Skin Substitutes (Formerly Skin Substitutes for Venous Ulcers and Diabetic Foot Ulcers)

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:

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.

Diabetic foot ulcers:

- Covered skin substitutes:
  - Allopatch HD (Q4128)
  - Apligraf (15271-15278)
  - Amnioband Membrance (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)

- Criteria (all apply):
  - 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 >1cm and <25 cm2
  - Ulcers are full thickness, extend through the dermis but without tendon, muscle, capsule, or bone exposure, and
  - Documentation that 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
    - 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; and
  - 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 to be obtained with each skin substitute application and retained by the provider and may be subject to retrospective review.

Venous Ulcers

- Covered skin substitutes

- Apligraf
- Oasis Wound Matrix

- Criteria
  - 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 >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:
    - regular dressing changes,
    - debridement of necrotic tissue,
    - and standard therapeutic compression.
  - Patient has adequate treatment of the underlying disease process(es) contributing to the ulcer; and
  - 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 to be obtained with each skin substitute application and retained by the provider and may be subject to retrospective review.

Burns

- Covered skin substitutes
  - Integra Dermal Regeneration Matrix (Omnigraft) Q4105
    - Insufficient autograft is available at the time of burn excision or the member is too ill to have more wound sites created; and
    - The burn site is free of residual eschar
  - Biobrane Q4100
    - The burn is superficial, partial thickness with limited involvement of the dermis (less than or equal to 25% total body surface area); and
    - The burn is clean, non-infected, and free of nonviable tissue and coagulation eschar.
  - Epicel
    - Full thickness burns over greater than 30% of the body;
    - Insufficient autograft is available at the time of burn excision; and
    - The burn site is free of residual eschar

Breast Reconstructions

- Covered skin substitutes following surgical mastectomy
  - Alloderm 19357 -19369
  - Allomax
  - DermACELL AWM Q4122
  - DermaMatrix
  - FlexHD
  - GraftJacket Q4107
  - Surgimend C9358

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.

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.

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.

- ACApatch, per sq cm Q4325
- Acellular pericardial tissue matrix of non-human origin (Veritas), per sq cm C9354
- Acesso, per sq cm Q4311
- Acesso AC, per sq cm Q4312
- Acesso DL, per sq cm Q4293
- Acesso TL, per sq cm Q4300
- Activate Matrix, per sq cm Q4301
- 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
- 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
- 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

- 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
- 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
- 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 wound, per sq cm Q4169
- Artacent Cord, per sq cm Q4216
- ArthroFlex, per sq cm Q4125
- Ascent, 0.5 mg Q4213
- Axolotl Graft, per sq cm Q4331
- Axolotl Ambient or Axolotl Cryo, 0.1 mg Q4215
- Axolotl DualGraft, per sq cm Q4332
- 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
- Bio-ConneKt wound matrix, per sq cm Q4161
- BioDFence DryFlex, per sq cm Q4138
- BioDFence, per sq cm Q4140
- 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
- Cocoon Membrane, per sq cm Q4264
- Cogenex Amniotic Membrane, per sq cm Q4229
- Cogenex Flowable Amnion, per 0.5 cc Q4230
- 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
- Cygnus, per sq cm Q4170
- Cygnus Dual, per sq cm Q4282
- Cygnus matrix, per sq cm Q4199
- Cymetra, injectable, 1 cc Q4112
- Cytal, per sq cm Q4166
- DermaBind DL, per sq cm Q4287
- DermaBind CH, per sq cm Q4288
- DermaBind FM, per sq cm Q4313
- DermaBind SL, per sq cm Q4284
- Dermacyte Amniotic Membrane Allograft, per sq cm Q4248
- Derma-Gide, per sq cm Q4203
- DermaPure, per sq cm Q4152
- Dermavest and Plurivest, per sq cm Q4153
- Derm-Maxx, per sq cm Q4238
- 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
- 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
- GammaGraft, per sq cm Q4111
- Genesis Amniotic Membrane, per sq cm Q4198
- GRAFTJACKET XPRESS, injectable, 1 cc Q4113
- 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 FS, per sq cm A2013
- 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
- Matrion, per sq cm Q4201
- MatriStem micromatrix, 1 mg Q4118
- 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
- Miroderm, per sq cm Q4175
- 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
- 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
- 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
- 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 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
- 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
- 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
- RevoShield+ Amniotic Barrier, per sq cm Q4289
- SanoGraft, per sq cm Q4319
- Sanopellis, per sq cm Q4308
- Signature APatch, per sq cm Q4260
- 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
- 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 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
- TheraSkin, per sq cm Q4121
- TOTAL, per sq cm Q4330
- Transcyte, per sq cm Q4182
- Truskin, per sq cm Q4167
- 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
- Zenith Amniotic Membrane, per sq cm Q4253

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

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 above.

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
Agency for Healthcare and Research and Quality (AHRQ) [web site]. Technology Assessment Program Skin Substitutes for Treating Chronic wounds. February 2, 2020. Available at: https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id109TA.pdf Accessed September 6, 2023.

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Hayes, Inc. Comparative Effectiveness Review Acellular Skin Substitutes for Chronic Foot Ulcers in Adults with Diabetes Mellitus. Lansdale PA; May 2020.

Hayes, Inc. Comparative Effectiveness Review Cellular Skin Substitutes for Chronic Foot Ulcers in Adults with Diabetes Mellitus. Lansdale PA; March 2020.

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White-Chu EF, Conner-Kerr TA. Overview of guidelines for the prevention and treatment of venous leg ulcers: a US perspective. J Multidiscip Healthc. 2014 Feb 11;7:111-7.

Regulatory References

New York State Department of Health, Division of Managed Care Response to Coverage Question (CovQuest). Email response July 20, 2021.

New York State Department of Health [web site]. New York State Medicaid Program Physician Procedure Codes. Section 2 – Medicine, Drugs, and Drug Administration. Version 2021-2. Available at: https://www.emedny.org/providermanuals/physician/PDFS/Physician_Procedure_Codes_Sect2.pdf . Accessed: September 6, 2023.

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
9/1/2024	Health Care Services	Revised
1/1/2024	Health Care Services	Revised
11/1/2023	Health Care Services	Reviewed
11/1/2022	Health Care Services	Revised
9/1/2022	Health Care Services	Revised
5/1/2022	Health Care Services	Revised
3/1/2022	Health Care Services	Revised