Clinical Policy: Skin Substitutes for Chronic Wounds of the Lower Extremities

Reference Number: MC.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

This policy outlines the medical necessity criteria for skin substitutes for diabetic foot ulcers (DFU) and venous leg ulcers (VLU) in the treatment of chronic wounds. This policy criteria is sourced from Local Coverage Determinations (LCDs) Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities (L36690), Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities (L36377), and Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds (L35041) and a clinical practice guideline from the American Society of Vascular Surgery on the Diabetic Foot.

The U.S. Food and Drug Administration (FDA) does not refer to any product or class of products as "skin substitutes." However, products commonly described as cellular and/or tissue-based products (CTPs) are regulated by the FDA under one of four categories depending on the origin and composition of the product. Product codes classified as not medically necessary in this policy have not obtained the required FDA approval or oversight, meaning that the FDA has not verified their safety and effectiveness or they have not completed the required steps for FDA regulation of the product, and therefore their clinical value to patients is still under investigation.

Standard treatment of chronic lower extremity ulcers or skin loss primarily includes infection and edema control, mechanical offloading, mechanical compression or limb elevation, debridement of necrotic or infected tissue, and management of concomitant and inciting medical issues (blood glucose control, tobacco use). Maintenance of a therapeutic environment with appropriate dressings to preclude further trauma facilitates development of healthy granulation tissue and encourages re-epithelialization. The fundamental basis for non-healing of a wound is of paramount importance and must be corrected prior to consideration of additional therapy, consistent with the criteria below. A failed response is defined as an ulcer or skin deficit that has failed to respond to documented appropriate wound-care measures, has increased in size or depth, or has not changed in baseline size or depth and has no indication that improvement is likely (such as granulation, epithelialization or progress towards closing).[1,2] Application of evidence-based wound care measures helps to ensure patients receive optimal care and progress towards treatment goals, thus minimizing the risks of treatment strategies of uncertain value.

Note: For criteria applicable to non-Medicare plans, please see CP.MP.185 Skin and Soft Tissue Substitutes for Chronic Wounds

Policy/Criteria

I. It is the policy of Medicare health plans affiliated with Centene Corporation® that skin and soft tissue substitutes will be considered medically reasonable and necessary for chronic wounds of the lower extremities when all of the following criteria are met:[1-3]

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[7];
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 extremity, vasculitis or continued tobacco smoking without physician attempt to effect smoking cessation);
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 Medicare health plans affiliated with Centene Corporation that skin and soft tissue substitutes for chronic wounds of the lower extremities are **not medically necessary** for the following indications or scenarios:[1-3]

A. Partial thickness loss with the retention of epithelial appendages is not a candidate for grafting or replacement, as epithelium will repopulate the deficit from the appendages, negating the benefit of overgrafting.
B. Skin substitute grafts will be allowed for the episode of wound care in compliance with FDA guidelines for the specific product (see utilization guidelines) not to exceed 10 applications or treatments. In situations where more than one specific product is used, it is expected that the number of applications or treatments will still not exceed 10.
C. Simultaneous use of more than one product for the episode of wound is not covered. Product change within the episode of wound is allowed, not to exceed the 10 application limit per wound per 12 week period of care.
D. Treatment of any chronic skin wound will typically last no more than twelve (12) weeks.
E. Repeat or alternative applications of skin substitute grafts are not considered medically reasonable and necessary when a previous full course of applications was unsuccessful. Unsuccessful treatment is defined as increase in size or depth of an ulcer or no change in baseline size or depth and no sign of improvement or indication that improvement is likely (such as granulation, epithelialization or progress towards closing) for a period of 4 weeks past start of therapy.
F. Retreatment of healed ulcers, those showing greater than 75% size reduction and smaller than 0.5 square cm, is not considered medically reasonable and necessary.
G. Skin substitute grafts are contraindicated and are not considered reasonable and necessary in patients with inadequate control of underlying conditions or exacerbating factors (e.g., uncontrolled diabetes, active infection, and active Charcot arthropathy of the ulcer extremity, vasculitis or continued tobacco smoking without physician attempt to affect smoking cessation).
H. Skin substitute grafts are contraindicated in patients with known hypersensitivity to any component of the specific skin substitute graft (e.g., allergy to avian, bovine, porcine, equine products).
I. Repeat use of surgical preparation services in conjunction with skin substitute application codes will be considered not reasonable and necessary. It is expected that

each wound will require the use of appropriate wound preparation code at least once at initiation of care prior to placement of the skin substitute graft.

J. Re-treatment within one (1) year of any given course of skin substitute treatment for a venous stasis ulcer or (diabetic) neuropathic foot ulcer is considered treatment failure and does not meet reasonable and necessary criteria for re-treatment of that ulcer with a skin substitute procedure.

