



MASSACHUSETTS

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Medical Policy

Bioengineered Skin and Soft Tissue Substitutes

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Related Policies

Amniotic Membrane and Amniotic Fluid, #[643](#)

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

Breast reconstructive surgery following cancer treatment using allogeneic acellular dermal matrix products^a may be considered [MEDICALLY NECESSARY](#).¹

Treatment of chronic, noninfected, full-thickness diabetic lower extremity ulcers using the following tissue-engineered skin substitutes may be considered [MEDICALLY NECESSARY](#):

- AlloPatch^{®a}
- Apligraf^{®b}
- Dermagraft^{®b}
- Integra[®] Omnigraft[™] Dermal Regeneration Matrix (also known as Omnigraft[™]) and Integra Flowable Wound Matrix.

Treatment of chronic, non-infected, partial- or full-thickness lower extremity skin ulcers due to venous insufficiency, which have not adequately responded following a 1-month period of conventional ulcer therapy, using the following tissue-engineered skin substitutes may be considered [MEDICALLY NECESSARY](#):

- Apligraf^{®b}
- Oasis[™] Wound Matrix^c.

Treatment of dystrophic epidermolysis bullosa using the following tissue-engineered skin substitutes may be considered [MEDICALLY NECESSARY](#):

- OrCel™ (for the treatment of mitten-hand deformity when standard wound therapy has failed and when provided in accordance with the humanitarian device exemption [HDE] specifications of the U.S. Food and Drug Administration [FDA])^d.

Treatment of second- and third-degree burns using the following tissue-engineered skin substitutes may be considered **MEDICALLY NECESSARY**:

- Epicel® (for the treatment of deep dermal or full-thickness burns comprising a total body surface area ≥30% when provided in accordance with the HDE specifications of the FDA)^d
- Integra® Dermal Regeneration Template^b.

^a Banked human tissue.

^b FDA premarket approval.

^c FDA 510(k) clearance.

^d FDA-approved under an HDE.

All other uses of the bio-engineered skin and soft tissue substitutes listed above are considered **INVESTIGATIONAL**.

All other skin and soft tissue substitutes not listed above are considered **INVESTIGATIONAL**, including, but not limited to:

- ACell® UBM Hydated/ Lyophilized Wound Dressing
- AlloSkin™
- AlloSkin™ RT
- Aongen™ Collagen Matrix
- Architect® ECM, PX, FX
- ArthroFlex™ (Flex Graft)
- Atlas Wound Matrix
- Avagen Wound Dressing
- AxoGuard® Nerve Protector (AxoGen)
- Biobrane®/Biobrane-L
- CollaCare®
- CollaCare® Dental
- Collagen Wound Dressing (Oasis Research)
- CollaGUARD®
- CollaMend™
- CollaWound™
- Collexa®
- Collieva®
- Conexa™
- Coreleader Colla-Pad
- CorMatrix®
- Cymetra™ (Micronized AlloDerm™)
- Cytal™ (previously MatriStem®)
- Dermadapt™ Wound Dressing
- DermaPure™
- DermaSpan™
- DressSkin
- Durepair Regeneration Matrix®
- Endoform Dermal Template™
- ENDURAGEN™
- Excellagen
- ExpressGraft™
- E-Z Derm™

- FlexiGraft®
- GammaGraft
- GraftJacket® Xpress, injectable
- Helicoll™
- Hyalomatrix®
- Hyalomatrix® PA
- hMatrix®
- Integra™ Bilayer Wound Matrix
- Keramatrix®
- Kerecis™
- MariGen /Kerecis™ Omega3™
- MatriDerm®
- Matrix HD™
- Mediskin®
- MemoDerm™
- Microderm® biologic wound matrix
- NeoForm™
- NuCel
- Oasis® Burn Matrix
- Oasis® Ultra
- Pelvicol®/PelviSoft®
- Permacol™
- PriMatrix
- Primatrix™ Dermal Repair Scaffold
- PuraPly™ Wound Matrix (previously-FortaDerm™)
- PuraPly™ AM (Antimicrobial Wound Matrix)
- Puros® Dermis
- RegenePro™
- Repliform®
- Repriza™
- StrataGraft®
- Strattice™ (xenograft)
- Suprathel®
- SurgiMend®
- Talymed®
- TenoGlide™
- TenSIX™ Acellular Dermal Matrix
- TissueMend
- TheraForm™ Standard/Sheet
- TheraSkin®
- TransCyte™
- TruSkin™
- Veritas® Collagen Matrix
- XCM Biologic® Tissue Matrix
- XenMatrix™ AB.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is not required .
Commercial PPO and Indemnity	Prior authorization is not required .
Medicare HMO BlueSM	Prior authorization is not required .
Medicare PPO BlueSM	Prior authorization is not required .

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

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

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
15271	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
15272	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)
15273	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
15274	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
15275	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
15276	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)
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 (eg, acellular dermal matrix) for soft tissue reinforcement (eg, breast, trunk) (List separately in addition to code for primary procedure)
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The above **medical necessity criteria MUST** be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

Breast Reconstructive Surgery

HCPCS Codes

HCPCS codes:	Code Description
Q4100	Skin substitute, not otherwise specified**for use with AlloMax™, AlloMend®, DermaMatrix™,
Q4107	GRAFTJACKET, per sq cm
Q4116	AlloDerm, per sq cm
Q4122	DermACELL, per sq cm
Q4128	FlexHD, AllopatchHD, or Matrix HD, per sq cm

The following ICD Diagnosis Codes are considered medically necessary when submitted with the HCPCS codes above if **medical necessity criteria** are met:

ICD-10 Diagnosis Coding

ICD-10-CM-diagnosis codes:	Code Description
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast

C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast

The above **medical necessity criteria** **MUST** be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

Diabetic Lower Extremity Ulcers

HCPCS Codes

HCPCS codes:	Code Description
Q4101	Apligraf, per sq cm
Q4105	Integra dermal regeneration template (DRT) or Integra Omnigraft dermal regeneration matrix, per square centimeter
Q4106	Dermagraft, per sq cm
Q4114	Integra flowable wound matrix, injectable, 1 cc
Q4128	FlexHD, AllopatchHD, or Matrix HD, per sq cm

The following ICD Diagnosis Codes are considered medically necessary when submitted with the HCPCS codes above if **medical necessity criteria** are met:

ICD-10 Diagnosis Coding

ICD-10-CM-diagnosis codes:	Code Description
E08.621	Diabetes mellitus due to underlying condition with foot ulcer

E08.622	Diabetes mellitus due to underlying condition with other skin ulcer
E09.621	Drug or chemical induced diabetes mellitus with foot ulcer
E09.622	Drug or chemical induced diabetes mellitus with other skin ulcer
E10.621	Type 1 diabetes mellitus with foot ulcer
E10.622	Type 1 diabetes mellitus with other skin ulcer
E11.621	Type 2 diabetes mellitus with foot ulcer
E11.622	Type 2 diabetes mellitus with other skin ulcer
E13.621	Other specified diabetes mellitus with foot ulcer
E13.622	Other specified diabetes mellitus with other skin ulcer

The above **medical necessity criteria** **MUST** be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

Lower Extremity Skin Ulcers Due to Venous Insufficiency

HCPCS Codes

HCPCS codes:	Code Description
Q4101	Apligraf, per sq cm
Q4102	Oasis wound matrix, per sq cm

The following ICD Diagnosis Codes are considered medically necessary when submitted with the HCPCS codes above if **medical necessity criteria** are met:

ICD-10 Diagnosis Coding

ICD-10-CM-diagnosis codes:	Code Description
I87.2	Venous insufficiency (chronic) (peripheral)
L97.101	Non-pressure chronic ulcer of unspecified thigh limited to breakdown of skin
L97.102	Non-pressure chronic ulcer of unspecified thigh with fat layer exposed
L97.105	Non-pressure chronic ulcer of unspecified thigh with muscle involvement without evidence of necrosis
L97.106	Non-pressure chronic ulcer of unspecified thigh with bone involvement without evidence of necrosis
L97.108	Non-pressure chronic ulcer of unspecified thigh with other specified severity
L97.109	Non-pressure chronic ulcer of unspecified thigh with unspecified severity
L97.111	Non-pressure chronic ulcer of right thigh limited to breakdown of skin
L97.112	Non-pressure chronic ulcer of right thigh with fat layer exposed
L97.115	Non-pressure chronic ulcer of right thigh with muscle involvement without evidence of necrosis
L97.116	Non-pressure chronic ulcer of right thigh with bone involvement without evidence of necrosis
L97.118	Non-pressure chronic ulcer of right thigh with other specified severity
L97.119	Non-pressure chronic ulcer of right thigh with unspecified severity
L97.121	Non-pressure chronic ulcer of left thigh limited to breakdown of skin
L97.122	Non-pressure chronic ulcer of left thigh with fat layer exposed
L97.125	Non-pressure chronic ulcer of left thigh with muscle involvement without evidence of necrosis
L97.126	Non-pressure chronic ulcer of left thigh with bone involvement without evidence of necrosis
L97.128	Non-pressure chronic ulcer of left thigh with other specified severity

