CLINICAL MEDICAL POLICY	
Policy Name:	Skin Replacement Therapy for Chronic Non-healing Wounds in the Outpatient Setting
Policy Number:	MP-032-MD-PA
Approved By:	Medical Management
Provider Notice Date:	04/01/2017
Original Effective Date:	05/01/2017
Annual Approval Date:	03/06/2018
Revision Date:	NA
Products:	Pennsylvania Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 26

Disclaimer

Gateway Health℠ (Gateway) medical payment and prior-authorization policy is intended to serve only as a general reference resource regarding payment and coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT:

Gateway Health℠ provides coverage under the medical-surgical benefits of the Company's Medicaid products for medically necessary skin replacement products when used in the treatment of chronic, non-healing wounds.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrants individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

DEFINITIONS:

Prior Authorization Review Panel – A panel of representatives from within the Pennsylvania Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

Autologous/Autografts Skin Grafts – Permanent skin coverings that use skin from other parts of the patient's body.

Allograft – Skin from another human being (e.g., cadaver) used as a temporary skin replacement and must be replaced by either an autograft or the ingrowth of the patient's own skin.

Bio-engineered Skin and Soft Tissues – Tissues that may be derived from human tissue (autologous or allogeneic), non-human tissue (xenographic), synthetic material, or a composite of these materials.

Acellular Products – Skin products that contains a matrix or scaffold composed of materials such as collagen, hyaluronic acid, and fibronectin.

Cellular Products – Skin products that contain living cells such as fibroblasts and keratinocytes with a matrix.

Chronic Wound – A wound that does not respond to standard wound treatment for at least a 30-day period during organized comprehensive therapy.

Failed Response – 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.

Standard Treatment of Chronic Lower Extremity Ulcers – Therapies that primarily includes: infection and edema control, mechanical off-loading, mechanical compression or limb elevation, debridement of necrotic or infected tissue, and management of concomitant medical issues (i.e., blood glucose control, tobacco use).

Lower Extremity – Anatomically defined as the hip, thigh, leg, ankle and foot.

PROCEDURES:

This medical policy addresses the use of skin replacement products for the treatment of chronic non-healing wounds.
The goal of this treatment is to provide temporary wound coverage, complete wound closure, reduced time to heal, lessen pain, minimize post-operative contracture, and improve overall quality of health.

The following general information is required for all covered indications:

- The ordering provider must be a physician licensed by the state with full scope of practice for the treatment of the systemic disease process that is responsible for causing the chronic non-healing wound.; AND
- In the situation when the performing provider is NOT the physician caring for the systemic disease, the performing provider must document in the medical record that he/she is aware of the systemic condition and notates the identity of the physician who is responsible for care related to the condition; AND
- Failure of Response is defined as an ulcer or skin deficit that has failed to respond to clearly documented appropriate wound care, has a wound that has increased in size or depth, or has not changed in baseline size or depth, and there is no indication that improvement is expected; AND

- There must be evidence of adequate arterial blood supply (e.g., ankle-brachial index of 0.65 or greater in the affected limb; AND
- There must be an evaluation and provision for adequate nutritional status, including pre-albumin and albumin levels.

1. Chronic Non-Healing Wounds
   In addition to the general information above, the following wound-specific medical necessity criteria must be met:
   a. Diabetic Foot Ulcers (DFU)
      1) Presence of a neuropathic diabetic foot ulcer of greater than four weeks which has failed to respond to documented conservative wound care measures such as surgical debridement, complete off-loading, and standard dressing changes; AND
      2) There must be documentation of patient compliance with all conservative wound care measures; AND
      3) The foot ulcer must extend through the dermis but without tendon, muscle, joint capsule or bone exposure; AND
      4) The diabetes is well managed and the HbA1C is within an acceptable range.

   b. Venous Leg Ulcers (VLU)
      1) The presence of a venous stasis ulcer which has not responded to documented appropriate therapy for greater than four weeks. These therapies would include the use of compression therapy using multilayer dressings or compression stockings with greater than 20 mmHG pressure or pneumatic compression; AND
      2) There must be documentation that the patient has been compliant with wound care measures.

2. Documentation requirements for all wound types
   a. Medical record documentation includes measurements of the initial ulcer, measurements at the completion of at least four weeks of appropriate wound care, and measurements immediately prior to skin replacement product and with each subsequent placement of skin products;
   b. Medical record documentation that specifically states the reason that the wound has failed to heal with standard wound care;
   c. Medical record documentation that demonstrates that the medical policy criteria have been met, along with appropriate diagnoses and response to treatment(s);
   d. Medical record has clear descriptions of the wound(s) relative to the location, stage, size duration and presence or lack of infection. There must be a wound description pre- and post-treatment with each skin replacement application.
   e. Documentation of the amount of skin replacement product used and amount wasted.
   f. Timing, frequency and number of reapplications of bioengineered skin substitutes should be appropriate for the material used and clinical condition of the patient.
   g. In a course of treatment, repeat application of skin substitutes/replacements are not indicated when application prior to were unsuccessful.

3. Contraindications
   Presence of any of the following:
      - Edema, venous hypertension or lymphedema
      - Active cellulitis, osteomyelitis, foreign body or malignant process
      - Tunneling and tracts, eschar and necrotic material

4. Covered Products
   Covered skin replacement products include: AlloDerm®, Apligraf®, Dermagraft®, Epifix®, Grafix®Core, Graft Jacket® Regeneration Tissue Matrix, Integra™, Oasis® Wound Matrix, and TheraSkin®.

5. Length of Coverage
   A single application of skin replacement products is usually all that is necessary in order to effect wound healing in wounds that are likely to be improved by this therapy. The use of more than two applications for the same ulcer within six months is considered not medically necessary. Requests for additional skin replacement applications will be reviewed on a case-by-case basis with supporting medical record documentation.

   Retreatment within one year following successful initial treatment (up to two applications) is not considered medically necessary.

6. When services are not covered
   a. Services are not covered for conditions other than those listed above because the scientific evidence has not been established.
   b. Services are not covered for the use of a skin replacement product for indications not approved by the FDA or in accordance with the manufacturer's package guidelines.
   c. Services are not covered for the use of Autologous Platelet Rich Plasma (PRP) and are considered experimental/investigation and therefore considered not medically necessary.
   d. Simultaneous use of more than one product for the episode of the wound is not covered.

7. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Gateway Health℠ at any time pursuant to the terms of your provider agreement.

8. Place of Service
   The place of service for the placement of skin replacement products can be outpatient, or provider office.

Governing Bodies Approval

Based on the skin substitute's composition and origin, the U.S. Food and Drug Administration (FDA) regulates skin substitutes under one of the following categories:

- Human- and human/animal-derived products regulated through the premarket approval (PMA) process
- Animal-derived products and synthetic products regulated through the 510(k) process
- Human-derived products regulated as human cells, tissue, and cellular and tissue-based products (HCT/Ps)
- Human- and human/animal-derived products regulated as a Humanitarian Use Device (HUD) obtained through a Humanitarian Device Exemption (HDE).

Premarket approval is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or that present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with Class III devices, the FDA has determined that general and special controls alone are insufficient to ensure the safety and effectiveness of Class III devices. Therefore, these devices require a premarket approval application in order to obtain marketing clearance.

PMA is the most stringent type of device marketing application required by the FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by the FDA that there is sufficient valid scientific evidence to ensure that the device is safe and effective for its intended use(s).

FDA PREMARKETING NOTIFICATION (510[k])
A Premarketing Notification (510[k]) is a process in which applicants must demonstrate that the device to be marketed (i.e., a Class II device) is "substantially equivalent" to a pre-existing legally marketed device (predicate) in terms of safety and effectiveness. The predicate must have been approved either via PMA or 510(k). This process is usually used when manufacturers make small changes to a previously approved device that are thought to improve effectiveness without compromising safety, thus allowing for expedited approval without costly and lengthy scientific studies confirming safety and effectiveness.

HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)
Cells and tissues taken from human donors and transplanted to a recipient are regulated under Public Health Services (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). CBER 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 the FDA and list their HCT/Ps. HCT/Ps establishments are not required to demonstrate the safety or effectiveness of their products and the FDA does not evaluate the safety or effectiveness of these products.

HUMANITARIAN DEVICE EXEMPTION (HDE)
In rare instances, certain medical devices intended to be used for humanitarian purposes are evaluated by the FDA through the Humanitarian Device Exemption (HDE) process. A device approved in this manner is designated as a Humanitarian Use Device (HUD). A HUD designation permits the use of certain medical devices when there is no comparable device available to treat or diagnose a disease or condition affecting fewer than 4,000 individuals annually. Because clinical investigation demonstrating the device's efficacy is not feasible (given the low prevalence of the disease in the population), an HDE grants manufacturers an exemption to the usual premarket approval process and allows marketing of the device only for the FDA-labeled HDE indication(s).

Under FDA requirements, an HUD may only be used after institutional review board (IRB) approval has been obtained for the use of the device in accordance with the FDA-labeled indication(s) under the HDE.

A. Platelet Rich Plasma (PRP)
FDA
The injection of PRP is a procedure and therefore, not subject to FDA regulation. However, any medical devices, drugs, biologics, or tests used as part of this procedure may be subject to FDA regulation.

Centers for Medicare and Medicaid Services (CMS)
Effective August 2, 2012, upon reconsideration, CMS determined that platelet rich plasma—an autologous blood-derived product—would be covered only for the treatment of chronic non-

healing diabetic, venous and/or pressure wounds and only when the patient is enrolled in a clinical trial that addresses certain questions when the clinical trial uses validated and reliable methods of evaluation. Any clinical study undertaken pursuant to the NCD needed to be approved no later than August 2, 2104. If there are no approved clinical studies on or before August 2, 2104, this Coverage with Evidence Development (CED) would expire. Any clinical study approved must adhere to the timeframe designated in the approved clinical study protocol. Medicare has no other National Coverage Determination (NCD) for PRP. No updates to this position were identified at the time of this medical policy development.

There are no Local Coverage Determinations (LCD) identified.

CODING REQUIREMENTS:

Procedure Codes

CPT/HCPCS Codes	Description
15150	Tissue cultured skin autograft, trunk, arms, legs; first 25 sq. cm or less
15151	Tissue cultured skin autograft, trunk, arms, legs; additional 1 sq. cm (list separately in addition to code for primary procedure
15152	Tissue cultured skin autograft, trunk, arms, legs; each additional 100 sq. cm, or each additional 1% of body area of infants and children, or part thereof. (list separately in addition to code for primary procedure)
15155	Tissue cultured skin autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 25 sq. cm or less
15156	Tissue cultured skin autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; additional 1 sq. cm to 75 sq. cm (list separately in addition to code for primary procedure)
15157	Tissue cultured skin autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)
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
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 of primary procedure)
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 area, or 1% of body area of 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)
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

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
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 up to 100 sq. cm; first 100 sq. cm wound surface area, or 1% of body of infants and children
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 up 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)
15777	Implantation of biologic implant (e.g., acellular dermal matrix) for soft tissue reinforcement (i.e., breast trunk). (list separately in addition to code for primary procedure)
Q4100	Skin substitute, not otherwise specified
Q4101	Apligraf, per sq. cm
Q4102*	Oasis wound matrix, per sq. cm **(Covered)**
Q4103*	Oasis burn matrix, per sq. cm (Covered)
Q4104	Integra bilayer matrix wound dressing (BMWD), per sq. cm
Q4105*	Integra dermal regeneration template (DRT), per sq. cm **(Covered)**
Q4106	Dermagraft, per sq. cm (**Covered**)
Q4107*	GRAFTJACKET, per sq. cm (**Covered**)
Q4108	Integra matrix, per sq. cm
Q4110	PriMatrix, per sq. cm
Q4112	Cymetra, injectable, 1cc
Q4114	Integra flowable wound matrix, injectable, 1 cc
Q4115	AlloSkin, per sq. cm
Q4116	AlloDerm, per sq. cm
Q4117	HYALOMATRIX, per sq. cm
Q4118	MatriStem micromatrix, 1 mg
Q4119	Matristem wound matrix, psmx, rs, or psm, per square centimeter
Q4120	MatriStem burn matrix, per sq. cm
Q4121*	TheraSkin, per sq. cm (**Covered**)
Q4122	Dermacell, per sq. cm
Q4123	AlloSkin RT, per sq. cm
Q4125	Arthroflex, per sq. cm
Q4126	Memoderm, dermaspan, tranzgraft or integuply, per sq. cm
Q4127	Talymed, per sq. cm
Q4128	FlexHD, Acellular Hydrated Dermis
Q4129	Unite Biomatrix, per sq. cm
Q4130	Strattice TM, per sq. cm
Q4131*	Epifix, per sq. cm (Covered)
Q4132*	Grafix core, per sq. cm (Covered)
Q4133	Grafix prime, per sq. cm

