Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:

Bioengineered Skin and Soft Tissue Substitutes

Effective: October 1, 2026

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request to the FAX numbers below	Yes ☐ No ☒
Notification Required IF REQUIRED, concurrent review may apply	Yes ☐ No ☒

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; 800-232-0816
☒ Tufts Health Plan Commercial products; 617-972-9409

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055
☐ Tufts Health Together – MassHealth Accountable Care Partnership Plans; 888-415-9055
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404
☐ Tufts Health One Care Plan – A dual-eligible product; 857-304-6304

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-972-9409
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-972-9409
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-972-9409

Note: While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

Overview

Bioengineered skin and soft tissue substitutes are either cellular or acellular matrices that are used to replace the functionality of the epidermis, dermis or both until the skin barrier repairs itself or a definitive skin replacement is acquired. These products may be derived from allogeneic, xenogeneic (e.g., porcine or bovine), synthetic sources or a combination of any or all of these types of materials. Human skin equivalents or cellular or tissue-based products are classified into the following types:

- Human skin allografts derived from donated human skin (cadavers)
- Allogeneic matrices derived from human tissue (fibroblasts or membrane)
- Composite matrices derived from human keratinocytes, fibroblasts and xenogeneic collagen supported by a scaffold of synthetic mesh or xenogeneic collagen
- Acellular matrices derived from xenogeneic collagen or tissue and provides a bioactive matrix consisting of collagens, elastin. blood vessel channels, and bioactive proteins that support revascularization, cell repopulation, and tissue remodeling.

There are a large number of potential applications for artificial skin and soft tissue products including non-healing diabetic neuropathic ulcers, vascular insufficiency ulcers, and pressure ulcers. These skin substitutes are also used in second-and third-degree burns, specific dermatologic conditions and utilized as a substitute for living skin grafts in post-surgical conditions (e.g., breast reconstruction) and for surgical wounds.

Clinical literature indicates studies comparing the efficacy of bioengineered skin substitute to alternative wound care approaches with patients' autologous skin are limited in number, apply mainly to generally healthy patients, and examine only a small portion of the skin substitute products available in the United States.

Clinical Guideline Coverage Criteria

The following products may be reasonable and medically necessary when used for breast reconstruction in Members who have coverage for breast surgery procedures.

Breast Reconstruction

Allogeneic Acellular Dermal Matrix Products covered when medical necessary	Medical Necessity Criteria
• AlloDerm®* • AlloMend® • Cortiva® (AlloMax™) • DermaMatrix™ • DermACELL™ • FlexHD® • FlexHD® Pliable™ • GraftJacket®	These skin substitutes may be medically necessary when used during a covered medically necessary breast surgery and **ONE** of the following are met: • Additional graft coverage is required when there is insufficient tissue expander or implant coverage by the pectoralis major muscle; **or** • Following mastectomy, skin flaps are at risk for dehiscence or necrosis; **or** • Inframammary fold and lateral mammary folds have been undermined during mastectomy and reestablishment of these landmarks is needed

The above medical necessity criteria must be met for the following codes to be covered for breast reconstruction surgery:

HCPCS Codes

HCPCS Codes	Description
Q4100	Skin substitute, not otherwise specified**for use with AlloMax™, AlloMend®, DermaMatrix™
Q4100	Cortiva
Q4107	GraftJacket, per sq cm
Q4116	AlloDerm, per sq cm
Q4122	DermACELL, DermACELL AWM or DermACELL AWM Porous, per sq cm
Q4128	FlexHD, or AllopatchHD, per sq cm

Diabetic Foot Ulcer (DFU) and Venous Leg Ulcer (VLU)

Application of a skin substitute graft for lower extremity DFU and VLU may be reasonable and medically necessary when the wound does not exhibit tendon, muscle, joint capsule or exposed bone and the treatment area is without evidence of infection or underlying osteomyelitis. Treatment with the following products will not exceed an 8-application limit per wound per the 12–16-week period of care regardless of wound status. The use of more than one product simultaneously will not be covered. (See Limitations below)

Diabetic Ulcer

Diabetic Ulcer	Medical Necessity Criteria
• AlloPatch® or Flex HD • Amnioband or Guardian • Apligraf® • Dermagraft® • Epicord® • Epifix® • GraftJacket NOW™ • Grafix CORE/Grafix PRIME • Grafix Duo	**DIABETIC FOOT ULCER** **AlloPatch** AlloPatch may be reasonale and medically necessary when **ALL** of the following are met: • Full-thickness diabetic foot ulcer of greater than six weeks duration; **and** • Failure to achieve at least 50% ulcer area reduction with standard ulcer therapy (e.g.,