L97.129	Non-pressure chronic ulcer of left thigh with unspecified severity
L97.201	Non-pressure chronic ulcer of unspecified calf limited to breakdown of skin
L97.202	Non-pressure chronic ulcer of unspecified calf with fat layer exposed
L97.205	Non-pressure chronic ulcer of unspecified calf with muscle involvement without evidence of necrosis
L97.206	Non-pressure chronic ulcer of unspecified calf with bone involvement without evidence of necrosis
L97.208	Non-pressure chronic ulcer of unspecified calf with other specified severity
L97.209	Non-pressure chronic ulcer of unspecified calf with unspecified severity
L97.211	Non-pressure chronic ulcer of right calf limited to breakdown of skin
L97.212	Non-pressure chronic ulcer of right calf with fat layer exposed
L97.215	Non-pressure chronic ulcer of right calf with muscle involvement without evidence of necrosis
L97.216	Non-pressure chronic ulcer of right calf with bone involvement without evidence of necrosis
L97.218	Non-pressure chronic ulcer of right calf with other specified severity
L97.219	Non-pressure chronic ulcer of right calf with unspecified severity
L97.221	Non-pressure chronic ulcer of left calf limited to breakdown of skin
L97.222	Non-pressure chronic ulcer of left calf with fat layer exposed
L97.225	Non-pressure chronic ulcer of left calf with muscle involvement without evidence of necrosis
L97.226	Non-pressure chronic ulcer of left calf with bone involvement without evidence of necrosis
L97.228	Non-pressure chronic ulcer of left calf with other specified severity
L97.229	Non-pressure chronic ulcer of left calf with unspecified severity
L97.301	Non-pressure chronic ulcer of unspecified ankle limited to breakdown of skin
L97.302	Non-pressure chronic ulcer of unspecified ankle with fat layer exposed
L97.305	Non-pressure chronic ulcer of unspecified ankle with muscle involvement without evidence of necrosis
L97.306	Non-pressure chronic ulcer of unspecified ankle with bone involvement without evidence of necrosis
L97.308	Non-pressure chronic ulcer of unspecified ankle with other specified severity
L97.309	Non-pressure chronic ulcer of unspecified ankle with unspecified severity
L97.311	Non-pressure chronic ulcer of right ankle limited to breakdown of skin
L97.312	Non-pressure chronic ulcer of right ankle with fat layer exposed
L97.315	Non-pressure chronic ulcer of right ankle with muscle involvement without evidence of necrosis
L97.316	Non-pressure chronic ulcer of right ankle with bone involvement without evidence of necrosis
L97.318	Non-pressure chronic ulcer of right ankle with other specified severity
L97.319	Non-pressure chronic ulcer of right ankle with unspecified severity
L97.321	Non-pressure chronic ulcer of left ankle limited to breakdown of skin
L97.322	Non-pressure chronic ulcer of left ankle with fat layer exposed
L97.325	Non-pressure chronic ulcer of left ankle with muscle involvement without evidence of necrosis
L97.326	Non-pressure chronic ulcer of left ankle with bone involvement without evidence of necrosis
L97.328	Non-pressure chronic ulcer of left ankle with other specified severity
L97.329	Non-pressure chronic ulcer of left ankle with unspecified severity
L97.401	Non-pressure chronic ulcer of unspecified heel and midfoot limited to breakdown of skin
L97.402	Non-pressure chronic ulcer of unspecified heel and midfoot with fat layer exposed

L97.405	Non-pressure chronic ulcer of unspecified heel and midfoot with muscle involvement without evidence of necrosis
L97.406	Non-pressure chronic ulcer of unspecified heel and midfoot with bone involvement without evidence of necrosis
L97.408	Non-pressure chronic ulcer of unspecified heel and midfoot with other specified severity
L97.409	Non-pressure chronic ulcer of unspecified heel and midfoot with unspecified severity
L97.411	Non-pressure chronic ulcer of right heel and midfoot limited to breakdown of skin
L97.412	Non-pressure chronic ulcer of right heel and midfoot with fat layer exposed
L97.415	Non-pressure chronic ulcer of right heel and midfoot with muscle involvement without evidence of necrosis
L97.416	Non-pressure chronic ulcer of right heel and midfoot with bone involvement without evidence of necrosis
L97.418	Non-pressure chronic ulcer of right heel and midfoot with other specified severity
L97.419	Non-pressure chronic ulcer of right heel and midfoot with unspecified severity
L97.421	Non-pressure chronic ulcer of left heel and midfoot limited to breakdown of skin
L97.422	Non-pressure chronic ulcer of left heel and midfoot with fat layer exposed
L97.425	Non-pressure chronic ulcer of left heel and midfoot with muscle involvement without evidence of necrosis
L97.426	Non-pressure chronic ulcer of left heel and midfoot with bone involvement without evidence of necrosis
L97.428	Non-pressure chronic ulcer of left heel and midfoot with other specified severity
L97.429	Non-pressure chronic ulcer of left heel and midfoot with unspecified severity
L97.501	Non-pressure chronic ulcer of other part of unspecified foot limited to breakdown of skin
L97.502	Non-pressure chronic ulcer of other part of unspecified foot with fat layer exposed
L97.505	Non-pressure chronic ulcer of other part of unspecified foot with muscle involvement without evidence of necrosis
L97.506	Non-pressure chronic ulcer of other part of unspecified foot with bone involvement without evidence of necrosis
L97.508	Non-pressure chronic ulcer of other part of unspecified foot with other specified severity
L97.509	Non-pressure chronic ulcer of other part of unspecified foot with unspecified severity
L97.511	Non-pressure chronic ulcer of other part of right foot limited to breakdown of skin
L97.512	Non-pressure chronic ulcer of other part of right foot with fat layer exposed
L97.515	Non-pressure chronic ulcer of other part of right foot with muscle involvement without evidence of necrosis
L97.516	Non-pressure chronic ulcer of other part of right foot with bone involvement without evidence of necrosis
L97.518	Non-pressure chronic ulcer of other part of right foot with other specified severity
L97.519	Non-pressure chronic ulcer of other part of right foot with unspecified severity
L97.521	Non-pressure chronic ulcer of other part of left foot limited to breakdown of skin
L97.522	Non-pressure chronic ulcer of other part of left foot with fat layer exposed
L97.525	Non-pressure chronic ulcer of other part of left foot with muscle involvement without evidence of necrosis
L97.526	Non-pressure chronic ulcer of other part of left foot with bone involvement without evidence of necrosis
L97.528	Non-pressure chronic ulcer of other part of left foot with other specified severity
L97.529	Non-pressure chronic ulcer of other part of left foot with unspecified severity
L97.801	Non-pressure chronic ulcer of other part of unspecified lower leg limited to breakdown of skin
L97.802	Non-pressure chronic ulcer of other part of unspecified lower leg with fat layer exposed