Background

Centers for Medicare & Medicaid Services[1,2,3]

According to the Centers for Medicare & Medicaid Services (CMS), chronic wounds of the lower extremities, including venous stasis ulcers (VSU), venous leg ulcers (VLU), diabetic foot ulcers (DFU) and pressure sores, are a major public health problem. While lower extremity ulcers have numerous causes, such as burns, trauma, mixed venous-arterial disease, immobility and vasculitis, nutritional or other neuropathy, over 90% of the lesions in the United States are related to venous stasis disease and diabetic neuropathy.

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.

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 various synthetic occlusive dressings, some ulcers fail to heal and may benefit from a skin substitute.

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.

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.

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.

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. There are currently a broad range of bioengineered products available for soft tissue coverage to affect closure. Sufficient data is available to establish distinct inferiority to human skin autografts and preclude their designation as skin equivalence.

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)

CPT Codes	Description
15277	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
15278	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)

HCPCS codes that support medical necessity criteria

HCPCS Codes	Description
A2001	InnovaMatrix AC, per sq cm
A2002	Mirragen Advanced Wound Matrix, per sq cm
A2004	XCelliStem, per sq cm
A2008	TheraGenesis, per sq cm
Q4100	Skin substitute, not otherwise specified
Q4101	Apligraf, per sq cm
Q4102	Oasis wound matrix, per sq cm
Q4103	Oasis burn matrix, per sq cm
Q4104	Integra bilayer matrix wound dressing (BMWD), per sq cm
Q4105	Integra dermal regeneration template (DRT) or Integra Omnigraft dermal regeneration matrix, per sq cm
Q4106	Dermagraft, per sq cm
Q4107	Graftjacket, per sq cm
Q4108	Integra matrix, per sq cm
Q4110	Primatrix, per sq cm
Q4111	Gammagraft, per sq cm
Q4115	Alloskin, per sq cm
Q4117	Hyalomatrix, per sq cm
Q4118	Matristem micromatrix, 1mg
Q4121	TheraSkin, per sq cm
Q4122	DermACELL, DermACELL AWM or DermACELL AWM Porous, per sq cm
Q4123	AlloSkin RT, per sq cm
Q4124	Oasis ultra tri-layer wound matrix, per sq cm
Q4126	MemoDerm, DermaSpan, TranZgraft or IntéguPly, per sq cm
Q4127	Talymed, per sq cm
Q4128	FlexHD, or AllopatchHD, per sq cm
Q4132	Grafix Core and GrafixPL Core, per sq cm
Q4133	Grafix PRIME, GrafixPL PRIME, Stravix and StravixPL, per sq cm
Q4134	Hmatrix, per sq cm

HCPCS Codes	Description
Q4135	Mediskin, per sq cm
Q4136	E-Z Derm, per sq cm
Q4137	Amnioexcel, amnioexcel plus or biodexcel, per sq cm
Q4140	BioDFence, per sq cm
Q4141	Alloskin AC, per sq cm
Q4146	Tensix, per sq cm
Q4147	Architect, Architect PX, or Architect FX, extracellular matrix, per sq cm
Q4148	Neox Cord 1K, Neox Cord RT, or Clarix Cord 1K, per sq cm
Q4151	AmnioBand or Guardian, per sq cm
Q4152	DermaPure, per sq cm
Q4153	Dermavest and Plurivest, per sq cm
Q4154	Biovance, per sq cm
Q4156	Neox 100 or Clarix 100, per sq cm
Q4157	Revitalon, per sq cm
Q4158	Kerecis Omega3, per sq cm
Q4159	Affinity, per sq cm
Q4160	Nushield, per sq cm
Q4161	bio-ConneKt wound matrix, per sq cm
Q4163	Woundex, bioskin, per sq cm
Q4164	Helicoll, per square cm
Q4165	Keramatrix or Kerasorb, per sq cm
Q4166	Cytal, per square centimeter
Q4169	Artacent wound, per sq cm
Q4170	Cygnus, per sq cm
Q4173	Palingen or Palingen Xplus, per sq cm
Q4175	Miroderm, per sq cm
Q4176	Neopatch or therion, per sq cm
Q4178	FlowerAmnioPatch, per sq cm
Q4180	Revita, per sq cm
Q4186	Epifix, per sq cm
Q4187	Epicord, per sq cm
Q4188	AmnioArmor, per sq cm
Q4195	PuraPly, per square cm
Q4196	PuraPly AM , per square cm
Q4197	Puraply XT, per square cm
Q4201	Matrion, per sq cm
Q4203	Derma-Gide, per sq cm
Q4232	Corplex, per sq cm
Q4236	carePATCH, per sq cm
Q4253	Zenith amniotic membrane, per sq cm
Q4254	Novafix DL, per sq cm
Q4262	Dual Layer Impax Membrane, per sq cm
Q4278	EPIEFFECT, per sq cm