Diabetic Ulcer	Medical Necessity Criteria
• Integra® Dermal Regeneration Template/ Omnigraft Dermal Regeneration Matrix • Oasis™ Wound Matrix • Oasis® Ultra Tri-Layer Matrix • TheraSkin®	surgical debridement, standard dressing changes, non-weight bearing or off-loading pressure) for a minimum of 4 weeks; **and** • Type 1 or type 2 diabetes mellitus with Optimal glucose control Glycated hemoglobin test (HgA1c) < 12% (within the last 90 days); **and** • No osteomyelitis, soft tissue infection or Charcot arthropathy; **and** • Treated foot has adequate circulation as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70. **AmnioBand** Amnioband may be reasonable and medically necessary when **ALL** of the following criteria are met: • Partial and full-thickness diabetic foot ulcer of greater than six weeks duration; **and** • Failure to achieve at least 50% ulcer area reduction with standard ulcer therapy (e.g., surgical debridement, standard dressing changes, non-weight bearing or off-loading pressure) for a minimum of 4 weeks; **and** • Type 1 or type 2 diabetes mellitus with Optimal glucose control Glycated hemoglobin test (HgA1c) < 12% (within the last 90 days) ; **and** • No osteomyelitis, soft tissue infection or Charcot arthropathy; **and** • Treated foot has adequate circulation as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70. **Apligraf** Apligraf may be reasonable and medically necessary when **ALL** of the following criteria are met: • Full-thickness diabetic foot ulcer of at least three weeks duration when used with standard; **and** therapeutic compression • Failure to achieve at least 50% ulcer area reduction with standard ulcer therapy (e.g., surgical debridement, standard dressing changes, non-weight bearing or off-loading pressure) for a minimum of 4 weeks; **and** • Type 1 or type 2 diabetes mellitus with Optimal glucose control Glycated hemoglobin test (HgA1c) < 12% (within the last 90 days); **and** • No osteomyelitis, soft tissue infection or Charcot arthropathy; **and** • Treated foot has adequate circulation as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70. **Dermagraft** Dermagraft may be reasonable and medically necessary when **ALL** of the following criteria are met: • Full-thickness diabetic foot ulcer of greater than six weeks duration; **and** • Failure to achieve at least 50% ulcer area reduction with standard ulcer therapy (e.g., surgical debridement, standard dressing changes,

Diabetic Ulcer	Medical Necessity Criteria
	non-weight bearing or off-loading pressure) for a minimum of 4 weeks; **and** • Type 1 or type 2 diabetes mellitus with Optimal glucose control Glycated hemoglobin test (HgA1c) < 12% (within the last 90 days); **and** • No osteomyelitis, soft tissue infection or Charcot arthropathy; **and** • Treated foot has adequate circulation as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70. **Epicord** Epicord may be reasonable and medically necessary when **ALL** of the following criteria are met: • Partial or full-thickness diabetic foot ulcer of greater than six weeks duration; **and** • Failure to achieve at least 50% ulcer area reduction with standard ulcer therapy (e.g., surgical debridement, standard dressing changes, non-weight bearing or off-loading pressure) for a minimum of 4 weeks; **and** • Type 1 or type 2 diabetes mellitus with Optimal glucose control Glycated hemoglobin test (HgA1c) < 12% (within the last 90 days); **and** • No osteomyelitis, soft tissue infection or Charcot arthropathy; **and** • Treated foot has adequate circulation as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70. **EpiFix Amniotic Membrane** EpiFix may be reasonable and medically necessary when **ALL** of the following criteria are met: • Partial or full-thickness diabetic foot ulcer of greater than six weeks duration; **and** • Failure to achieve at least 50% ulcer area reduction with standard ulcer therapy (e.g., surgical debridement, standard dressing changes, non-weight bearing or off-loading pressure) for a minimum of 4 weeks; **and** • Type 1 or type 2 diabetes mellitus with Optimal glucose control Glycated hemoglobin test (HgA1c) < 12% (within the last 90 days); **and** • No osteomyelitis, soft tissue infection or Charcot arthropathy; **and** • Treated foot has adequate circulation as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70. **GrafJacket Now** GrafJacket may be reasonable and medically necessary when **ALL** of the following criteria are met: • Partial and full-thickness diabetic foot ulcer of greater than six weeks duration; **and** • Failure to achieve at least 50% ulcer area reduction with standard ulcer therapy (e.g., surgical debridement, standard dressing changes, non-weight bearing or off-loading pressure) for a minimum of 4 weeks; **and**

Diabetic Ulcer	Medical Necessity Criteria
	• Type 1 or type 2 diabetes mellitus with Optimal glucose control Glycated hemoglobin test (HgA1c) < 12% (within the last 90 days) ; **and** • No osteomyelitis, soft tissue infection or Charcot arthropathy; **and** • Treated foot has adequate circulation as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70. **Note:** GraftJacket is supplied as a single-use, per patient package and intended for use as only once per procedure. When the above criteria is met, one application is considered medically necessary **Grafix CORE / Grafix PRIME / Grafix Duo** Grafix may be reasonable and medically necessary when **ALL** of the following criteria are met: • Partial or full-thickness diabetic foot ulcer of greater than four weeks duration; **and** • Failure to achieve at least 50% ulcer area reduction with standard ulcer therapy (e.g., surgical debridement, standard dressing changes, non-weight bearing or off-loading pressure) for a minimum of 4 weeks; **and** • Type 1 or type 2 diabetes mellitus with Optimal glucose control Glycated hemoglobin test (HgA1c) < 12% (within the last 90 days); **and** • No osteomyelitis, soft tissue infection or Charcot arthropathy; **and** • Treated foot has adequate circulation as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70. **Integra Dermal Regeneration Template/Integra Omnigraft Dermal Regeneration Matrix** Integra Dermal Regeneration Template / Omnigraft Dermal Regeneration Matrix may be reasonable and medically necessary medically necessary when **ALL** of the following criteria are met: • Partial or full-thickness diabetic foot ulcer of greater than six weeks duration; **and** • Failure to achieve at least 50% ulcer area reduction with standard ulcer therapy (e.g., surgical debridement, standard dressing changes, non-weight bearing or off-loading pressure) for a minimum of 4 weeks; **and** • Type 1 or type 2 diabetes mellitus with Optimal glucose control Glycated hemoglobin test (HgA1c) < 12% (within the last 90 days); **and** • No osteomyelitis, soft tissue infection or Charcot arthropathy; **and** • Treated foot has adequate circulation as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70. **Oasis Wound Matrix and Oasis® Ultra Tri-Layer Matrix** Oasis Wound Matrix and Oasis® Ultra Tri-Layer Matrix may be reasonable and medically necessary when **ALL** of the following criteria are met: • Partial or full-thickness diabetic foot ulcer of greater than four weeks; **and**

