and midfoot with fat layer exposed
I70.331	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of thigh	L97.413	Non-pressure chronic ulcer of right heel and midfoot with necrosis of muscle

ICD-10-CM Code[13]	ICD-10-CM Description	ICD-10-CM Code	ICD-10-CM Description
I70.341	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of thigh	L97.414	Non-pressure chronic ulcer of right heel and midfoot with necrosis of bone
I70.431	Atherosclerosis of autologous vein bypass graft(s) of the right leg with ulceration of thigh	L97.419	Non-pressure chronic ulcer of right heel and midfoot with unspecified severity
I70.441	Atherosclerosis of autologous vein bypass graft(s) of the left leg with ulceration of thigh	L97.421	Non-pressure chronic ulcer of left heel and midfoot limited to breakdown of skin
I70.531	Atherosclerosis of nonautologous biological bypass graft(s) of the right leg with ulceration of thigh	L97.422	Non-pressure chronic ulcer of left heel and midfoot with fat layer exposed
I70.541	Atherosclerosis of nonautologous biological bypass graft(s) of the left leg with ulceration of thigh	L97.423	Non-pressure chronic ulcer of left heel and midfoot with necrosis of muscle
I70.631	Atherosclerosis of nonbiological bypass graft(s) of the right leg with ulceration of thigh	L97.424	Non-pressure chronic ulcer of left heel and midfoot with necrosis of bone
I70.641	Atherosclerosis of nonbiological bypass graft(s) of the left leg with ulceration of thigh	L97.429	Non-pressure chronic ulcer of left heel and midfoot with unspecified severity
I70.731	Atherosclerosis of other type of bypass graft(s) of the right leg with ulceration of thigh	L97.414	Non-pressure chronic ulcer of right heel and midfoot with necrosis of bone
I70.741	Atherosclerosis of other type of bypass graft(s) of the left leg with ulceration of thigh	L97.419	Non-pressure chronic ulcer of right heel and midfoot with unspecified severity
L97.101	Non-pressure chronic ulcer of unspecified thigh limited to breakdown of skin	L97.421	Non-pressure chronic ulcer of left heel and midfoot limited to breakdown of skin
L97.102	Non-pressure chronic ulcer of unspecified thigh with fat layer exposed	L97.422	Non-pressure chronic ulcer of left heel and midfoot with fat layer exposed

ICD-10-CM Code[13]	ICD-10-CM Description	ICD-10-CM Code	ICD-10-CM Description
L97.103	Non-pressure chronic ulcer of unspecified thigh with necrosis of muscle	L97.423	Non-pressure chronic ulcer of left heel and midfoot with necrosis of muscle
L97.104	Non-pressure chronic ulcer of unspecified thigh with necrosis of bone	L97.424	Non-pressure chronic ulcer of left heel and midfoot with necrosis of bone
L97.109	Non-pressure chronic ulcer of unspecified thigh with unspecified severity	L97.429	Non-pressure chronic ulcer of left heel and midfoot with unspecified severity
L97.111	Non-pressure chronic ulcer of right thigh limited to breakdown of skin	I70.235	Atherosclerosis of native arteries of right leg with ulceration of other part of foot
L97.112	Non-pressure chronic ulcer of right thigh with fat layer exposed	I70.245	Atherosclerosis of native arteries of left leg with ulceration of other part of foot
L97.113	Non-pressure chronic ulcer of right thigh with necrosis of muscle	I70.335	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of other part of foot
L97.114	Non-pressure chronic ulcer of right thigh with necrosis of bone	I70.345	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of other part of foot
L97.119	Non-pressure chronic ulcer of right thigh with unspecified severity	I70.435	Atherosclerosis of autologous vein bypass graft(s) of the right leg with ulceration of other part of foot
L97.121	Non-pressure chronic ulcer of left thigh limited to breakdown of skin	I70.445	Atherosclerosis of autologous vein bypass graft(s) of the left leg with ulceration of other part of foot
L97.122	Non-pressure chronic ulcer of left thigh with fat layer exposed	I70.535	Atherosclerosis of nonautologous biological bypass graft(s) of the right leg with ulceration of other part of foot
L97.123	Non-pressure chronic ulcer of left thigh with necrosis of muscle	I70.545	Atherosclerosis of nonautologous biological bypass graft(s) of the left leg with ulceration of other part of foot

