Clinical Policy: Skin and Soft Tissue Substitutes for Chronic Wounds

Reference Number: WA.CP.MP.185
Date of Last Revision: 05/23
Effective Date: 06/01/23

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Patients receiving skin replacement surgery with a skin substitute graft should be under the care of a wound care physician or surgeon. It is imperative that systemic disease be monitored/treated in order to insure adequate healing of the wound site.

Note: *For skin substitutes for burns, refer to CP.MP.186 Burn Surgery.*

Policy/Criteria

I. It is the policy of Coordinated Care of Washington, Inc., in accordance with the Health Care Authority's Billing Guidelines, that skin substitutes are **medically necessary** for wound treatment under the following conditions:

A. For treatment of *diabetic foot ulcers*, when *all* of the following are met:
   a. Partial or full-thickness diabetic foot ulcer of ≥ 4 weeks duration;
   b. Ulcer has extended through the dermis but without tendon, muscle, or bone exposure;
   c. Unresponsive to standard wound therapy, including all of the following:
      i. Assessment of vascular status with treatment as indicated
      ii. Nutritional optimization
      iii. Optimal glucose control
      iv. Adequate debridement
      v. Moist dressing
      vi. Off-loading
      vii. Treatment of infection
      viii. Tobacco/nicotine cessation intervention when applicable.

B. For the treatment of *chronic venous stasis ulcers*, when *all* of the following are met:
   a. Partial or full-thickness venous stasis ulcer;
   b. Failure of ≥ 4 weeks standard ulcer therapy using regular dressing changes and therapeutic compression;
   c. No active infection

Note: Treatment of any chronic skin wound will typically last no more than 12 weeks.

II. It is the policy of Coordinated Care of Washington, Inc., in accordance with the Health Care Authority's Billing Guidelines, that skin substitutes are **medically necessary** for the treatment of wounds related to dystrophic *epidermolysis bullosa* when standard wound therapy has failed.

III. It is the policy of Coordinated Care of Washington, Inc., in accordance with the Health Care Authority's Billing Guidelines, that skin substitutes are **medically necessary** for *breast reconstruction surgery* as a part of breast cancer treatment.

IV. It is the policy of Coordinated Care of Washington, Inc., in accordance with the Health Care Authority's Billing Guidelines, that reapplication of a skin substitute when the initial treatment episode is not successful is **not covered**.

V. It is the policy of Coordinated Care of Washington, Inc., in accordance with the Health Care Authority's Billing Guidelines, that coverage is limited to a maximum of 10 applications per year for all indications in sections I-IV.

VI. It is the policy of Coordinated Care of Washington, Inc., that skin substitutes are **not medically necessary** for the following indications or scenarios:

A. Decubitus (pressure) ulcer treatment;
B. Retreatment of healed ulcers (those showing greater than 75% size reduction and smaller than 1 square cm);
C. Continued skin or soft tissue substitute use after treatment failure, which is defined as the repeat or alternative application course (of up to 12 weeks) of skin substitute grafts within one year of any given course of skin substitute treatment for a venous stasis ulcer or diabetic foot ulcer.

Background

According to the Centers for Medicare & Medicaid Services (CMS), chronic wounds of the lower extremities, including venous stasis ulcers (VSU), venous leg ulcers (VLU), diabetic foot ulcers (DFU) and pressure sores, are a major public health problem. While lower extremity ulcers have numerous causes, such as burns, trauma, mixed venous-arterial disease, immobility and vasculitis, nutritional or other neuropathy, over 90% of the lesions in the United States are related to venous stasis disease and diabetic neuropathy.[1] These wounds frequently require detailed interventions to start the healing process again; furthermore, patients experience significant functional loss, wound recurrence, and increased morbidity.[6]

Standard care for lower extremity wounds and ulcers includes infection control, management of edema, mechanical offloading of the affected limb, mechanical compression, limb elevation, debridement of necrotic tissue, management of systemic disease and counseling on the risk of continued tobacco use. Additionally, maintenance of a therapeutic wound environment with appropriate dressings can facilitate development of healthy granulation tissue and re-epithelialization. Dressings are essential to wound management because the appropriate dressing not only maintains the moisture balance within the wound, but the dressing also controls exudate, which protects the wound from additional trauma.[1,2]

