Department:	Medical Management	**Original Approval:**	08/13/2025
Policy No:	MM211	**Last Approval:**	05/15/2026
Policy Title:	Skin Substitute Grafts and Cellular and Tissue-Based Products Clinical Coverage Criteria		
Approved By:	UM Criteria Subcommittee		
Applicable Line(s) of Business:	☒ **Washington Apple Health (Medicaid)** ☐ **Behavioral Health Services Only** ☒ **Apple Health Expansion** ☐ **Medicare Advantage/Special Needs Plan** ☐ **Medicare Advantage Only** ☒ **Cascade Select**		

Required Clinical Documentation for Review

1. Medical records including history and physical examination and relevant specialty consultation notes that address the problem and need for the service
2. All previous interventions for the problem, including dates, and the patient's response to the intervention (dressings, wound care, debridement procedures).
3. Details of all Standard of Care wound treatments (dressings, wound care, debridement procedures, medications, antibiotics) that have been tried including dates, duration, and patient participation and adherence to the therapy
4. Details of wound measurements over time
5. Pertinent imaging studies and vascular studies
6. General health information including BMI, HbA1C for patients with diabetes, tobacco cessation counseling if applicable
7. Price per square centimeter
8. Details of any specific needs related to risk, trauma, or cultural concerns, specifically to address health equity concerns.

Background

The clinical coverage criteria for Apple Health, Apple Health Expansion, Cascade Select members is based on the CMS LCD: Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers, L39764, as this is a comprehensive resource.

To qualify as skin substitute grafts/cellular and tissue-based products the product must be:

1. A non-autologous human cellular or tissue product (e.g., dermal or epidermal, cellular and acellular, homograft, **OR** allograft), **OR** non-human cellular and tissue product (i.e., xenograft), **OR** biological product (synthetic or xenogeneic) applied as a sheet, allowing scaffold for skin growth, intended to remain on the patient and grow in place or allow patient's cells to grow into the implanted graft material **AND**
2. Supported by high certainty supporting evidence to demonstrate the product's safety, effectiveness, and positive clinical outcomes in the function as a graft for Diabetic Foot Ulcers (DFU) and/or Venous Leg Ulcers (VLU).
3. Note: Liquid or gel preparations are not considered grafts. Their fluidity does not allow graft placement and stabilization of the product on the wound.

1. **CMS Technology Assessment Program: Skin Substitutes for Treating Chronic Wounds (February 2, 2020)**
   https://www.cms.gov/medicare/coverage/determinationprocess/downloads/id109ta.pdf

"Findings: We identified 76 commercially available skin substitutes and categorized them based on the Davison-Kotler classification system. Sixty-eight (89%) were categorized as acellular dermal substitutes, mostly replacements from human placental membranes and animal tissue sources. Three systematic reviews and 22 RCTs examined use of 16 distinct skin substitutes, including acellular dermal substitutes, cellular dermal substitutes, and cellular epidermal and dermal substitutes in diabetic foot ulcers, pressure ulcers, and venous leg ulcers. Twenty-one ongoing clinical trials (all RCTs) examined an additional nine skin substitutes with similar classifications. Studies rarely reported clinical outcomes, such as amputation, wound recurrence at least 2 weeks after treatment ended, or patient-related outcomes, such as return to function, pain, exudate, and odor. The lack of studies examining the efficacy of most skin substitute products and the need for better-designed and -reported studies providing more clinically relevant data in this field are this Technical Brief's clearest implications."

"We found little information on the long-term effects of using skin substitutes. Wound recurrence was seldom reported, and potential toxic or carcinogenic effects are not known. Information on amputations and hospitalizations due to infections is also missing. Before findings can be relied upon, more data are needed on hospitalization, pain reduction, need for amputation, exudate and odor control, and return to baseline activities of daily living and function"

Equity Considerations:

- Disproportionate burden of chronic wounds among people with diabetes, vascular disease, mobility impairments, and older adults—particularly Black, Hispanic, Native American, rural, and low-income members
- Limited access to wound care specialists or clinics, especially in rural and medically underserved areas
- Documentation requirements (e.g., serial measurements, offloading confirmation, frequent visits) may disadvantage members with transportation barriers, unstable housing, or caregiving/work constraints
- Unequal access to adjunctive supports (offloading devices, compression, home health) needed for treatment success

Definitions

Autografts/tissue cultured autografts: The harvest or application of a graft made from the patient's skin. Tissue cultured autografts are grown from the patient's skin and require smaller donor sites.

Chronic Wound: A wound with disrupted healing cycle for 4 weeks or longer, due to impaired circulation, innervation, cellular migration or other causes.