ICD-10-CM Code[13]	ICD-10-CM Description	ICD-10-CM Code	ICD-10-CM Description
L97.124	Non-pressure chronic ulcer of left thigh with necrosis of bone	I70.635	Atherosclerosis of nonbiological bypass graft(s) of the right leg with ulceration of other part of foot
L97.129	Non-pressure chronic ulcer of left thigh with unspecified severity	I70.645	Atherosclerosis of nonbiological bypass graft(s) of the left leg with ulceration of other part of foot
I70.232	Atherosclerosis of native arteries of right leg with ulceration of calf	I70.735	Atherosclerosis of other type of bypass graft(s) of the right leg with ulceration of other part of foot
I70.242	Atherosclerosis of native arteries of left leg with ulceration of calf	I70.745	Atherosclerosis of other type of bypass graft(s) of the left leg with ulceration of other part of foot
I70.332	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of calf	L97.501	Non-pressure chronic ulcer of other part of unspecified foot limited to breakdown of skin
I70.342	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of calf	L97.502	Non-pressure chronic ulcer of other part of unspecified foot with fat layer exposed
I70.432	Atherosclerosis of autologous vein bypass graft(s) of the right leg with ulceration of calf	L97.503	Non-pressure chronic ulcer of other part of unspecified foot with necrosis of muscle
I70.442	Atherosclerosis of autologous vein bypass graft(s) of the left leg with ulceration of calf	L97.504	Non-pressure chronic ulcer of other part of unspecified foot with necrosis of bone
I70.532	Atherosclerosis of nonautologous biological bypass graft(s) of the right leg with ulceration of calf	L97.509	Non-pressure chronic ulcer of other part of unspecified foot with unspecified severity
I70.542	Atherosclerosis of nonautologous biological bypass graft(s) of the left leg with ulceration of calf	L97.511	Non-pressure chronic ulcer of other part of right foot limited to breakdown of skin
I70.632	Atherosclerosis of nonbiological bypass graft(s) of the right leg with ulceration of calf	L97.512	Non-pressure chronic ulcer of other part of right foot with fat layer exposed

ICD-10-CM Code[13]	ICD-10-CM Description	ICD-10-CM Code	ICD-10-CM Description
I70.642	Atherosclerosis of nonbiological bypass graft(s) of the left leg with ulceration of calf	L97.513	Non-pressure chronic ulcer of other part of right foot with necrosis of muscle
I70.732	Atherosclerosis of other type of bypass graft(s) of the right leg with ulceration of calf	L97.514	Non-pressure chronic ulcer of other part of right foot with necrosis of bone
I70.742	Atherosclerosis of other type of bypass graft(s) of the left leg with ulceration of calf	L97.519	Non-pressure chronic ulcer of other part of right foot with unspecified severity
L97.202	Non-pressure chronic ulcer of unspecified calf with fat layer exposed	L97.521	Non-pressure chronic ulcer of other part of left foot limited to breakdown of skin
L97.203	Non-pressure chronic ulcer of unspecified calf with necrosis of muscle	L97.522	Non-pressure chronic ulcer of other part of left foot with fat layer exposed
L97.204	Non-pressure chronic ulcer of unspecified calf with necrosis of bone	L97.523	Non-pressure chronic ulcer of other part of left foot with necrosis of muscle
L97.209	Non-pressure chronic ulcer of unspecified calf with unspecified severity	L97.524	Non-pressure chronic ulcer of other part of left foot with necrosis of bone
L97.211	Non-pressure chronic ulcer of right calf limited to breakdown of skin	L97.529	Non-pressure chronic ulcer of other part of left foot with unspecified severity
L97.212	Non-pressure chronic ulcer of right calf with fat layer exposed	I70.238	Atherosclerosis of native arteries of right leg with ulceration of other part of lower right leg
L97.213	Non-pressure chronic ulcer of right calf with necrosis of muscle	I70.239	Atherosclerosis of native arteries of right leg with ulceration of unspecified site
L97.214	Non-pressure chronic ulcer of right calf with necrosis of bone	I70.248	Atherosclerosis of native arteries of left leg with ulceration of other part of lower left leg

ICD-10-CM Code[13]	ICD-10-CM Description	ICD-10-CM Code	ICD-10-CM Description
L97.219	Non-pressure chronic ulcer of right calf with unspecified severity	I70.249	Atherosclerosis of native arteries of left leg with ulceration of unspecified site
L97.221	Non-pressure chronic ulcer of left calf limited to breakdown of skin	I70.338	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of other part of lower leg
L97.222	Non-pressure chronic ulcer of left calf with fat layer exposed	I70.339	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of unspecified site
L97.223	Non-pressure chronic ulcer of left calf with necrosis of muscle	I70.348	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of other part of lower leg
L97.224	Non-pressure chronic ulcer of left calf with necrosis of bone	I70.349	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of unspecified site
L97.229	Non-pressure chronic ulcer of left calf with unspecified severity	I70.438	Atherosclerosis of autologous vein bypass graft(s) of the right leg with ulceration of other part of lower leg
I70.233	Atherosclerosis of native arteries of right leg with ulceration of ankle	I70.439	Atherosclerosis of autologous vein bypass graft(s) of the right leg with ulceration of unspecified site
I70.243	Atherosclerosis of native arteries of left leg with ulceration of ankle	I70.448	Atherosclerosis of autologous vein bypass graft(s) of the left leg with ulceration of other part of lower leg
I70.333	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of ankle	I70.449	Atherosclerosis of autologous vein bypass graft(s) of the left leg with ulceration of unspecified site
I70.343	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of ankle	I70.538	Atherosclerosis of nonautologous biological bypass graft(s) of the right leg with ulceration of other part of lower leg
I70.433	Atherosclerosis of autologous vein bypass graft(s) of the right leg with ulceration of ankle	I70.539	Atherosclerosis of nonautologous biological bypass graft(s) of the right leg with ulceration of unspecified site