Q4134	hMatrix, per sq. cm
Q4135	Mediskin, per sq. cm
Q4136	Ez-derm, per sq. cm
Q4137	Amnioexcel or biodexcel, per sq. cm
Q4138	Biodfence Dryflex, per sq. cm
Q4139	Amniomatrix or biodmatrix, injectable, 1 cc
Q4140	Biodfence, per sq. cm
Q4141	AlloSkin AC, per sq. cm
Q4142	XMC Biologic tissue matrix, per sq. cm
Q4143	Repriza, per sq. cm
Q4146	TenSIX, per sq. cm
Q4147	Architect, architect PX, or architect FX, extracellular matrix, per sq. cm
Q4148	Neox 1k, per sq. cm
Q4149	Excellagen, 0.1 cc
Q4150	AlloWrap DS or dry, per sq. cm
Q4151	Amnioband or guardian, per sq. cm
Q4152	Dermapure, per sq. cm
Q4153	Dermavest and plurivest, per sq. cm
Q4154	Biovance, per sq. cm
Q4155	Neoxflo or clarixflo, 1mg
Q4156	Neox 100, per sq. cm
Q4157	Revitalon, per sq. cm
Q4158	Marigen, per sq. cm
Q4159	Affinity, per sq. cm
Q4160	Nushield, per sq. cm
Q4161	Bio-Connekt wound matrix, per sq. cm
Q4162	Amniopro flow, bioskin flow, biorenew flow, woundex flow, amniogen-a, amniogen-c, 0.5 cc
Q4163	Amniopro, bioskin, biorenew, woundex, amniogen-45, amniogen-200, per sq. cm
Q4164	Helicoll, per sq. cm
Q4165	Keramatrix, per sq. cm
HCPCS Codes	**Description**
C5271	Application of low cost 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
C5272	Application of low cost 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 procedure)
C5273	Application of low cost 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 infants and children
C5274	Application of low cost 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)

C5275	Application of low cost 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
C5276	Application of low cost 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)
C5277	Application of low cost 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

Noncovered Procedure Codes

CPT Code	Description
Q4111*	GammaGraft, per sq. cm
Q4113*	GRAFT JACKET XPRESS, injectable, 1cc
Q4124*	OASIS ultra tri-layer wound matrix, per sq. cm
Q4145*	Epifix, injectable, 1 mg
0232T	Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed
G0460	Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment
P9020	Platelet rich plasma, each unit
P9022	Red blood cells, washed, each unit
S9055	Procuren or other growth factor preparation to promote wound healing

*= TAG Decision

Diagnosis Codes

ICD 10 Codes	Description
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast

C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.512	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
D05.00	Lobular carcinoma in situ of unspecified breast
D05.01	Lobular carcinoma in situ of right breast
D05.02	Lobular carcinoma in situ of left breast
D05.10	Intraductal carcinoma in situ of unspecified breast
D05.11	Intraductal carcinoma in situ of right breast
D05.12	Intraductal carcinoma in situ of left breast

D05.80	Other specified type of carcinoma in situ of unspecified breast
D05.81	Other specified type of carcinoma in situ of right breast
D05.82	Other specified type of carcinoma in situ of left breast
D05.90	Unspecified type of carcinoma in situ of unspecified breast
D05.91	Unspecified type of carcinoma in situ of right breast
D05.92	Unspecified type of carcinoma in situ of left breast
E08.621	Diabetes mellitus due to underlying condition with foot ulcer [full-thickness neuropathic diabetic foot ulcers of greater than 3-weeks duration]
E09.621	Drug or chemical induced diabetes mellitus with foot ulcer [full-thickness neuropathic diabetic foot ulcers of greater than 3-weeks duration]
E10.621	Type 1 diabetes mellitus with foot ulcer [full-thickness neuropathic diabetic foot ulcers of greater than 3-weeks duration]
E11.621	Type 2 diabetes mellitus with foot ulcer [full-thickness neuropathic diabetic foot ulcers of greater than 3-weeks duration]
E13.621	Other specified diabetes mellitus with foot ulcer [full-thickness neuropathic diabetic foot ulcers of greater than 3-weeks duration]
E13.622	Other specified diabetes mellitus with other skin ulcer
I70.231	Atherosclerosis of native arteries of right leg with ulceration of thigh
I70.232	Atherosclerosis of native arteries of right leg with ulceration of calf
I70.233	Atherosclerosis of native arteries of right leg with ulceration of ankle
I70.234	Atherosclerosis of native arteries of right leg with ulceration of heel and midfoot
I70.235	Atherosclerosis of native arteries of right leg with ulceration of other part of foot
I70.238	Atherosclerosis of native arteries of right leg with ulceration of other part of lower right leg
I70.241	Atherosclerosis of native arteries of left leg with ulceration of thigh
I70.242	Atherosclerosis of native arteries of left leg with ulceration of calf
I70.243	Atherosclerosis of native arteries of left leg with ulceration of ankle
I70.244	Atherosclerosis of native arteries of left leg with ulceration of heel and midfoot
I70.245	Atherosclerosis of native arteries of left leg with ulceration of other part of foot
I70.248	Atherosclerosis of native arteries of left leg with ulceration of other part of lower left leg
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
I70.331	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of thigh
I70.332	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of calf
I70.333	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of ankle
I70.334	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of heel and midfoot
I70.335	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of other part of foot
I70.338	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of other part of lower leg