Cellular and Tissue-Based Products (CTP) grafts (also called skin substitute graft): Human cellular and tissue products (dermal or epidermal, cellular and acellular) made from other individuals (allograft and homograft), non-human cellular and tissue products (xenograft), and biological products (synthetic or xenogeneic) that form a scaffold for skin growth when applied in a sheet over an open wound.

Skin substitute: Per the AMA CPT Codebook: "non-human skin substitute grafts and biological products that form a sheet scaffolding for skin growth". This surface is not removed but grows into place and serves as base for growth of new skin.

Cellular, acellular, and matrix-like products (CAMPs): Cellular, acellular, and matrix-like products, also referred to as cellular/tissue product (CTP).

Episode: An episode of skin replacement therapy is defined as 12 to 16 weeks from the first application of a skin substitute graft/CTP.

Failed response: Increased size or depth, no change in baseline size or depth, or no sign of improvement or indication of likely improvement (such as granulation, epithelialization, or progress towards closing.

Healed ulcer (completed healing): Complete re-epithelialization without drainage noted on 2 occasions at least 2 weeks apart.

Scaffolding: a support, delivery vehicle, or matrix for facilitating the migration, binding, or transport of cells or bioactive molecules used to replace, repair, or regenerate tissues.

Stalled Wound: An ulcer that has entered a nonhealing or intransigent phase.

Standard of Care (SOC): Best Practice recommendations for wound care (not a legal definition).

Wound dressing or coverings: Selective barriers to cover and protect wounds from the surrounding environment to promote optimal environment for wound healing

Standard of Care Treatment includes

1. Comprehensive patient assessment including history, exam, vascular evaluation and diagnostic tests indicated as part of the implemented treatment plan.
2. For patients with a diabetic foot ulcer (DFU): assessment of Type 1 or Type 2 diabetes and management history with attention to certain comorbidities (e.g., vascular disease, neuropathy, osteomyelitis), review of current blood glucose levels, hemoglobin A1c (HbA1c), diet and nutritional status, activity level, physical exam including body mass index (BMI), assessment of skin, ulcer, and vascular perfusion. Documentation should include assessment of off-loading device and/or use of appropriate footwear as applicable.
3. For patients with a venous leg ulcer (VLU): The clinical history should include prior ulcers, history of pulmonary embolism or superficial/deep venous thrombosis, number of pregnancies, and physical inactivity. The physical exam should include BMI, edema, skin changes, vascular competence, evaluation of superficial or deep venous reflux, perforator incompetence, and chronic (or acute) venous thrombosis. The documented use of a firm strength compression garment (>20 mmHg) or multi-layered compressive dressings is an essential component of SOC for venous stasis ulcers.

4. An implemented treatment plan to be continued throughout the course of treatment demonstrating all the following:
   a. Debridement as appropriate to a clean granular base.
   b. Documented evidence of offloading for DFU and some form of sustained compression dressings for VLU
   c. Infection control with removal of foreign body or nidus of infection.
   d. Management of exudate with maintenance of a moist environment (moist saline gauze, other classic dressings, bioactive dressing, etc.).
   e. Documentation of smoking history, and counselling on the effect of smoking on wound healing, treatment for smoking cessation, and outcome of counselling, if applicable.
5. Records must show that the patient is under the care of a qualified provider for the treatment of the underlying condition (such as, venous insufficiency, diabetes, neuropathy).

Indications/Criteria

Application of a skin substitute graft/Cellular Tissue Product (CTP) in the treatment of Diabetic Foot Ulcer (DFU) or Venous Leg Ulcer (VLU) is considered medically necessary if the patient meets all the following criteria:

1. The presence of a chronic, non-infected DFU that failed to achieve at least 50% ulcer area reduction with documented standard of care (SOC) treatment for a minimum of 4 weeks with documented compliance.
2. The presence of a chronic, non-infected VLU that failed to respond to documented SOC treatment for a minimum of 4 weeks with documented compliance.
3. The skin substitute graft/cellular tissue product (CTP) is applied to an ulcer having failed to heal or stalled in response to at least 4 weeks of documented SOC treatment. Documentation of response requires measurements of the initial ulcer, pre-SOC ulcer measurements, weekly SOC ulcer measurements, ulcer measurements following (at least) 4 weeks of SOC, ulcer measurements at initial placement of the skin substitute graft/CTP, and ulcer measurements before each subsequent placement of the skin substitute graft/CTP.
4. Established SOC treatment must continue for the course of therapy for both DFU and VLU. Continuous compression therapy for VLU must be documented for the episode of care.

5. The medical record documentation must include the interventions having failed during prior ulcer evaluation and management. The record must include an updated medication history, review of pertinent medical problems diagnosed since the previous ulcer evaluation, and explanation of the planned skin replacement with choice of skin substitute graft/CTP product. The procedure risks and complications must also be reviewed and documented.