ICD-10-CM Code[13]	ICD-10-CM Description	ICD-10-CM Code	ICD-10-CM Description
I70.443	Atherosclerosis of autologous vein bypass graft(s) of the left leg with ulceration of ankle	I70.548	Atherosclerosis of nonautologous biological bypass graft(s) of the left leg with ulceration of other part of lower leg
I70.533	Atherosclerosis of nonautologous biological bypass graft(s) of the right leg with ulceration of ankle	I70.549	Atherosclerosis of nonautologous biological bypass graft(s) of the left leg with ulceration of unspecified site
I70.543	Atherosclerosis of nonautologous biological bypass graft(s) of the left leg with ulceration of ankle	I70.638	Atherosclerosis of nonbiological bypass graft(s) of the right leg with ulceration of other part of lower leg
I70.633	Atherosclerosis of nonbiological bypass graft(s) of the right leg with ulceration of ankle	I70.639	Atherosclerosis of nonbiological bypass graft(s) of the right leg with ulceration of unspecified site
I70.643	Atherosclerosis of nonbiological bypass graft(s) of the left leg with ulceration of ankle	I70.648	Atherosclerosis of nonbiological bypass graft(s) of the left leg with ulceration of other part of lower leg
I70.733	Atherosclerosis of other type of bypass graft(s) of the right leg with ulceration of ankle	I70.649	Atherosclerosis of nonbiological bypass graft(s) of the left leg with ulceration of unspecified site
I70.743	Atherosclerosis of other type of bypass graft(s) of the left leg with ulceration of ankle	I70.738	Atherosclerosis of other type of bypass graft(s) of the right leg with ulceration of other part of lower leg
L97.301	Non-pressure chronic ulcer of unspecified ankle limited to breakdown of skin	I70.739	Atherosclerosis of other type of bypass graft(s) of the right leg with ulceration of unspecified site
L97.302	Non-pressure chronic ulcer of unspecified ankle with fat layer exposed	I70.748	Atherosclerosis of other type of bypass graft(s) of the left leg with ulceration of other part of lower leg
L97.303	Non-pressure chronic ulcer of unspecified ankle with necrosis of muscle	I70.749	Atherosclerosis of other type of bypass graft(s) of the left leg with ulceration of unspecified site
L97.304	Non-pressure chronic ulcer of unspecified ankle with necrosis of bone	L97.801	Non-pressure chronic ulcer of other part of unspecified lower leg limited to breakdown of skin

ICD-10-CM Code[13]	ICD-10-CM Description	ICD-10-CM Code	ICD-10-CM Description
L97.309	Non-pressure chronic ulcer of unspecified ankle with unspecified severity	L97.802	Non-pressure chronic ulcer of other part of unspecified lower leg with fat layer exposed
L97.311	Non-pressure chronic ulcer of right ankle limited to breakdown of skin	L97.803	Non-pressure chronic ulcer of other part of unspecified lower leg with necrosis of muscle
L97.312	Non-pressure chronic ulcer of right ankle with fat layer exposed	L97.804	Non-pressure chronic ulcer of other part of unspecified lower leg with necrosis of bone
L97.313	Non-pressure chronic ulcer of right ankle with necrosis of muscle	L97.809	Non-pressure chronic ulcer of other part of unspecified lower leg with unspecified severity
L97.314	Non-pressure chronic ulcer of right ankle with necrosis of bone	L97.811	Non-pressure chronic ulcer of other part of right lower leg limited to breakdown of skin
L97.319	Non-pressure chronic ulcer of right ankle with unspecified severity	L97.812	Non-pressure chronic ulcer of other part of right lower leg with fat layer exposed
L97.321	Non-pressure chronic ulcer of left ankle limited to breakdown of skin	L97.813	Non-pressure chronic ulcer of other part of right lower leg with necrosis of muscle
L97.322	Non-pressure chronic ulcer of left ankle with fat layer exposed	L97.814	Non-pressure chronic ulcer of other part of right lower leg with necrosis of bone
L97.323	Non-pressure chronic ulcer of left ankle with necrosis of muscle	L97.819	Non-pressure chronic ulcer of other part of right lower leg with unspecified severity
L97.324	Non-pressure chronic ulcer of left ankle with necrosis of bone	L97.821	Non-pressure chronic ulcer of other part of left lower leg limited to breakdown of skin
L97.329	Non-pressure chronic ulcer of left ankle with unspecified severity	L97.822	Non-pressure chronic ulcer of other part of left lower leg with fat layer exposed