Diabetic Ulcer	Medical Necessity Criteria
	• Failure to achieve at least 50% ulcer area reduction with standard ulcer therapy (e.g., surgical debridement, standard dressing changes, non-weight bearing or off-loading pressure) for a minimum of 4 weeks; **and** • Type 1 or type 2 diabetes mellitus with Optimal glucose control Glycated hemoglobin test (HgA1c) < 12% (within the last 90 days); **and** • No osteomyelitis, soft tissue infection or Charcot arthropathy; **and** • Treated foot has adequate circulation as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70. **TheraSkin** TheraSkin may be reasonable and medically necessary when **ALL** of the following criteria are met: • Partial or full-thickness diabetic foot ulcer of greater than four weeks duration; **and** • Failure to achieve at least 50% ulcer area reduction with standard ulcer therapy (e.g., surgical debridement, standard dressing changes, non-weight bearing or off-loading pressure) for a minimum of 4 weeks; **and** • Type 1 or type 2 diabetes mellitus with Optimal glucose control Glycated hemoglobin test (HgA1c) < 12% (within the last 90 days); **and** • No osteomyelitis, soft tissue infection or Charcot arthropathy; **and** • Treated foot has adequate circulation as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70.

The above medical necessity criteria must be met for the following codes to be covered for diabetic foot ulcers:

HCPCS Codes

HCPCS Codes	Description
Q4101	Apligraf, per sq cm
Q4102	Oasis wound matrix, 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 square centimeter
Q4121	TheraSkin, per square centimeter
Q4124	Oasis tri-layer wound matrix
Q4128	FlexHD, or AllopatchHD, per sq cm
Q4132	Grafix Core and GrafixPL Core, per sq cm
Q4133	Grafix prime and GrafixPL prime, stravix and stravixpl, per square centimeter
Q4151	AmnioBand or Guardian, per sq cm
Q4168	AmnioBand, 1 mg
Q4186	Epifix, per square centimeter
Q4187	Epicord 1 sq cm
Q4392	Grafix Duo, per sq cm

Venous insufficiency ulcers	Medical Necessity Criteria
Amnioband® or Guardian® **Apligraf®** **Epifix®** **TheraSkin®** **PriMatrix™** **Oasis Wound Matrix®** **Oasis® Ultra Tri-Layer Matrix**	Products may be considered medically necessary for treatment of venous insufficiency ulcers when **ALL** of the following criteria are met: • Partial or full-thickness lower extremity venous stasis skin ulcer of greater than four weeks duration; **and** • Failed at least four weeks of standard ulcer therapy (e.g., dressing changes, therapeutic compression therapy); **and** • No osteomyelitis or soft tissue infection; **and** • Treated lower extremity has adequate blood supply as evidenced by a vascular assessment (e.g., presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70.

The above medical necessity criteria must be met for the following codes to be covered for venous insufficiency ulcers:

HCPCS Codes

HCPCS Codes	Description
Q4101	Apligraf, per sq cm
Q4102	Oasis wound matrix, per sq cm
Q4110	PriMatrix
Q4121	TheraSkin, per square centimeter
Q4124	Oasis® Ultra Tri-Layer Matrix
Q4151	Amnioband or Guardian, per sq cm
Q4186	Epifix, per square centimeter

Burns

Burns	Medical Necessity Criteria
Biobrane™/ Biobrane L™ **Biobrane Glove** **Epicel®** **Integra® Dermal Regeneration Template** **Integra™ Bilayer Matrix Wound Dressing** **Integra™ Matrix Wound Dressing** **Integra™ Meshed Bilayer Wound Matrix** **Transcyte®**	**Biobrane** The use of Biobrane may be reasonable and medically necessary for use as a temporary wound covering for surgically excised or debrided partial-thickness burn wound **Biobrane L** The use of Biobrane L may be reasonable and medically necessary for use as a temporary wound covering for surgically excised or debrided partial-thickness burn wound or Biobrane L may be used as an adjunct to mesh autograft. **EpiCel** Epicel may be reasonable and medically necessary for deep dermal or full-thickness burns comprising a total body surface area (TBSA) greater than or equal to 30% and provided in accordance with the humanitarian device exemption (HDE) specifications of the US Food and Drug Administration (FDA)

	Integra® Dermal Regeneration Template, Integra™ Bilayer Matrix Wound Dressing Integra™, Matrix Wound Dressing Integra™, Meshed Bilayer Wound Matrix These products may be reasonable and medically necessary for the treatment of full-thickness or deep partial-thickness burns. The **Integra Dermal Regeneration Template** is used in the treatment of life-threatening burn injuries and may be reasonable and medically necessary when **BOTH** of the following are met: • Post-excisional treatment of a full-thickness or deep partial-thickness burn; **and** • Sufficient autograft is not available at the time of excision or contraindicated. **TransCyte** TransCyte may be reasonable and medically necessary for use as a temporary wound covering for surgically excised full-thickness and deep partial-thickness thermal burn wounds in members who require such a covering prior to autograft placement.