The following are considered reasonable and necessary if the above criteria are met:

1. The maximum number of applications considered at one time for the wound(s) is 4 applications in 4 weeks. This is because four applications is the mean number associated with complete wound healing. However, with documentation of medical necessity and of progression of wound closure under the current treatment plan, additional 4 applications in 4 weeks may be allowed, up to a total of 8-16 applications.
2. The usual episode of care for skin substitute graft/CTP is 12 weeks; however, some wounds may take longer to heal. An additional 4 weeks (totaling 16 weeks from initial application) may be medically necessary with documentation demonstrating progression of wound closure under the current treatment plan.
3. The skin substitute graft/CTP must be used in an efficient manner utilizing the most appropriate size product available at the time of treatment. Excessive wastage (discarded amount) should be avoided by utilization of size appropriate packaging of the product consistent with wound size. The graft must be applied in a single layer without overlay of product or adjacent skin in compliance with the correct label application techniques for the skin substitute graft/CTP.
4. Only skin substitute grafts/CTP with labeled indications for use over exposed muscle, tendon or bone can be used in these cases and only in the absence of contraindications (e.g., infected, ischemic, or necrotic wound bed).

The following are considered not reasonable and necessary:

1. Greater than 8 applications of skin substitute graft/CTP within an episode of care (up to 16 weeks).
2. Repeat applications of skin substitute graft/CTP when a previous application was unsuccessful. Unsuccessful treatment is defined as increase in size or depth of an ulcer, no measurable change from baseline, and no sign of significant improvement or

indication that significant improvement is likely (such as granulation, epithelialization, or progress towards closure).

3. Application of skin substitute graft/CTP in patients with inadequate control of underlying conditions or exacerbating factors, or other contraindications (such as, active infection, progressive necrosis, active Charcot arthropathy of the ulcer extremity, active vasculitis, ischemia).
4. Use of surgical preparation services (such as, debridement), in conjunction with routine, simple or repeat skin replacement therapy with a skin substitute graft/CTP.
5. All liquid or gel skin substitute products or CTPs for ulcer care.
6. Placement of skin substitute graft/CTP on infected, ischemic, or necrotic wound bed.
7. A price greater than $127.19/cm^2$125.38 per square cm is generally not medically necessary.

Special Considerations

N/A

Limitations/Exclusions

Please see link to member coverage documents below:

Line of Business	Link to Member Coverage Documents
Medicare Advantage Plans (Including D-SNP)	https://medicare.chpw.org/ Select the appropriate plan from the "Plans" drop down on the top navigation bar.
Apple Health	https://www.chpw.org/for-members/benefits-and-coverage-imc/
Cascade Select	https://chnwhealthinsurance.chpw.org/member-center/plan-benefits/

List of Appendices

A. **Coding;** Not all codes are covered. Please reference the Procedure Code Look Up Tool for Guidance. (https://forms.chpw.org/pclt)

Citations & References

CFR	

WAC		
RCW		
LOB & Contract Citation	☒ **WAHIMC** ☐ **BHSO** ☐ **Wraparound** ☐ **SMAC** ☐ **HH**	IMC Section 1.200: Medically Necessary; IMC Section 11.1: Utilization Management General Requirements; IMC Section 11.3: Medical Necessity Determination
	☒ **AHE**	AHE Section 1.51: Medically Necessary Services; AHE Section 11.1: Utilization Management General Requirements; AHE Section 11.3: Medical Necessity Determination
	☐ **MA/DSNP**	
	☒ **CS**	P&P supports all LOB requirements
Other Requirements		
NCQA Elements	UM 2, UM 5	
References	Optum EncoderPro CMS: Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers, L39764 MCG 29th Edition: Skin Substitute, Tissue-Engineered (Human Cellular), for Diabetic Foot Ulcer and Venous Ulcer (A-0326) https://govhealth.distilinfo.com/2025/07/17/cms-announces-fixed-price-skin/ Federal Register :: Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program	

Revision History

Revision Date	Revision Description	Revision Made By
07/23/2025	Creation of policy	LuAnn Chen, MD

08/13/2025	Approval	UM Criteria Subcommittee
01/08/2026	Requirement for price quote with the request. Maximum price of $125.38 per square centimeter and reference. Equity considerations. Citations updated.	LuAnn Chen, MD
01/09/2026	Approval	UM Criteria Subcommittee
04/08/2026	Added findings from the CMS Technology Assessment Program: Skin Substitutes for Treating Chronic Wounds (February 2, 2020). Defined episode. Clarified that the maximum applications considered one time is 4. Price limit increased from $125.38 to $127.19 in alignment with CMS.	LuAnn Chen, MD
05/15/2026	Approval	UM Criteria Subcommittee