ICD-10-CM Code[13]	ICD-10-CM Description	ICD-10-CM Code	ICD-10-CM Description
I70.234	Atherosclerosis of native arteries of right leg with ulceration of heel and midfoot	L97.823	Non-pressure chronic ulcer of other part of left lower leg with necrosis of muscle
I70.244	Atherosclerosis of native arteries of left leg with ulceration of heel and midfoot	L97.824	Non-pressure chronic ulcer of other part of left lower leg with necrosis of bone

Disclaimer: *This information is for educational/informational purposes only and should not be construed as authoritative. The information presented here is current as of January 2018 and is based upon publicly available source information. Codes and values are subject to frequent change without notice. The entity billing Medicare and/or third party payors is solely responsible for the accuracy of the codes assigned to the services or items in the medical record. When making coding decisions, we encourage you to seek input from the AMA, relevant medical societies, CMS, your local Medicare Administrative Contractor and other health plans to which you submit claims. Items and services that are billed to payors must be medically necessary and supported by appropriate documentation. It is important to remember that while a code may exist describing certain procedures and/or technologies, it does not guarantee payment by payors.*

5. Documentation Support

Documentation of a patient's history, conservative therapies and reason for any service or procedure is the key to a positive reimbursement scenario. When a skin substitute graft procedure is indicated by the physician, the patient's medical record should clearly state the reason for the procedure as well as the outcomes and recommended therapies to follow. This documentation will support claim review and pre-authorization alike. Follow-up or staged procedures will depend on the initial documentation to support medical necessity. The following general documentation guidelines should be followed for all payors.

Clinical notes should contain the following details:

- Reason for the procedure based on physical exam
- All conservative therapies previously used in the treatment of the current disease
- Specific reason why this treatment is indicated for this patient
- Anticipated outcomes
- Recommended therapies or treatments

Operational and office visit notes might include the following:

- History of patient encounters including conservative therapies
- Current diagnosis or history of disease state
- Details of findings on exam
- Reason for procedure relevant to condition
- Usual details of procedure
- Explanation of technology specific to Dermacell AWM
- Findings and any anticipated further treatments

A letter of medical necessity (LMN) may be required for pre-authorization of a skin substitute graft procedure or for supporting documentation following a request for a claim review. Details of the LMN should include the items on the checklist above. An example LMN is provided in the following section of this guide.

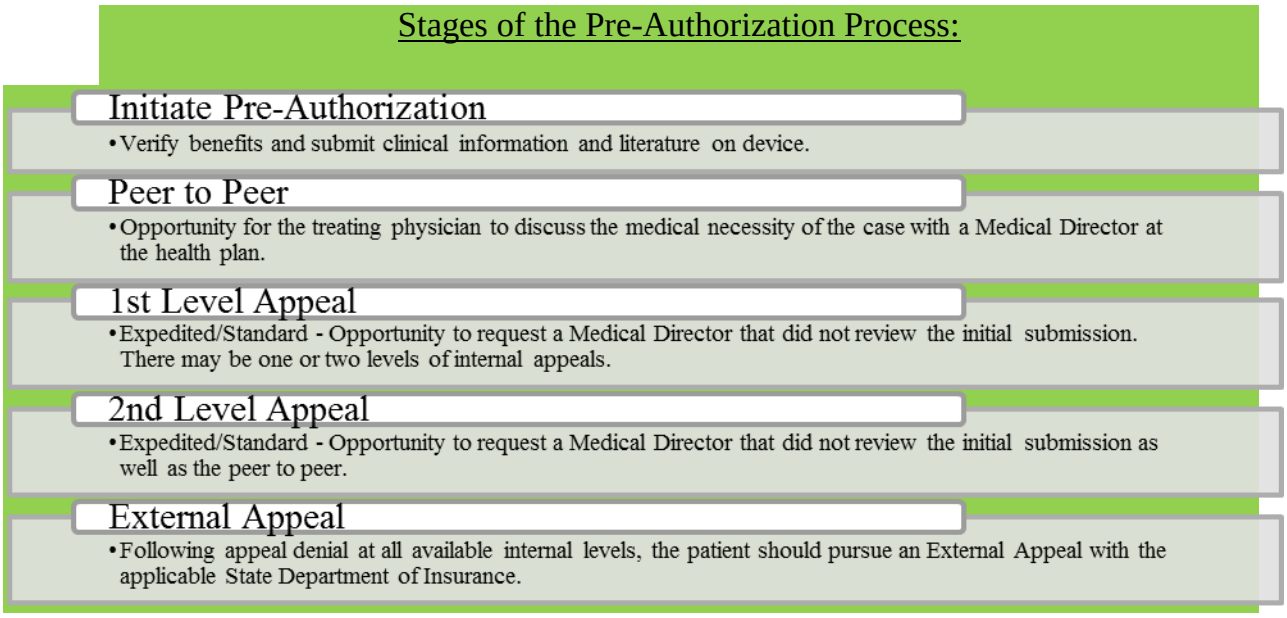
6. Pre-Authorization Overview

In order to facilitate coverage access for a proposed procedure, the physician may request a pre-authorization from the patient's private insurance carrier. Some health plans require pre-authorization for all surgical procedures. Requesting pre-authorization may only involve a simple contact by the physician's office to verify benefits and acquire an approval number to submit with the claim. Alternatively, pre-authorization may require that the physician provide more substantive information about the case.