L97.805	Non-pressure chronic ulcer of other part of unspecified lower leg with muscle involvement without evidence of necrosis
L97.806	Non-pressure chronic ulcer of other part of unspecified lower leg with bone involvement without evidence of necrosis
L97.808	Non-pressure chronic ulcer of other part of unspecified lower leg with other specified severity
L97.809	Non-pressure chronic ulcer of other part of unspecified lower leg with unspecified severity
L97.811	Non-pressure chronic ulcer of other part of right lower leg limited to breakdown of skin
L97.812	Non-pressure chronic ulcer of other part of right lower leg with fat layer exposed
L97.815	Non-pressure chronic ulcer of other part of right lower leg with muscle involvement without evidence of necrosis
L97.816	Non-pressure chronic ulcer of other part of right lower leg with bone involvement without evidence of necrosis
L97.818	Non-pressure chronic ulcer of other part of right lower leg with other specified severity
L97.819	Non-pressure chronic ulcer of other part of right lower leg with unspecified severity
L97.821	Non-pressure chronic ulcer of other part of left lower leg limited to breakdown of skin
L97.822	Non-pressure chronic ulcer of other part of left lower leg with fat layer exposed
L97.825	Non-pressure chronic ulcer of other part of left lower leg with muscle involvement without evidence of necrosis
L97.826	Non-pressure chronic ulcer of other part of left lower leg with bone involvement without evidence of necrosis
L97.828	Non-pressure chronic ulcer of other part of left lower leg with other specified severity
L97.829	Non-pressure chronic ulcer of other part of left lower leg with unspecified severity
L97.901	Non-pressure chronic ulcer of unspecified part of unspecified lower leg limited to breakdown of skin
L97.902	Non-pressure chronic ulcer of unspecified part of unspecified lower leg with fat layer exposed
L97.905	Non-pressure chronic ulcer of unspecified part of unspecified lower leg with muscle involvement without evidence of necrosis
L97.906	Non-pressure chronic ulcer of unspecified part of unspecified lower leg with bone involvement without evidence of necrosis
L97.908	Non-pressure chronic ulcer of unspecified part of unspecified lower leg with other specified severity
L97.909	Non-pressure chronic ulcer of unspecified part of unspecified lower leg with unspecified severity
L97.911	Non-pressure chronic ulcer of unspecified part of right lower leg limited to breakdown of skin
L97.912	Non-pressure chronic ulcer of unspecified part of right lower leg with fat layer exposed
L97.915	Non-pressure chronic ulcer of unspecified part of right lower leg with muscle involvement without evidence of necrosis
L97.916	Non-pressure chronic ulcer of unspecified part of right lower leg with bone involvement without evidence of necrosis
L97.918	Non-pressure chronic ulcer of unspecified part of right lower leg with other specified severity
L97.919	Non-pressure chronic ulcer of unspecified part of right lower leg with unspecified severity
L97.921	Non-pressure chronic ulcer of unspecified part of left lower leg limited to breakdown of skin
L97.922	Non-pressure chronic ulcer of unspecified part of left lower leg with fat layer exposed
L97.925	Non-pressure chronic ulcer of unspecified part of left lower leg with muscle involvement without evidence of necrosis
L97.926	Non-pressure chronic ulcer of unspecified part of left lower leg with bone involvement without evidence of necrosis

L97.928	Non-pressure chronic ulcer of unspecified part of left lower leg with other specified severity
L97.929	Non-pressure chronic ulcer of unspecified part of left lower leg with unspecified severity

The above **medical necessity criteria MUST** be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

Dystrophic Epidermolysis Bullosa

HCPCS Codes

HCPCS codes:	Code Description
Q4100	Skin substitute, not otherwise specified**for use with OrCel™

The above **medical necessity criteria MUST** be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

Second and Third Degree Burns

HCPCS Codes

HCPCS codes:	Code Description
Q4100	Skin substitute, not otherwise specified**for use with Epicel®
Q4105	Integra dermal regeneration template (drt) or integra omnigraft dermal regeneration matrix, per square centimeter

The following ICD Diagnosis Codes are considered medically necessary when submitted with the HCPCS codes above if **medical necessity criteria** are met:

ICD-10 Diagnosis Coding

ICD-10-CM-diagnosis codes:	Code Description
T20.20XA	Burn of second degree of head, face, and neck, unspecified site, initial encounter
T20.20XD	Burn of second degree of head, face, and neck, unspecified site, subsequent encounter
T20.20XS	Burn of second degree of head, face, and neck, unspecified site, sequela
T20.211A	Burn of second degree of right ear [any part, except ear drum], initial encounter
T20.211D	Burn of second degree of right ear [any part, except ear drum], subsequent encounter
T20.211S	Burn of second degree of right ear [any part, except ear drum], sequela
T20.212A	Burn of second degree of left ear [any part, except ear drum], initial encounter
T20.212D	Burn of second degree of left ear [any part, except ear drum], subsequent encounter
T20.212S	Burn of second degree of left ear [any part, except ear drum], sequela
T20.219A	Burn of second degree of unspecified ear [any part, except ear drum], initial encounter
T20.219D	Burn of second degree of unspecified ear [any part, except ear drum], subsequent encounter
T20.219S	Burn of second degree of unspecified ear [any part, except ear drum], sequela
T20.22XA	Burn of second degree of lip(s), initial encounter
T20.22XD	Burn of second degree of lip(s), subsequent encounter

T20.22XS	Burn of second degree of lip(s), sequela
T20.23XA	Burn of second degree of chin, initial encounter
T20.23XD	Burn of second degree of chin, subsequent encounter
T20.23XS	Burn of second degree of chin, sequela
T20.24XA	Burn of second degree of nose (septum), initial encounter
T20.24XD	Burn of second degree of nose (septum), subsequent encounter
T20.24XS	Burn of second degree of nose (septum), sequela
T20.25XA	Burn of second degree of scalp [any part], initial encounter
T20.25XD	Burn of second degree of scalp [any part], subsequent encounter
T20.25XS	Burn of second degree of scalp [any part], sequela
T20.26XA	Burn of second degree of forehead and cheek, initial encounter
T20.26XD	Burn of second degree of forehead and cheek, subsequent encounter
T20.26XS	Burn of second degree of forehead and cheek, sequela
T20.27XA	Burn of second degree of neck, initial encounter
T20.27XD	Burn of second degree of neck, subsequent encounter
T20.27XS	Burn of second degree of neck, sequela
T20.29XA	Burn of second degree of multiple sites of head, face, and neck, initial encounter
T20.29XD	Burn of second degree of multiple sites of head, face, and neck, subsequent encounter
T20.29XS	Burn of second degree of multiple sites of head, face, and neck, sequela
T20.30XA	Burn of third degree of head, face, and neck, unspecified site, initial encounter
T20.30XD	Burn of third degree of head, face, and neck, unspecified site, subsequent encounter
T20.30XS	Burn of third degree of head, face, and neck, unspecified site, sequela
T20.311A	Burn of third degree of right ear [any part, except ear drum], initial encounter
T20.311D	Burn of third degree of right ear [any part, except ear drum], subsequent encounter
T20.311S	Burn of third degree of right ear [any part, except ear drum], sequela
T20.312A	Burn of third degree of left ear [any part, except ear drum], initial encounter
T20.312D	Burn of third degree of left ear [any part, except ear drum], subsequent encounter
T20.312S	Burn of third degree of left ear [any part, except ear drum], sequela
T20.319A	Burn of third degree of unspecified ear [any part, except ear drum], initial encounter
T20.319D	Burn of third degree of unspecified ear [any part, except ear drum], subsequent encounter
T20.319S	Burn of third degree of unspecified ear [any part, except ear drum], sequela
T20.32XA	Burn of third degree of lip(s), initial encounter
T20.32XD	Burn of third degree of lip(s), subsequent encounter
T20.32XS	Burn of third degree of lip(s), sequela
T20.33XA	Burn of third degree of chin, initial encounter
T20.33XD	Burn of third degree of chin, subsequent encounter
T20.33XS	Burn of third degree of chin, sequela
T20.34XA	Burn of third degree of nose (septum), initial encounter
T20.34XD	Burn of third degree of nose (septum), subsequent encounter
T20.34XS	Burn of third degree of nose (septum), sequela
T20.35XA	Burn of third degree of scalp [any part], initial encounter
T20.35XD	Burn of third degree of scalp [any part], subsequent encounter
T20.35XS	Burn of third degree of scalp [any part], sequela
T20.36XA	Burn of third degree of forehead and cheek, initial encounter
T20.36XD	Burn of third degree of forehead and cheek, subsequent encounter
T20.36XS	Burn of third degree of forehead and cheek, sequela
T20.37XA	Burn of third degree of neck, initial encounter
T20.37XD	Burn of third degree of neck, subsequent encounter
T20.37XS	Burn of third degree of neck, sequela

