

Clinical Policy: Skin and Soft Tissue Substitutes for Chronic Wounds

Reference Number: CP.MP.185

Date of Last Revision: 03/24

[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 (including silver dressings), compression, off-loading;
 2. Wound area has reduced <50% in four weeks²⁰;
 - 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

CLINICAL POLICY

Skin and Soft Tissue Substitutes for Chronic Wounds

- 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 \geq 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 ulcer VSU or VLU has failed to respond to documented conservative wound-care measures for \geq 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. If VLU is present, 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 \geq 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;

CLINICAL POLICY

Skin and Soft Tissue Substitutes for Chronic Wounds

- 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

CLINICAL POLICY

Skin and Soft Tissue Substitutes for Chronic Wounds

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. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| CPT Codes | Description |
|------------------|--|
| 15271 | Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area |
| 15272 | Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure) |
| 15273 | Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children |
| 15274 | Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure) |
| 15275 | Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area |
| 15276 | Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; 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 |

CLINICAL POLICY

Skin and Soft Tissue Substitutes for Chronic Wounds

| HCPCS Codes | Description |
|--------------------|---|
| 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 InteguPly, 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 Plurinvest, 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 |

CLINICAL POLICY

Skin and Soft Tissue Substitutes for Chronic Wounds

| HCPCS Codes | Description |
|--------------------|---------------------------------------|
| 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 |
| 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 |

CLINICAL POLICY

Skin and Soft Tissue Substitutes for Chronic Wounds

| HCPCS Codes | Description |
|--------------------|---|
| A2017 | PermeaDerm Glove, each |
| 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 |

CLINICAL POLICY

Skin and Soft Tissue Substitutes for Chronic Wounds

| HCPCS Codes | Description |
|--------------------|---|
| 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 |
| 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 |

CLINICAL POLICY
Skin and Soft Tissue Substitutes for Chronic Wounds

| HCPCS Codes | Description |
|-------------|--|
| 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 |
| 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. | 04/20 | 04/20 |

CLINICAL POLICY
Skin and Soft Tissue Substitutes for Chronic Wounds

| Reviews, Revisions, and Approvals | Revision Date | Approval Date |
|---|---------------|---------------|
| <p>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.</p> | | |
| <p>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.</p> | 05/20 | 06/20 |
| <p>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.</p> | 04/21 | 04/21 |
| <p>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.</p> | 04/22 | 04/22 |
| <p>Updated description for code Q4128.</p> | 10/22 | |
| <p>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,</p> | 04/23 | 04/23 |

| Reviews, Revisions, and Approvals | Revision Date | Approval Date |
|--|---------------|---------------|
| 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. | | |
| 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

1. Local coverage determination: wound application of cellular and/or tissue based products (CTPs), lower extremities (L36690). Centers for Medicare and Medicaid Services Web site. <https://www.cms.gov/medicare-coverage-database/search.aspx>. Published October 10, 2016 (revised September 1, 2022). Accessed January 22, 2024.
2. Local coverage determination: application of bioengineered skin substitutes to lower extremity chronic non-healing wounds (L35041). Centers for Medicare and Medicaid Services Web site. <https://www.cms.gov/medicare-coverage-database/search.aspx>. Published October 1, 2015 (revised September 26, 2019). Accessed January 22, 2024.
3. Gohel MS, Heatley F, Liu X, et al. A randomized trial of early endovenous ablation in venous ulceration. *N Engl J Med*. 2018;378(22):2105 to 2114. doi:10.1056/NEJMoa1801214
4. Local coverage determination: application of skin substitute grafts for treatment of DFU and VLU of lower extremities (L36377). Centers for Medicare and Medicaid Services Web site. <https://www.cms.gov/medicare-coverage-database/search.aspx>. Published October 1, 2015 (revised January 8, 2019). Accessed January 22, 2024.
5. Armstrong DG, deAsla RJ. Management of diabetic foot ulcers. UpToDate. www.uptodate.com. Updated April 25, 2022. Accessed January 22, 2024.
6. Snyder D, Sullivan N, Margolis D, Schoelles K. Skin substitutes for treating chronic wounds. Technology Assessment Program Project ID No.WNDR0818. (Prepared by the ECRI Institute-Penn Medicine Evidence-based Practice Center under Contract No. HHS 290-2015-0005-I) Rockville, MD: Agency for Healthcare Research and Quality. February 2020. <https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id109TA.pdf> Accessed January 22, 2024.