To prepare a pre-authorization request that requires additional information beyond basic coding, the physician's staff must provide technical information about the procedure and the unique technology involved. The treating physician must also establish the medical necessity for the procedure, as it applies to the specific patient.

Typically the pre-authorization process and/or appeal process may require submitting some or all of the following documentation:

- Patient clinical notes, including documentation of prior conservative care
- Supporting technical information in the form of the FDA registration letter, peer-reviewed clinical literature, clinical trial information and other available technical resources
- Description of the technology and its use in this patient's case
- Description of medical necessity of the procedure for the specific patient



6.1 DermACELL AWM Pre-Authorization/LMN – Example Letter

DERMACELL® PRE-AUTHORIZATION/LETTER OF MEDICAL NECESSITY

Providers, please note: *Coverage requirements will typically vary by payor. Therefore, physicians may seek pre-authorization for the procedure, during which time health plans will determine whether the procedure is covered as described in the pre-authorization submission.*

This template and the information provided herein are intended to provide context for the procedure and related coding. Providers should select the procedure, diagnosis, and technology coding that best represents each patient's medical condition and treatment and should reflect the services and products that are medically necessary for the treatment of that patient. Providers must ensure that all statements made to insurance carriers are true and correct.

[Site Letterhead]

[DATE]

[NAME OF INSURANCE COMPANY]
[ATTN:]
[FAX #:]

RE: [PATIENT NAME]
[INSURANCE IDENTIFICATION NUMBER]
[REFERENCE #:]
[PRIMARY CPT CODE:]
[PRIMARY DX:]

Dear Utilization Review Manager:

On behalf of my patient, [PATIENT NAME], this letter serves as a pre-authorization request and provides clinical information on this patient's condition. It also serves as a formal request for coverage by [INSURANCE COMPANY] for the medically necessary health care services captioned above. This letter and its supporting documents will provide you with a better depiction of this patient's clinical history and this patient's need for the [DERMACELL SKIN SUBSTITUTE GRAFT PROCEDURE]. It is my sincere hope that this additional information will inform your decision to approve this surgery.

Description of Procedure: [PHYSICIAN INSERTS DETAILED PROCEDURE DESCRIPTION INCLUDING THE USE OF THE DERMACELL SKIN SUBSTITUTE GRAFT].

Skin Substitute Description: DermACELL is a technologically advanced human acellular dermal matrix. Dermacell is decellularized using Matracell®, proprietary, patented and validated processing technology that removes cells and ≥ 97% of donor DNA without compromising the desired biomechanical or

biochemical properties of the graft and allowing for rapid cellular infiltration and re-vascularization. Dermacell is ready to use out of the package and stored at room temperature, eliminating the need for refrigeration and rehydrating processes.

Key Benefits of Dermacell Skin Graft Substitute:

- Retains native growth factors, collagen and elastin
- Pull-out strength and load to failure are comparable to native dermis
- Facilitates cell proliferation and migration, critical for wound management

Dermacell is regulated by the U.S. Food and Drug Administration (FDA) as a human skin tissue under its Human Cells, Tissues, and Tissue-Based Products (HCT/P) guidelines, subject to Section 361 of the Public Health Service Act and 21 CFR 1270 and 1271.

Patient's Clinical Need for the DermACELL Skin Substitute Graft Procedure: [PATIENT NAME] is a [AGE] [GENDER] who presented to me with [DESCRIBE SYMPTOMS WITH SPECIFICITY]. Prior treatments have included [DESCRIBE CONSERVATIVE CARE, USE OF MEDICATIONS, PRIOR TREATMENTS, and PHYSICAL AIDS].

In a discussion with [INSERT MR/MS] following an exam, a decision was made to move forward with a skin substitute graft procedure. The unique design of DermACELL® allows for easy manipulation and repositioning, making it a flexible, dependable option for wound and soft tissue healing for my patient.

I have attached the FDA registration letter for [DERMACELL SKIN SUBSTITUTE GRAFT]. Should you have further questions or concerns, please do not hesitate to call me at [INSERT PHYSICIAN TELEPHONE NUMBER]. Thank you for your immediate attention and anticipated authorization of these services for your insured.