T20.39XA	Burn of third degree of multiple sites of head, face, and neck, initial encounter
T20.39XD	Burn of third degree of multiple sites of head, face, and neck, subsequent encounter
T20.39XS	Burn of third degree of multiple sites of head, face, and neck, sequela
T21.20XA	Burn of second degree of trunk, unspecified site, initial encounter
T21.20XD	Burn of second degree of trunk, unspecified site, subsequent encounter
T21.20XS	Burn of second degree of trunk, unspecified site, sequela
T21.21XA	Burn of second degree of chest wall, initial encounter
T21.21XD	Burn of second degree of chest wall, subsequent encounter
T21.21XS	Burn of second degree of chest wall, sequela
T21.22XA	Burn of second degree of abdominal wall, initial encounter
T21.22XD	Burn of second degree of abdominal wall, subsequent encounter
T21.22XS	Burn of second degree of abdominal wall, sequela
T21.23XA	Burn of second degree of upper back, initial encounter
T21.23XD	Burn of second degree of upper back, subsequent encounter
T21.23XS	Burn of second degree of upper back, sequela
T21.24XA	Burn of second degree of lower back, initial encounter
T21.24XD	Burn of second degree of lower back, subsequent encounter
T21.24XS	Burn of second degree of lower back, sequela
T21.25XA	Burn of second degree of buttock, initial encounter
T21.25XD	Burn of second degree of buttock, subsequent encounter
T21.26XA	Burn of second degree of male genital region, initial encounter
T21.26XD	Burn of second degree of male genital region, subsequent encounter
T21.26XS	Burn of second degree of male genital region, sequela
T21.27XA	Burn of second degree of female genital region, initial encounter
T21.27XD	Burn of second degree of female genital region, subsequent encounter
T21.27XS	Burn of second degree of female genital region, sequela
T21.29XA	Burn of second degree of other site of trunk, initial encounter
T21.29XD	Burn of second degree of other site of trunk, subsequent encounter
T21.29XS	Burn of second degree of other site of trunk, sequela
T21.30XA	Burn of third degree of trunk, unspecified site, initial encounter
T21.30XD	Burn of third degree of trunk, unspecified site, subsequent encounter
T21.30XS	Burn of third degree of trunk, unspecified site, sequela
T21.31XA	Burn of third degree of chest wall, initial encounter
T21.31XD	Burn of third degree of chest wall, subsequent encounter
T21.31XS	Burn of third degree of chest wall, sequela
T21.32XA	Burn of third degree of abdominal wall, initial encounter
T21.32XD	Burn of third degree of abdominal wall, subsequent encounter
T21.32XS	Burn of third degree of abdominal wall, sequela
T21.33XA	Burn of third degree of upper back, initial encounter
T21.33XD	Burn of third degree of upper back, subsequent encounter
T21.33XS	Burn of third degree of upper back, sequela
T21.34XA	Burn of third degree of lower back, initial encounter
T21.34XD	Burn of third degree of lower back, subsequent encounter
T21.34XS	Burn of third degree of lower back, sequela
T21.35XA	Burn of third degree of buttock, initial encounter
T21.35XD	Burn of third degree of buttock, subsequent encounter
T21.35XS	Burn of third degree of buttock, sequela
T21.36XA	Burn of third degree of male genital region, initial encounter
T21.36XD	Burn of third degree of male genital region, subsequent encounter
T21.36XS	Burn of third degree of male genital region, sequela
T21.37XA	Burn of third degree of female genital region, initial encounter

T21.37XD	Burn of third degree of female genital region, subsequent encounter
T21.37XS	Burn of third degree of female genital region, sequela
T21.39XA	Burn of third degree of other site of trunk, initial encounter
T21.39XD	Burn of third degree of other site of trunk, subsequent encounter
T21.39XS	Burn of third degree of other site of trunk, sequela
T22.20XA	Burn of second degree of shoulder and upper limb, except wrist and hand, unspecified site, initial encounter
T22.20XD	Burn of second degree of shoulder and upper limb, except wrist and hand, unspecified site, subsequent encounter
T22.20XS	Burn of second degree of shoulder and upper limb, except wrist and hand, unspecified site, sequela
T22.211A	Burn of second degree of right forearm, initial encounter
T22.211D	Burn of second degree of right forearm, subsequent encounter
T22.211S	Burn of second degree of right forearm, sequela
T22.212A	Burn of second degree of left forearm, initial encounter
T22.212D	Burn of second degree of left forearm, subsequent encounter
T22.212S	Burn of second degree of left forearm, sequela
T22.219A	Burn of second degree of unspecified forearm, initial encounter
T22.219D	Burn of second degree of unspecified forearm, subsequent encounter
T22.219S	Burn of second degree of unspecified forearm, sequela
T22.221A	Burn of second degree of right elbow, initial encounter
T22.221D	Burn of second degree of right elbow, subsequent encounter
T22.221S	Burn of second degree of right elbow, sequela
T22.222A	Burn of second degree of left elbow, initial encounter
T22.222D	Burn of second degree of left elbow, subsequent encounter
T22.222S	Burn of second degree of left elbow, sequela
T22.229A	Burn of second degree of unspecified elbow, initial encounter
T22.229D	Burn of second degree of unspecified elbow, subsequent encounter
T22.229S	Burn of second degree of unspecified elbow, sequela
T22.231A	Burn of second degree of right upper arm, initial encounter
T22.231D	Burn of second degree of right upper arm, subsequent encounter
T22.231S	Burn of second degree of right upper arm, sequela
T22.232A	Burn of second degree of left upper arm, initial encounter
T22.232D	Burn of second degree of left upper arm, subsequent encounter
T22.232S	Burn of second degree of left upper arm, sequela
T22.239A	Burn of second degree of unspecified upper arm, initial encounter
T22.239D	Burn of second degree of unspecified upper arm, subsequent encounter
T22.239S	Burn of second degree of unspecified upper arm, sequela
T22.241A	Burn of second degree of right axilla, initial encounter
T22.241D	Burn of second degree of right axilla, subsequent encounter
T22.241S	Burn of second degree of right axilla, sequela
T22.242A	Burn of second degree of left axilla, initial encounter
T22.242D	Burn of second degree of left axilla, subsequent encounter
T22.242S	Burn of second degree of left axilla, sequela
T22.249A	Burn of second degree of unspecified axilla, initial encounter
T22.249D	Burn of second degree of unspecified axilla, subsequent encounter
T22.249S	Burn of second degree of unspecified axilla, sequela
T22.251A	Burn of second degree of right shoulder, initial encounter
T22.251D	Burn of second degree of right shoulder, subsequent encounter
T22.251S	Burn of second degree of right shoulder, sequela
T22.252A	Burn of second degree of left shoulder, initial encounter

T22.252D	Burn of second degree of left shoulder, subsequent encounter
T22.252S	Burn of second degree of left shoulder, sequela
T22.259A	Burn of second degree of unspecified shoulder, initial encounter
T22.259D	Burn of second degree of unspecified shoulder, subsequent encounter
T22.259S	Burn of second degree of unspecified shoulder, sequela
T22.261A	Burn of second degree of right scapular region, initial encounter
T22.261D	Burn of second degree of right scapular region, subsequent encounter
T22.261S	Burn of second degree of right scapular region, sequela
T22.262A	Burn of second degree of left scapular region, initial encounter
T22.262D	Burn of second degree of left scapular region, subsequent encounter
T22.262S	Burn of second degree of left scapular region, sequela
T22.269A	Burn of second degree of unspecified scapular region, initial encounter
T22.269D	Burn of second degree of unspecified scapular region, subsequent encounter
T22.269S	Burn of second degree of unspecified scapular region, sequela
T22.291A	Burn of second degree of multiple sites of right shoulder and upper limb, except wrist and hand, initial encounter
T22.291D	Burn of second degree of multiple sites of right shoulder and upper limb, except wrist and hand, subsequent encounter
T22.291S	Burn of second degree of multiple sites of right shoulder and upper limb, except wrist and hand, sequela
T22.292A	Burn of second degree of multiple sites of left shoulder and upper limb, except wrist and hand, initial encounter
T22.292D	Burn of second degree of multiple sites of left shoulder and upper limb, except wrist and hand, subsequent encounter
T22.292S	Burn of second degree of multiple sites of left shoulder and upper limb, except wrist and hand, sequela
T22.299A	Burn of second degree of multiple sites of unspecified shoulder and upper limb, except wrist and hand, initial encounter
T22.299D	Burn of second degree of multiple sites of unspecified shoulder and upper limb, except wrist and hand, subsequent encounter
T22.299S	Burn of second degree of multiple sites of unspecified shoulder and upper limb, except wrist and hand, sequela
T22.30XA	Burn of third degree of shoulder and upper limb, except wrist and hand, unspecified site, initial encounter
T22.30XD	Burn of third degree of shoulder and upper limb, except wrist and hand, unspecified site, subsequent encounter
T22.30XS	Burn of third degree of shoulder and upper limb, except wrist and hand, unspecified site, sequela
T22.311A	Burn of third degree of right forearm, initial encounter
T22.311D	Burn of third degree of right forearm, subsequent encounter
T22.311S	Burn of third degree of right forearm, sequela
T22.312A	Burn of third degree of left forearm, initial encounter
T22.312D	Burn of third degree of left forearm, subsequent encounter
T22.312S	Burn of third degree of left forearm, sequela
T22.319A	Burn of third degree of unspecified forearm, initial encounter
T22.319D	Burn of third degree of unspecified forearm, subsequent encounter
T22.319S	Burn of third degree of unspecified forearm, sequela
T22.321A	Burn of third degree of right elbow, initial encounter
T22.321D	Burn of third degree of right elbow, subsequent encounter
T22.321S	Burn of third degree of right elbow, sequela
T22.322A	Burn of third degree of left elbow, initial encounter
T22.322D	Burn of third degree of left elbow, subsequent encounter

