

Skin Substitutes

Policy Number: **M20211221065**
 Effective Date: **3/1/2022**
 Sponsoring Department: **Health Care Services**
 Impacted Department(s): **Health Care Services**

Type of Policy: ☒ Internal ☒ External

Data Classification: ☐ Confidential ☐ Restricted ☒ Public

Applies to (Line of Business):

- ☐ Corporate (All)
- ☒ State Products, if yes which plan(s): ☒ MediSource; ☒ MediSource Connect; ☒ Child Health Plus; ☒ Essential Plan
- ☒ Medicare, if yes, which plan(s): ☒ MAPD; ☐ PDP; ☒ ISNP; ☒ CSNP
- ☒ Commercial, if yes, which type: ☒ Large Group; ☒ Small Group; ☒ Individual
- ☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes ☐ No ☒

Purpose and Applicability:

To set forth Independent Health's medical necessity criteria for the use of **skin substitutes**.

Policy:

Background:

The skin's purpose is to regulate body temperature and store water, fat, and vitamin D. Wounds are disruptions of the skin's structural and functional integrity. Chronic wounds have failed to pass through the normal healing process in an orderly and timely manner. Patients with chronic wounds deal with loss of function, wound recurrence, and significant morbidity. Chronic wounds include, among others, diabetic foot ulcers, and venous leg ulcers. Chronic wounds may need specific interventions to restart

the healing process which is evidenced by reepithelization of epidermis and repair of the dermis. Successful healing of chronic wounds depends on critical factors, such as proper blood flow and nutrition to ensure tissue growth, infection control, maintenance of a moist environment, and removal of dead tissue to allow space for new cells and tissue to fill in the wound void

Care for chronic wounds involves removing necrotic tissue, applying dressings that maintain a moist wound environment, treating wound infections, and restoring blood flow to the wound site. If these procedures fail to restore the healing process, additional therapies may be considered.

Skin substitutes are indicated for use as an adjunct to standard wound care for uninfected wounds. The wound bed must be prepared prior to their application, generally with sharp debridement and cleansing. Skin substitutes are heterogeneous and can generally be classified into 2 main types, cellular (comprised of living cells) and acellular (composed of synthetic materials or tissue from which living cells have been removed).

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined below.

Commercial, Self-Funded and Medicare Advantage: Based upon Independent Health's criteria and assessment of the peer-reviewed literature, each of the following bioengineered tissue products has been proven to be medically effective and, therefore, is considered medically appropriate for the listed indications, when criteria are met.

MediSource, MediSource Connect, Child Health Plus and Essential Plan:

MediSource, MediSource Connect, Essential Plan, and CHP cover skin substitutes utilizing the Commercial criteria above.

Note: It is expected that a specific skin substitute product will be used for the episode of each documented wound, and in compliance with FDA assessments and submitted guidelines for the specific product. Greater than 10 applications for the treatment of a single wound within a 12-week period of time will be considered Not Reasonable and Necessary and will be subject to review with the exception of:

- EpiFix is limited to one application per week for up to 12 weeks.
- Grafix is limited to one application per week for up to 12 weeks.

In the event a new skin substitute does not appear below, an Independent Health Medical Director with make the determination regarding clinical utility for the requested indication.

Clinical indications

Skin substitutes may be considered medically necessary for **1 or more** of the following indications:

- Diabetic foot ulcers and **ALL** of the following:
 - Photographic documentation is submitted of wound(s) prior to treatment
 - The patient has adequate arterial blood supply as evidenced by ankle-brachial index (ABI) of 0.65 or greater in the limb being treated
 - The patient is competent and/or has support system required to participate in follow-up care associated with treatment with a bioengineered tissue product
 - Ulcer size is >1cm and <25 cm²

