PROVIDER POLICIES & PROCEDURES

SKIN SUBSTITUTES

The purpose of this document is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP) with the information needed to support a medical necessity determination for the use of skin substitutes in non-hospital outpatient settings. By clarifying the information needed for prior authorization of services, HUSKY Health hopes to facilitate timely review of requests so that individuals obtain the medically necessary care they need as quickly as possible.

Bioengineered skin and soft tissue skin substitutes are materials designed to replace damaged or missing skin or other soft tissue. These materials can be used as a protective barrier, to facilitate tissue regeneration, or to restore the functionality of the skin and are derived from various sources (i.e., human, animal, man-made/synthetic).

Benefit and Prior Authorization Requirements

- Prior authorization of skin substitutes is required when provided in all outpatient settings except outpatient hospital.
- Outpatient hospitals should refer to CMAP Addendum B for information on coverage and reimbursement for skin substitutes provided in an outpatient hospital setting.

CLINICAL GUIDELINE

Coverage guidelines for the use of skin substitutes in non-hospital outpatient settings are made in accordance with the Department of Social Services definition of Medical Necessity. The following criteria are guidelines *only*. Coverage determinations are based on an assessment of the individual and his or her clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail. The guidelines are as follows:

The use of skin substitutes for the treatment of chronic, partial-thickness and full-thickness non-infected diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs) in a non-hospital, outpatient setting, may be considered medically necessary when:

A. The ulcer has failed to demonstrate adequate healing (as evidenced by documented wound measurements pre and post treatment) after a minimum of four (4) weeks of treatment with standard wound care, which includes the following: application of dressings to maintain a moist wound environment, debridement of any necrotic tissue, use of offloading devices/shoes (DFUs) or compression garments/dressings (VLUs);
B. Standard wound care and ongoing management, including use of offloading devices/shoes (DFUs) and compression garments/dressings (VLUs), will continue after application of the skin substitute;
C. There is adequate control of any underlying condition(s) that could impact wound healing (e.g., diabetes, edema);
D. There is adequate circulation and oxygenation to support tissue growth and wound healing as

evidenced by both of the following:
   1. Ankle-Brachial Index (ABI) of no less than 0.60;
   2. Palpable pedal pulse or pulses confirmed with doppler examination;

E. There are no known contraindications that could disrupt the normal healing process or interfere with the integration of the skin substitute including, but not limited to:
   1. Vasculitis;
   2. Active Charcot deformity or major structural abnormalities of the affected foot/lower extremity;
   3. Known or suspected malignancy of the current ulcer being treated;

F. Counseling and education related to smoking cessation has been provided (as applicable); and
G. The skin substitute is considered medically necessary and is included in one of the lists below.

Skin Substitutes Considered Medically Necessary:

The following skin substitutes may be considered medically necessary for the treatment of **DFUs** if the above criteria are met:

- Affinity®
- Dermacel®
- Derma-Gide®
- Epicord®
- Flex HD/Allopatch HD®
- Grafix Stravix Prime®
- Graftjacket™
- Integra OmniGraft DRT®
- Kerecis® Omega3 Marigen Shield
- Kerecis® Omega3
- NuShield®
- Primatrix®
- Theraskin®

The following skin substitutes may be considered medically necessary for the treatment of **DFUs and VLUs** if the above criteria are met:

- Amnioband®/Guardian
- Apligraf®
- Dermagraft®
- Epifix®
- Oasis® Wound Matrix

Initial Treatment
For initial requests a maximum of four (4) applications with one of the above skin substitutes may be considered medically necessary if all criteria, as outlined above, are met.

Subsequent Treatment
Subsequent treatment with additional applications of one of the above skin substitutes may be considered medically necessary if all criteria, as outlined above, are met and supporting documentation indicates that there is evidence of healing with progressive wound closure. Subsequent treatment is typically limited to a maximum of eight (8) applications over a sixteen (16) week period.

Note: subsequent treatment beyond eight (8) applications or for longer than sixteen (16) weeks is typically

considered not medically necessary as it does not align with current standards of practice and will be reviewed on a case-by-case basis.

Not Medically Necessary
The use of skin substitutes in the following scenarios is generally considered not medically necessary as it does not align with current standards of practice:

- Simultaneous use of more than one skin substitute.
- Retreatment of a healed wound or wound showing significant improvement with granulation, epithelialization, and progress towards closure.

Investigational and Not Medically Necessary
The use of skin substitutes for indications other than DFUs or VLUs in non-hospital, outpatient settings is considered investigational and not medically necessary as there is insufficient evidence in peer-reviewed, published medical literature supporting their use.