I70.341	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of thigh
I70.342	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of calf
I70.343	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of ankle
I70.344	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of heel and midfoot
I70.345	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of other part of foot
I70.348	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of other part of lower leg
I83.011	Varicose veins of right lower extremity with ulcer of thigh
I83.012	Varicose veins of right lower extremity with ulcer of calf
I83.013	Varicose veins of right lower extremity with ulcer of ankle
I83.014	Varicose veins of right lower extremity with ulcer of heel and midfoot
I83.015	Varicose veins of right lower extremity with ulcer other part of foot
I83.018	Varicose veins of right lower extremity with ulcer other part of lower leg
I83.021	Varicose veins of left lower extremity with ulcer of thigh
I83.022	Varicose veins of left lower extremity with ulcer of calf
I83.023	Varicose veins of left lower extremity with ulcer of ankle
I83.024	Varicose veins of left lower extremity with ulcer of heel and midfoot
I83.025	Varicose veins of left lower extremity with ulcer other part of foot
I83.028	Varicose veins of left lower extremity with ulcer other part of lower leg
I83.211	Varicose veins of right lower extremity with both ulcer of thigh and inflammation
I83.212	Varicose veins of right lower extremity with both ulcer of calf and inflammation
I83.213	Varicose veins of right lower extremity with both ulcer of ankle and inflammation
I83.214	Varicose veins of right lower extremity with both ulcer of heel and midfoot and inflammation
I83.215	Varicose veins of right lower extremity with both ulcer other part of foot and inflammation
I83.218	Varicose veins of right lower extremity with both ulcer of other part of lower extremity and inflammation
I83.221	Varicose veins of left lower extremity with both ulcer of thigh and inflammation
I83.222	Varicose veins of left lower extremity with both ulcer of calf and inflammation
I83.223	Varicose veins of left lower extremity with both ulcer of ankle and inflammation
I83.224	Varicose veins of left lower extremity with both ulcer of heel and midfoot and inflammation
I83.225	Varicose veins of left lower extremity with both ulcer other part of foot and inflammation
I83.228	Varicose veins of left lower extremity with both ulcer of other part of lower extremity and inflammation
I87.011	Post thrombotic syndrome with ulcer of right lower extremity
I87.012	Post thrombotic syndrome with ulcer of left lower extremity
I87.013	Post thrombotic syndrome with ulcer of bilateral lower extremity
I87.031	Post thrombotic syndrome with ulcer and inflammation of right lower extremity

I87.032	Post thrombotic syndrome with ulcer and inflammation of left lower extremity
I87.033	Post thrombotic syndrome with ulcer and inflammation of bilateral lower extremity
I87.311	Chronic venous hypertension (idiopathic) with ulcer of right lower extremity
I87.312	Chronic venous hypertension (idiopathic) with ulcer of left lower extremity
I87.313	Chronic venous hypertension (idiopathic) with ulcer of bilateral lower extremity
I87.331	Chronic venous hypertension (idiopathic) with ulcer and inflammation of right lower extremity
I87.332	Chronic venous hypertension (idiopathic) with ulcer and inflammation of left lower extremity
I87.333	Chronic venous hypertension (idiopathic) with ulcer and inflammation of bilateral lower extremity
L89.152	Pressure ulcer of sacral region, stage 2
L89.153	Pressure ulcer of sacral region, stage 3
L89.154	Pressure ulcer of sacral region, stage 4
L89.212	Pressure ulcer of right hip, stage 2
L89.213	Pressure ulcer of right hip, stage 3
L89.214	Pressure ulcer of right hip, stage 4
L89.222	Pressure ulcer of left hip, stage 2
L89.223	Pressure ulcer of left hip, stage 3
L89.224	Pressure ulcer of left hip, stage 4
L89.312	Pressure ulcer of right buttock, stage 2
L89.313	Pressure ulcer of right buttock, stage 3
L89.314	Pressure ulcer of right buttock, stage 4
L89.322	Pressure ulcer of left buttock, stage 2
L89.323	Pressure ulcer of left buttock, stage 3
L89.324	Pressure ulcer of left buttock, stage 4
L89.42	Pressure ulcer of contiguous site of back, buttock and hip, stage 2
L89.43	Pressure ulcer of contiguous site of back, buttock and hip, stage 3
L89.44	Pressure ulcer of contiguous site of back, buttock and hip, stage 4
L89.512	Pressure ulcer of right ankle, stage 2
L89.513	Pressure ulcer of right ankle, stage 3
L89.514	Pressure ulcer of right ankle, stage 4
L89.522	Pressure ulcer of left ankle, stage 2
L89.523	Pressure ulcer of left ankle, stage 3
L89.524	Pressure ulcer of left ankle, stage 4
L89.612	Pressure ulcer of right heel, stage 2
L89.613	Pressure ulcer of right heel, stage 3
L89.614	Pressure ulcer of right heel, stage 4
L89.622	Pressure ulcer of left heel, stage 2
L89.623	Pressure ulcer of left heel, stage 3
L89.624	Pressure ulcer of left heel, stage 4
L89.892	Pressure ulcer of other site, stage 2
L89.893	Pressure ulcer of other site, stage 3
L89.894	Pressure ulcer of other site, stage 4
L97.111	Non-pressure chronic ulcer of right thigh limited to breakdown of skin

