Clinical Policy: Skin and Soft Tissue Substitutes for Chronic Wounds

Reference Number: CP.MP.185
Date of Last Revision: 03/25

Coding Implications
Revision Log

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

Description
Patients receiving treatment with a skin substitute graft should be under the care of a wound care physician or surgeon and systemic disease should 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.

Skin substitutes range widely in terms of origin, additives, and processing. Processing variations lead to broad differences between products within the same class, with a need for more comparative product studies. The result is that products within the same class vary significantly and the impact on the product's function is indeterminant in many cases.[31] A 2024 systematic review/meta-analysis concluded that "enough evidence is still lacking to determine a statistical difference between broad categories of CAMPs [cellular, acellular and matrix-like products]; hence decision-makers should consider published head-head comparative studies, real-world evidence, and cost-effectiveness evidence between individual CAMPs to decide on which to use in practice."[32]

Medical necessity determinations regarding preferred products when deemed medically necessary are applicable to FDA-labeled indications. Preferred products are subject to change based on new product launches, product approvals, product withdrawals and other market changes.

Note:
- *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 and venous leg ulcers.*

Policy/Criteria
I. It is the policy of non-Medicare health plans affiliated with Centene Corporation® that skin and soft tissue substitutes/cellular and tissue-based products (CTPs) are **medically necessary** for diabetic foot ulcers (DFU) or venous leg ulcers (VLU) when all of the following criteria are met:
   A. Presence of a non-infected wound and one of the following:
      1. For patients with a DFU, documentation of all the following:
         a. Failure to achieve at least 50% ulcer area reduction, despite compliance with standard of care (SOC) wound treatment for a minimum of 4 weeks, as noted in I.C.;
         b. Assessment of type 1 or type 2 diabetes and management history with attention to certain comorbidities (e.g., vascular disease, neuropathy, osteomyelitis);

c. Review of current blood glucose levels/hemoglobin A1c (HbA1c);
d. Diet, nutritional status, and activity level;
e. Updated medication history, including review of pertinent medical problems diagnosed since the previous ulcer evaluation;
f. Physical exam assessing skin, ulcer, and vascular perfusion, as well as off-loading devices or use of appropriate footwear;

2. For patients with a VLU, documentation of all the following:
   a. Failure to respond, despite compliance with standard of care (SOC) wound treatment for a minimum of 4 weeks, as noted in I.C;
   b. Assessment of clinical history (prior ulcers, body mass index, history of pulmonary embolism or superficial/deep venous thrombosis, number of pregnancies, and physical inactivity);
   c. Updated medication history, including review of pertinent medical problems diagnosed since the previous ulcer evaluation;
   d. Physical exam assessing for edema, skin changes and evaluation of vascular competence (including venous reflux and perforator incompetence) and venous thrombosis;
   e. Documentation supporting the use of a firm strength compression garment (>20 mmHg) or multi-layered compressive dressing;

B. Documentation that modifiable risk factors, such as diabetes, venous insufficiency, and neuropathy are being addressed adequately to improve likelihood of healing;
C. Documentation of implemented SOC treatment plan demonstrating all the following:
   1. Debridement as appropriate to a clean granular base;
   2. Documented evidence of one of the following:
      a. Offloading for DFUs;
      b. Sustained compression dressings for VLUs;
   3. Infection control with removal of foreign body or nidus of infection;
   4. Management of exudate with maintenance of a moist environment;
   5. Documentation of smoking history, and counselling on the effect of smoking on wound healing, as well as treatment for smoking cessation and outcome of counselling (if applicable);
D. Documentation to support failure to heal or stalled healing with SOC, including all the following:
   1. Measurements of the initial ulcer;
   2. Pre-SOC ulcer measurements;
   3. Weekly SOC ulcer measurements;
   4. Post-completion SOC ulcer measurements following at least 4 weeks of SOC treatment;
   5. Other interventions, as applicable;
E. Request is for one of the following preferred products:
   1. TheraGenesis (A2008);
   2. Kerecis Omega3 Margen Shield (A2019);
   3. Apligraf (Q4101);
   4. Oasis Wound Matrix (Q4102);
   5. Integra Bilayer Matrix Wound Dressing (Q4104);
   6. Integra dermal regeneration template or Integra Omnigraft dermal regeneration matrix (Q4105);