The above medical necessity criteria must be met for the following codes to be covered for second and third-degree burns:

HCPCS Codes

HCPCS Codes	Description
A2043	BIOBRANE, (add-on, list separately in addition to primary procedure), per sq cm
A2044	Biobrane, Glove, each
C9363	Skin substitute, Integra meshed bilayer wound matrix, per square cm
Q4100	Skin substitute, not otherwise specified**for use with Epicel®, Biobrane™/ Biobrane L
Q4104	Integra Bilayer Matrix wound dressing (BMWD), per square centimeter
Q4105	Integra dermal regeneration template (DRT) or Integra Omnigraft dermal regeneration matrix, per sq cm
Q4108	Integra matrix, per square centimeter
Q4182	Transcyte, per sq cm

Dystrophic Epidermolysis Bullosa

Dystrophic epidermolysis bullosa (Mitten-hand deformity)	Medical Necessity Criteria
OrCel™	Orcel may be reasonable and medically necessary in the treatment of mitten-hand deformity surgery for epidermolysis bullosa when standard wound therapy has failed and when provided in accordance with the humanitarian device exemption (HDE) specifications of the US Food and Drug Administration (FDA).

The above medical necessity criteria must be met for the following code to be covered for Dystrophic epidermolysis bullosa:

HCPCS Codes

HCPCS Codes	Description
Q4100	Skin substitute, not otherwise specified for use with OrCel

Limitations

1. For DFU and VLU;
    - Skin and soft tissue substitutes are not covered in Members with uncontrolled diabetes, active Charcot arthropathy of the affected extremity, and/or vasculitis
    - Skin and soft tissue substitutes are not covered when the application site is infected or member has an allergy to the product
    - Repeat or alternative applications of skin soft tissue substitutes are not considered medically reasonable and necessary when a previously full course of applications were unsuccessful as defined by both of the following:
        - Increase in size and depth of ulcer
        - Ulcer showed no signs of healing or indication that improvement is likely such as granulation tissue, epithelialization or progress towards closing for a period of 1 month past start of therapy
    - The use of more than one product to treat a wound simultaneously is not covered. A wound care product may be changed in the treatment of the wound, but should not exceed the 8-application limit per wound per 12-16 week period of care
2. All other skin and soft tissue substitutes not listed above are considered investigational, including, but not limited to the following:

ACell® UBM Hydrated/Lyophilized Wound Dressing Aongen™ Collagen Matrix CollaCare® CollaCare® Dental Collagen Wound Dressing CollaWound™ Collexa® Collieva® Conexa™ Coreleader Colla-Pad CorMatrix® Dermadapt™ Wound Dressing DressSkin Durepair Regeneration Matrix® Endoform Dermal Template™ ENDURAgen™ ExpressGraft™ FlexiGraft® Geistlich Derma-Gide™ Hyalomatrix® PA InteguPly®	MatriDerm® Microderm® biologic wound matrix Ologen™ Collagen Matrix Puracol® and Puracol® Plus Collagen Wound Dressings Puros® Dermis RegenePro™ Repliform® ReCell® StrataGraft® TheraForm™ Standard/Sheet XenMatrix™ AB

Codes

The codes included below for informational purposes only; this is not an all-inclusive list

List of Medically Necessary ICD-10 Codes

CPT Codes / HCPCS Codes / ICD Codes

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

CPT® Codes	Description
	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)
15777	Implantation of biologic implant (e.g., acellular dermal matrix) for soft tissue reinforcement (e.g., breast, trunk) (List separately in addition to code for primary procedure)

HCPCS Codes	Description
C5271	Application of low cost 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
C5272	Application of low cost 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)
C5273	Application of low cost 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
C5274	Application of low cost 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)
C5275	Application of low cost 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
C5276	Application of low cost 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)
C5277	Application of low cost 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
C5278	Application of low cost 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)

The following codes are considered investigational

HCPCS Codes	Description
A2001	Innovamatrix ac, per sq cm
A2002	Mirragen advanced wound matrix, per square centimet
A2004	Xcellistem, per square centimeter
A2005	Microlyte matrix, per square centimeter
A2006	Novosorb synpath dermal matrix, per square centimeter
A2007	Restrata per square centimeter A2007 R
A2008	Theragenesis, per square centimeter
A2009	Symphony, per square centimeter