- Ulcers are full thickness, extend through the dermis but without tendon, muscle, capsule, or bone exposure
- Documentation has been submitted that the ulcer has failed to demonstrate measurable signs of healing with at least 4 weeks of standard wound care which includes **ALL** of the following:
 - Application of dressings to maintain a moist wound environment
 - Debridement of necrotic tissue if present or no necrotic tissue is present
 - Offloading
- Patient has adequate treatment of underlying disease process(es) contributing to the ulcer
- Ulcers are located on foot or toes and are free of infection, redness, drainage, underlying osteomyelitis, surrounding cellulitis, tunnels and tracts, eschar, or any necrotic material that would interfere with adherence of a bioengineered tissue product and wound healing
- Patient's current HbA1C does not exceed 12% within the last 60 days
- Patient does not have a known or suspected malignancy of the current ulcer being treated
- Photographic documentation of wound is obtained with each skin substitute application and retained by the provider and may be subject to retrospective review
- **1 or more** of the following covered skin substitutes is being requested:
 - Allopatch HD (Q4128)
 - Apligraf (15271-15278)
 - Amnioband Membrane (Q4151)
 - Dermagraft (15275)
 - Epicord (Q4187)
 - Epifix (Q4186)
 - Grafix CORE (Q4132)
 - Grafix PL Core (Q4132)
 - Grafix PRIME (Q4133)
 - Grafix PL Prime (Q4133)
 - Integra (28899)
 - Integra Dermal Regeneration Matrix (Omnigraft) (Q4105)
 - Oasis Wound Matrix (15430 or Q4102)
- Venous ulcers and **ALL** of the following:
 - Photographic documentation is submitted of wound(s) prior to treatment
 - The patient has adequate arterial blood supply as evidenced by ankle-brachial index (ABI) of 0.65 or greater in the limb being treated
 - The patient is competent and/or has support system required to participate in follow-up care associated with treatment with a bioengineered tissue product
 - Ulcer size is >1cm and <25 cm²
 - Ulcers are partial or full thickness and have failed to demonstrate measurable signs of healing of at least one month duration including **ALL** of the following:
 - Regular dressing changes
 - Debridement of necrotic tissue
 - Standard therapeutic compression
 - Patient has adequate treatment of the underlying disease process(es) contributing to the ulcer

- Ulcers are free of infection, redness, drainage, underlying osteomyelitis, surrounding cellulitis, tunnels and tracts, eschar or any necrotic material that would interfere with adherence of a bioengineered tissue product and wound healing
- Photographic documentation is obtained with each skin substitute application and retained by the provider and may be subject to retrospective review
- **1 or more** of the following covered skin substitutes is being requested:
 - Apligraf
 - Oasis Wound Matrix
- Burns and **1 or more** of the following covered skin substitutes:
 - Integra Dermal Regeneration Matrix (Omnigraft) (Q4105) and **ALL** of the following:
 - Insufficient autograft is available at the time of burn excision, or the member is too ill to have more wound sites created
 - The burn site is free of residual eschar
 - Biobrane (Q4100) and **ALL** of the following:
 - The burn is superficial, partial thickness with limited involvement of the dermis (less than or equal to 25% total body surface area)
 - The burn is clean, non-infected, and free of nonviable tissue and coagulation eschar
 - Epicel and **ALL** of the following:
 - Full thickness burns over greater than 30% of the body
 - Insufficient autograft is available at the time of burn excision
 - The burn site is free of residual eschar
- Breast Reconstruction and **1 or more** of the following covered skin substitutes following surgical mastectomy:
 - Alloderm (19357-19369)
 - Allomax
 - DermACELL AWM (Q4122)
 - DermaMatrix
 - FlexHD
 - GraftJacket (Q4107)
 - Surgimend (C9358)

All other bioengineered tissue products not listed above have not been medically proven to be effective and, therefore, are considered investigational or unproven for any indication due to insufficient evidence of efficacy and **NOT COVERED** for **ANY** of the following:

- Abiomed membrane and abiomed hydromembrane per sq cm (Q4356)
- Abiomed XPlus membrane and Abiomed XPlus hydromembrane per sq cm (Q4355)
- ACAPatch, per sq cm (Q4325)
- Acelagraft, per sq cm (Q4395)
- Acellular pericardial tissue matrix of non-human origin (Veritas), per sq cm (C9354)
- Acceso, per sq cm (Q4311)
- Acceso AC, per sq cm (Q4312)
- Acceso DL, per sq cm (Q4293)
- Acceso TL, per sq cm (Q4300)
- Acceso TrifACA, per sq cm (Q4386)
- Activate Matrix, per sq cm (Q4301)
- A/C Wrap, per sq cm (Q4422)

- Affinity, per sq cm (Q4159)
- AlloGen, per cc (Q4212)
- alloPLY, per sq cm (Q4323)
- AlloSkin AC, per sq cm (Q4141)
- AlloSkin RT, per sq cm (Q4123)
- AlloSkin, per sq cm (Q4115)
- AlloWrap DS or dry, per sq cm (Q4150)
- AmchoPlast, per sq cm (Q4316)
- AmchoPlast fr, per sq cm (Q4360)
- American Amnion AC Tri-Layer, per sq cm (Q4305)
- American Amnion AC, per sq cm (Q4306)
- American Amnion, per sq cm (Q4307)
- AmniCore Pro, per sq cm (Q4298)
- AmniCore Pro+, per sq cm (Q4299)
- AmnioPlast 1, per sq cm (Q4334)
- AmnioPlast 2, per sq cm (Q4335)
- Amnio Quad-Core, per sq cm (Q4294)
- Amnio Tri-Core Amniotic, per sq cm (Q4295)
- Amnio Wound, per sq cm (Q4181)
- Amnio Wrap2, per sq cm (Q4221)
- AmnioAmp-MP, per sq cm (Q4250)
- AmnioArmor, per sq cm (Q4188)
- AmnioBand, 1 mg (Q4168)
- AmnioBind, per sq cm (Q4225)
- Amino burgeon membrane and hydromembrane, per sq cm (Q4363)
- Amino burgeon dual layer membrane, per sq cm (Q4365)
- Amino burgeon xplus membrane and xplus hydromembrane, per sq cm (Q4364)
- Amniocore SL, per sq cm (Q4367)
- AmnioCore TM, per sq cm (Q4227)
- AmnioCyte Plus, per 0.5 cc (Q4242)
- AmnioExcel, AmnioExcel Plus or BioDExcel, per sq cm (Q4137)
- AmnioMatrix or BioDMatrix, injectable, 1 cc (Q4139)
- Amnio-Maxx or Amnio-Maxx Lite, per sq cm (Q4239)
- Amnion Bio or axoBioMembrane, per sq cm (Q4211)
- AmnioPlast Double, per sq cm (Q4391)
- AMNIOREPAIR or AltiPly, per sq cm (Q4235)
- Amniotext patch, per sq cm (Q4247)
- AmnioText, per cc (Q4245)
- AmnioTX, per sq cm (Q4324)
- AMNIPLY, for topical use only, per sq cm (Q4249)
- Apis, per sq cm (A2010)
- Application of a non-sheet skin substitute (G0681)
- Application of non-sheet skin substitute, additional (G0682)
- Application of non-sheet skin substitute, graft (G0683)
- Application of non-sheet skin substitute, graft additional (G0684)
- Apollo FT, per sq cm (Q4385)
- Architect, Architect PX, or Architect FX, extracellular matrix, per sq cm (Q4147)