L97.112	Non-pressure chronic ulcer of right thigh with fat layer exposed
L97.113	Non-pressure chronic ulcer of right thigh with necrosis of muscle
L97.114	Non-pressure chronic ulcer of right thigh with necrosis of bone
L97.121	Non-pressure chronic ulcer of left thigh limited to breakdown of skin
L97.122	Non-pressure chronic ulcer of left thigh with fat layer exposed
L97.123	Non-pressure chronic ulcer of left thigh with necrosis of muscle
L97.124	Non-pressure chronic ulcer of left thigh with necrosis of bone
L97.211	Non-pressure chronic ulcer of right calf limited to breakdown of skin
L97.212	Non-pressure chronic ulcer of right calf with fat layer exposed
L97.213	Non-pressure chronic ulcer of right calf with necrosis of muscle
L97.214	Non-pressure chronic ulcer of right calf with necrosis of bone
L97.221	Non-pressure chronic ulcer of left calf limited to breakdown of skin
L97.222	Non-pressure chronic ulcer of left calf with fat layer exposed
L97.223	Non-pressure chronic ulcer of left calf with necrosis of muscle
L97.224	Non-pressure chronic ulcer of left calf with necrosis of bone
L97.311	Non-pressure chronic ulcer of right ankle limited to breakdown of skin
L97.312	Non-pressure chronic ulcer of right ankle with fat layer exposed
L97.313	Non-pressure chronic ulcer of right ankle with necrosis of muscle
L97.314	Non-pressure chronic ulcer of right ankle with necrosis of bone
L97.321	Non-pressure chronic ulcer of left ankle limited to breakdown of skin
L97.322	Non-pressure chronic ulcer of left ankle with fat layer exposed
L97.323	Non-pressure chronic ulcer of left ankle with necrosis of muscle
L97.324	Non-pressure chronic ulcer of left ankle with necrosis of bone
L97.411	Non-pressure chronic ulcer of right heel and midfoot limited to breakdown of skin
L97.412	Non-pressure chronic ulcer of right heel and midfoot with fat layer exposed
L97.413	Non-pressure chronic ulcer of right heel and midfoot with necrosis of muscle
L97.414	Non-pressure chronic ulcer of right heel and midfoot with necrosis of bone
L97.421	Non-pressure chronic ulcer of left heel and midfoot limited to breakdown of skin
L97.422	Non-pressure chronic ulcer of left heel and midfoot with fat layer exposed
L97.423	Non-pressure chronic ulcer of left heel and midfoot with necrosis of muscle
L97.424	Non-pressure chronic ulcer of left heel and midfoot with necrosis of bone
L97.511	Non-pressure chronic ulcer of other part of right foot limited to breakdown of skin
L97.512	Non-pressure chronic ulcer of other part of right foot with fat layer exposed
L97.513	Non-pressure chronic ulcer of other part of right foot with necrosis of muscle
L97.514	Non-pressure chronic ulcer of other part of right foot with necrosis of bone
L97.521	Non-pressure chronic ulcer of other part of left foot limited to breakdown of skin
L97.522	Non-pressure chronic ulcer of other part of left foot with fat layer exposed
L97.523	Non-pressure chronic ulcer of other part of left foot with necrosis of muscle
L97.524	Non-pressure chronic ulcer of other part of left foot with necrosis of bone
L97.811	Non-pressure chronic ulcer of other part of right lower leg limited to breakdown of skin
L97.812	Non-pressure chronic ulcer of other part of right lower leg with fat layer exposed
L97.813	Non-pressure chronic ulcer of other part of right lower leg with necrosis of muscle
L97.814	Non-pressure chronic ulcer of other part of right lower leg with necrosis of bone

L97.821	Non-pressure chronic ulcer of other part of left lower leg limited to breakdown of skin
L97.822	Non-pressure chronic ulcer of other part of left lower leg with fat layer exposed
L97.823	Non-pressure chronic ulcer of other part of left lower leg with necrosis of muscle
L97.824	Non-pressure chronic ulcer of other part of left lower leg with necrosis of bone
L97.912	Non-pressure chronic ulcer of unspecified part of right lower leg with fat layer exposed
L97.913	Non-pressure chronic ulcer of unspecified part of right lower leg with necrosis of muscle
L97.914	Non-pressure chronic ulcer of unspecified part of right lower leg with necrosis of bone
L97.922	Non-pressure chronic ulcer of unspecified part of left lower leg with fat layer exposed
L97.923	Non-pressure chronic ulcer of unspecified part of left lower leg with necrosis of muscle
L97.924	Non-pressure chronic ulcer of unspecified part of left lower leg with necrosis of bone

REIMBURSEMENT:

Participating facilities will be reimbursed per their Gateway Health℠ contract.

POLICY SOURCE(S):

AediCell. Dermavest. [AediCell Web site]. Available at: http://aedicell.com/about/. Accessed on October 5, 2016.

Agency for Healthcare Research and Quality (AHRQ). Skin substitutes for treating chronic wounds. 2011. Available at: https://www.pharmamedtechbi.com/~/media/Supporting%20Documents/The%20Gray%20Sheet/38/2/skinsubstitutes_ahrq. Accessed on October 5, 2016.

Pennsylvania Department of Human Services. Technology Assessment Group Coverage Decisions. Managed Care Operations Memorandum: OP # 01/2016-001. Option # 2. Available at: https://dpwintra.dpw.state.pa.us/HealthChoices/custom/post/mcopsmemo/mcopsmemo.asp. Accessed on October 17, 2016.

Pennsylvania Department of Human Services. Technology Assessment Group Coverage Decisions. Managed Care Operations Memorandum: OP #02/2008-005. Graft Jacket Flowable Scaffold. Option #4. Available at: https://dpwintra.dpw.state.pa.us/HealthChoices/custom/post/mcopsmemo/mcopsmemo.asp. Accessed on October 17, 2016.

Pennsylvania Department of Human Services. Technology Assessment Group Coverage Decisions. Managed Care Operations Memorandum: OP #12/2014-014. Graft Jacket Xpress. Option #4. Available at: https://dpwintra.dpw.state.pa.us/HealthChoices/custom/post/mcopsmemo/mcopsmemo.asp. Accessed on October 17, 2016.

Pennsylvania Department of Human Services. Technology Assessment Group Coverage Decisions. Managed Care Operations Memorandum: OP #5/2016-014. Oasis Wound Matrix. Option #3. Available at: https://dpwintra.dpw.state.pa.us/HealthChoices/custom/post/mcopsmemo/mcopsmemo.asp. Accessed on October 17, 2016.

Pennsylvania Department of Human Services. Technology Assessment Group Coverage Decisions. Managed Care Operations Memorandum: OP #Oasis Burn Matrix. Option #3. Available at: https://dpwintra.dpw.state.pa.us/HealthChoices/custom/post/mcopsmemo/mcopsmemo.asp. Accessed on October 17, 2016.

Pennsylvania Department of Human Services. Technology Assessment Group Coverage Decisions. Managed Care Operations Memorandum: OP #05/2016-004. Oasis Ultra TRI-Layer Wound Matrix. Available at: https://dpwintra.dpw.state.pa.us/HealthChoices/custom/post/mcopsmemo/mcopsmemo.asp. Accessed on October 17, 2016.

Pennsylvania Department of Human Services. Technology Assessment Group Coverage Decisions. Managed Care Operations Memorandum: OP #11/2005-006. SafeBlood for wound care (Platelet Rich Plasma Protein). Option #3. Available at: https://dpwintra.dpw.state.pa.us/HealthChoices/custom/post/mcopsmemo/mcopsmemo.asp. Accessed on October 17, 2016.

Pennsylvania Department of Human Services. Technology Assessment Group Coverage Decisions. Managed Care Operations Memorandum: OP #05/2016-004. TheraSkin. Option #3. Available at: https://dpwintra.dpw.state.pa.us/HealthChoices/custom/post/mcopsmemo/mcopsmemo.asp. Accessed on October 17, 2016.