Sincerely,

[PHYSICIAN NAME], [DEGREE]

7. Plan Denial Appeal Process Overview

When a third party health plan denies a procedure in accordance with their medical policy guidelines, there is a process available to appeal that decision. Insurance carriers provide this check and balance to allow for reconsideration of the decision per their plan provisions and applicable state regulations. The process will vary depending on the plan and regulatory requirements; however, there are basic steps that can assist the provider in appealing the initial denial.

To present an effective appeal, follow these steps:

1. Carefully review the denial reason and understand the specific health plan's policy;

2. Write an appeal letter clearly addressing the specific denial reasons;

3. Provide supporting information including product details and FDA registration; and

4. Submit the appeal on time.

The following additional considerations may be helpful:

1. If the health plan is self-funded (employer based), patients can contact their Human Resources (HR) department to assist in the patient's appeal of the decision. HR departments may have contacts within the health plan that can provide helpful support.

2. The patient can contact the health plan directly and is the policy-holder with an influence on the decision.

3. There are multiple steps in the appeal process and providers and patients may exercise these rights according to their third party payor and state guidelines.

<u>Writing the Appeal Letter</u>

When appealing a denial, the first step is often composing a letter to the health plan that initially reviewed the case. This letter is submitted by the provider on behalf of the patient, with the patient's approval, and should outline the reasons the denial should be overturned.

Detailed information regarding the denial reason should be prepared utilizing the case specific information in the denial, as well as the more general technology specific information and supporting clinical literature.

First, collect all the information required to support the appeal:

- Denial letter
- Health plan contracts and provider agreements
- Applicable medical policy guidelines from the health plan (website access is often a good resource for general policy)
- Literature supporting the technology
- FDA registration letter
- Safety and effectiveness documentation
- Peer-reviewed literature references (when available)

In drafting an appeal letter, consider the following:

- Did the reviewer miss information about the technology?
- Did the reviewer overlook a case specific detail?
- Does the health plan clearly understand the procedure?
- Was the information provided about the case correctly submitted?
- Review the plan's official policy online for more detailed understanding of the denial reason

Be mindful of details, including:

- Patient's name
- Subscriber's name
- Policy number
- Description of exact service denied
- Date denied

7.1 DermACELL AWM PA Denial Appeal– Example Letter

DERMACELL® PRE-AUTHORIZATION APPEAL LETTER

Providers, please note: *Despite the filing of a pre-authorization request, certain commercial health plans may still elect not to cover or grant pre-authorization for this procedure without further information and clinical evidence supporting its use. Should pre-authorization be denied, the physician requesting coverage should immediately file a written appeal with the health plan and request reconsideration of the coverage decision. When requesting a pre-authorization appeal it is important to remember that payors may require all elements of a procedure to be pre-authorized per their payor guidelines. To assist you, the following example is offered as a starting point for your pre-authorization denial appeal and reconsideration request.*

[Site Letterhead]

[DATE]

[NAME OF INSURANCE COMPANY]
[ATTN:]
[FAX #:]

RE: [PATIENT NAME]
[INSURANCE IDENTIFICATION NUMBER]
[REFERENCE #:]
[PRIMARY CPT CODE]
[PRIMARY DX CODE]

Dear Utilization Review Manager:

Please accept this letter on behalf of [PATIENT NAME], as an appeal to [INSURANCE COMPANY]'s decision to deny coverage for the recommended [PROCEDURE]. It is my understanding, per [INSURANCE COMPANY]'s denial letter dated [INSERT DENIAL LETTER DATE], that this procedure has been denied because [REASON FOR DENIAL].

I respectfully request that [INSURANCE COMPANY] reconsider its denial and provide authorization for this treatment option. I believe this denial was made in error. This letter and its supporting documents will provide you with a better depiction of this patient's clinical history and this patient's need for the [DERMACELL SKIN SUBSTITUTE GRAFT PROCEDURE].

Description of Procedure: [PHYSICIAN INSERTS DETAILED PROCEDURE DESCRIPTION INCLUDING THE USE OF THE DERMACELL SKIN SUBSTITUTE GRAFT].

Skin Substitute Description: DermACELL is a technologically advanced human acellular dermal matrix. Dermacell is decellularized using Matracell®, proprietary, patented and validated processing technology that removes cells and at least 97% of donor DNA without compromising the desired biomechanical or biochemical properties of the graft and allowing for rapid cellular infiltration and re-vascularization. DermACELL is ready to use out of the package and stored at room temperature, eliminating the need for refrigeration and rehydrating processes.

Key Benefits of Dermacell Skin Graft Substitute:

- Retains native growth factors, collagen and elastin
- Pull-out strength and load to failure are comparable to native dermis
- Facilitates cell proliferation and migration, critical for wound management

Dermacell is regulated by the U.S. Food and Drug Administration (FDA) as a human skin tissue under its Human Cells, Tissues, and Tissue-Based Products (HCT/P) guidelines, subject to Section 361 of the Public Health Service Act and 21 CFR 1270 and 1271.