CLINICAL POLICY

Skin and Soft Tissue Substitutes for Chronic Wounds

7. Dai C, Shih S, Khachemoune A. Skin substitutes for acute and chronic wound healing: an updated review. *J Dermatolog Treat.* 2020;31(6):639 to 648. doi:10.1080/09546634.2018.1530443
8. Health Technology Assessment. Cellular skin substitutes for chronic foot ulcers in adults with diabetes mellitus. Hayes. www.hayesinc.com. Published March 26, 2020 (annual review April 24, 2023). Accessed January 22, 2024.
9. Health Technology Assessment. Skin substitutes for venous leg ulcers in adults. Hayes. www.hayesinc.com. Published July 23, 2020 (annual review July 11, 2023). Accessed January 22, 2024.
10. Santema TB, Poyck PP, Ubbink DT. Skin grafting and tissue replacement for treating foot ulcers in people with diabetes. *Cochrane Database Syst Rev.* 2016;2(2):CD011255. Published 2016 Feb 11. doi:10.1002/14651858.CD011255.pub2
11. Lavery LA, Davis KE, Berriman SJ, et al. WHS guidelines update: Diabetic foot ulcer treatment guidelines. *Wound Repair Regen.* 2016;24(1):112 to 126. doi:10.1111/wrr.12391
12. Local coverage article. billing and coding: wound application of cellular and/or tissue based products (CTPs), lower extremities (A56696). Centers for Medicare and Medicaid Services Web site: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Published July 11, 2019 (revised December 28, 2023). Accessed January 22, 2024.
13. Urciuolo F, Casale C, Imperato G, Netti PA. Bioengineered Skin Substitutes: the Role of Extracellular Matrix and Vascularization in the Healing of Deep Wounds. *J Clin Med.* 2019;8(12):2083. Published 2019 Dec 1. doi:10.3390/jcm8122083
14. Shahrokhi S. Skin substitutes. UpToDate. www.uptodate.com. Updated August 02, 2023. Accessed January 22, 2024.
15. Ontario Health. Skin substitutes for adults with diabetic foot ulcers and venous leg ulcers: a health technology assessment. Ont Health Technol Assess Ser [Internet]. 2021 June 21(7):1 to 165. Available from: <https://www.hqontario.ca/evidence-to-improve-care/health-technology-assessment/reviews-and-recommendations/skin-substitutes-for-adults-with-diabetic-foot-ulcers-and-venous-leg-ulcers> Accessed January 22, 2024.
16. Local coverage article. billing and coding: application of bioengineered skin substitutes to lower extremity chronic non-healing wounds (A54117). Centers for Medicare and Medicaid Services Web site: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Published October 1, 2015 (revised August 13, 2020). Accessed January 22, 2024.
17. Xiang J, Wang S, He Y, Xu L, Zhang S, Tang Z. Reasonable glycemic control would help wound healing during the treatment of diabetic foot ulcers. *Diabetes Ther.* 2019;10(1):95 to 105. doi:10.1007/s13300-018-0536-8
18. Diabetic foot problems: prevention and management. NICE guideline[NG19] on diabetes and other endocrinal, nutritional and metabolic conditions. <https://www.nice.org.uk/guidance/ng19/chapter/Recommendations#diabetic-foot-ulcer> Published August 26, 2015 (updated October 11, 2019). Accessed January 22, 2024.
19. Health Technology Assessment. Acellular skin substitutes for chronic foot ulcers in adults with diabetes mellitus. Hayes. www.hayesinc.com. Published May 6, 2020 (annual review May 10, 2023). Accessed January 22, 2024.
20. Hingorani A, LaMuraglia GM, Henke P, et al. The management of diabetic foot: A clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. *J Vasc Surg.* 2016;63(2 Suppl):3S-21S. doi:10.1016/j.jvs.2015.10.003

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,

CLINICAL POLICY

Skin and Soft Tissue Substitutes for Chronic Wounds

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.

©2020 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.