- ArdeoGraft, per sq cm(Q4333)
- Artacent AC, 1 mg (Q4189)
- Artacent AC, per sq cm (Q4190)
- Artacent C, per sq cm (Q4336)
- Artacent Trident, per sq cm (Q4337)
- Artacent Velos, per sq cm (Q4338)
- Artacent Vericlen, per sq cm (Q4339)
- Artacent wound, per sq cm (Q4169)
- Artacent Cord, per sq cm (Q4216)
- ArthroFlex, per sq cm (Q4125)
- Ascendion, per sq cm (Q4390)
- Ascent, 0.5 mg (Q4213)
- Axolotl Graft, per sq cm (Q4331)
- Axolotl Graft Ultra, per sq cm (Q4383)
- Axolotl Ambient or Axolotl Cryo, 0.1 mg (Q4215)
- Axolotl DualGraft, per sq cm (Q4332)
- Axolotl DualGraft Ultra, per sq cm (Q4384)
- Axolotl Graft or Axolotl DualGraft, per sq cm (Q4210)
- Barrera SL or Barrera DL, per sq cm (Q4281)
- BellaCell HD or Surederm, per sq cm (Q4220)
- BIOBRANE, per sq cm (A2043)
- BIOBRANE Glove, each (A2044)
- Bio-ConneKt wound matrix, per sq cm (Q4161)
- BioDFence DryFlex, per sq cm (Q4138)
- BioDFence, per sq cm (Q4140)
- BioLab Membrane Wrap Flow, per sq cm (Q4418)
- BioLab Membrane Wrap Lite Flow, per sq cm (Q4419)
- BioLab Membrane Wrap Solo, per sq cm (Q4421)
- BioLab Tri-Membrane Wrap Flow, per sq cm (Q4423)
- Biovance Tri-Layer or Biovance 3L, per sq cm (Q4283)
- CaregraFT, per sq cm (Q4322)
- CarePATCH, per sq cm (Q4236)
- Celera Dual Layer or Celera Dual Membrane, per sq cm (Q4259)
- Cellesta Cord per sq cm (Q4214)
- Cellesta Flowable Amnion 25 mg per cc; per 0.5 cc (Q4185)
- Cellesta or Cellesta Duo, per sq cm (Q4184)
- Choripty, per sq cm (Q4359)
- Cocoon Membrane, per sq cm (Q4264)
- Cogenex Amniotic Membrane, per sq cm (Q4229)
- Cogenex Flowable Amnion, per 0.5 cc (Q4230)
- Cohealyx Collagen Dermal Matrix, per sq cm (A2036)
- Coll-e-Derm, per sq cm (Q4193)
- Complete AA, per sq cm (Q4303)
- Complete ACA, per sq cm (Q4302)
- Complete FT, per sq cm (Q4271)
- Complete SL, per sq cm (Q4270)
- CoreCyte, for topical use only, per 0.5 cc. (Q4240)

- CoreText or ProText, per cc (Q4246)
- Corplex P, per cc (Q4231)
- Corplex, per sq cm (Q4232)
- Cryo-Cord, per sq cm (Q4237)
- CuraMatrix, per sq cm (Q4440)
- Cygnus, per sq cm (Q4170)
- Cygnus disk, per sq cm (Q4362)
- Cygnus Dual, per sq cm (Q4282)
- Cygnus matrix, per sq cm (Q4199)
- Cymetra, injectable, 1 cc (Q4112)
- Cytal, per sq cm (Q4166)
- Denosumab-bbdz 1mg (Q5136)
- DermaBind CH, per sq cm (Q4288)
- DermaBind CH N or DermaBind CH X, per sq cm (Q4429)
- DermaBind DL, per sq cm (Q4287)
- DermaBind DL N, DermaBind DL +, or DermaBind DL X, per sq cm (Q4427)
- DermaBind FM, per sq cm (Q4313)
- DermaBind SL, per sq cm (Q4284)
- DermaBind SL N, DermaBind SL +, or DermaBind SL X, per sq cm (Q4428)
- DermaBind TL + or DermaBind TL X, per sq cm (Q4426)
- Dermacyte AC Matrix Amniotic Membrane Allograft, per sq cm (Q4343)
- Dermacyte Amniotic Membrane Allograft, per sq cm (Q4248)
- Derma-Gide, per sq cm (Q4203)
- DermaPure, per sq cm (Q4152)
- Dermavest and Plurinvest, per sq cm (Q4153)
- Derm-Maxx, per sq cm (Q4238)
- Dual layer amino burgeon membrane, per sq cm (Q4366)
- Dual Layer Impax Membrane, per sq cm (Q4262)
- DuoAmnion, per sq cm (Q4327)
- E-Graft, per sq cm (Q4318)
- Emerge Matrix, per sq cm (Q4297)
- Enverse, per sq cm (Q4258)
- EPEFFEICT, per sq cm (Q4278)
- EpiFix, injectable, 1 mg (Q4145)
- Epicpress, per sq cm (Q4361)
- Esano A, per sq cm (Q4272)
- Esano AAA, per sq cm (Q4273)
- Esano AC, per sq cm (Q4274)
- Esano ACA, per sq cm (Q4275)
- Excellagen, 0.1 cc (Q4149)
- E-Z Derm, per sq cm (Q4136)
- FlowerAmnioFlo, 0.1 cc (Q4177)
- FlowerAmnioPatch, per sq cm (Q4178)
- FlowerDerm, per sq cm (Q4179)
- Fluid Flow or Fluid GF, 1 cc (Q4206)
- Foundation DRS+ Duo, per sq cm (A2041)
- Foundation DRS+ Solo, per sq cm (A2042)