The skin substitutes listed below are considered investigational and not medically necessary due to a lack of sufficient evidence in published, peer-reviewed medical literature.

Insufficient Evidence Supporting Use for Treatment of DFUs or VLUs:

- Alloskin™ AC
- Allowrap® DS/Allowrap® Dry
- ArthroFLEX®
- Bellacell™ HD
- Ez-Derm®
- Helicoll®
- Hmatrix®
- Interfyl®
- Matriderm
- Matristem Micromatrix®
- Alloderm™
- Mediskin™
- Oasis® Burn Matrix
- Palingen® Dual-Layer Membrane
- Palingen®/Palingen® Xplus
- Palingen®/Promatrx™
- Repriza
- Strattice® TM
- Supra SDRM®
- TheraGenesis®
- TransCyte™
- XCM Biologic™ Tissue Matrix

Insufficient Evidence Supporting Use for Any Indication:

- Abiomend/Abiomend Hydromembrane
- Abiomend Xplus/Abiomend
- ACApatch™
- Acesso
- Acesso AC
- Acesso DL
- Acesso TL
- Activate Matrix™
- AdvoGraft One
- AdvoGraft Membrane Dual
- AeroGuard™
- AlloGen™
- AlloPLY™
- Alloskin™
- Alloskin™ RT
- AmchoPlast Excel™
- AmchoThick™
- Amochoplast™
- Amochoplast FD™
- Amochoplast FD™
- American Amnion™
- American Amnion AC™
- American Amnion Tri-Layer™
- AmnioCore™ Pro
- AmnioCore™ Pro +
- Amnio Burgeon Dual-Layer
- Amnio Burgeon membrane
- Amnio Burgeon hydromembrane
- Amnio Burgeon Xplus
- Amnio Burgeon Xplus hydromembrane

- Amnio Quad-Core
- Amnio Tri-Core™
- Amnio Wound™
- AmnioAMP-mp™
- AmnioArmor™
- AmnioBand®
- AmnioBind™/DermaBind TL™
- AmnioCore™
- AmnioCore™ SL
- AmnioCyte™ Plus
- AmnioDefend™ FT Matrix
- AMNIOEXCEL®
- AMNIOEXCEL® Plus/Biodexcel™
- AMNIOMATRIX®/Biodmatrix™
- Amnio-Maxx™/Amnio-Maxx™ Lite
- Amnion Bio™/AxoBioMembrane™
- AmnioPlast 1™
- AmnioPlast 2™
- AmnioPlast 3™
- AmnioRepair®/Altiply™
- Amniotext™
- Amniotext™ Patch
- AmnioTX™
- AmnioWrap 2™
- AMNIPLY™
- APIS®
- Architect™ ECM
- Architect™ PX
- Architect™ FX
- ArdeoGraft
- Artacent® AC
- Artacent® C
- Artacent® Cord
- Artacent® Trident
- Artacent® Velos
- Artacent® Vericlen
- Artacent® Wound
- Ascent™
- Axolotl Ambient™
- Axolotl Cryo™
- Axolotl DualGraft™
- Axolotl Graft™
- Barrera™ SL/Barrera™ DL
- Bio-Connekt® Wound Matrix
- Biodfence™
- Biodfence Dryflex™
- Biovance®
- Biovance® Tri-Layer/Biovance® 3L
- Caregraft™
- carePATCH™
- Celera™ Dual Layer/Celera™ Dual Membrane
- Cellesta™ Cord
- Cellesta™ Flowable Amnion
- Cellesta™/Cellesta™ Duo
- Choriply
- Cocoon Membrane
- Cogenex Amnio Membrane
- Cogenex Flowable Amnion
- Coll-e-Derm™
- Complete™ AA
- Complete™ ACA
- Complete™ FT
- Complete™ SL
- Connective Human Tissue (incl. fascia)
- Connective Tissue, Non-Human
- Corecyte™
- CoreText™/ProText™
- Corplex™
- Corplex™ P
- Cryo-cord™
- Cygnus®
- Cygnus® Disk
- Cygnus® Dual
- Cygnus® Matrix
- Cymetra®, injectable
- Cytal™
- DermaBind CH
- DermaBind DL
- DermaBind FM
- DermaBind SL
- DermaBind SL
- Dermacyte AC Matrix
- Dermacyte Amniotic Membrane
- DermaPure®
- Dermavest®
- Derm-Maxx™
- Dual Layer Amnio Burgeon X-Membrane
- Dual Layer Impax™ Membrane
- Duoamnion
- Duograft AA™
- Duograft AC™
- E-graft