A wound that has not healed within one to three months may be considered a chronic wound and can be a challenge to treat effectively. Even with advancements in standard wound care and synthetic occlusive dressings, some ulcers fail to heal and may benefit from a skin substitute.1,2 The National Institute for Health and Care Excellence (NICE) recommends consideration of dermal or skin substitutes as an adjunct to standard care when treating diabetic wounds that are

not healing.18 Skin substitutes promote wound healing by replacing extracellular matrix.7 Skin substitutes are categorized based on the composition of epidermal, dermal, and composite skin present.7 They are heterogeneous and can be largely separated into two primary categories: cellular (comprised of living cells); or acellular (composed of synthetic materials or tissue from which living cells have been removed).8,9 The categories are further split based on composition and source of material, including xenograft, acellular allograft, cellular allograft, autograft and synthetic skin substitute choices.7

For VLU, an evaluation for the presence of saphenous vein reflux is essential prior to consideration of skin substitutes. If there is significant saphenous vein incompetency and reflux (valve closure time defined as > 500 milliseconds), or if ulcer bed veins are identified as contributory on ultrasound, a referral to a vascular surgeon or interventional radiologist is required. Endovascular laser or radiofrequency ablation can enhance rates of healing compared to other treatments for significant saphenous vein reflux. Without significant reflux, sclerotherapy may also be more beneficial.[3]

According to a 2016 Cochrane review, the overall therapeutic outcome of skin grafts and tissue replacements used with standard wound care demonstrated an increase in the healing rate of foot ulcers and slightly fewer amputations in patients with diabetes compared with standard wound care alone.10 The Wound Healing Society updated their guidelines in 2016, indicating that cellular and acellular skin equivalents positively affect healing in diabetic ulcers by "releasing therapeutic amounts of growth factors, cytokines, and other proteins that stimulate the wound bed."11 A health technology assessment of skin substitutes conducted for adults with neuropathic diabetic foot ulcers and venous leg ulcers found that adults with difficult to heal neuropathic diabetic ulcers and difficult to heal venous leg ulcers who used skin substitutes were more likely to experience complete wound healing than those who used standard care alone.15 A systematic review of 17 trials using several skin substitutes to treat diabetic foot ulcers noted that completed closure of diabetic ulcers was significantly improved when compared to standard care alone.14

Autologous skin grafts, also referred to as autografts, are permanent covers that use skin from different parts of the individual's body. These grafts consist of the epidermis and a dermal component of variable thickness. A split-thickness skin graft (STSG) includes the entire epidermis and a portion of the dermis. A full-thickness skin graft (FTSG) includes all layers of the skin. Although autografts are the optimal choice for full thickness wound coverage, areas for skin harvesting may be limited, particularly in cases of large burns or venous stasis ulceration. Harvesting procedures are painful, disfiguring and require additional wound care.1,2,4

Allografts, which use skin from another human (e.g., cadaver), and Xenografts, which use skin from another species (e.g., porcine or bovine), may also be employed as temporary skin replacements. However, they must later be replaced by an autograft or the ingrowth of the patient's own skin.1,2,4

Bioengineered Skin and Cultured Epidermal Autografts (CEA) are autografts derived from the patient's own skin cells grown or cultured from very small amounts of skin or hair follicle. Production time is prolonged. One such product is grown on a layer of irradiated mouse cells,

displaying some components of a xenograft. Widespread usage has not been available due to limited availability or access to the technology.1,2,4

Cellular and/or Tissue Based Products (CTPs) were developed to address problems with autografts, allografts, and xenografts. These consist of biologic covers for refractory wounds with full thickness skin loss secondary to third degree burns, diabetic neuropathic ulcers and the skin loss of chronic venous stasis or venous hypertension. The production of these biologic CTPs varies by company and product, but generally involves the creation of immunologically inert biological products containing protein, hormones or enzymes seeded into a matrix which may provide protein or growth factors intended to stimulate or facilitate healing or promote epithelization.1,2 There are currently a broad range of bioengineered products available for soft tissue coverage to affect closure.1,2,6 Sufficient data is available to establish distinct inferiority to human skin autografts and preclude their designation as skin equivalence.1,2 Although there is no universally accepted classification system for the various bioengineered products, it is advised that the clinician understands the materials used and their fundamental purpose.14

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2020, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT® Codes	Description
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 for 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 surface 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;

CPT® Codes	Description
	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 greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area 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 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)