Pennsylvania Department of Human Services. Technology Assessment Group Coverage Decisions. Managed Care Operations Memorandum: OP #07/2005-13. Dermal Tissue of Human Origin. Option #2. Available at: https://dpwintra.dpw.state.pa.us/HealthChoices/custom/post/mcopsmemo/mcopsmemo.asp. Accessed on October 17, 2016.

Pennsylvania Department of Human Services. Technology Assessment Group Coverage Decisions. Managed Care Operations Memorandum: OP #07/2005-13. Dermal/Epidermal Tissue of Non-human Origin. Option #2. Available at: https://dpwintra.dpw.state.pa.us/HealthChoices/custom/post/mcopsmemo/mcopsmemo.asp. Accessed on October 17, 2016.

Pennsylvania Department of Human Services. Technology Assessment Group Coverage Decisions. Managed Care Operations Memorandum: OP #02/2010-010. Integra Dermal Regeneration Template. Option #3. Available at: https://dpwintra.dpw.state.pa.us/HealthChoices/custom/post/mcopsmemo/mcopsmemo.asp. Accessed on October 17, 2016.

UpToDate® Website. Management of diabetic foot ulcers. Sept. 2016. Available at: https://www.uptodate.com/contents/management-of-diabetic-foot-ulcers?source=search_result&search=management%20of%20diabetic%20foot%20ulcers&selectedTitle=1~48. Accessed on October 17, 2016.

AediCell. Dermavest. [AediCell Web site]. Available at: http://aedicell.com/about/. Accessed on October 5, 2016.

Agency for Healthcare Research and Quality {AHRQ). Skin substitutes for treating chronic wounds. 2011. Available le at: http://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/ta/skinsubs/HCPR0610_skinsubst-final.pdf. Accessed on October 5, 2016.

Novitas Solutions, Inc. Local Coverage Determination {LCD) L35041: Application of bioengineered skin substitutes to lower extremity chronic non-healing wounds. Revision Date: 9/8/2016. Available at: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35041&ver=38&name=331*1%7c314*1&UpdatePeriod=685&bc=AQAAEAAAIAAAAA%3d%3d&. Accessed on October 14, 2016.

Centers for Medicare and Medicaid Services. National Coverage Determination {NCD) 270.3: Blood-derived products for chronic non-healing wounds. Implementation Date 7/1/2013. Available at: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=217&ncdver=5&CoverageSelection=National&KeyWord=blood-derived&KeyWordLookUp=Title&KeyWordSearchType=And&ncd_id=270.3&ncd_version=4&basket=ncd*3a%24270.3*3a%244*3a%24blood-derived+products+for+chronic+non-healing+wounds&bc=gAAAACAAAAAAAA%3d%3d&. Accessed on October 14, 2016.

Ehrenreich M, Ruszczak A.Update on tissue-engineered biologic dressing. Tissue Eng. 2006 Sept. 12{9): 2407-24. Available at: https://www.ncbi.nlm.nih.gov/pubmed/16995775. Accessed on October 14, 2016.

United Health Care Medical Policy. Human Skin Equivalents and Skin Substitutes. Available at: https://www.oxhp.com/providers/toolsResources/practicalResources/policy/human_skin.html. Accessed on October 17, 2016.

Martinez-Zapata MJ, Marti-Carvajal AJ, Sola I, et al. Autologous platelet-rich plasma for treating chronic wounds. Cochrane Database Syst Rev. 2012; CD006899.PMID 23076929. Available at: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD006899.pub2/abstract. Accessed on October 18, 2017.

Vannini F, Di Matteo B, et al. Platelet-rich Plasma for foot and ankle pathologies: a systematic review, Foot Ankle Surg 2014; Mar20 (1)2-9. Available at: https://www.ncbi.nlm.nih.gov/pubmed/24480491. Accessed on October 18, 2016.

National Institute for Health and Care Excellence. Diabetic foot problems; prevention and management. NICE guideline [NG19]. August 2015; Updated January 2016. Available at: https://www.nice.org.uk/guidance/ng19. Accessed on October 18, 2016.

American Society of Plastic Surgeons. Evidence-based clinical practice guideline: chronic wounds of the lower extremity. Available at: http://www.plasticsurgery.org/Documents/medical-

professionals/health-policy/evidence-practice/Evidence-based-Clinical-Practice-Guideline-Chronic-Wounds-of-the-Lower-Extremity.pdf. Accessed on October 18, 2016.

Other References

The table below lists skin substitutes, which are represented by a specific HCPCS code, and their approved indications. This list does not include all FDA approved/regulated skin substitutes. This list does not imply coverage for all products. Please refer to the 'Covered Products' section of the policy for details on specific products.

Skin Substitute	Approved Indications
Affinity	Intended to be applied as an on-lay graft for acute and chronic wounds, including, but not limited to, neuropathic ulcers, venous stasis ulcers, pressure ulcers, burns, post-traumatic wounds and post-surgical wounds.
AlloSkin	Indicated for use in chronic wounds, dehisced wounds, diabetic foot ulcers, non/minimally exudating wounds, pressure ulcers, surgical wounds, and venous ulcers.
AlloSkin AC	Indicated for use in chronic wounds, dehisced wounds, diabetic foot ulcers, non/minimally exudating wounds, pressure ulcers, surgical wounds, and venous ulcers.
AlloSkin RT	Indicated for use in chronic wounds, dehisced wounds, diabetic foot ulcers, non/minimally exudating wounds, pressure ulcers, surgical wounds, and venous ulcers.
AmnioBand or Guardian	Intended for interior or exterior wounds including use as a covering for the surgical site. Usage includes various wounds and ulcers and other soft tissue defects.
AmnioExCel or BioDExCel	Used in the treatment of wounds including: diabetic ulcers, venous and arterial ulcers, pressure ulcers, traumatic injuries, surgical wounds, and burns.
AmnioMatrix or BioDMatrix	Used in the treatment of wounds including: diabetic ulcers, venous and arterial ulcers, pressure ulcers, traumatic injuries, surgical wounds, and burns.
Apligraf	Indicated for use with standard therapeutic compression for the treatment of non-infected partial and full-thickness skin ulcers due to venous insufficiency. Indicated for use with standard diabetic foot ulcer care for the treatment of full-thickness neuropathic diabetic foot ulcers and which extend through the dermis but without tendon, muscle, and capsule or bone exposure.
Architect Extracellular Collagen Matrix	Indicated for the local management of moderately to heavy exuding wounds, including: partial and full thickness wounds, draining wounds, pressure sores/ulcers, venous ulcers, chronic vascular ulcers, diabetic ulcers, trauma wounds (e.g., abrasions, lacerations, partial thickness burns, skin tears), surgical wounds (e.g., donor sites/grafts, post-laser surgery, post-Moh's surgery, podiatric wounds, dehisced surgical incisions).