- Emerge™ Matrix
- Enclose™ TL Matrix
- Enverse®
- EpiEffect™
- Epifix®, injectable
- EPIXPRESS™
- Esano™
- Esano™ AAA
- Esano™ AC
- Esano™ ACA
- Excellagen®
- FlowerAmnioFlo™
- FlowerAmnioPatch™
- Flowerderm™
- Fluid Flow™ /Fluid GF
- Foundation DRS Solo
- GammaGraft™
- Genesis™ Amniotic Membrane
- Grafix Core/Grafix PL Core
- Grafix Plus
- Graftjacket® Xpress
- Human Health Factor 10 Amniotic Patch (hhf10-p)
- Hyalomatrix®
- Innovaburn®/Innovaburn® XL
- Innovamatrix® AC
- Innovamatrix® FS
- Innovamatrix® PD
- Integra™ Bilayer Matrix (BMWD)
- Integra™ Flowable Wound Matrix
- Integra™ Matrix
- Integra™ Meshed Bilateral Wound Matrix
- Keramatrix®/Kerasorb®
- Keroxx®
- Lamellas
- Lamellas XT
- Mantle™ DL Matrix
- Matrion®
- Matrix HD® Allograft Dermis
- Membrane Wrap-Lite™
- Membrane Graft™/Membrane Wrap™
- Membrane Wrap-Hydro™
- MemoDerm™/Dermaspan/ Tranzgraft/Integuply
- Microlyte Matrix
- MicroMatrix® Flex
- Miro3d®
- Miro3d® Fibers
- MiroDerm®
- MiroDry™ Wound Matrix
- MiroTract® Wound Matrix Sheet
- Mirragen® Advanced Wound Matrix
- MLG-Complete™
- MOST
- MyOwn Skin™
- Myriad Matrix™
- Myriad Morcells™
- NeoGuard™
- NeoMatrix®
- Neopatch/Therion
- Neostim DL
- Neostim Membrane
- Neostim TL
- NEOX® 100/Clarix® 100
- NEOX® Cord 1k/NEOX® Cord RT/ Clarix® Cord 1k
- NEOX® FLO/Clarix® FLO
- Novachor™
- Novafix®
- Novafix® DL
- Novosorb® Synpath Dermal Matrix
- NuDYN™ DL/NuDYN™ DL Mesh
- NuDYN SL™/NuDYN™ SLW
- Oasis® Ultra Tri-layer Matrix
- Omeza® Collagen Matrix
- Orion™
- Overlay™ SL Matrix
- Palisade™ DM Matrix
- PelloGraft
- Permeaderm B
- Permeaderm C
- Permeaderm Glove
- Phoenix wound matrix®
- Polycyte™
- Procenta®
- Progenamatrix®
- PuraPLY®
- PuraPLY® AM
- PuraPLY® XT
- Rampart™ DL Matrix
- Rebound™ Matrix

- Reeva FT™
- RegeneLink® Amniotic Membrane Allograft
- REGUaRD
- Relese™
- Renew FT Matrix
- RenoGraft
- Resolve Matrix™/Xenopatch
- Restorigin™
- Restorigin™
- Restrata®
- Restrata® MiniMatrix
- Revita®
- Revitalon™
- Revoshield +® Amniotic Barrier
- SanoGraft®
- Sanopellis
- Sentry™ SL Matrix
- Shelter™ DM Matrix
- Signature Apatch
- SimpliGraft®
- Singlay®
- Skin Substitute, not otherwise specified (Q4100)
- Skin TE
- Suprathel®
- SurFactor® /Nudyn™
- SurgiCORD
- SurgiGraft™
- SurgiGraft™-Dual
- SurGraft®
- SurGraft® FT
- SurGraft® TL
- SurGraft® XT
- Symphony™
- Tag
- Talymed®
- Tensix
- Theramend™
- Total
- triGRAFT FT™
- Tri-Membrane Wrap™
- TruSkin™
- Vendaje®
- Vendaje AC®
- Veritas® Collagen Matrix
- VIA Matrix™
- Vim®
- Vitograft
- WoundEX Bioskin®
- WoundEX® Flow
- WoundfiX™BioWound/WoundFiX™ Plus/BioWound Plus/WoundFiX™ Xplus/BioWound XPL
- WoundPlus™
- Xceed™ TL Matrix
- Xcell Amino Matrix™
- Xcellerate™
- Xcellistem
- Xwrap®/Dual/Plus
- Zenith™ Amniotic Membrane

NOTE: EPSDT Special Provision
Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a federal Medicaid requirement that requires the Connecticut Medical Assistance Program (CMAP) to cover services, products, or procedures for Medicaid enrollees under 21 years of age where the service or good is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination. The applicable definition of medical necessity is set forth in Conn. Gen. Stat. Section 17b-259b (2011) [ref. CMAP Provider Bulletin PB 2011-36].