7. Dermagraft (Q4106);
8. Graftjacket (Q4107);
9. Primatrix (Q4110);
10. Gammagraft (Q4111);
11. Alloskin (Q4115);
12. Hyalomatrix (Q4117);
13. Matristem micromatrix (Q4118);
14. Theraskin (Q4121);
15. Oasis ultra trilayer wound matrix (Q4124);
16. Flex HD or Allopatch HD (Q4128);
17. Grafix Core and Grafix PL Core (Q4132);
18. Grafix PRIME, GrafixPL; PRIME, Stravix and Stravix PL (Q4133);
19. Amnioexcel, amnioexcel plus or biodexcel (Q4137);
20. Alloskin AC (Q4141);
21. Tensix (Q4146);
22. Neox cord 1K, Neox Cord RT or Clarix Cord 1K (Q4148);
23. AmnioBand or Guardian (Q4151);
24. DermaPure (Q4152);
25. Biovance (Q4154);
26. Neox 100 or Clarix 100 (Q4156);
27. Kerecis Omega3 (Q4158);
28. Affinity (Q4159);
29. Nushield (Q4160);
30. Cytal (Q4166);
31. Cygnus (Q4170);
32. Miroderm (Q4175);
33. FlowerAmnioPatch (Q4178);
34. Epifix (Q4186);
35. Epicord (Q4187);
36. AmnioArmor (Q4188);
37. Puraply (Q4195);
38. PuraPly AM (Q4196);
39. Puraply XT (Q4197);
40. Matrion (Q4201);
41. Derma-gide (Q4203)
42. carePATCH (Q4236);
43. Zenith amniotic membrane (Q4253);
44. Dual Layer Impax Membrane (Q4262);

F. Requested use complies with FDA-approved indications;
G. Only one skin substitute will be simultaneously in place per wound episode with a maximum of 8 applications per wound per 12-16 week episode of care, with the first skin substitute graft/CTP application beginning the episode of care.
Note:
- Product change within the wound episode is allowed; total applications not to exceed the 8-application limit per wound per 12–16-week episode of care.
- If skin substitute grafts/CTP are applied greater than four times in a 12-16 week period, documentation includes all the following:
  - Explanation of why extended time or additional applications is medically necessary for the specific member/enrollee's wound;
  - That the current treatment plan has resulted in wound healing and expectation that the wound will continue to heal with this plan;
  - Estimated time for extended treatment, number of additional applications anticipated, and plan of care if healing is not achieved as planned;
  - Which modifiable risk factors, such as diabetes optimization, are being approached to improve likelihood of healing;
  - For venous leg ulcers, appropriate consultation and management for the diagnosis and stabilization of any venous-related disease;

- 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;
- An operative note must document each application of skin substitute grafts/CTPs, including the following:
  - The reason for the procedure;
  - A complete description of the procedure including product used (with identifying package label or National Drug Code (NDC) in the chart), and relevant findings;
- Graphic evidence of ulcer size, depth, and characteristics of the ulcer or photo documentation of the ulcer at baseline and follow-up with measurements of wound including size and depth must be part of the medical record.
- Regarding potential wastage, all of the following:
  - Where multiple sizes of a specific product are available, the size that best fits the wound with the least amount of wastage must be utilized;
  - When a portion of a product is discarded, the medical record must clearly demonstrate the following:
    - The amount administered;
    - The amount wasted;
    - Documentation must include the date, time, amount of product wasted and the reason for the wastage;
  - When a portion of a single use package must be discarded, payment will be made for the portion discarded along with the amount applied up to the amount of the product on the package label;
- All documentation must be maintained in the member/enrollee's medical record and made available upon request.

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. Any usage not listed in section I. of the policy;
B. Greater than 8 applications of a skin substitute graft/CTP within an episode of care (up to 16 weeks);
C. Repeat applications of skin substitute grafts/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 improvement or indication that improvement is likely (such as granulation, epithelialization, or progress towards closure);
D. Inadequate control of underlying conditions or exacerbating factors, or other contraindications (e.g., active infection, progressive necrosis, active Charcot arthropathy of the ulcer extremity, active vasculitis, or ischemia);
E. Use of surgical preparation services (e.g., debridement), with routine, simple, or repeat skin replacement surgery with a skin substitute graft/CTP;
F. Use of liquid or gel skin substitute products/CTP for ulcer care;
G. Placement of skin substitute grafts/CTP on an infected, ischemic, or necrotic wound bed.

