Clinical Policy: Skin and Soft Tissue Substitutes for Chronic Wounds

Reference Number: CP.MP.185
Date of Last Revision: 03/24
Effective Date: 09/01/24

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 criteria applicable to Medicare plans, please see MC.CP.MP.185 Skin Substitutes for Chronic Wounds of the Lower Extremities*
- *For skin substitutes for burns, refer to 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 non-Medicare health plans affiliated with Centene Corporation® 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. 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;
B. Wound characteristics and treatment plan are documented;
C. 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];
D. 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;
E. 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]);

F. One of the following:
   1. Diabetic foot ulcer (DFU), and all of the following:
      a. 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;
   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;

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

H. 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;

I. 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).

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

II. It is the policy of non-Medicare health plans affiliated with Centene Corporation 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;

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

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; 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

HCPCS Codes	Description
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
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

HCPCS Codes	Description
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
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

HCPCS Codes	Description
A2018	PermeaDerm C, per sq cm
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
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

HCPCS Codes	Description
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
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

HCPCS Codes	Description
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
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

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy adapted from WellCare's HS433 Skin Substitutes policy. Removed description information about identification of MD managing chronic conditions. Removed requirement for MD review of all requests. Rearranged some not medically necessary indications into the contraindications section. In I.D, changed requirement for no nicotine use for at least 4 weeks to documentation of effort to cease nicotine use, or no nicotine use for at least 4 weeks. In the diabetic foot ulcer criteria, removed requirement of neuropathy. In I.I.1, changed contraindication of "active Charcot arthropathy of the ulcer extremity" to "active Charcot arthropathy of the ulcer surface." In DFU section, removed documentation of assessment of physical activity, nutrition, physical exam, check of prosthetics, and history of diabetes management, including comorbidities. Changed requirement of HbA1c ≤7% to ≤8%, or with documented improvement of blood glucose in last 4 weeks. Changed HbA1c contraindication to >8% or with no document	04/20	04/20

Reviews, Revisions, and Approvals	Revision Date	Approval Date
improvement of blood glucose in last 4 weeks. Reworded some extraneous language with no clinical significance. Removed criteria stating that switching products during an episode of wound care is not allowed. Removed not medically necessary language about repeated billing of surgical preparation services. Revised name of the policy to Skin Substitutes for Chronic Wounds.		
Added criteria of age ≥ 18 years, or type 1 diabetic. Added to the requirement for documentation of effort to cease nicotine use that this does not include nicotine replacement therapy. 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.	05/20	06/20
References reviewed and updated. All instances of "member" changed to "member/enrollee." 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.	04/21	04/21
Annual review completed. 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.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. Added the following HCPCS codes: A2001-A2010, Q4199, Q4201, Q4232 and Q4254. Removed Q4119, Q4174. Added reference CMS A56696. Specialist reviewed.	04/22	04/22
Updated description for code Q4128.	10/22	
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,	04/23	04/23

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Q4263 and Q4264 to HCPCS table 1. Added additional codes to not medically necessary table, Table 2. References reviewed and updated.		
Annual review. In note and policy statements I and II, specified that this policy applies to non-Medicare plans. 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 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. Coding reviewed. References reviewed and updated. Reviewed by external specialist.	03/24	03/24

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. 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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, member/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

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.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.