HCPCS Codes	Description
A2010	Apis, per square centimeter
A2011	Supra sdrm, per square centimeter
A2012	Suprathel, per square centimeter
A2013	Innovamatrix fs, per sq cm
A2014	Omeza Collagen Matrix, per 100 mg
A2015	Phoenix wnd mtrx, per sq cm
A2016	Permeaderm b, per sq cm
A2018	Permeaderm c, per sq cm
A2019	Kerecis omega3 marigen shield, per square centimet
A2020	Ac5 advanced wound system (ac5)
A2021	Neomatrix, per square centimeter
A2022	Innovaburn or innovamatrix xl, per square centimeter
A2023	Innovamatrix pd, 1 mg
A2024	Resolve matrix, per square centimeter
A2036	Cohealyx Collagen Dermal Matrix, per sq cm
A2037	G4Derm Plus, per ml
A2038	MariGen Pacto, per sq cm
A2039	InnovaMatrix FD, per sq cm
A2040	Microlyte PainGuard (add-on, list separately in addition to primary procedure), per sq cm
A2041	Foundation DRS+ Duo (add-on, list separately in addition to primary procedure), per sq cm
A2042	Foundation DRS+ Solo (add-on, list separately in addition to primary procedure), per sq cm
A2045	NovaShield or NovoGen Wound Matrix (add-on, list separately in addition to primary procedure), per sq cm
A2046	DermiSphere hDRT, per sq cm (add-on, list separately in addition to primary procedure)
A2047	LacertaMatrix, per sq cm (add-on, list separately in addition to primary procedure)
A2048	PuraPly MZ, per mg
A2049	Theracor, per sq cm (add-on, list separately in addition to primary procedure)
A2050	Fibrillar Collagen Wound Dressing, per mg
C9358	Dermal substitute, native, non-denatured collagen, fetal bovine origin (surgimend collagen matrix), per 0.5 square centimeters
G0681	Application of a premarket approval (PMA), 510(k), 361 human cells, tissues or cellular and tissue-based products (HCT/P) nonsheet form skin substitute for a wound surface area up to 100 sq cm; first 25 sq cm or less of wound surface area
G0682	Application of a premarket approval (PMA), 510(k), 361 human cells, tissues or cellular and tissue-based products (HCT/P) nonsheet form skin substitute for a 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)
G0683	Application of a premarket approval (PMA), 510(k), 361 human cells, tissues or cellular and tissue-based products (HCT/P) nonsheet form skin substitute graft for a wound surface greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
G0684	Application of a premarket approval (PMA), 510(k), 361 human cells, tissues or cellular and tissue-based products (HCT/P) nonsheet form skin substitute graft for a wound surface 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)
Q4125	ArthroFlex, per square centimeter
Q4134	hMatrix, per square centimeter
Q4135	Mediskin, per square centimeter
Q4136	E-Z Derm, per square centimeter
Q4138	BioDFence Dryflex, per square centimeter
Q4139	Amniomatrix or BioDMatrix, injectable, 1 cc
Q4140	BioDFence, per square centimeter
Q4148	Neox Cord 1K, Neox Cord RT, or CLarix Cord, per square centimeter
Q4150	AlloWrap ds or dry, per square centimeter
Q4152	DermaPure, per square centimeter
Q4153	Dermavest and Plurivest, per square centimeter
Q4154	BioVance, per square centimeter
Q4155	Neoxflo or Clarixflo, 1 mg
Q4156	NEOX 100 or Clarix 100, per square centimeter
Q4157	Revitalon, per square centimeter

HCPCS Codes	Description
Q4158	Kerecis Omega3, per square centimeter
Q4159	Affinity, per square centimeter
Q4160	NuShield, per square centimeter
Q4161	Bio-ConneKt Wound Matrix, per square centimeter
Q4162	Woundex Flow, Bioskin flow, 0.5 cc
Q4163	Woundex, Bioskin, per square centimeter
Q4164	Helicoll, per square centimeter
Q4165	Keramatrix, per square centimeter
Q4166	Cytal, per square centimeter
Q4167	TruSkin, per square centimeter
Q4169	Artacent Wound, per square centimeter
Q4170	CYGNUS, per square centimeter
Q4171	Interfyl, 1 mg
Q4173	PaliGen or PaliGen XPlus, per square centimeter
Q4174	PalinGen or ProMatrx, 0.36 mg per 0.25 cc
Q4175	MIRODERM, per square centimeter
Q4176	NeoPatch, per square centimeter
Q4177	Floweramnioflo, 0.1 cc
Q4178	Floweramniopatch, per square centimeter
Q4179	FlowerDerm, per square centimeter
Q4180	Revita, per square centimeter
Q4181	Amnio Wound, per square centimeter
Q4183	Surgigraft, per square centimeter
Q4184	Cellesta, per square centimeter
Q4185	Cellesta flowable amnion (25 mg per cc); per 0.5 cc
Q4188	Amnioarmor, per square centimeter
Q4189	Artacent ac, 1 mg
Q4190	Artacent ac, per square centimeter
Q4191	Restorigin, per square centimeter
Q4192	Restorigin, 1 cc
Q4193	Coll-e-derm, per square centimeter
Q4194	Novachor, per square centimeter
Q4195	Puraply, per square centimeter
Q4196	Puraply AM, per square centimeter
Q4197	Puraply xt, per square centimeter
Q4198	Genesis amniotic membrane, per square centimeter
Q4199	Cygnus matrix, per sq cm
Q4200	Skin te, per square centimeter
Q4201	Matrion, per square centimeter
Q4202	Keroxx (2.5g/cc), 1cc
Q4203	Derma-gide, per square centimeter
Q4204	Xwrap, per square centimeter
Q4205	Membrane graft or Membrane wrap, per sq cm
Q4206	Fluid Flow or Fluid GF, 1 cc
Q4207	Carbon Life, per sq cm (add-on, list separately in addition to primary procedure)
Q4208	Novafix, per sq cm
Q4209	Surgraft per sq cm
Q4211	Amnion bio or axobio sq cm
Q4212	AlloGen, per cc
Q4213	Ascent, 0.5 mg
Q4214	Cellesta Cord, per sq cm
Q4215	Axolotl Ambient or Axolotl Cryo, 0.1 mg
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	Amniowrap2 per sq cm