BioDFence	Usage includes allograft application to wounds including: traumatic injuries, burns, Moh's procedures or surgical wounds, diabetic ulcers, venous and arterial leg ulcers, pressure ulcers or cutaneous ulcers.
Biovance	Indicated for a broad range of wound types, including: Moh's surgery, burns, trauma, surgical, venous leg ulcers, diabetic ulcers, pressure ulcers, arterial ulcers.
Clarix Flo	Used in the treatment of partial- and full-thickness wounds including: diabetic foot ulcers, venous leg ulcers, arterial ulcers, and pressure ulcers.
DermACELL	Indications for use include: arterial ulcers, chronic wounds, deep wounds, diabetic foot ulcers, and pressure ulcers.
Dermagraft	Indicated for use in the treatment of full-thickness diabetic foot ulcers, which extend through the dermis, but without tendon, muscle, joint capsule, or bone exposure.
DermaPure	Used as a covering for difficult or hard to heal, acute and chronic wounds.
DermaSpan Acellular Dermal Matrix	Intended use is for the repair or replacement of damaged or inadequate integumental tissue (wound coverage).
Dermavest	An advanced wound therapy for burns, chronic diabetic, decubitus (pressure) and venous stasis wounds.
EpiFix	Used in the treatment of partial and full-thickness wounds including, but not limited to: diabetic foot ulcers, venous leg ulcers, arterial ulcers, pressure ulcers, and inflammatory ulcers.
EpiFix, Injectable	Usage includes injectable applications for neuropathic ulcers, venous stasis ulcers, post traumatic ulcers, post-surgical ulcers and pressure ulcers.
Excellagen	Indicated for the management of wounds including partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/ undermined wounds, surgical wounds (e.g., donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (e.g., abrasions, lacerations, second-degree burns, skin tears) and draining wounds.
E-Z Derm Biosynthetic Wound Dressing	Indicated for use on partial-thickness skin loss, donor sites, skin ulcerations and abrasions. Other applications may include temporary covering for full-thickness skin loss.
GammaGraft	Indications for use include: venous stasis ulcers, diabetic foot ulcers, full thickness ulcers, Moh's surgery sites, skin graft donor sites, partial thickness wounds, and areas of dermabrasion.
Grafix Core	For the management of diabetic foot ulcers, venous stasis ulcers and pressure ulcers that have not responded to standard of care therapy.
Grafix Prime	For the management of diabetic foot ulcers, venous stasis ulcers and pressure ulcers that have not responded to standard of care therapy.
Graftjacket Xpress Flowable Soft Tissue Scaffold	For repair or replacement of damaged or inadequate integumental tissue, such as diabetic foot ulcers, venous leg ulcers, pressure ulcers, or for other homologous uses of human integument.

Graftjacket Regenerative Tissue Matrix (RTM)	For repair or replacement of damaged or inadequate integumental tissue, such as diabetic foot ulcers, venous leg ulcers, pressure ulcers, or for other homologous uses of human integument.
hMatrix Acellular Dermis	Indicated for use to replace damaged or inadequate integumental tissue.
Hyalomatrix PA	Indicated for the management of wounds including: partial and full-thickness wounds, second-degree burns, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undetermined wounds, surgical wounds (e.g., donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (e.g., abrasions, lacerations, skin tears), and draining wounds.
Integra Bilayer Matrix Wound Dressing (BMWD)	Indicated for the management of wounds including: partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (e.g., donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (e.g., abrasions, lacerations, second-degree burns, and skin tears) and draining wounds.
Integra Flowable Wound Matrix	Indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds, (e.g., donor sites/grafts, post-Moh's surgery, post laser surgery, podiatric, wound dehiscence), trauma wounds (e.g., abrasions, lacerations, second-degree burns, skin tears) and draining wounds.
Integra Matrix Wound Dressing	Indicated for the management of wounds including: partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (e.g., donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (e.g., abrasions, lacerations, second-degree burns, and skin tears) and draining wounds.
Integra Meshed Bilayer Wound Dressing	Indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (e.g., donor sites/grafts, post-Moh’s surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (e.g., abrasions, lacerations, second-degree burns, and skin tears) and draining wounds.
Integuply	Typically used in conjunction with a chronic wound care management regimen for the treatment of diabetic ulcers, Charcot foot ulcers, venous ulcers, trauma wounds, pressure ulcers, partial and full thickness wounds, and surgical wounds.
Marigen Omega3 Acellular Dermal Matrix	Indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, chronic vascular ulcers, diabetic ulcers, trauma wounds (e.g., abrasions, lacerations, second-degree burns, skin tears), surgical wounds (e.g., donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), and draining wounds.
MatriStem Burn Matrix	Intended for the management of wounds including: second-degree burns, partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (e.g., donor

	sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (e.g., abrasions, lacerations, skin tears), and draining wounds.
MatriStem MicroMatrix	Intended for the management of topical wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (e.g., donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (e.g., abrasions, lacerations, second-degree burns, and skin tears), and draining wounds.
MatriStem Wound Matrix	Intended for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (e.g., donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (e.g., abrasions, lacerations, second-degree burns, and skin tears), and draining wounds.
Mediskin	Intended for the management of wounds that include: partial and full thickness wounds, pressure ulcers, diabetic ulcers, venous ulcers chronic vascular ulcers, second-degree burns, surgical wounds (e.g., donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (e.g., abrasions, lacerations, skin tears), tunneled/undermined wounds, and draining wounds.
MemoDerm Acellular Dermal Matrix	Intended use is for chronic diabetic foot ulcers.
Neox 100 Wound Matrix	Used in the treatment of partial- and full-thickness wounds including: diabetic foot ulcers, venous leg ulcers, arterial ulcers, and pressure ulcers.
Neox 1k Wound Matrix	Used in the treatment of partial- and full-thickness wounds including: diabetic foot ulcers, venous leg ulcers, arterial ulcers, and pressure ulcers.
Neox Flo	Used in the treatment of partial- and full-thickness wounds including: diabetic foot ulcers, venous leg ulcers, arterial ulcers, and pressure ulcers.
NuShield	Intended to be applied as an on-lay graft for acute and chronic wounds, including, but not limited to, neuropathic ulcers, venous stasis ulcers, pressure ulcers, burns, post-traumatic wounds and post-surgical wounds.
Oasis Burn Matrix	Intended use is for the management of second-degree burns and donor sites.
Oasis Ultra Tri-Layer Wound Matrix	Indicated for the management of: partial and full-thickness wounds, pressure ulcers, venous ulcers, chronic vascular ulcers, tunneled/undermined wounds, diabetic ulcers, trauma wounds (e.g., abrasions, lacerations, second-degree burns, skin tears), surgical wounds (e.g., donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), and draining wounds.
Oasis Wound Matrix	Intended use is for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (e.g., donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (e.g., abrasions, lacerations, second-degree burns, and skin tears), and draining wounds.