PROCEDURE
Prior authorization for the use of skin substitutes in non-hospital outpatient settings is required. Coverage determinations will be based upon a review of requested and/or submitted case-specific information.

The following information is needed to review a request for skin substitutes:
1. Fully completed authorization request via on-line web portal;
2. Fully completed *Skin Substitute Prior Authorization Request Form*;

3. Clinical documentation from the requesting provider supporting medical necessity as outlined in the *Clinical Guideline* section of this policy; and
4. Subsequent requests only, clinical documentation supporting the need for continued applications including evidence of healing and progressive wound closure.

EFFECTIVE DATE
This Policy is effective for prior authorization requests for the use of skin substitutes, in non-hospital outpatient settings, for individuals covered under the HUSKY Health Program beginning August 1, 2025.

LIMITATIONS
N/A

CODES

Codes Considered Medically Necessary if Above Criteria are Met

A2019	Kerecis omega3 marigen shield per square centimeter
Q4101	Apligraf per square centimeter
Q4102	Oasis wound matrix per square centimeter
Q4105	Integra dermal regeneration template (drt) or Integra OmniGraft dermal regeneration
Q4106	Dermagraft per square centimeter
Q4107	Graftjacket per square centimeter
Q4110	Primatrix per square centimeter
Q4121	Theraskin per square centimeter
Q4122	Dermacell, Dermacell awm, or Dermacell awm porous per square centimeter
Q4128	Flex hd or Allopatch hd per square centimeter
Q4133	Grafix prime, Grafix pl prime, Stravix, and Stravix pl per square centimeter
Q4151	Amnioband or guardian per square centimeter
Q4158	Kerecis omega3 per square centimeter
Q4159	Affinity per square centimeter
Q4160	Nushield per square centimeter
Q4186	Epifix per square centimeter
Q4187	Epicord per square centimeter
Q4203	Derma-gide per square centimeter

Codes/Code Ranges Considered Investigational and Not Medically Necessary

A2001-A2018	A2021-A2035	Q4100
Q4103-Q4104	Q4108	Q4111-Q4118
Q4123-Q4127	Q4130	Q4132
Q4134-Q4150	Q4152-Q4157	Q4161-Q4171
Q4173-Q4185	Q4188-Q4202	Q4204-Q4209
Q4211-Q4222	Q4224-Q4227	Q4230
Q4232-Q4235	Q4238-Q4242	Q4245-Q4276
Q4278-Q4367	Q4368-Q4373	Q4375-Q4382

DEFINITIONS

1. **HUSKY A**: Connecticut children and their parents or a relative caregiver; and pregnant women may qualify for HUSKY A (also known as Medicaid). Income limits apply.
2. **HUSKY B**: Uninsured children under the age of 19 in higher income households may be eligible for HUSKY B (also known as the Children's Health Insurance Program) depending on their family income level. Family cost-sharing may apply.
3. **HUSKY C**: Connecticut residents who are age 65 or older or residents who are ages 18-64 and who are blind, or have another disability, may qualify for Medicaid coverage under HUSKY C (this includes Medicaid for Employees with Disabilities (MED-Connect), if working). Income and asset limits apply.
4. **HUSKY D**: Connecticut residents who are ages 19-64 without dependent children and who: (1) do not qualify for HUSKY A; (2) do not receive Medicare; and (3) are not pregnant, may qualify for HUSKY D (also known as Medicaid for the Lowest-Income populations).
5. **HUSKY Health Program**: The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.
6. **HUSKY Limited Benefit Program or HUSKY, LBP**: Connecticut's implementation of limited health insurance coverage under Medicaid for individuals with tuberculosis or for family planning purposes and such coverage is substantially less than the full Medicaid coverage.
7. **Medically Necessary or Medical Necessity**: (as defined in Connecticut General Statutes § 17b-259b) Those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain the individual's achievable health and independent functioning provided such services are: (1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is generally recognized by the relevant medical community, (B)recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors; (2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the individual's illness, injury or disease; (3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers; (4) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and (5) based on an assessment of the individual and his or her medical condition.
8. **Prior Authorization**: A process for approving covered services prior to the delivery of the service or initiation of the plan of care based on a determination by CHNCT as to whether the requested service is medically necessary.

ADDITIONAL RESOURCES AND REFERENCES:

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