T22.322S	Burn of third degree of left elbow, sequela
T22.329A	Burn of third degree of unspecified elbow, initial encounter
T22.329D	Burn of third degree of unspecified elbow, subsequent encounter
T22.329S	Burn of third degree of unspecified elbow, sequela
T22.331A	Burn of third degree of right upper arm, initial encounter
T22.331D	Burn of third degree of right upper arm, subsequent encounter
T22.331S	Burn of third degree of right upper arm, sequela
T22.332A	Burn of third degree of left upper arm, initial encounter
T22.332D	Burn of third degree of left upper arm, subsequent encounter
T22.332S	Burn of third degree of left upper arm, sequela
T22.339A	Burn of third degree of unspecified upper arm, initial encounter
T22.339D	Burn of third degree of unspecified upper arm, subsequent encounter
T22.339S	Burn of third degree of unspecified upper arm, sequela
T22.341A	Burn of third degree of right axilla, initial encounter
T22.341D	Burn of third degree of right axilla, subsequent encounter
T22.341S	Burn of third degree of right axilla, sequela
T22.342A	Burn of third degree of left axilla, initial encounter
T22.342D	Burn of third degree of left axilla, subsequent encounter
T22.342S	Burn of third degree of left axilla, sequela
T22.349A	Burn of third degree of unspecified axilla, initial encounter
T22.349D	Burn of third degree of unspecified axilla, subsequent encounter
T22.349S	Burn of third degree of unspecified axilla, sequela
T22.351A	Burn of third degree of right shoulder, initial encounter
T22.351D	Burn of third degree of right shoulder, subsequent encounter
T22.351S	Burn of third degree of right shoulder, sequela
T22.352A	Burn of third degree of left shoulder, initial encounter
T22.352D	Burn of third degree of left shoulder, subsequent encounter
T22.352S	Burn of third degree of left shoulder, sequela
T22.359A	Burn of third degree of unspecified shoulder, initial encounter
T22.359D	Burn of third degree of unspecified shoulder, subsequent encounter
T22.359S	Burn of third degree of unspecified shoulder, sequela
T22.361A	Burn of third degree of right scapular region, initial encounter
T22.361D	Burn of third degree of right scapular region, subsequent encounter
T22.361S	Burn of third degree of right scapular region, sequela
T22.362A	Burn of third degree of left scapular region, initial encounter
T22.362D	Burn of third degree of left scapular region, subsequent encounter
T22.362S	Burn of third degree of left scapular region, sequela
T22.369A	Burn of third degree of unspecified scapular region, initial encounter
T22.369D	Burn of third degree of unspecified scapular region, subsequent encounter
T22.369S	Burn of third degree of unspecified scapular region, sequela
T22.391A	Burn of third degree of multiple sites of right shoulder and upper limb, except wrist and hand, initial encounter
T22.391D	Burn of third degree of multiple sites of right shoulder and upper limb, except wrist and hand, subsequent encounter
T22.391S	Burn of third degree of multiple sites of right shoulder and upper limb, except wrist and hand, sequela
T22.392A	Burn of third degree of multiple sites of left shoulder and upper limb, except wrist and hand, initial encounter
T22.392D	Burn of third degree of multiple sites of left shoulder and upper limb, except wrist and hand, subsequent encounter
T22.392S	Burn of third degree of multiple sites of left shoulder and upper limb, except wrist and hand, sequela

T22.399A	Burn of third degree of multiple sites of unspecified shoulder and upper limb, except wrist and hand, initial encounter
T22.399D	Burn of third degree of multiple sites of unspecified shoulder and upper limb, except wrist and hand, subsequent encounter
T22.399S	Burn of third degree of multiple sites of unspecified shoulder and upper limb, except wrist and hand, sequela
T23.201A	Burn of second degree of right hand, unspecified site, initial encounter
T23.201D	Burn of second degree of right hand, unspecified site, subsequent encounter
T23.201S	Burn of second degree of right hand, unspecified site, sequela
T23.202A	Burn of second degree of left hand, unspecified site, initial encounter
T23.202D	Burn of second degree of unspecified hand, unspecified site, subsequent encounter
T23.202S	Burn of second degree of left hand, unspecified site, sequela
T23.209A	Burn of second degree of unspecified hand, unspecified site, initial encounter
T23.209D	Burn of second degree of unspecified hand, unspecified site, subsequent encounter
T23.209S	Burn of second degree of unspecified hand, unspecified site, sequela
T23.211A	Burn of second degree of right thumb (nail), initial encounter
T23.211D	Burn of second degree of right thumb (nail), subsequent encounter
T23.211S	Burn of second degree of right thumb (nail), sequela
T23.212A	Burn of second degree of left thumb (nail), initial encounter
T23.212D	Burn of second degree of left thumb (nail), subsequent encounter
T23.212S	Burn of second degree of left thumb (nail), sequela
T23.219A	Burn of second degree of unspecified thumb (nail), initial encounter
T23.219D	Burn of second degree of unspecified thumb (nail), subsequent encounter
T23.219S	Burn of second degree of unspecified thumb (nail), sequela
T23.221A	Burn of second degree of single right finger (nail) except thumb, initial encounter
T23.221D	Burn of second degree of single right finger (nail) except thumb, subsequent encounter
T23.221S	Burn of second degree of single right finger (nail) except thumb, sequela
T23.222A	Burn of second degree of single left finger (nail) except thumb, initial encounter
T23.222D	Burn of second degree of single left finger (nail) except thumb, subsequent encounter
T23.222S	Burn of second degree of single left finger (nail) except thumb, sequela
T23.229A	Burn of second degree of unspecified single finger (nail) except thumb, initial encounter
T23.229D	Burn of second degree of unspecified single finger (nail) except thumb, subsequent encounter
T23.229S	Burn of second degree of unspecified single finger (nail) except thumb, sequela
T23.231A	Burn of second degree of multiple right fingers (nail), not including thumb, initial encounter
T23.231D	Burn of second degree of multiple right fingers (nail), not including thumb, subsequent encounter
T23.231S	Burn of second degree of multiple right fingers (nail), not including thumb, sequela
T23.232A	Burn of second degree of multiple left fingers (nail), not including thumb, initial encounter
T23.232D	Burn of second degree of multiple left fingers (nail), not including thumb, subsequent encounter
T23.232S	Burn of second degree of multiple left fingers (nail), not including thumb, sequela
T23.239A	Burn of second degree of unspecified multiple fingers (nail), not including thumb, initial encounter
T23.239D	Burn of second degree of unspecified multiple fingers (nail), not including thumb, subsequent encounter
T23.239S	Burn of second degree of unspecified multiple fingers (nail), not including thumb, sequela

T23.241A	Burn of second degree of multiple right fingers (nail), including thumb, initial encounter
T23.241D	Burn of second degree of multiple right fingers (nail), including thumb, subsequent encounter
T23.241S	Burn of second degree of multiple right fingers (nail), including thumb, sequela
T23.241S	Burn of third degree of multiple right fingers (nail), including thumb, sequela
T23.242A	Burn of second degree of multiple left fingers (nail), including thumb, initial encounter
T23.242D	Burn of second degree of multiple left fingers (nail), including thumb, subsequent encounter
T23.242S	Burn of second degree of multiple left fingers (nail), including thumb, sequela
T23.249A	Burn of second degree of unspecified multiple fingers (nail), including thumb, initial encounter
T23.249D	Burn of second degree of unspecified multiple fingers (nail), including thumb, subsequent encounter
T23.249S	Burn of second degree of unspecified multiple fingers (nail), including thumb, sequela
T23.251A	Burn of second degree of right palm, initial encounter
T23.251D	Burn of second degree of right palm, subsequent encounter
T23.251S	Burn of second degree of right palm, sequela
T23.252A	Burn of second degree of left palm, initial encounter
T23.252D	Burn of second degree of left palm, subsequent encounter
T23.252S	Burn of second degree of left palm, sequela
T23.259A	Burn of second degree of unspecified palm, initial encounter
T23.259D	Burn of second degree of unspecified palm, subsequent encounter
T23.259S	Burn of second degree of unspecified palm, sequela
T23.261A	Burn of second degree of back of right hand, initial encounter
T23.261D	Burn of second degree of back of right hand, subsequent encounter
T23.261S	Burn of second degree of back of right hand, sequela
T23.262A	Burn of second degree of back of left hand, initial encounter
T23.262D	Burn of second degree of back of left hand, subsequent encounter
T23.262S	Burn of second degree of back of unspecified hand, sequela
T23.269A	Burn of second degree of back of unspecified hand, initial encounter
T23.269D	Burn of second degree of back of unspecified hand, subsequent encounter
T23.269S	Burn of second degree of back of unspecified hand, sequela
T23.271A	Burn of second degree of right wrist, initial encounter
T23.271D	Burn of second degree of right wrist, subsequent encounter
T23.271S	Burn of second degree of right wrist, sequela
T23.272A	Burn of second degree of left wrist, initial encounter
T23.272D	Burn of second degree of left wrist, subsequent encounter
T23.272S	Burn of second degree of left wrist, sequela
T23.279A	Burn of second degree of unspecified wrist, initial encounter
T23.279D	Burn of second degree of unspecified wrist, subsequent encounter
T23.279S	Burn of second degree of left wrist, sequela
T23.291A	Burn of second degree of multiple sites of right wrist and hand, initial encounter
T23.291D	Burn of second degree of multiple sites of right wrist and hand, subsequent encounter
T23.291S	Burn of second degree of multiple sites of right wrist and hand, sequela
T23.292A	Burn of second degree of multiple sites of left wrist and hand, initial encounter
T23.292D	Burn of second degree of multiple sites of left wrist and hand, subsequent encounter
T23.292S	Burn of second degree of multiple sites of left wrist and hand, sequela
T23.299A	Burn of second degree of multiple sites of unspecified wrist and hand, initial encounter
T23.299D	Burn of second degree of multiple sites of unspecified wrist and hand, subsequent encounter