- GammaGraft, per sq cm (Q4111)
- Genesis Amniotic Membrane, per sq cm (Q4198)
- GRAFIX Duo, per sq cm (Q4392)
- GRAFTJACKET XPRESS, injectable, 1 cc (Q4113)
- G4Derm Plus, per ml (A2037)
- Helicoll, per sq cm (Q4164)
- HMatrix, per sq cm (Q4134)
- Human Health Factor 10 Amniotic Patch HHF10-P), per sq cm (Q4224)
- HYALOMATRIX, per sq cm (Q4117)
- Innovamatrix ac, per sq cm (A2001)
- InnovaMatrix FD, per sq cm (A2039)
- Innovamatrix FS, per sq cm (A2013)
- InstaGraft, per sq cm (Q4439)
- Integra bilayer matrix wound dressing BMWd), per square cm (Q4104)
- Integra flowable wound matrix, injectable, 1 cc (Q4114)
- Interfyl, 1 mg (Q4171)
- Keramatrix or Kerasorb, per sq cm (Q4165)
- Kerecis Omega3, per sq cm (Q4158)
- Keroxx 2.5 g/cc), 1cc (Q4202)
- Lamellas XT, per sq cm (Q4291)
- Lamellas, per sq cm (Q4292)
- MariGen Pacto, per sq cm (A2038)
- MatriDerm, per sq cm (A2027)
- Matrimon, per sq cm (Q4201)
- MatriStem micromatrix, 1 mg (Q4118)
- Matrix HD Allograft Dermis, per sq cm (Q4345)
- Mediskin, per sq cm (Q4135)
- Membrane Graft or Membrane Wrap, per sq cm (Q4205)
- Membrane Wrap-Hydro, per sq cm (Q4290)
- MemoDerm, DermaSpan, TranZgraft or InteguPly, per sq cm (Q4126)
- Microlyte matrix, per sq cm (A2005)
- Microlyte PainGuard, per sq cm (A2040)
- MicroMatrix Flex, per mg (A2028)
- Miroderm, per sq cm (Q4175)
- MiroTract Wound Matrix sheet, per CC (A2029)
- Mirragen advanced wound matrix, per sq cm (A2002)
- MLG-Complete, per sq cm (Q4256)
- MOST, per sq cm (Q4328)
- MyOwn Skin, includes harvesting and preparation procedures, per sq cm (Q4226)
- Natalin, per sq cm (Q4396)
- NeoMatrix, per sq cm (A2021)
- Neopatch or therion, per square centimeter (Q4176)
- NeoStim DL, per sq cm (Q4267)
- NeoStim Membrane, per sq cm (Q4266)
- NeoStim TL, per sq cm (Q4265)
- NeoThelium FT, per sq cm (Q4387)
- NeoThelium 4L, per sq cm (Q4388)