HCPCS Codes	Description
Q4222	ProgenaMatrix, per sq cm
Q4223	DermaBind SL Optic, per sq cm (add-on, list separately in addition to primary procedure)
Q4224	Human Health Factor 10 Amniotic Patch (HHF10-P), per sq cm
Q4225	Amnio or derma tl, per sq cm
Q4226	MyOwn skin, includes harvesting and preparation procedures, per square centimet
Q4227	Amniocore per sq cm
Q4229	Cogenex amnio memb per sq cm
Q4230	Cogenex flow amnion 0.5 cc
Q4231	Corplex p, per cc
Q4232	Corplex, per sq cm
Q4233	Surfactor /nudyn per 0.5 cc
Q4234	Xcellerate, per sq cm
Q4235	Amniorepair or altiply sq cm
Q4236	Carepatch per sq cm
Q4237	Cryo-cord, per sq cm
Q4238	Derm-maxx, per sq cm
Q4239	Amnio-maxx or lite per sq cm
Q4240	Corecyte topical only 0.5 cc
Q4241	Polycyte, topical only 0.5cc
Q4242	Amniocyte plus, per 0.5 cc
Q4243	AmchoMatrix, per sq cm (add-on, list separately in addition to primary procedure)
Q4245	Amniotext, per cc
Q4246	Coretext or protext, per cc
Q4247	Amniotext patch, per sq cm
Q4248	Dermacyte amn mem allo sq cm
Q4249	Amniply, for topical use only, per square centimeter
Q4250	Amnioamp-mp, per square centimeter
Q4251	Vim, per square centimeter
Q4252	Vendaje, per square centimet
Q4253	Zenith amniotic membrane psc
Q4254	Novafix dl per sq cm
Q4255	Reguard, topical use per sq
Q4256	Mlg complet, per sq cm
Q4257	Relese, per sq cm
Q4258	Enverse, per sq cm
Q4259	Celera per sq cm
Q4260	Signature apatch, per sq cm
Q4261	Tag, per square centimeter
Q4262	Dual layer impax, per sq cm
Q4263	Surgraft tl, per sq cm
Q4264	Cocoon membrane, per sq cm
Q4265	Neostim tl per sq cm
Q4266	Neostim per sq cm
Q4267	Neostim dl per sq cm
Q4268	Surgraft ft per sq cm
Q4269	Surgraft xt per sq cm
Q4270	Complete sl per sq cm
Q4271	Complete ft per sq cm
Q4272	Esano a, per sq cm
Q4273	Esano aaa, per sq cm
Q4274	Esano ac, per sq cm
Q4275	Esano aca, per sq cm
Q4276	Orion, per sq cm
Q4278	Epieffect, per sq cm
Q4279	Vendaje ac, per sq cm
Q4280	Xcell amnio matrix per sq cm
Q4281	Barrera slor dl per sq cm
Q4282	Cygnus dual per sq cm
Q4283	Biovance tri or 3l, sq cm

HCPCS Codes	Description
Q4284	Dermabind sl, per sq cm
Q4285	Nudyn dl or dl mesh pr sq cm
Q4286	Nudyn sl or slw, per sq cm
Q4288	Dermabind ch, per sq cm
Q4289	Revoshield+ amnio, per sq cm
Q4290	Membrane wrap hydr per sq cm
Q4291	Lamellas xt, per sq cm
Q4292	Lamellas, per sq cm
Q4294	Amnio quad-core, per sq cm
Q4295	Amnio tri-core, 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
Q4305	Amer am ac tri-lay per sq cm
Q4306	Americ amnion ac per sq cm
Q4307	American amnion, per sq cm
Q4308	Sanopellis, per sq cm
Q4309	Via matrix, per sq cm
Q4310	Procenta, per 100 mg
Q4311	Acesso, per sq cm
Q4312	Acesso AC, per sq cm
Q4313	DermaBind FM, per sq c
Q4314	Reeva FT, per sq cm
Q4315	RegeneLink Amniotic Membrane Allograft, per sq cm
Q4316	AmchoPlast, per sq cm
Q4317	VitoGraft, per sq cm
Q4318	E-Graft, per sq cm
Q4319	SanoGraft, per sq cm
Q4320	PelloGraft, per sq cm
Q4321	RenoGraft, per sq cm
Q4322	CaregraFT, per sq cm
Q4323	alloPLY, per sq cm
Q4324	AmnioTX, per sq cm
Q4325	ACApatch, per sq cm
Q4326	WoundPlus, per sq cm
Q4327	DuoAmnion, per sq cm
Q4328	MOST, per sq cm
Q4329	Singlay, per sq
Q4330	TOTAL, per sq cm
Q4331	Axolotl Graft, per sq cm
Q4332	Axolotl DualGraft, per sq cm
Q4333	ArdeoGraft, per sq cm
Q4334	AmnioPlast 1, per sq cm I
Q4335	AmnioPlast 2, per sq cm
Q4336	Artacent C, per sq cm
Q4337	Artacent Trident, per sq cm
Q4338	Artacent Velos, per sq cm
Q4339	Artacent Vericlen, per sq cm
Q4340	SimpliGraft, per sq cm
Q4341	SimpliMax, per sq cm
Q4342	TheraMend, per sq cm
Q4343	Dermacyte AC Matrix Amniotic Membrane Allograft, per sq cm
Q4344	Tri-Membrane Wrap, per sq cm