Skin Substitutes That May be Covered by Apple Health

HCPCS®* Codes	Description
Q4100	Skin substitute, nos
Q4101	Apligraf, per sq cm
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 drt or omnigraft
Q4106	Dermagraft, per sq cm
Q4107	Graftjacket, per square centimeter
Q4108	Integra matrix, per sq cm
Q4110	Primatrix, per square centimeter
Q4111	Gammagraft, per sq cm
Q4115	Alloskin, per sq cm
Q4116	AlloDerm, per sq cm
Q4117	Hyalomatrix, per sq cm
Q4121	TheraSkin, per sq cm
Q4122	Dermacell, per square centimeter
Q4123	AlloSkin RT, per sq cm
Q4124	Oasis ultra tri-layer wound matrix, per sq cm
Q4126	MemoDerm, DermaSpan, TranZgraft or IntéguPly, per sq cm
Q4127	Talymed, per sq cm
Q4128	FlexHD, or AllopatchHD, 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	E-Z Derm, per sq cm
Q4137	Amnioexcel, amnioexcel plus or biodexcel, per square centimeter
Q4138	Biodefence, per sq cm

HCPCS®* Codes	Description
Q4139	AmnioMatrix of bioD, inj 1cc
Q4140	Biodfence, per square centimeter
Q4141	Alloskin ac, per square centimeter
Q4143	Repriza, per square centimeter
Q4146	Tensix, per square centimeter
Q4147	Architect, architect px, or architect fx, extracellular matrix, per square centimeter
Q4148	Neox cord 1k, neox cord rt, or clarix cord 1k, per square centimeter
Q4149	Excellagen, 0.1 cc
Q4150	Allowrap ds or dry, per square centimeter
Q4151	Allowrap ds or dry, per square centimeter
Q4152	Amnioband or guardian, per square centimeter
Q4153	Dermapure, per square centimeter
Q4154	Dermavest and plurivest, per square centimeter
Q4156	Neoxflo or clarixflo, 1 mg
Q4157	Neox 100 or clarix 100, per square centimeter
Q4158	Revitalon, per square centimeter
Q4159	Kerecis omega3, per square centimeter
Q4160	Nushield, per square centimeter
Q4161	bio-ConneKt wound matrix, per sq cm
Q4162	WouldEx Flow, bioSkin Flow, 0.5cc
Q4163	Woundex, bioskin, per sq cm
Q4164	Helicoll, per square cm
Q4165	Keramatrix or Kerasorb, per sq cm
Q4166	Cytal, per square centimeter
Q4167	Truskin, per sq cm
Q4168	AmnioBand, 1 mg
Q4169	Artacent wound, per sq cm
Q4170	Cygnus, per sq cm
Q4171	Interfyl, 1 mg
Q4173	Palingen or Palingen Xplus, per sq cm
Q4174	Paligen or promatrx
Q4175	Miroderm, per sq cm
Q4176	Neopatch or therion, per square centimeter
Q4177	FlowerAmnioFlo, 0.1cc
Q4178	FlowerAmnioPatch, per sq cm
Q4179	Flowerderm, per sq cm
Q4180	Revita, per sq cm
Q4181	Amnio wound, per sq cm
Q4182	Transcyte, per sq cm
Q4183	Surgigraft, 1 sq cm
Q4184	Cellesta or Cellesta Duo, per sq cm
Q4186	Epifix, per square centimeter
Q4187	Epicord, per square centimeter

HCPCS®* Codes	Description
Q4188	AmnioArmor, per sq cm
Q4190	Artacent AC, per sq cm
Q4191	Restorigin 1 sq cm
Q4193	Coll-e-derm 1 sq cm
Q4194	Novachor 1 sq cm
Q4195	PuraPly, per square cm
Q4196	PuraPly AM , per square cm
Q4197	Puraply XT, per square cm
Q4198	Genesis Amniotic Membrane, per sq cm
Q4200	Skin te 1 sq cm
Q4201	Matrion 1 sq cm
Q4203	Derma-Gide, per sq cm
Q4204	Xwrap 1 sq cm
Q4205	Membrane graft or wrap sq cm
Q4206	Fluid flow or fluid gf 1cc
Q4208	Novafix, per sq cm
Q4209	SurGraft, per sq cm
Q4210	Axolotl Graft or DualGraft, per sq cm
Q4211	Amnion Bio or AxoBioMembrane, per sq cm
Q4212	Qllogen, per cc
Q4213	Ascent. 0.5 mg
Q4214	Cellesta Cord, per sq cm
Q4215	Axolotl ambient, cryo 0.1 mg
Q4216	Artacent Cord, per sq cm
Q4217	Woundfix biowound plus xplus per sq cm
Q4218	SurgiCORD, per sq cm
Q4219	SurgiGRAFT-DUAL, per sq cm
Q4220	BellaCell HD or Surederm, per sq cm
Q4221	Amnio Wrap2 per sq cm
Q4222	ProgenaMatrix, per sq cm
Q4226	MyOwn Skin harv and prep per sq cm
Q4229	Cogenex amnio memb per sq cm
Q4232	Corplex, per sq cm
Q4237	Cryo-Cord, per sq cm
Q4238	Derm-Maxx, per sq cm
Q4239	Amnio-Maxx or Lite, per sq cm
Q4247	Amniotext patch, per sq cm
Q4248	Dermacyte amn mem allo sq cm
Q4249	Amniply, per sq cm
Q4250	Amnioam-mp per sq cm
Q4251	Vim, per sq cm
Q4252	Vendaje, per sq cm
Q4253	Zenith Amniotic membrane psc