- NeoThelium 4L Plus, per sq cm (Q4389)
- Neox Cord 1K, Neox Cord RT, or Clarix Cord 1K, per sq cm (Q4148)
- Neox 100 or Clarix 100, per sq cm (Q4156)
- Neox Flo or Clarix Flo, 1 mg (Q4155)
- Novachor, per sq cm (Q4194)
- Novafix DL, per sq cm (Q4254)
- Novafix, per sq cm (Q4208)
- NovaShield or NovoGen Wound Matrix, per sq cm (A2045)
- Novosorb Synpath Dermal Matrix (A2006)
- NuDYN DL or NuDYN DL MESH, per sq cm (Q4285)
- NuDYN SL or NuDYN SLW, per sq cm (Q4286)
- NuShield, per sq cm (Q4160)
- Oasis burn matrix, per sq cm (Q4103)
- OASIS ultra tri-layer wound matrix, per sq cm (Q4124)
- Omeza collagen matrix, per 100 mg (A2014)
- ORION, per sq cm (Q4276)
- PalinGen dual-layer membrane, per sq cm (Q4354)
- PalinGen or PalinGen Xplus, per sq cm (Q4173)
- PalinGen or ProMatrX, 0.36 mg per 0.25 cc (Q4174)
- PelloGraft, per sq cm (Q4320)
- PermeaDerm B, per sq cm (A2016)
- PermeaDerm C, per sq cm (A2018)
- PermeaDerm glove, each (A2017)
- Phoenix wound matrix, per sq cm (A2015)
- PolyCyte, for topical use only, per 0.5 cc (Q4241)
- Porcine implant, Permacol, per sq cm (C9364)
- Pretect, per sq cm (Q4438)
- PriMatrix, per sq cm (Q4110)
- Procenta (Q4244)
- Procenta, per 100 mg (Q4310)
- ProgenaMatrix, per sq cm (Q4222)
- PuraPly, per sq cm (Q4195)
- PuraPly AM, per sq cm (Q4196)
- PuraPly XT, per sq cm (Q4197)
- Rebound Matrix, per sq cm (Q4296)
- Reeva FT, per sq cm (Q4314)
- RegeneLink Amniotic Membrane Allograft, per sq cm (Q4315)
- REGUaRD, for topical use only, per sq cm (Q4255)
- Relese, per sq cm (Q4257)
- RenoGraft, per sq cm (Q4321)
- Renati Membrane, per sq cm (Q4435)
- Renati AC Membrane, per sq cm (Q4436)
- Repriza, per sq cm (Q4143)
- Restorigin, 1 cc (Q4192)
- Restorigin, per sq cm (Q4191)
- Restrata MiniMatrix, 5 mg (A2026)
- Restrata, per sq cm (A2007)