PriMatrix Dermal Repair Scaffold	Intended for the management of wounds that include: partial and full thickness wounds, pressure ulcers, diabetic ulcers, venous ulcers, second-degree burns, surgical wounds (e.g., donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (e.g., abrasions, lacerations, and skin tears), tunneled/undermined wounds, and draining wounds.
PuraPly (formerly called Fortaderm Wound Dressing) PuraPly Antimicrobial Wound Dressing (formerly called Fortaderm Antimicrobial Wound Dressing)	Indicated for the management of: partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (e.g., donor sites/grafts, post-Moh's surgery, post-laser surgery, wound dehiscence), trauma wounds (e.g., abrasions, lacerations, second-degree burns, skin tears) and draining wounds.
Revitalon	Indicated for the management of wounds including: diabetic ulcers and venous ulcers.
Talymed	Indicated for the management of wounds including: diabetic ulcers, venous ulcers, pressure wounds, ulcers caused by mixed vascular etiologies, full thickness and partial thickness wounds, second degree burns, surgical wounds (e.g., donor sites/grafts, post-Moh's surgery, post-laser surgery), abrasions, lacerations, traumatic wounds healing by secondary intention, chronic vascular ulcers, and dehisced surgical wounds.
TenSIX Acellular Dermal Matrix	Chronic diabetic foot ulcers
TheraSkin	Can be used to replace or repair skin over any wound, including those with exposed muscle, tendon, bone and joint capsule. This includes, but is not limited to, diabetic foot ulcers, venous leg ulcers, arterial ulcers, pressure sores, dehisced surgical wounds, and wounds that might otherwise require an autograft.
TranZgraft Acellular Dermal Matrix	Intended use is for ulcer repair.
Unite Biomatrix	Intended for the management of moderately to severely exudating wounds, including: partial and full thickness wounds, draining wounds, pressure sores/ulcers, venous ulcers, chronic vascular ulcers, diabetic ulcers, trauma wounds (e.g., abrasions, lacerations, second-degree burns, skin tears), and surgical wounds (e.g., donor sites/grafts, post-laser surgery, post-Moh's surgery, podiatric wounds, dehisced surgical incisions).

Summary of Literature

Chronic wounds of the lower extremity are known to be a condition associated with high prevalence, high cost and poor clinical outcome. Wounds become chronic when they are unresponsive to initial therapy or persistent in the face of appropriate care. The most common types of chronic wounds of the lower extremity are described by their etiology:

- Vascular (e.g. Arterial, venous or mixed ulcers)
- Pressure ulcers
- Neuropathic (e.g. diabetic ulcers)

Skin grafting has evolved from the initial autograft and allograft preparations to biosynthetic and tissue engineered human skin equivalents. There are a large number of potential applications for these products and one large category is non-healing wounds. Non-healing wounds encompass diabetic neuropathic ulcers, vascular insufficiency ulcers and pressure ulcers. These types of wounds are known to heal inadequately with standard wound care, leading to prolonged morbidity and increased risk of mortality.

Numerous clinical trials have been published for the majority of commercially available skin replacement products for several medical conditions ranging from non-healing wounds, pressure ulcer, inflammatory ulcers and burns. In addition, there are ongoing and unpublished trials.

In 2015, the U. K.'s National Institute for Health and Care Excellence (NICE) published clinical guidelines on the prevention and management of diabetic foot problems. NICE recommends that clinicians consider dermal or skin substitutes as an adjunct to standard care when treating diabetic foot ulcers, only when healing has not progressed and on the advice of the multidisciplinary foot care service.

Autologous platelet-derived growth factors are referred to as platelet rich plasma (PRP), autologous platelet gel, or platelet releasate and several PRP preparations available today that are FDA approved. There are PRP preparations intended to be used to mix with bone graft materials in order to enhance bone grafting properties in orthopedic practices. There are two preparations that can be prepared at the bedside for immediate application (e.g., AutoGel and SafeBlood) specifically for wound healing. Procuren® (Cytomedix, Inc.) was another product used for chronic wound healing however, it is no longer manufactured or commercially available.

Platelet-derived growth factor has been suggested for adjunctive use in the management of chronic non-healing wounds. It is not clearly understood how PRP works, but some practitioners speculate that if the acute healing pathways can be activated, the body can be induced to repair damage. Therefore, an injection into the injury site is thought to stimulate an acute injury and may possibly induce an acute healing process.

Several agencies have concluded that the effectiveness of growth factors for this condition have not been adequately established to warrant recommendation for use (AHRQ, 2011) (CMS, 2013). The available studies have mixed results with some trials reporting improvement with PRP and other trials reporting improvement. Additional studies are needed in order to truly resolve these issues.

In 2012, a Cochrane analysis was completed to address autologous PRP used for healing chronic wounds. There were nine eligible random controlled trials (RCT) with a total of 325 participants and 44% were women. Four RCTs recruited patients with mixed chronic wounds, three RCTs for venous leg ulcers and two trials with people with diabetic foot ulcers. The median length of treatment was 12 weeks. The authors reported that there were no statistically significant differences in groups treated with PRP compared to the groups that were not treated with PRP. In conclusion, there is no evidence to suggest that autologous PRP is of value for treating chronic wounds and well-designed, adequately powered clinical trials are needed.

Policy History:

Date	Activity
10/17/2016	Initial policy developed
10/20/2016	QI/UM Committee approval
03/06/2017	PARP approval
05/01/2017	Provider effective date