Clinical Policy: Skin and Soft Tissue Substitutes for Chronic Wounds

Reference Number: LA.CP.MP.185c
Date of Last Revision: 5/24

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 to ensure adequate healing of the wound site. This policy addresses the medical necessity criteria for skin substitutes in the treatment of chronic wounds.

Note:
- *For skin substitutes for burns, refer to LA.CP.MP.186 Burn Surgery.*
- *This policy only applies to skin and soft tissue substitute requests for diabetic foot ulcers, venous leg ulcers, or full thickness skin-loss ulcers.*

Policy/Criteria
I. It is the policy of Louisiana Healthcare Connections that skin and soft tissue substitutes are **medically necessary** for diabetic foot ulcers, venous leg ulcers, or full thickness skin-loss ulcers when all of the following criteria are met:
A. Age ≥ 18 years
B. Wound is chronic, defined as a wound that does not respond to at least four weeks of standard wound treatment as a component of organized, comprehensive, conservative therapy; signs of healing, is defined as a decrease in surface area and depth or a decreased amount of exudate and necrotic tissue,
C. Wound characteristics and treatment plan are documented; and must include at least all of the following:
    1. Offloading of weight
    2. Smoking cessation counseling and/or medications, if applicable;
    3. Edema control
    4. Improvement in diabetes control and nutritional status; and
    5. Identification and treatment of other comorbidities that may affect wound healing such as ongoing monitoring for infection
D. Standard wound care has failed, evidenced by all of the following:
    1. The ulcer or skin deficit has been treated with appropriate wound-care measures, including debridement, standard dressings, compression, off-loading;
    2. Wound area has reduced <50% in four weeks[20];
E. Documentation of effort to cease nicotine use, including from sources other than cigarettes, but excluding nicotine replacement therapy, for at least four weeks during conservative wound care and prior to planned bioengineered skin replacement therapy, or no nicotine use;
F. Wound characteristics, all of the following:
    1. Partial- or full-thickness ulcer with a clean, granular base;

2. No involvement of tendon, muscle, joint capsule, or exposed bone or sinus tracts, unless Integra® is used per U.S. Food and Drug Administration (FDA) guidelines;
3. No wound infection; wound must be clean and free of necrotic debris or exudate;
4. Member/enrollee has adequate circulation/oxygenation to support tissue growth/wound healing, as evidenced by physical examination (e.g., Ankle-Brachial Index [ABI] of no less than 0.6 or toe pressure greater than 30 millimeters of mercury [mmHg]); Toe-brachial index (TBI) of at least 0.5; Triphasic or biphasic Doppler arterial waveforms at the ankle of the affected leg.

G. One of the following:
1. Diabetic foot ulcer (DFU), and all of the following:
a. Hgb A1c of ≤ 9 or within the last 90 days or a documented to improve control; to HbA1c to 9% or below as soon as possible
a. b. Diagnosis of Type 1 or Type 2 Diabetes and medical management for the condition;
b. Documented conservative wound care for ≥ four weeks;
c. Wound is without evidence of osteomyelitis or nidus of infection;
d. Is at least 1.0 square centimeter (cm) in size
2. Venous leg ulcers (VLU), all of the following:
a. A chronic, non-infected VLU has failed to respond to documented conservative wound-care measures for ≥ four weeks with documented compliance;
b. Completed assessment includes:
i. History (prior ulcers, thrombosis risks);
ii. Physical exam (edema, skin changes);
iii. ABI (Ankle-Brachial Index) and duplex scan to confirm Clinical-Etiology-Anatomy-Pathophysiology (*CEAP);
c. A venous duplex ultrasound has been completed to assess saphenous vein incompetency/venous reflux and contributory superficial ulcer bed perforators;
3. Full thickness skin-loss ulcer is the result of abscess, injury or trauma and has failed to respond to appropriate control of infection, foreign body, tumor resection, or other disease process for ≥ four weeks;

H. Requested use complies with FDA-approved indications for the specific product, and requested applications do not to exceed 10 applications or treatments;

I. Only one skin substitute will be simultaneously in place per wound episode. Product change within the wound episode is allowed, not to exceed the 10 application limit per wound per 12 week episode of care;

J. None of the following contraindications:
1. Inadequate control of underlying conditions or exacerbating factors (e.g., uncontrolled diabetes, active infection, and active Charcot arthropathy of the ulcer surface, vasculitis or continued nicotine use, including from sources other than cigarettes, but excluding nicotine replacement therapy, without physician attempt to affect nicotine use);
2. Known hypersensitivity to any component of the specific skin substitute graft (e.g., allergy to avian, bovine, porcine, equine products);
3. Partial thickness loss with the retention of epithelial appendages (epithelium will repopulate the deficit).
4. Active and untreated autoimmune connective tissue disease;