Dermacell is an appropriate clinical option in the treatment of DFUs (Diabetic Foot Ulcer) with significant increase in healing rates and rate of percentage of wound closure as compared with conventional care options. (Walters, 2016).

In a randomized clinical trial, a Single application Dermacell subjects showed significantly greater wound closure rates than conventional care at all three endpoints. The DermACELL arm demonstrated significantly greater wound healing, larger wound area reduction, and a better capability of keeping healed wounds closed than conventional care in treatment of chronic DFUs. (Cazzell, 2017).

Please consider the following references in support of Dermacell procedures:

- Walters J, Cazzell S. Healing Rates in a Multicenter Assessment of a Sterile, Room Temperature, Acellular Dermal Matrix Versus Conventional Care Wound Management and an Active Comparator in the Treatment of Full-Thickness Diabetic Foot Ulcers. *Open Access Journal of Plastic Surgery*. 2016; 16: e10.
- Cole W. DermACELL: Human Acellular Dermal Matrix Allograft A Case Report. J Am Podiatr Med Assoc. 2013; Mar, 106(2):133-7.
- Cazzell S, Vayser D. A Randomized Clinical Trial of a Human Acellular Dermal Matrix Demonstrated Superior Healing Rates for Chronic Diabetic Foot Ulcers over Conventional Care and an Active Acellular Dermal Matrix Comparator. Wound Repair Regen. 2017; May;25(3):483-497.

Patient's Clinical Need for the Dermacell Skin Substitute Graft Procedure: [PATIENT NAME] is a [AGE] [GENDER] who presented to me with [DESCRIBE SYMPTOMS WITH SPECIFICITY]. Prior treatments have included [DESCRIBE CONSERVATIVE CARE, USE OF MEDICATIONS, PRIOR TREATMENTS, and PHYSICAL AIDS].

To assist in your reconsideration of this patient's clinical need for the intended procedure, a copy of the relevant clinical notes that support use of the [DERMACELL SKIN SUBSTITUTE GRAFT] is enclosed to support you with your decision to overturn your initial denial of coverage for these services. It is my sincere hope that [INSURANCE COMPANY] will respond with a positive decision so that [PATIENT

NAME] can benefit from the results of this procedure. Should you have further questions or concerns, please do not hesitate to call me at [INSERT PHYSICIAN TELEPHONE NUMBER]. Thank you for your immediate attention and reconsideration.

Sincerely,

[PHYSICIAN NAME], [DEGREE]
[PRACTICE NAME]

8. Resources for Dermacell AWM Technology Support

The following resources can provide support when preparing a pre-authorization for the Dermacell AWM skin substitute graft procedure when performed in the office, outpatient or surgery center setting of care.

Complete understanding of the product, FDA registration, and directions for use can provide a payor with the information they need to review and approve a procedure.

These resources have been referenced in this guide and can be utilized when required. They can be accessed in the accompanying Tool Kit.

- FDA Registration Letter
  (*DermACELL AWM is registered with the FDA as a human tissue product for 2018)*
- DermACELL AWM Product Brochures
- Instructions for Use (IFU)

For ICD-10-CM/PCS code mappings access the following links.

- http://www.cms.gov/Medicare/Coding/ICD10/2018-ICD-10-PCS-and-GEMs.html
- http://www.cms.gov/Medicare/Coding/ICD10/2018-ICD-10-CM-and-GEMs.html

The following links can also provide information to assist providers when procedures and technologies are considered for reimbursement.

- AMA CPT Code Search Tool
- Medicare Physician Fee Schedule Look-up Tool
- American Association of Tissue Banks (AATB)
- National Association of Insurance Commissioners (NAIC) Homepage
- OMHA ALJ Appeal Status Information System (AASIS)

9. Coverage Summaries

Skin Substitute Graft Procedures

The coverage landscape for Skin Substitute Graft Procedures varies by insurance carrier. Please review policies for all payors on a regular basis for updates and changes.

Coverage defines what medical technologies, services and procedures a health plan will reimburse, and generally varies by payor. Private health plans, as well as Medicare, may vary in their consideration of coverage for a particular technology or procedure. Further, the patient's individual benefit plan will delineate what items and services may be covered by the health plan.

Case by case pre-authorization approval should be considered following specific payor guidelines for the pre-authorization and appeal process.

Please check and confirm your insurer's specific medical policies and pre-authorization guidelines to help facilitate the attainment of coverage. It is the provider's and patient's responsibility to verify coverage based upon the patient's health plan and individual plan benefit.

Even where medical policies may deny separate reimbursement for specific Skin Substitute Grafts it may still be possible to obtain reimbursement on a case by case basis through utilization of the health plan's pre-authorization process.

General guidance regarding this pre-authorization process, including documentation required as well as instructions for handling subsequent denials and appeals, is provided in this Resource Guide. Pre-authorization signifies that the health plan has given a general approval of treatment for the patient before the procedure has actually occurred. Final approval and reimbursement is only given after claim submittal and at the time of adjudication by the health plan.