- Revita, per sq cm (Q4180)
- Revitalon, per sq cm (Q4157)
- Revival AC, per sq cm (Q4437)
- Revive FT, per sq cm (Q4424)
- Revive TL, per sq cm (Q4425)
- RevoShield+ Amniotic Barrier, per sq cm (Q4289)
- SanoGraft, per sq cm (Q4319)
- Sanopellis, per sq cm (Q4308)
- Signature APatch, per sq cm (Q4260)
- SmipliGraft, per sq cm (Q4340)
- SimpliMax, per sq cm (Q4341)
- Singlay, per sq cm (Q4329)
- Skin substitute Integra Meshed Bilayer Wound Matrix), per sq cm (C9363)
- SkinTE, per sq cm (Q4200)
- Strattice TM, per sq cm (Q4130)
- Summit AAA, per sq cm (Q4397)
- Supra SDRM, per sq cm (A2011)
- SUPRATHEL, per sq cm (A2012)
- SurFactor or NuDyn, per 0.5 cc (Q4233)
- SurgiCORD, per sq cm (Q4218)
- Surgigraft, per sq cm (Q4183)
- SurgiGRAFT-DUAL, per sq cm (Q4219)
- SurGraft AC, per sq cm (Q4393)
- SurGraft ACA, per sq cm (Q4394)
- SurGraft FT, per sq cm (Q4268)
- SurGraft TL, per sq cm (Q4263)
- SurGraft XT, per sq cm (Q4269)
- SurGraft, per sq cm (Q4209)
- Symphony, per sq cm (A2009)
- TAG, per sq cm (Q4261)
- Talymed, per sq cm (Q4127)
- Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix TenoGlide Tendon Protector Sheet), per sq cm (C9356)
- Tensix, per sq cm (Q4146)
- TheraGenesis, per sq cm (A2008)
- TheraMend, per sq cm (Q4342)
- TheraSkin, per sq cm (Q4121)
- TOTAL, per sq cm (Q4330)
- Transcyte, per sq cm (Q4182)
- Tri-Membrane Wrap, per sq cm (Q4344)
- Truskin, per sq cm (Q4167)
- Tyenne, 1mg (Q5135)
- Vendaje AC, per sq cm (Q4279)
- Vendaje, per sq cm (Q4252)
- VIA Matrix, per sq cm (Q4309)
- VIM per sq cm (Q4251)
- VitoGraft, per sq cm (Q4317)

- WoundEx Flow, BioSkin Flow, 0.5 cc (Q4162)
- WoundEx, BioSkin, per sq cm (Q4163)
- WoundFix, BioWound, WoundFix Plus, BioWound Plus, WoundFix Xplus or BioWound Xplus, per sq cm (Q4217)
- Woundplus membrane or e-graft (Q4277)
- WoundPlus, per sq cm (Q4326)
- Xcell Amnio Matrix, per sq cm (Q4280)
- XCellerate, per sq cm (Q4234)
- Xcellistem, 1 mg (A2004)
- XCM biologic tissue matrix, per sq cm (Q4142)
- XWRAP, per sq cm (Q4204)
- XWRAP dual per sq cm (Q4358)
- XWRAP plus per sq cm (Q4357)
- Zenith Amniotic Membrane, per sq cm (Q4253)

Pre-Authorization Required? Yes ☒ No ☐

Preauthorization is required for this service.

Definitions

Diabetic foot ulcer is an open break of the skin of the foot associated with neuropathy and/or peripheral arterial disease of the lower limb in a patient with diabetes.

Full-Thickness Thermal Burn (Third Degree Burn): A burn with destruction of all layers of the skin. These burns involve all of the epidermal and dermal layers, with varying amounts of the sub-cutaneous layer involvement.

Measurable signs of healing is defined as a wound diminishing in size (either surface or depth) and there is decreased amount of exudate and necrotic tissue.

Partial-Thickness Thermal Burn (Second Degree Burn): A burn that involves the epidermis and only part of the dermis. Deep Partial Thickness Thermal Burns involve the epidermis and most parts of the dermis, leaving few intact skin appendages and nerve endings.

Skin substitutes are a group of biologic, synthetic, or biosynthetic materials that can provide temporary or permanent coverage of open skin wounds, replicating the properties of the normal skin. Skin substitutes may be used to cover defects following burns or other injuries, or for reconstruction, such as for release of extensive severe post-burn contractures.

Venous stasis ulcer is an open break of the skin in an area in which circulation is sluggish and the venous return is poor, commonly in the ankle.

References

Related Policies, Processes and Other Documents

N/A

Non-Regulatory references

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This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member’s contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No ☐

Revision Date	Owner	Notes
6/1/2026	Health Care Services	Revised
1/1/2026	Health Care Services	Revised
9/1/2025	Health Care Services	Revised-Formatting only
6/1/2025	Health Care Services	Revised
12/1/2024	Health Care Services	Revised
9/1/2024	Health Care Services	Revised
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