5. Known or suspected malignancy of the ulcer;
6. Member/enrollee is receiving radiation therapy or chemotherapy
7. Re-treatment of the same ulcer within one year
8. While providers may change products used for the diabetic lower extremity ulcers, simultaneous use of more than one product for the diabetic lower extremity ulcers is not covered

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

II. It is the policy of Louisiana Healthcare Connections that skin and soft tissue substitutes are **not medically necessary** for the following indications or scenarios:

A. Pressure (decubitus) ulcer treatment;
B. 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 leg ulcer or diabetic foot ulcer; If there is no measurable decrease in surface area or depth after five applications, then further applications are not covered;
C. Retreatment of healed ulcers (those showing greater than 75% size reduction and smaller than 1 square cm).

Background

According to the Centers for Medicare & Medicaid Services (CMS), chronic wounds of the lower extremities, including 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 2023, 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 and may bot support medical necessity. 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.

NOTE: Coverage is subject to each requested code's inclusion on the corresponding LDH fee schedule. Non-covered codes are denoted (*) and are reviewed for Medical Necessity for members under 21 years of age on a per case basis.

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

CPT Codes	Description
	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 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)

HCPCS codes that support medical necessity criteria

HCPCS Codes	Description
A2001*	InnovaMatrix AC, per sq cm
A2002*	Mirragen Advanced Wound Matrix, per sq cm
A2004*	XCelliStem, per sq cm
A2008*	TheraGenesis, per sq cm
Q4100*	Skin substitute, not otherwise specified
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 dermal regeneration template (DRT) or Integra Omnigraft dermal regeneration matrix, per sq cm
Q4106	Dermagraft, per sq cm
Q4107*	Graftjacket, per sq cm
Q4108*	Integra matrix, per sq cm
Q4110*	Primatrix, per sq cm
Q4111*	Gammagraft, per sq cm
Q4115*	Alloskin, per sq cm
Q4117*	Hyalomatrix, per sq cm
Q4118*	Matristem micromatrix, 1mg
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
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

HCPCS Codes	Description
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 sq cm
Q4140*	BioDFence, per sq cm
Q4141*	Alloskin AC, per sq cm
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
Q4151*	AmnioBand or Guardian, per sq cm
Q4152*	DermaPure, per sq cm
Q4153*	Dermavest and Plurivest, per sq cm
Q4154*	Biovance, per sq cm
Q4156*	Neox 100 or Clarix 100, per sq cm
Q4157*	Revitalon, per sq cm
Q4158*	Kerecis Omega3, per sq cm
Q4159*	Affinity, per sq cm
Q4160	Nushield, per sq cm
Q4161*	bio-ConneKt wound matrix, per sq cm
Q4163*	Woundex, bioskin, per sq cm
Q4164*	Helicoll, per square cm
Q4165*	Keramatrix or Kerasorb, per sq cm
Q4166*	Cytal, per square centimeter
Q4169*	Artacent wound, per sq cm
Q4170*	Cygnus, per sq cm
Q4173*	Palingen or Palingen Xplus, per sq cm
Q4175*	Miroderm, per sq cm
Q4176*	Neopatch or therion, per sq cm
Q4178*	FlowerAmnioPatch, per sq cm
Q4180*	Revita, per sq cm
Q4186	Epifix, per sq cm
Q4187*	Epicord, per sq cm
Q4188*	AmnioArmor, per sq cm
Q4195	PuraPly, per square cm
Q4196	PuraPly AM , per square cm
Q4197*	Puraply XT, per square cm
Q4201*	Matrion, per sq cm
Q4203*	Derma-Gide, per sq cm
Q4232*	Corplex, per sq cm
Q4236*	carePATCH, per sq cm
Q4253*	Zenith amniotic membrane, per sq cm
Q4254*	Novafix DL, per sq cm

HCPCS Codes	Description
Q4262	Dual Layer Impax Membrane, per sq cm
Q4278*	EPIEFFECT, per sq cm

HCPCS codes that do not support medical necessity criteria

HCPCS Codes	Description
A2005*	Microlyte Matrix, per sq cm
A2006*	NovoSorb SynPath dermal matrix, per sq cm
A2007*	Restrata, 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, per sq cm
A2025*	Miro3D, per cu cm
A2026*	Restrata MiniMatrix, 5 mg
A4100*	Skin substitute, FDA-cleared as a device, not otherwise specified
C9358*	Dermal substitute, native, nondenatured collagen, fetal bovine origin (SurgiMend Collagen Matrix), per 0.5 sq cm
C9360*	Dermal substitute, native, nondenatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 sq cm
C9363*	Skin substitute (Integra Meshed Bilayer Wound Matrix), per sq cm
Q4112*	Cymetra, injectable, 1 cc
Q4113*	GRAFTJACKET XPRESS, injectable, 1 cc
Q4114*	Integra flowable wound matrix, injectable, 1 cc
Q4125*	ArthroFlex, per sq cm
Q4130*	Strattice TM, per sq cm
Q4138*	BioDFence DryFlex, per sq cm
Q4139*	AmnioMatrix or BioDMatrix, injectable, 1 cc
Q4143*	Repriza, per sq cm
Q4145*	EpiFix, injectable, 1 mg
Q4149*	Excellagen, 0.1 cc