T23.299S	Burn of second degree of multiple sites of unspecified wrist and hand, sequela
T23.301A	Burn of third degree of right hand, unspecified site, initial encounter
T23.301D	Burn of third degree of right hand, unspecified site, subsequent encounter
T23.301S	Burn of third degree of right hand, unspecified site, sequela
T23.302A	Burn of third degree of left hand, unspecified site, initial encounter
T23.302D	Burn of third degree of left hand, unspecified site, subsequent encounter
T23.302S	Burn of third degree of left hand, unspecified site, sequela
T23.309A	Burn of third degree of unspecified hand, unspecified site, initial encounter
T23.309D	Burn of third degree of unspecified hand, unspecified site, subsequent encounter
T23.309S	Burn of third degree of unspecified hand, unspecified site, sequela
T23.311A	Burn of third degree of right thumb (nail), initial encounter
T23.311D	Burn of third degree of right thumb (nail), subsequent encounter
T23.311S	Burn of third degree of right thumb (nail), sequela
T23.312A	Burn of third degree of left thumb (nail), initial encounter
T23.312D	Burn of third degree of left thumb (nail), subsequent encounter
T23.312S	Burn of third degree of left thumb (nail), sequela
T23.319A	Burn of third degree of unspecified thumb (nail), initial encounter
T23.319D	Burn of third degree of unspecified thumb (nail), subsequent encounter
T23.319S	Burn of third degree of unspecified thumb (nail), sequela
T23.321A	Burn of third degree of single right finger (nail) except thumb, initial encounter
T23.321D	Burn of third degree of single right finger (nail) except thumb, subsequent encounter
T23.321S	Burn of third degree of single right finger (nail) except thumb, sequela
T23.322A	Burn of third degree of single left finger (nail) except thumb, initial encounter
T23.322D	Burn of third degree of single left finger (nail) except thumb, subsequent encounter
T23.322S	Burn of third degree of single left finger (nail) except thumb, sequela
T23.329A	Burn of third degree of unspecified single finger (nail) except thumb, initial encounter
T23.329D	Burn of third degree of unspecified single finger (nail) except thumb, subsequent encounter
T23.329S	Burn of third degree of unspecified single finger (nail) except thumb, sequela
T23.331A	Burn of third degree of multiple right fingers (nail), not including thumb, initial encounter
T23.331D	Burn of third degree of multiple right fingers (nail), not including thumb, subsequent encounter
T23.331S	Burn of third degree of multiple right fingers (nail), not including thumb, sequela
T23.332A	Burn of third degree of multiple left fingers (nail), not including thumb, initial encounter
T23.332D	Burn of third degree of multiple left fingers (nail), not including thumb, subsequent encounter
T23.332S	Burn of third degree of multiple left fingers (nail), not including thumb, sequela
T23.339A	Burn of third degree of unspecified multiple fingers (nail), not including thumb, initial encounter
T23.339D	Burn of third degree of unspecified multiple fingers (nail), not including thumb, subsequent encounter
T23.339S	Burn of third degree of unspecified multiple fingers (nail), not including thumb, sequela
T23.341A	Burn of third degree of multiple right fingers (nail), including thumb, initial encounter
T23.341D	Burn of third degree of multiple right fingers (nail), including thumb, subsequent encounter
T23.342A	Burn of third degree of multiple left fingers (nail), including thumb, initial encounter
T23.342D	Burn of third degree of multiple left fingers (nail), including thumb, subsequent encounter
T23.342S	Burn of third degree of multiple left fingers (nail), including thumb, sequela

T23.349A	Burn of third degree of unspecified multiple fingers (nail), including thumb, initial encounter
T23.349D	Burn of third degree of unspecified multiple fingers (nail), including thumb, subsequent encounter
T23.349S	Burn of third degree of unspecified multiple fingers (nail), including thumb, sequela
T23.351A	Burn of third degree of right palm, initial encounter
T23.351D	Burn of third degree of right palm, subsequent encounter
T23.351S	Burn of third degree of right palm, sequela
T23.352A	Burn of third degree of left palm, initial encounter
T23.352D	Burn of third degree of left palm, subsequent encounter
T23.352S	Burn of third degree of left palm, sequela
T23.359A	Burn of third degree of unspecified palm, initial encounter
T23.359D	Burn of third degree of unspecified palm, subsequent encounter
T23.359S	Burn of third degree of unspecified palm, sequela
T23.361A	Burn of third degree of back of right hand, initial encounter
T23.361D	Burn of third degree of back of right hand, subsequent encounter
T23.361S	Burn of third degree of back of right hand, sequela
T23.362A	Burn of third degree of back of left hand, initial encounter
T23.362D	Burn of third degree of back of left hand, subsequent encounter
T23.362S	Burn of third degree of back of left hand, sequela
T23.369A	Burn of third degree of back of unspecified hand, initial encounter
T23.369D	Burn of third degree of back of unspecified hand, subsequent encounter
T23.369S	Burn of third degree of back of unspecified hand, sequela
T23.371A	Burn of third degree of right wrist, initial encounter
T23.371D	Burn of third degree of right wrist, subsequent encounter
T23.371S	Burn of third degree of right wrist, sequela
T23.372A	Burn of third degree of left wrist, initial encounter
T23.372D	Burn of third degree of left wrist, subsequent encounter
T23.372S	Burn of third degree of left wrist, sequela
T23.379A	Burn of third degree of unspecified wrist, initial encounter
T23.379D	Burn of third degree of unspecified wrist, subsequent encounter
T23.379S	Burn of third degree of unspecified wrist, sequela
T23.391A	Burn of third degree of multiple sites of right wrist and hand, initial encounter
T23.391D	Burn of third degree of multiple sites of right wrist and hand, subsequent encounter
T23.391S	Burn of third degree of multiple sites of right wrist and hand, sequela
T23.392A	Burn of third degree of multiple sites of left wrist and hand, initial encounter
T23.392D	Burn of third degree of multiple sites of left wrist and hand, subsequent encounter
T23.392S	Burn of third degree of multiple sites of left wrist and hand, sequela
T23.399A	Burn of third degree of multiple sites of unspecified wrist and hand, initial encounter
T23.399D	Burn of third degree of multiple sites of unspecified wrist and hand, subsequent encounter
T23.399S	Burn of third degree of multiple sites of unspecified wrist and hand, sequela
T24.201A	Burn of second degree of unspecified site of right lower limb, except ankle and foot, initial encounter
T24.201D	Burn of second degree of unspecified site of right lower limb, except ankle and foot, subsequent encounter
T24.201S	Burn of second degree of unspecified site of right lower limb, except ankle and foot, sequela
T24.202A	Burn of second degree of unspecified site of left lower limb, except ankle and foot, initial encounter
T24.202D	Burn of second degree of unspecified site of left lower limb, except ankle and foot, subsequent encounter