HCPCS Codes	Description
Q4345	Matrix HD Allograft Dermis, per sq
Q4346	Shelter DM Matrix, per sq cm
Q4347	Rampart DL Matrix, per sq cm
Q4348	Sentry SL Matrix, per sq cm
Q4349	Mantle DL Matrix, per sq cm
Q4350	Palisade DM Matrix, per sq cm
Q4351	Enclose TL Matrix, per sq cm
Q4352	Overlay SL Matrix, per sq cm
Q4353	Xceed TL Matrix, per sq cm
Q4354	PalinGen Dual-Layer Membrane, per sq cm
Q4355	Abiomend Xplus Membrane and Abiomend Xplus Hydromembrane, per sq cm
Q4356	Abiomend Membrane and Abiomend Hydromembrane, per sq cm
Q4357	Xwrap plus, per sq cm
Q4358	Xwrap dual, per sq cm
Q4359	Choriply, per sq cm
Q4360	Amchoplast fd, per sq cm
Q4361	Epixpress, per sq cm
Q4362	Cygnus disk, per sq cm
Q4363	Amnio burgeon membrane and hydromembrane, per sq cm
Q4364	Amnio burgeon xplus membrane and xplus hydromembrane, per sq cm
Q4365	Amnio burgeon dual-layer membrane,
Q4366	Dual layer amnio burgeon x-membrane, per sq cm
Q4367	Amniocore sl, per sq cm
Q4368	Amchothick, per square centimeter
Q4369	Amnioplast 3, per square centimeter
Q4370	Aeroguard, per square centimeter
Q4371	Neoguard, per square centimeter
Q4372	Amchoplast excel, per square centimeter
Q4373	Membrane wrap lite, per square centimeter
Q4375	Duograft ac, per square centimeter
Q4376	Duograft aa, per square centimeter
Q4377	Trigraft ft, per square centimeter
Q4378	Renew ft matrix, per square centimeter
Q4379	Amniodefend ft matrix, per square centimeter
Q4380	Advograft one, per square centimeter
Q4381	Matrix hd allograft dermis, per square centimeter
Q4382	Advograft dual, per square centimeter
Q4383	Axolotl Graft Ultra, per sq cm
Q4384	Axolotl DualGraft Ultra, per sq cm
Q4385	Apollo FT, per sq cm
Q4386	Acesso TrifACA, per sq cm
Q4387	NeoThelium FT, per sq cm
Q4388	NeoThelium 4L, per sq cm
Q4389	NeoThelium 4L Plus, per sq cm
Q4390	Ascendion, per sq cm
Q4391	AmnioPlast Double, per sq cm
Q4393	SurGraft AC, per sq cm
Q4394	SurGraft ACA, per sq cm
Q4395	Acelagraft, per sq cm
Q4396	Natalin, per sq cm
Q4397	Summit AAA, per sq cm
Q4418	BioLab Membrane Wrap Flow, per sq cm (add-on, list separately in addition to primary procedure)
Q4419	BioLab Membrane Wrap Lite Flow, per sq cm (add-on, list separately in addition to primary procedure)
Q4421	BioLab Membrane Wrap Solo, per sq cm (add-on, list separately in addition to primary procedure)
Q4422	A/C Wrap, per sq cm (add-on, list separately in addition to primary procedure)
Q4423	BioLab Tri-Membrane Wrap Flow, per sq cm (add-on, list separately in addition to primary procedure)
Q4424	Revive FT, per sq cm (add-on, list separately in addition to primary procedure)

HCPCS Codes	Description
Q4425	Revive TL, per sq cm (add-on, list separately in addition to primary procedure)
Q4426	DermaBind TL + or DermaBind TL X, per sq cm (add-on, list separately in addition to primary procedure)
Q4427	DermaBind DL N, DermaBind DL +, or DermaBind DL X, per sq cm (add-on, list separately in addition to primary procedure)
Q4428	DermaBind SL N, DermaBind SL +, or DermaBind SL X, per sq cm (add-on, list separately in addition to primary procedure)
Q4429	DermaBind CH N or DermaBind CH X, per sq cm (add-on, list separately in addition to primary procedure)
Q4435	Renati Membrane, per sq cm (add-on, list separately in addition to primary procedure)
Q4436	Renati AC Membrane, per sq cm (add-on, list separately in addition to primary procedure)
Q4437	Revival AC, per sq cm (add-on, list separately in addition to primary procedure)
Q4438	Pretect, per sq cm (add-on, list separately in addition to primary procedure)
Q4439	InstaGraft, per sq cm (add-on, list separately in addition to primary procedure)
Q4440	CuraMatrix, per sq cm (add-on, list separately in addition to primary procedure)

References:

1. Acellular Skin Substitutes for Chronic Foot Ulcers in Adults with Diabetes Mellitus. Hayesinc.com/login [via subscription only]. Published May 6, 2022. Updated May 10, 2023. Accessed April 10, 2024.
2. Biological Tissue-Engineered Skin Substitutes for Wound Healing. Hayesinc.com/login [via subscription only]. Accessed June 10, 2020.
3. Cellular Skin Substitutes for Chronic Foot Ulcers in Adults with Diabetes Mellitus. Hayesinc.com/login [via subscription only]. Published March 26, 2020. Published April 24, 2023. Accessed April 7, 2024.
4. Centers for Medicare and Medicaid Services. Local Coverage Determination (LCD): Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds (L35041). Accessed March 30, 2026.
5. Glynou SP, Sousi S, Cook H, Zargaran A, Zargaran D, Mosahebi A. A comparison of acellular dermal matrices (ADM) efficacy and complication profile in women undergoing implant-based breast reconstruction: a systematic review and network meta-analysis. BMC Cancer. 2024;24(1):1598. Published 2024 Dec 31. doi:10.1186/s12885-024-13359-3.
6. Grafix Cryopreserved Placental Membrane (Osiris Technologies Inc.) for Treatment of Chronic Foot Ulcers in Patients with Diabetes Mellitus. Hayesinc.com/login [via subscription only]. Published September 3, 2019. Updated October 25, 2022. Accessed April 7, 2024.
7. Integra Template and Matrix Wound Skin Substitutes (Integra LifeSciences Corp) for Treating Chronic Wounds. ECRI.org/login [via subscription only]. Accessed June 3, 2020.
8. Kagan RJ, Peck MD, Ahrenholz DH, et al. Surgical management of the burn wound and use of skin substitutes: an expert panel white paper. *J Burn Care Res*. 2013;34(2):e60-e79. doi:10.1097/BCR.0b013e31827039a6.
9. Kerecis Omega3 (Kerecis LLC) for Treating Burns. ECRI.org/login [via subscription only]. February 23, 2024. Accessed March 30, 2026.
10. Khalil HH, Kalkat M, Malahias MN, et al. Chest Wall Reconstruction with Porcine Acellular Dermal Matrix (Strattice) and Autologous Tissue Transfer for High Risk Patients with Chest Wall Tumors. Plast Reconstr Surg Glob Open. 2018;6(5):e1703. Published 2018 May 18. doi:10.1097/GOX.0000000000001703.
11. Lee KT, Mun GH. A Meta-analysis of Studies Comparing Outcomes of Diverse Acellular Dermal Matrices for Implant-Based Breast Reconstruction. Ann Plast Surg. 2017;79(1):115-123. doi:10.1097/SAP.0000000000001085.
12. Petrie K, Cox CT, Becker BC, MacKay BJ. Clinical applications of acellular dermal matrices: A review. Scars Burn Heal. 2022;8:20595131211038313. Published 2022 Jan 19. doi:10.1177/205951312110383.
13. Pittman TA, Fan KL, Knapp A, Frantz S, Spear SL. Comparison of Different Acellular Dermal Matrices in Breast Reconstruction: The 50/50 Study. Plast Reconstr Surg. 2017;139(3):521-528. doi:10.1097/PRS.0000000000003048
14. PuraPly Antimicrobial (AM) Wound Matrix (Organogenesis Inc.) for Treatment of Wounds. Hayesinc.com/login [via subscription only]. Published December 12, 2022. Updated December 20, 2023. Accessed April 7, 2024.
15. Samuels K, Millet E, Wong L. Efficacy of Acellular Dermal Matrix Type in Treatment of Capsular Contracture in Breast Augmentation: A Systematic Review and Meta-Analysis. Aesthet Surg J. 2023;44(1):26-35. doi:10.1093/asj/sjad265.
16. Sawad AB, Turkistani F. Treatment of venous leg ulcers using bilayered living cellular construct. J Comp Eff Res. 2020;9(13):907-918. doi:10.2217/cer-2020-0076.
17. Skin Substitutes. UpToDate.com/login [via subscription only]. July 31, 2025. Accessed March 30, 2026.
18. Skin Substitutes for Treating Burns in Patients Aged 65 Years or Older. ECRI.com/login [via subscription only]. January 23, 2025. Accessed March 30, 2026.
19. Snyder D, Sullivan N, Margolis D, Schoelles K. Skin Substitutes for Treating Chronic Wounds. Rockville (MD): Agency for Healthcare Research and Quality (US); February 2, 2020.
20. Topical agents and dressings for local burn wound care. UpToDate.com/login [via subscription only]. June 17, 2025. Accessed March 30, 2026.

21. Treadwell T, Sabolinski M, Skornicki M, Parsons N. Comparative Effectiveness of a Bioengineered Living Cellular Construct and Cryopreserved Cadaveric Skin Allograft for the Treatment of Venous Leg Ulcers in a Real-World Setting. Adv Wound Care (New Rochelle). 2018;7(3):69-76. doi:10.1089/wound.2017.0738.
22. Vecin NM, Kirsner RS. Skin substitutes as treatment for chronic wounds: current and future directions. Front Med (Lausanne). 2023 Aug 29;10:1154567. doi: 10.3389/fmed.2023.1154567. PMID: 37711741; PMCID: PMC10498286.

Approval And Revision History

December 18, 2024: Reviewed by the Medical Policy Approval Committee (MPAC); new Medical Necessity Guideline (MNG) to address bioengineered skin and soft tissue skin substitutes, effective March 1, 2025

Subsequent endorsement date(s) and changes made:

- April 16, 2025: Reviewed by MPAC, renewed without changes effective June 1, 2025
- May 13, 2025: Codes Q4354-Q4367 added to investigational list, effective April 1, 2025. Codes Q4368-Q4382 added to investigational list, effective July 1, 2025
- September 25, 2025: Fax number for Senior Care Options, Tufts Medicare Preferred HMO and Tufts Medicare Preferred PPO updated; language for Carelink removed; Harvard Pilgrim Health Care Stride Medicare Advantage removed as an applicable product from the template
- October 1, 2025: Code Q4392 added for PA and added the following codes to investigational list; A2036-A2039, Q4383-Q4391, and Q4393-Q4397, effective October 1, 2025.
- March 30, 2026: Coding updated per AMA HCPCS, A2043-A2044 added for PA and added the following codes to investigational list; A2014, A2037, A2040-A2042, A2045, Q4418-Q4419, Q4421-Q4429, Q4435-Q4440, G0681-G0684, effective April 1, 2026
- May 20, 2026: Reviewed by MPAC; administrative update to guideline template, renewed without changes effective July 1, 2026
- September 23, 2026: Coding updated per AMA, added the following codes as investigational; A2046-A2050, Q4207, Q4223, Q4243, effective October 1, 2026

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.