HCPCS Codes	Description
Q4155*	Neox Flo or Clarix Flo 1 mg
Q4162*	WoundEx Flow, BioSkin Flow, 0.5 cc
Q4167*	Truskin, per sq cm
Q4168*	AmnioBand, 1 mg
Q4171*	Interfyl, 1 mg
Q4174*	PalinGen or ProMatrX, 0.36 mg per 0.25 cc
Q4177*	FlowerAmnioFlo, 0.1 cc
Q4179*	FlowerDerm, per sq cm
Q4181*	Amnio Wound, per sq cm
Q4182*	Transcyte, per sq cm
Q4183*	Surgigraft, per sq cm
Q4184*	Cellesta or Cellesta Duo, per sq cm
Q4185*	Cellesta Flowable Amnion (25 mg per cc); per 0.5 cc
Q4189*	Artacent AC, 1 mg
Q4190*	Artacent AC, per sq cm
Q4191*	Restorigin, per sq cm
Q4192*	Restorigin, 1 cc
Q4193*	Coll-e-Derm, per sq cm
Q4194*	Novachor, per sq cm
Q4198*	Genesis Amniotic Membrane, per sq cm
Q4199*	Cygnus matrix, per sq cm
Q4200*	SkinTE, per sq cm
Q4202*	Keroxx (2.5 g/cc), 1 cc
Q4204*	XWRAP, per sq cm
Q4205*	Membrane Graft or Membrane Wrap, per sq cm
Q4206*	Fluid Flow or Fluid GF, 1 cc
Q4208*	Novafix, per sq cm
Q4209*	SurGraft, per sq cm
Q4210*	Axolotl Graft or Axolotl DualGraft, per sq cm
Q4211*	Amnion Bio or AxoBioMembrane, per sq cm
Q4212*	AlloGen, per cc
Q4214*	Cellesta Cord, per sq cm
Q4216*	Artacent Cord, per sq cm
Q4217*	WoundFix, BioWound, WoundFix Plus, BioWound Plus, WoundFix Xplus or BioWound 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
Q4224*	Human Health Factor 10 Amniotic Patch (HHF10-P), per sq cm
Q4225*	AmnioBind or DermaBind TL, per sq cm
Q4226*	MyOwn Skin, includes harvesting and preparation procedures, per sq cm

HCPCS Codes	Description
Q4227*	AmnioCore TM, per sq cm
Q4229*	Cogenex Amniotic Membrane, per sq cm
Q4230*	Cogenex Flowable Amnion, per 0.5 cc
Q4231*	Corplex P, per cc
Q4233*	SurFactor or NuDyn, per 0.5 cc
Q4234*	Xcellerate, per sq cm
Q4235*	AMNIOREPAIR or AltiPly, per sq cm
Q4237*	Cryo-Cord, per sq cm
Q4238*	Derm-Maxx, per sq cm
Q4239*	Amnio-Maxx or Amnio-Maxx Lite, per sq cm
Q4240*	CoreCyte, for topical use only, per 0.5 cc
Q4241*	PolyCyte, for topical use only, per 0.5 cc
Q4242*	AmnioCyte Plus, per 0.5 cc
Q4244*	Procenta, per 200 mg
Q4245*	AmnioText, per cc
Q4246*	CoreText or ProText, per cc
Q4247*	Amniotext patch, per sq cm
Q4248*	Dermacyte Amniotic Membrane Allograft, per sq cm
Q4249*	AMNIPLY, for topical use only, per sq cm
Q4250*	AmnioAmp-MP, per sq cm
Q4251*	Vim, per sq cm
Q4252*	Vendaje, per sq cm
Q4255*	REGUaRD, for topical use only, per sq cm
Q4256*	MLG-Complete, per sq cm
Q4257*	Relese, per sq cm
Q4258*	Enverse, per sq cm
Q4259*	Celera Dual Layer or Celera Dual Membrane, per sq cm
Q4260*	Signature Apatch, per sq cm
Q4261*	TAG, per sq cm
Q4263*	SurGraft TL, per sq cm
Q4264*	Cocoon Membrane, per sq cm
Q4265*	NeoStim TL, per sq cm
Q4266*	NeoStim Membrane, per sq cm
Q4279*	Vendaje AC, per sq cm
Q4287*	DermaBind DL, per sq cm
Q4288*	DermaBind CH, per sq cm
Q4289*	RevoShield+ Amniotic Barrier, per sq cm
Q4290*	Membrane Wrap-Hydro(TM), per sq cm
Q4291*	Lamellas XT, per sq cm
Q4292*	Lamellas, per sq cm
Q4293*	Acesso DL, per sq cm
Q4294*	Amnio Quad-Core, per sq cm
Q4295*	Amnio Tri-Core Amniotic, per sq cm