T24.202S	Burn of second degree of unspecified site of left lower limb, except ankle and foot, sequela
T24.209A	Burn of second degree of unspecified site of unspecified lower limb, except ankle and foot, initial encounter
T24.209D	Burn of second degree of unspecified site of unspecified lower limb, except ankle and foot, subsequent encounter
T24.209S	Burn of second degree of unspecified site of unspecified lower limb, except ankle and foot, sequela
T24.211A	Burn of second degree of right thigh, initial encounter
T24.211D	Burn of second degree of right thigh, subsequent encounter
T24.211S	Burn of second degree of right thigh, sequela
T24.212A	Burn of second degree of left thigh, initial encounter
T24.212D	Burn of second degree of left thigh, subsequent encounter
T24.212S	Burn of second degree of left thigh, sequela
T24.219A	Burn of second degree of unspecified thigh, initial encounter
T24.219D	Burn of second degree of unspecified thigh, subsequent encounter
T24.219S	Burn of second degree of unspecified thigh, sequela
T24.221A	Burn of second degree of right knee, initial encounter
T24.221D	Burn of second degree of right knee, subsequent encounter
T24.221S	Burn of second degree of right knee, sequela
T24.222A	Burn of second degree of left knee, initial encounter
T24.222D	Burn of second degree of left knee, subsequent encounter
T24.222S	Burn of second degree of left knee, sequela
T24.229A	Burn of second degree of unspecified knee, initial encounter
T24.229D	Burn of second degree of unspecified knee, subsequent encounter
T24.229S	Burn of second degree of unspecified knee, sequela
T24.231A	Burn of second degree of right lower leg, initial encounter
T24.231D	Burn of second degree of right lower leg, subsequent encounter
T24.231S	Burn of second degree of right lower leg, sequela
T24.232A	Burn of second degree of left lower leg, initial encounter
T24.232D	Burn of second degree of left lower leg, subsequent encounter
T24.232S	Burn of second degree of left lower leg, sequela
T24.239A	Burn of second degree of unspecified lower leg, initial encounter
T24.239D	Burn of second degree of unspecified lower leg, subsequent encounter
T24.239S	Burn of second degree of unspecified lower leg, sequela
T24.291A	Burn of second degree of multiple sites of right lower limb, except ankle and foot, initial encounter
T24.291D	Burn of second degree of multiple sites of right lower limb, except ankle and foot, subsequent encounter
T24.291S	Burn of second degree of multiple sites of right lower limb, except ankle and foot, sequela
T24.292A	Burn of second degree of multiple sites of left lower limb, except ankle and foot, initial encounter
T24.292D	Burn of second degree of multiple sites of left lower limb, except ankle and foot, subsequent encounter
T24.292S	Burn of second degree of multiple sites of left lower limb, except ankle and foot, sequela
T24.299A	Burn of second degree of multiple sites of unspecified lower limb, except ankle and foot, initial encounter
T24.299D	Burn of second degree of multiple sites of unspecified lower limb, except ankle and foot, subsequent encounter
T24.299S	Burn of second degree of multiple sites of unspecified lower limb, except ankle and foot, sequela

T24.301A	Burn of third degree of unspecified site of right lower limb, except ankle and foot, initial encounter
T24.301D	Burn of third degree of unspecified site of right lower limb, except ankle and foot, subsequent encounter
T24.301S	Burn of third degree of unspecified site of right lower limb, except ankle and foot, sequela
T24.302A	Burn of third degree of unspecified site of left lower limb, except ankle and foot, initial encounter
T24.302D	Burn of third degree of unspecified site of left lower limb, except ankle and foot, subsequent encounter
T24.302S	Burn of third degree of unspecified site of left lower limb, except ankle and foot, sequela
T24.309A	Burn of third degree of unspecified site of unspecified lower limb, except ankle and foot, initial encounter
T24.309D	Burn of third degree of unspecified site of unspecified lower limb, except ankle and foot, subsequent encounter
T24.309S	Burn of third degree of unspecified site of unspecified lower limb, except ankle and foot, sequela
T24.311A	Burn of third degree of right thigh, initial encounter
T24.311D	Burn of third degree of right thigh, subsequent encounter
T24.311S	Burn of third degree of right thigh, sequela
T24.312A	Burn of third degree of left thigh, initial encounter
T24.312D	Burn of third degree of left thigh, subsequent encounter
T24.312S	Burn of third degree of left thigh, sequela
T24.319A	Burn of third degree of unspecified thigh, initial encounter
T24.321A	Burn of third degree of right knee, initial encounter
T24.321D	Burn of third degree of right knee, subsequent encounter
T24.321S	Burn of third degree of right knee, sequela
T24.322A	Burn of third degree of left knee, initial encounter
T24.322D	Burn of third degree of left knee, subsequent encounter
T24.322S	Burn of third degree of left knee, sequela
T24.329A	Burn of third degree of unspecified knee, initial encounter
T24.329D	Burn of third degree of unspecified knee, subsequent encounter
T24.329S	Burn of third degree of unspecified knee, sequela
T24.331A	Burn of third degree of right lower leg, initial encounter
T24.331D	Burn of third degree of right lower leg, subsequent encounter
T24.331S	Burn of third degree of right lower leg, sequela
T24.332A	Burn of third degree of left lower leg, initial encounter
T24.332D	Burn of third degree of left lower leg, subsequent encounter
T24.332S	Burn of third degree of left lower leg, sequela
T24.339A	Burn of third degree of unspecified lower leg, initial encounter
T24.339D	Burn of third degree of unspecified lower leg, subsequent encounter
T24.339S	Burn of third degree of unspecified lower leg, sequela
T24.391A	Burn of third degree of multiple sites of right lower limb, except ankle and foot, initial encounter
T24.391D	Burn of third degree of multiple sites of right lower limb, except ankle and foot, subsequent encounter
T24.391S	Burn of third degree of multiple sites of right lower limb, except ankle and foot, sequela
T24.392A	Burn of third degree of multiple sites of left lower limb, except ankle and foot, initial encounter
T24.392D	Burn of third degree of multiple sites of left lower limb, except ankle and foot, subsequent encounter

T24.392S	Burn of third degree of multiple sites of left lower limb, except ankle and foot, sequela
T24.399A	Burn of third degree of multiple sites of unspecified lower limb, except ankle and foot, initial encounter
T24.399D	Burn of third degree of multiple sites of unspecified lower limb, except ankle and foot, subsequent encounter
T24.399S	Burn of third degree of multiple sites of unspecified lower limb, except ankle and foot, sequela
T25.211A	Burn of second degree of right ankle, initial encounter
T25.211D	Burn of second degree of right ankle, subsequent encounter
T25.211S	Burn of second degree of right ankle, sequela
T25.212A	Burn of second degree of left ankle, initial encounter
T25.212D	Burn of second degree of left ankle, subsequent encounter
T25.212S	Burn of second degree of left ankle, sequela
T25.219A	Burn of second degree of unspecified ankle, initial encounter
T25.219D	Burn of second degree of unspecified ankle, subsequent encounter
T25.219S	Burn of second degree of unspecified ankle, sequela
T25.221A	Burn of second degree of right foot, initial encounter
T25.221D	Burn of second degree of right foot, subsequent encounter
T25.221S	Burn of second degree of right foot, sequela
T25.222A	Burn of second degree of left foot, initial encounter
T25.222D	Burn of second degree of left foot, subsequent encounter
T25.222S	Burn of second degree of left foot, sequela
T25.229A	Burn of second degree of unspecified foot, initial encounter
T25.229D	Burn of second degree of unspecified foot, subsequent encounter
T25.229S	Burn of second degree of unspecified foot, sequela
T25.231A	Burn of second degree of right toe(s) (nail), initial encounter
T25.231D	Burn of second degree of right toe(s) (nail), subsequent encounter
T25.231S	Burn of second degree of right toe(s) (nail), sequela
T25.232A	Burn of second degree of left toe(s) (nail), initial encounter
T25.232D	Burn of second degree of left toe(s) (nail), subsequent encounter
T25.232S	Burn of second degree of left toe(s) (nail), sequela
T25.239A	Burn of second degree of unspecified toe(s) (nail), initial encounter
T25.239D	Burn of second degree of unspecified toe(s) (nail), subsequent encounter
T25.239S	Burn of second degree of unspecified toe(s) (nail), sequela
T25.291A	Burn of second degree of multiple sites of right ankle and foot, initial encounter
T25.291D	Burn of second degree of multiple sites of right ankle and foot, subsequent encounter
T25.291S	Burn of second degree of multiple sites of right ankle and foot, sequela
T25.292A	Burn of second degree of multiple sites of left ankle and foot, initial encounter
T25.292D	Burn of second degree of multiple sites of left ankle and foot, subsequent encounter
T25.292S	Burn of second degree of multiple sites of left ankle and foot, sequela
T25.299A	Burn of second degree of multiple sites of unspecified ankle and foot, initial encounter
T25.299D	Burn of second degree of multiple sites of unspecified ankle and foot, subsequent encounter
T25.299S	Burn of second degree of multiple sites of unspecified ankle and foot, sequela
T25.311A	Burn of third degree of right ankle, initial encounter
T25.311D	Burn of third degree of right ankle, subsequent encounter
T25.311S	Burn of third degree of right ankle, sequela
T25.312A	Burn of third degree of left ankle, initial encounter
T25.312D	Burn of third degree of left ankle, subsequent encounter
T25.312S	Burn of third degree of left ankle, sequela
T25.319A	Burn of third degree of unspecified ankle, initial encounter