HCPCS®* Codes	Description
Q4254	Novafix dl per sq cm
Q4255	Reguard, topicak use per sq

Skin Substitutes Not Covered by Apple Health

HCPCS®* Codes	Description
A2001	InnovaMatrix AC, per sq cm
A2002	Mirragen Advanced Wound Matrix, per sq cm
A2003	bio-ConneKt Wound Matrix, per sq cm
A2004	XCelliStem, per sq cm
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
Q4112	Cymetra injectable
Q4113	Graftjacket xpress
Q4114	Integra flowable wound matrix
Q4118	Matristem micromatrix, 1 mg
Q4125	Arthroflex
Q4130	Strattice TM
Q4142	Xcm biologic tiss matrix 1 cm
Q4145	Epifix, inj, 1 mg
Q4155	Neox Flo or Clarix Flo 1mg
Q4177	Floweramnioflo, 0.1cc
Q4185	Cellesta flowab amnion 0.5cc
Q4189	Artacent AC, 1mg
Q4192	Restorigin, 1cc
Q4199	Cygnus matrix, per sq cm
Q4202	Keroxx (2.5g/cc), 1cc
Q4204	Xwrap 1 sq cm
Q4224	Hhf10-p per sq cm
Q4225	Amniobind, per sq cm
Q4227	Amniocore per sq cm

HCPCS®* Codes	Description
Q4230	Cogenex flow amnion 0.5 cc
Q4231	Corplex p, per cc
Q4233	Surfactor/nudyn per 0.5 cc
Q4234	Xcellerate, per sq cm
Q4235	Amniorepair or altiply sq cm
Q4240	Corecyte topica only 0.5cc
Q4241	Polycyte, topical only 0.5cc
Q4242	Amniocyte plus, per 0.5 cc
Q4244	Procenta, per 200 mg
Q4245	Amniotext, per cc
Q4246	Coretext or protext, per cc
Q4256	Mlg complet, per sq cm
Q4257	Release, per sq cm
Q4258	Enverse, per sq cm
Q4259	Celera Dual, per sq cm
Q4260	Signature Apatch, per sq cm
Q4261	Tag, per sq cm

Reviews, Revisions, and Approvals	Revision Date	Approval Date
New policy adapted from WellCare's HS433 Skin Substitutes policy.	05/20	06/20
Reworded section regarding nicotine use. Added to section II that all indications not noted in section I are not medically necessary. Added CPT codes: 15271-15278; updated list of HCPCS codes of current products available, although not inclusive or guarantee of coverage.	07/20	08/20
References reviewed and updated. All instances of "member" changed to "member/enrollee." HCPCS code listing updated. Non-covered codes reported separately.	05/21	06/21
Annual review. References reviewed and updated. Changed "Review Date" in the header to "Date of Last Revision" and "Date" in the revision log header to "Revision Date." Reworded some extraneous language with no clinical significance. Added to I.F.2. "unless Integra® is used per FDA guidelines". Removed I.J.3. "Concurrent treatment with hyperbaric oxygen therapy". Background section updated with no additional impact to criteria. Update code listing of covered and non-covered codes to mirror HCA Billing Guidelines. Added reference CMS A56696. Specialist reviewed.	04/22	05/22
Updated description for code Q4128. Added new HCPCS codes that are covered and not covered per the HCA.	11/22	11/22
Annual review. References reviewed and updated. Policy name changed to align with corporate policy. Section I. medical necessity criteria updated to mirror billing guidelines. Moved HCA limit of 10	05/23	05/23

Reviews, Revisions, and Approvals	Revision Date	Approval Date
applications per year to new section V. Section VI. updated to include continued use after treatment failure per corporate policy update. Background section updated with no additional impact to criteria.		

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20. Washington State Health Care Authority. *Physician-Related Services/Health Care Billing Guide*. https://www.hca.wa.gov/assets/billers-and-providers/physician-related-serv-bg-20220401.pdf Revision effective April 1, 2022.
21. Washington State Health Care Authority. Outpatient Hospital *OPPS Fee Schedule.* https://www.hca.wa.gov/assets/billers-and-providers/Physician-related-services-bg-20230501.pdf Revision effective May 1, 2023.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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