HCPCS Codes	Description
Q4296*	Rebound Matrix, per sq cm
Q4297*	Emerge Matrix, per sq cm
Q4298*	AmniCore Pro, per sq cm
Q4299*	AmniCore Pro+, per sq cm
Q4300*	Acesso TL, per sq cm
Q4301*	Activate Matrix, per sq cm
Q4302*	Complete ACA, per sq cm
Q4303*	Complete AA, per sq cm
Q4304*	GRAFIX PLUS, per sq cm
Q4305*	American Amnion AC Tri-Layer, per sq cm
Q4306*	American Amnion AC, per sq cm
Q4307*	American Amnion, per sq cm
Q4308*	Sanopellis, per sq cm
Q4309*	VIA Matrix, per sq cm
Q4310*	Procenta, per 100 mg

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Converted corporate to local policy.	08/15/20	
References reviewed and updated. HCPCS codes removed as they are not included in Medicare Article A56696: Q4150, Q4183, Q4190, Q4208-Q4226. Q4210, Q4217, Q4219, and Q4220 removed. New codes added (from Article A56696): Q4176, Q4237, Q4238, and Q4239. Added LA specific Criteria for Chronic Diabetic Lower Extremity Ulcers	1/22	3/26/22
Updated description for code Q4128.	10/22	
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." Added "type 2 diabetes" to I.A. Reworded some extraneous language with no clinical significance. Added to I. F. 4.: Toe-brachial index (TBI) of at least 0.5; Triphasic or biphasic Doppler arterial waveforms at the ankle of the affected leg. Added to I. G.: Is at least 1.0 square centimeter (cm) in size Change A1c from 8 to 9 Added to section I. J.: 1. Active and untreated autoimmune connective tissue disease; 2. Known or suspected malignancy of the ulcer; 3. Member/Enrollee is receiving radiation therapy or chemotherapy 4. Re-treatment of the same ulcer within one year Background section updated with no additional impact to criteria. Coding was reviewed and updated. Changed all instances of member to member/enrollee	1/23	4/3/23

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Annual review completed. Changed policy title and statements in I. and II. to reflect the inclusion of soft tissue substitutes for chronic wounds. Added note specifying that requests for skin and soft tissue substitutes other than for the indications noted in the policy is outside of the scope of the policy. Updated policy statement I. to include full thickness skin-loss ulcers. Revised criteria I.G. In I.H clarified that the request complies with FDA-approved indications and application limits. Removed criteria II.A. Reworded extraneous language and background updated with no clinical significance. Removed deleted HCPCS code A2003. Labeled HCPCS Table 1 to note support of medical necessity. Added HCPCS Table 2 of codes that do not support medical necessity. Moved the following codes from the previous code reference table to table 2, HCPCS codes that do not support medical necessity: A2002, A2005, A2006, A2007, A2009, A2010, Q4184, Q4199, Q4237, Q4238, Q4239, Q4262, Q4263, and Q4264 Added new codes Q4253, Q4262, Q4263 and Q4264 to HCPCS table 1. Added additional codes to not medically necessary table, Table 2. References reviewed and updated.	5/23	7/21/23
Annual review. Removed language related to venous stasis ulcers. Removed criteria 1.A Age ≥ 18 years, or diabetic (Type 1 or Type 2). Removed "including silver dressings in C.1. Replaced C2 "wound has increased in size or depth or has not changed… with "Wound area has reduced <50% in four weeks". Updated description for HCPCS code A4225. Removed the following codes from HCPCS codes that do not support medical necessity criteria and added to table for HCPCS codes that support medical necessity criteria: A2002, Q4236, and Q4262. Added HCPCS code Q4278 and A2019-A4100 to table for HCPCS codes that support medical necessity criteria. Added the following codes to table for HCPCS codes that do not support medical necessity criteria: Q4279 and Q4287 through Q4304. Added Q4305-Q4310. Coding reviewed. References reviewed and updated. Reviewed by external specialist.	5/24	7/16/24

References

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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. LHCC 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.

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 LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. 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. LHCC 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 LHCC has no control or right of control. Providers are not agents or employees of LHCC.

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