Background

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.[1-8]

The Centers for Medicare & Medicaid Services (CMS), define a chronic wound as a wound A wound that is physiologically impaired due to a disruption of the wound healing cycle because of impaired angiogenesis, innervation, or cellular migration, or other deficits for 4 weeks or longer. Even with advancements in standard wound care and synthetic occlusive dressings, some ulcers fail to heal and may benefit from a skin substitute.[1-8] The United Kingdom's 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.[29] Skin substitutes promote wound healing by replacing extracellular matrix.[20] Skin substitutes are categorized based on the composition of epidermal, dermal, and composite skin present.[20] 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).[21,22] The categories are further split based on composition and source of material, including xenograft, acellular allograft, cellular allograft, autograft and synthetic skin substitute choices.[20]

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.[17]

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.[23] 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."[24] 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.[27] 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.[26]

Outlined in a 2020 technical brief prepared for the Agency for Healthcare Research and Quality (AHRQ) are the various products commercially available in the United States that may be considered skin substitutes and identifies and assesses the clinical literature evaluating skin substitutes and their efficacy. Synder et al. (2020) conducted a systematic review of the published literature, grey literature and scientific packets received from manufacturers. The authors searched for systematic reviews/meta-analyses, randomized controlled trials (RCTs), and prospective nonrandomized comparative studies examining commercially available skin substitutes. The authors 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. Of the 22 included RCTs, 16 studies compared a skin substitute with standard of care (e.g., debridement, glucose control, compression bandages for venous leg ulcers, daily dressing changes with moisture-retentive dressing, such as an alginate or hydrocolloid). Twenty-one ongoing clinical trials (all RCTs) examined an additional nine skin substitutes with similar classifications. The authors found that the 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 authors concluded that there is a 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. 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.[19]

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 2024, 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

CPT Codes	Description
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
A2008	TheraGenesis, per sq cm
A2019	Kerecis Omega3 MariGen Shield, per sq cm
Q4101	Apligraf, per sq cm
Q4102	Oasis wound 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
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
Q4124	Oasis ultra tri-layer wound matrix, 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

HCPCS Codes	Description
Q4137	Amnioexcel, amnioexcel plus or biodexcel, per sq cm
Q4141	AlloSkin AC, per sq cm
Q4146	TENSIX, 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
Q4154	Biovance, per sq cm
Q4156	Neox 100 or Clarix 100, per sq cm
Q4158	Kerecis Omega3, per sq cm
Q4159	Affinity, per sq cm
Q4160	Nushield, per sq cm
Q4166	Cytal, per square centimeter
Q4170	Cygnus, per sq cm
Q4175	Miroderm, per sq cm
Q4178	FlowerAmnioPatch, 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
Q4236	carePATCH, per sq cm
Q4253	Zenith amniotic membrane, per sq cm
Q4262	Dual Layer Impax Membrane, per sq cm

HCPCS codes that do not support medical necessity criteria

HCPCS Codes	Description
A2001	InnovaMatrix AC, per sq cm
A2002	Mirragen Advanced Wound Matrix, per sq cm
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

HCPCS Codes	Description
A2017	PermeaDerm Glove, each
A2018	PermeaDerm C, 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
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
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
C9364	Porcine implant, Permacol, per sq cm
Q4100	Skin substitute, not otherwise specified
Q4103	Oasis burn matrix, per sq cm
Q4108	Integra matrix, per sq cm
Q4112	Cymetra, injectable, 1 cc
Q4113	GRAFTJACKET XPRESS, injectable, 1 cc
Q4114	Integra flowable wound matrix, injectable, 1 cc
Q4116	AlloDerm, per sq cm
Q4122	DermACELL, DermACELL AWM or DermACELL AWM Porous, per sq cm
Q4123	AlloSkin RT, per sq cm
Q4125	ArthroFlex, per sq cm
Q4126	MemoDerm, DermaSpan, TranZgraft or Integuply, per sq cm
Q4127	Talymed, per sq cm
Q4130	Strattice TM, per sq cm
Q4134	Hmatrix, per sq cm
Q4135	Mediskin, per sq cm
Q4136	E Z Derm, per sq cm
Q4138	BioDFence DryFlex, per sq cm
Q4139	AmnioMatrix or BioDMatrix, injectable, 1 cc
Q4140	BioDFence, per sq cm
Q4142	XCM biologic tissue matrix, per sq cm
Q4143	Repriza, per sq cm
Q4145	EpiFix, injectable, 1 mg
Q4147	Architect, Architect PX, or Architect FX, extracellular matrix, per sq cm