HCPCS codes that do not support medical necessity criteria

HCPCS Codes	Description
A2005	Microlyte Matrix, per sq cm
A2006	NovoSorb SynPath dermal matrix, per sq cm
A2007	Restrata, per sq cm
A2009	Symphony, per sq cm
A2010	Apis, per sq cm
A2011	Supra SDRM, per sq cm
A2012	Suprathel, per sq cm
A2013	Innovamatrix FS, per sq cm
A2014	Omeza Collagen Matrix, per 100 mg
A2015	Phoenix Wound Matrix, per sq cm
A2016	PermeaDerm B, per sq cm
A2017	PermeaDerm Glove, each
A2018	PermeaDerm C, per sq cm
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

HCPCS Codes	Description
Q4189	Artacent AC, 1 mg
Q4190	Artacent AC, per sq cm
Q4191	Restorigin, per sq cm
Q4192	Restorigin, 1 cc
Q4193	Coll-e-Derm, per sq cm
Q4194	Novachor, per sq cm
Q4198	Genesis Amniotic Membrane, per sq cm
Q4199	Cygnus matrix, per sq cm
Q4200	SkinTE, per sq cm
Q4202	Keroxx (2.5 g/cc), 1 cc
Q4204	XWRAP, per sq cm
Q4205	Membrane Graft or Membrane Wrap, per sq cm
Q4206	Fluid Flow or Fluid GF, 1 cc
Q4208	Novafix, per sq cm
Q4209	SurGraft, per sq cm
Q4210	Axolotl Graft or Axolotl DualGraft, per sq cm
Q4211	Amnion Bio or AxoBioMembrane, per sq cm
Q4212	AlloGen, per cc
Q4214	Cellesta Cord, per sq cm
Q4216	Artacent Cord, per sq cm
Q4217	WoundFix, BioWound, WoundFix Plus, BioWound Plus, WoundFix Xplus or BioWound Xplus, per sq cm
Q4218	SurgiCORD, per sq cm
Q4219	SurgiGRAFT-DUAL, per sq cm
Q4220	BellaCell HD or Surederm, per sq cm
Q4221	Amnio Wrap2, per sq cm
Q4222	ProgenaMatrix, per sq cm
Q4224	Human Health Factor 10 Amniotic Patch (HHF10-P), per sq cm
Q4225	AmnioBind or DermaBind TL, per sq cm
Q4226	MyOwn Skin, includes harvesting and preparation procedures, per sq cm
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

HCPCS Codes	Description
Q4244	Procenta, per 200 mg
Q4245	AmnioText, per cc
Q4246	CoreText or ProText, per cc
Q4247	Amniotext patch, per sq cm
Q4248	Dermacyte Amniotic Membrane Allograft, per sq cm
Q4249	AMNIPLY, for topical use only, per sq cm
Q4250	AmnioAmp-MP, per sq cm
Q4251	Vim, per sq cm
Q4252	Vendaje, per sq cm
Q4255	REGUaRD, for topical use only, per sq cm
Q4256	MLG-Complete, per sq cm
Q4257	Relese, per sq cm
Q4258	Enverse, per sq cm
Q4259	Celera Dual Layer or Celera Dual Membrane, per sq cm
Q4260	Signature Apatch, per sq cm
Q4261	TAG, per sq cm
Q4263	SurGraft TL, per sq cm
Q4264	Cocoon Membrane, per sq cm
Q4265	NeoStim TL, per sq cm
Q4266	NeoStim Membrane, per sq cm
Q4279	Vendaje AC, per sq cm
Q4287	DermaBind DL, per sq cm
Q4288	DermaBind CH, per sq cm
Q4289	RevoShield+ Amniotic Barrier, per sq cm
Q4290	Membrane Wrap-Hydro(TM), per sq cm
Q4291	Lamellas XT, per sq cm
Q4292	Lamellas, per sq cm
Q4293	Acesso DL, per sq cm
Q4294	Amnio Quad-Core, per sq cm
Q4295	Amnio Tri-Core Amniotic, per sq cm
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 developed	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. 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.
4. 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.
5. 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.
6. Health C for D and R. Device Approvals, Denials and Clearances. FDA. Published September 9, 2020. https://www.fda.gov/medical-devices/products-and-medical-procedures/device-approvals-denials-and-clearances. Accessed February 15, 2024.
7. 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.

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

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.