Appendix A:

Coding; Not all codes are covered. Please reference the Procedure Code Look Up Tool for Guidance. (https://forms.chpw.org/pclt)

C5271-C5278 Skin Substitute Outpatient PPS (Application of low cost skin substitute graft to various areas and sizes)

A2001	InnovaMatrix AC, per sq cm
A2002	Mirragen Advanced Wound Matrix, per sq cm
A2004	XCelliStem, 1 mg
A2005	Microlyte Matrix, per sq cm
A2006	NovoSorb SynPath dermal matrix, per sq cm
A2007	Restrata, per sq cm
A2008	TheraGenesis, per sq cm
A2009	Symphony, per sq cm
A2010	Apis, per sq cm
A2011	Supra SDRM, per sq cm
A2012	SUPRATHEL, per sq cm
A2013	InnovaMatrix FS, per sq cm

A2014	Omeza Collagen Matrix, per 100 mg
A2015	Phoenix Wound Matrix, per sq cm
A2016	PermeaDerm B, per sq cm
A2017	PermeaDerm Glove, each
A2018	PermeaDerm C, per sq cm
A2019	Kerecis Omega3 MariGen Shield, per sq cm
A2020	AC5 Advanced Wound System (AC5)
A2021	NeoMatriX, per sq cm
A2022	InnovaBurn or InnovaMatrix XL, per sq cm
A2023	InnovaMatrix PD, 1 mg
A2024	Resolve Matrix or XenoPatch, per sq cm
A2025	Miro3D, per cu cm
A2026	Restrata MiniMatrix, 5 mg
A2027	MatriDerm, per sq cm
A2028	MicroMatrix Flex, per mg
A2029	MiroTract Wound Matrix sheet, per cc
A2030	Miro3D Fibers, per mg

A2031	MiroDry Wound Matrix, per sq cm
A2032	Myriad Matrix, per sq cm
A2033	Myriad Morcells, 4 mg
A2034	Foundation DRS Solo, per sq cm
A2035	Corplex P or Theracor P or Allacor P, per mg
A4100	Skin substitute, FDA-cleared as a device, not otherwise specified
Q4100	Skin substitute, not otherwise specified
Q4101	Apligraf, per sq cm, (previously Graftskin) bilayered living skin substitute made from allogeneic human keratinocytes and fibroblasts in a bovine collagen lattice.
Q4102	Oasis wound matrix, per sq cm
Q4103	Oasis burn matrix, per sq cm
Q4104	Integra bilayer matrix wound dressing (BMWD), per sq cm
Q4105	Integra dermal regeneration template (DRT) or Integra Omnigraft dermal regeneration matrix, per sq cm
Q4106	Dermagraft, per sq cm, cryopreserved living, single-layer skin substitute derived from human allogeneic fibroblasts.
Q4107	GRAFTJACKET, per sq cm
Q4108	Integra matrix, per sq cm
Q4110	PriMatrix, per sq cm

Q4111	GammaGraft, per sq cm
Q4112	Cymetra, injectable, 1 cc
Q4113	GRAFTJACKET XPRESS, injectable, 1 cc
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
Q4121	TheraSkin, per sq cm
Q4122	DermACELL, DermACELL AWM or DermACELL AWM Porous, per sq cm
Q4123	AlloSkin RT, per sq cm
Q4124	OASIS ultra tri-layer wound matrix, per sq cm
Q4125	ArthroFlex, per sq cm
Q4126	MemoDerm, DermaSpan, TranZgraft or IntéguPly, per sq cm
Q4127	Talymed, per sq cm
Q4128	FlexHD, or AllopatchHD, per sq cm
Q4130	Strattice, per sq cm

Q4132	Grafix Core and GrafixPL Core, per sq cm
Q4133	Grafix PRIME, GrafixPL PRIME, Stravix and StravixPL, per sq cm
Q4134	HMatrix, per sq cm
Q4135	Mediskin, per sq cm
Q4136	EZ Derm, per sq cm
Q4137	AmnioExcel, AmnioExcel Plus 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	XCM biologic tissue matrix, per sq cm
Q4143	Repriza, per sq cm
Q4145	EpiFix, injectable, 1 mg
Q4146	TENSIX, per sq cm
Q4147	Architect, Architect PX, or Architect FX, extracellular matrix, per sq cm
Q4148	Neox Cord 1K, Neox Cord RT, or Clarix Cord 1K, per sq cm
Q4149	Excellagen, 0.1 cc

Q4150	AlloWrap DS or dry, per sq cm