HCPCS Codes	Description
Q4149	Excellagen, 0.1 cc
Q4150	AlloWrap DS or dry, per sq cm
Q4153	Dermavest and Plurivest, per sq cm
Q4155	Neox Flo or Clarix Flo 1 mg
Q4157	Revitalon, per sq cm
Q4161	Bio-connekt wound matrix, per sq cm
Q4162	WoundEx Flow, BioSkin Flow, 0.5 cc
Q4163	Woundex, bioskin, per sq cm
Q4164	Helicoll, per sq cm
Q4165	Keramatrix or Kerasorb, per sq cm
Q4167	Truskin, per sq cm
Q4168	AmnioBand, 1 mg
Q4169	Artacent wound, per sq cm
Q4171	Interfyl, 1 mg
Q4173	Palingen or Palingen Xplus, per sq cm
Q4174	PalinGen or ProMatrX, 0.36 mg per 0.25 cc
Q4176	Neopatch or therion, per sq cm
Q4177	FlowerAmnioFlo, 0.1 cc
Q4179	FlowerDerm, per sq cm
Q4180	Revita, 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

HCPCS Codes	Description
Q4214	Cellesta Cord, per sq cm
Q4215	Axolotl Ambient or Axolotl Cryo, 0.1 mg
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
Q4232	Corplex, per sq cm
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
Q4254	Novafix, 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

HCPCS Codes	Description
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
Q4267	NeoStim DL, per sq cm
Q4268	SurGraft FT, per sq cm
Q4269	SurGraft XT, per sq cm
Q4270	Complete SL, per sq cm
Q4271	Complete FT, per sq cm
Q4272	Esano A, per sq cm
Q4273	Esano AAA, per sq cm
Q4274	Esano AC, per sq cm
Q4275	Esano ACA, per sq cm
Q4276	ORION, per sq cm
Q4278	EPIEFFECT, per sq cm
Q4279	Vendaje AC, per sq cm
Q4281	Barrera SL or Barrera DL, per sq cm
Q4282	Cygnus Dual, per sq cm
Q4283	Biovance Tri-Layer or Biovance 3L, per sq cm
Q4284	DermaBind SL, per sq cm
Q4285	NuDYN DL or NuDYN DL MESH, per sq cm
Q4286	NuDYN SL or NuDYN SLW, 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
Q4305	American Amnion AC Tri-Layer, per sq cm
Q4306	American Amnion AC, per sq cm

HCPCS Codes	Description
Q4307	American Amnion, per sq cm
Q4308	Sanopellis, per sq cm
Q4309	VIA Matrix, per sq cm
Q4310	Procenta, per 100 mg
Q4354	PalinGen Dual-Layer Membrane, per sq cm
Q4355	Abiomend Xplus Membrane and Abiomend Xplus Hydromembrane, per sq cm
Q4356	Abiomend Membrane and Abiomend Hydromembrane, per sq cm
Q4357	XWRAP Plus, per sq cm
Q4358	XWRAP Dual, per sq cm
Q4359	ChoriPly, per sq cm
Q4360	AmchoPlast FD, per sq cm
Q4361	EPIXPRESS, per sq cm
Q4362	CYGNUS Disk, per sq cm
Q4363	Amnio Burgeon Membrane and Hydromembrane, per sq cm
Q4364	Amnio Burgeon Xplus Membrane and Xplus Hydromembrane, per sq cm
Q4365	Amnio Burgeon Dual-Layer Membrane, per sq cm
Q4366	Dual Layer Amnio Burgeon X-Membrane, per sq cm
Q4367	AmnioCore SL, 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 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.	04/20	04/20

Reviews, Revisions, and Approvals	Revision Date	Approval Date
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, Q4263 and Q4264 to HCPCS table 1. Added additional codes to not medically necessary table, Table 2. References reviewed and updated.	04/23	04/23
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.	03/24	03/24

Reviews, Revisions, and Approvals	Revision Date	Approval Date
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.		
Annual review. Removed note under description to refer to MC.CP.MP.185 for Medicare plans. Updated and replaced previous criteria I.A. through I. with new criteria I.A. through G. Also updated and replaced previous criteria II.A. through C. with new criteria I.A. through G. Description and Background reviewed and updated. Coding updated to reflect addition of preferred product list in criteria I.E. References reviewed and updated. Reviewed by external specialist.	03/25	03/25

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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.