10. Supportive Literature

Dermacell

The following literature links may provide additional information about the use of DermACELL acellular dermal matrix to support medical necessity.

- Walters J, Cazzell S. Healing Rates in a Multicenter Assessment of a Sterile, Room Temperature, Acellular Dermal Matrix Versus Conventional Care Wound Management and an Active Comparator in the Treatment of Full-Thickness Diabetic Foot Ulcers. *Open Access Journal of Plastic Surgery*. 2016; 16: e10.
  Access at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4750365/

- Cole W, Samsell B. Biological Incorporation of Human Acellular Dermal Matrix used in Achilles Tendon Repair. *Cell and Tissue Banking.* 2017; Volume 178, Issue 3, pp 403-411.
  Access at: https://link.springer.com/article/10.1007/s10561-017-9628-3

- Cole W. DermACELL: Human Acellular Dermal Matrix Allograft A Case Report. *J Am Podiatr Med Assoc.* 2013; Mar, 106(2):133-7.
  Access at: https://www.ncbi.nlm.nih.gov/pubmed/27031550

- Cornwell KG, Landsman A. Extracellular Matrix Biomaterials for Soft Tissue Repair. *Clin Podiatr Med Surg.* 2009; Oct; 26(4): 507-23.
  Access at: https://www.ncbi.nlm.nih.gov/pubmed/19778685

- Capito A, Tholpady S. Evaluation of Host Tissue Integration, Revascularization, and Cellular Infiltration within Various Dermal Substrates. *Annals of Plastic Surgery*. 2012; 68(5): 495-500.
  Access at: https://www.ncbi.nlm.nih.gov/pubmed/22531405

- Yonehiro L. Use of new acellular dermal matrix for treatment of non-healing wounds in the lower extremities of patients and diabetes. *Wounds.* 2013; 25(12):340-4.
  Access at: https://www.ncbi.nlm.nih.gov/pubmed/25867746

- Bertasi G. Case study: Treatment of Diabetic Foot Ulcer with Human Acellular Dermal Matrix (ADM). 68-20-108.
  Access at: https://www.lifenethealth.org/sites/default/files/files/68-20-143%282%29.pdf

- Buchbaum EJ. Case study: Treatment of Plantar Diabetic Ulcer with Human Acellular Dermal Matrix. (ADM).
  Access at: https://www.lifenethealth.org/sites/default/files/files/68-20-143%282%29.pdf

- Cazzell S, Vayser D. A Randomized Clinical Trial of a Human Acellular Dermal Matrix Demonstrated Superior Healing Rates for Chronic Diabetic Foot Ulcers Over Conventional Care Access at: Access at: https://www.ncbi.nlm.nih.gov/pubmed/28544150

- Mulder G. Tissue Augmentation and Replacement of a Heel Fat Pad with a Decellularized Sterile Human Dermal Matrix. *Wounds.* 2012; 24(7):185-9.
  Access at: https://www.ncbi.nlm.nih.gov/pubmed/25874540

- Roussalis J. Novel Use of an Acellular Dermal Matrix Allograft to Treat a Chronic Scalp Wound with Bone Exposure: A case study. *Int J Burn Trauma.* 2014;4(2):49-52.
  Access at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4212880/

- Shitrit SB. Use of a Novel Acellular Dermal Matrix allograft to Treat Complex Trauma Wound: a case study. *Int J Burn Trauma.* 2014;4(2):62-5.
  Access at: https://www.ncbi.nlm.nih.gov/pubmed/25356372

- Cazzell S, Vayser D. A Multicenter, Randomized Study to Access a Sterile, Hydrated Acellular Dermal Matrix Versus Conventional Care Wound Management in Subjects with Venous Stasis Ulcers: A Interim Analysis. (CR-006) *SAWC* April 29-May 3, 2015.
  Access at: https://www.lifenethealth.org/sites/default/files/files/68-20-143%282%29.pdf

- Cazzell S, Vayser D. A Multicenter, Randomized Study to Access a Sterile, Hydrated Acellular Dermal Matrix Versus Conventional Care Wound Management in Subjects with Venous Stasis Ulcers: A Interim Analysis. (CR-004) *SAWC* September 26-28, 2015.
  Access at: https://www.lifenethealth.org/sites/default/files/files/68-20-143%282%29.pdf

- Deanesi W. Case Report: Treatment of a Venous Leg Ulcer Using DermACELL®, a Human Acellular Dermal Matrix (ADM).
  Access at: https://www.lifenethealth.org/sites/default/files/files/68-20-143%282%29.pdf

- Chen SG, Tzeng YS. Case Report: Treatment of a Severe Burn with DermACELL®, an Acellular Dermal Matrix. *Int J Burn Trauma.* 2012;2(2):105-9.
  Access at: https://pdfs.semanticscholar.org/9911/283883f2cf5a2a22d0ecad80f43d35e21741.pdf