T25.319D	Burn of third degree of unspecified ankle, subsequent encounter
T25.319S	Burn of third degree of unspecified ankle, sequela
T25.321A	Burn of third degree of right foot, initial encounter
T25.321D	Burn of third degree of right foot, subsequent encounter
T25.321S	Burn of third degree of right foot, sequela
T25.322A	Burn of third degree of left foot, initial encounter
T25.322D	Burn of third degree of left foot, subsequent encounter
T25.322S	Burn of third degree of left foot, sequela
T25.329A	Burn of third degree of unspecified foot, initial encounter
T25.329D	Burn of third degree of unspecified foot, subsequent encounter
T25.329S	Burn of third degree of unspecified foot, sequela
T25.331A	Burn of third degree of right toe(s) (nail), initial encounter
T25.331D	Burn of third degree of right toe(s) (nail), subsequent encounter
T25.331S	Burn of third degree of right toe(s) (nail), sequela
T25.332A	Burn of third degree of left toe(s) (nail), initial encounter
T25.332D	Burn of third degree of left toe(s) (nail), subsequent encounter
T25.332S	Burn of third degree of left toe(s) (nail), sequela
T25.339A	Burn of third degree of unspecified toe(s) (nail), initial encounter
T25.339D	Burn of third degree of unspecified toe(s) (nail), subsequent encounter
T25.339S	Burn of third degree of unspecified toe(s) (nail), sequela
T25.391A	Burn of third degree of multiple sites of right ankle and foot, initial encounter
T25.391D	Burn of third degree of multiple sites of right ankle and foot, subsequent encounter
T25.391S	Burn of third degree of multiple sites of right ankle and foot, sequela
T25.392A	Burn of third degree of multiple sites of left ankle and foot, initial encounter
T25.392D	Burn of third degree of multiple sites of left ankle and foot, subsequent encounter
T25.392S	Burn of third degree of multiple sites of left ankle and foot, sequela
T25.399A	Burn of third degree of multiple sites of unspecified ankle and foot, initial encounter
T25.399D	Burn of third degree of multiple sites of unspecified ankle and foot, subsequent encounter
T25.399S	Burn of third degree of multiple sites of unspecified ankle and foot, sequela

The following HCPCS codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO Indemnity, Medicare HMO Blue and Medicare PPO Blue:

HCPCS Codes

HCPCS codes:	Code Description
C9354	Acellular pericardial tissue matrix of nonhuman origin (Veritas), per square centimeter
C9356	Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix (TenoGlide Tendon Protector Sheet), per sq cm
C9358	Dermal substitute, native, nondenatured collage, fetal bovine origin (SurgiMend Collagen Matrix), per 0.5 square centimeters
C9360	Dermal substitute, native, nondenatured collage, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 square centimeters
C9363	Skin substitute (Integra Meshed Bilayer Wound Matrix), per square cm
C9364	Porcine implant, Permacol, per square centimeter
Q4102	Oasis wound matrix, per sq cm
Q4103	Oasis burn matrix, per sq cm
Q4104	Integra bilayer matrix wound dressing (BMWD), per sq cm
Q4108	Integra matrix, per sq cm
Q4110	PriMatrix, per sq cm

Q4111	GammaGraft, per sq cm
Q4112	Cymetra, injectable, 1 cc
Q4113	GRAFTJACKET XPRESS, injectable, 1cc
Q4115	AlloSkin, per sq cm
Q4117	HYALOMATRIX, per sq cm
Q4118	MatriStem micromatrix, 1 mg
Q4121	TheraSkin, per sq cm
Q4123	AlloSkin RT, per sq cm
Q4124	OASIS ultra tri-layer wound matrix, per sq cm
Q4125	Arthroflex, per sq cm
Q4126	MemoDerm, per sq cm
Q4127	Talymed, per sq cm
Q4130	Strattice TM, per sq cm
Q4134	Hmatrix, per square centimeter
Q4135	Mediskin, per square centimeter
Q4136	Ez-derm, per square centimeter
Q4141	Alloskin ac, per square centimeter
Q4142	Xcm biologic tissue matrix, per square centimeter
Q4143	Repriza, per square centimeter
Q4146	Tensix, per square centimeter
Q4147	Architect extracellular matrix, per square centimeter
Q4149	Excellagen, 0.1 cc
Q4152	Dermapure, per square centimeter
Q4161	Bio-connekt wound matrix, per square centimeter
Q4164	Helicoll, per square centimeter
Q4165	Keramatrix, per square centimeter
Q4166	Cytal, per square centimeter
Q4167	Truskin, per square centimeter
Q4175	Miroderm, per square centimeter
Q4179	Flowerderm, per square centimeter
Q4182	Transcyte, per square centimeter
Q4193	Coll-e-derm, per square centimeter
Q4195	Puraply, per square centimeter
Q4196	Puraply am, per square centimeter
Q4197	Puraply xt, per square centimeter
Q4200	Skin te, per square centimeter
Q4202	Keroxx (2.5g/cc), 1cc
Q4203	Derma-gide, per square centimeter

Description

Skin and Soft Tissue Substitutes

Bioengineered skin and soft tissue substitutes may be either acellular or cellular. Acellular products (eg, dermis with cellular material removed) contain a matrix or scaffold composed of materials such as collagen, hyaluronic acid, and fibronectin. Acellular dermal matrix (ADM) products can differ in a number of ways, including as species source (human, bovine, porcine), tissue source (eg dermis, pericardium, intestinal mucosa), additives (eg antibiotics, surfactants), hydration (wet, freeze-dried), and required preparation (multiple rinses, rehydration).

Cellular products contain living cells such as fibroblasts and keratinocytes within a matrix. The cells contained within the matrix may be autologous, allogeneic, or derived from other species (eg, bovine, porcine). Skin substitutes may also be composed of dermal cells, epidermal cells, or a combination of

dermal and epidermal cells, and may provide growth factors to stimulate healing. Bioengineered skin substitutes can be used as either temporary or permanent wound coverings.

Applications

There are a large number of potential applications for artificial skin and soft tissue products. One large category is nonhealing wounds, which potentially encompasses diabetic neuropathic ulcers, vascular insufficiency ulcers, and pressure ulcers. A substantial minority of such wounds do not heal adequately with standard wound care, leading to prolonged morbidity and increased risk of mortality. For example, nonhealing lower-extremity wounds represent an ongoing risk for infection, sepsis, limb amputation, and death. Bioengineered skin and soft tissue substitutes have the potential to improve rates of healing and reduce secondary complications.

Other situations in which bioengineered skin products might substitute for living skin grafts include certain postsurgical states (eg, breast reconstruction) in which skin coverage is inadequate for the procedure performed, or for surgical wounds in patients with compromised ability to heal. Second- and third-degree burns are another indication in which artificial skin products may substitute for auto- or allografts. Certain primary dermatologic conditions that involve large areas of skin breakdown (eg, bullous diseases) may also be conditions in which artificial skin products can be considered as substitutes for skin grafts. ADM products are also being evaluated in the repair of other soft tissues including rotator cuff repair, following oral and facial surgery, hernias, and other conditions.

SUMMARY

Bioengineered skin and soft tissue substitutes may be derived from human tissue (autologous or allogeneic), nonhuman tissue (xenographic), synthetic materials, or a composite of these materials. Bioengineered skin and soft tissue substitutes are being evaluated for a variety of conditions, including breast reconstruction and healing lower-extremity ulcers and severe burns. Acellular dermal matrix (ADM) products are also being evaluated for soft tissue repair.

Breast Reconstruction

For individuals who are undergoing breast reconstruction who receive allogeneic ADM products, the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, morbid events, functional outcomes, quality of life, and treatment-related morbidity. A systematic review found no difference in overall complication rates with ADM allograft compared with standard procedures for breast reconstruction. Reconstructions with ADM have been reported to have higher seroma, infection, and necrosis rates than reconstructions without ADM. However, capsular contracture and malposition of implants may be reduced. Thus, in cases where there is limited tissue coverage, the available evidence may inform patient decision making about reconstruction options. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Tendon Repair

For individuals who are undergoing tendon repair who receive Graftjacket, the evidence includes an RCT. Relevant outcome are symptoms, morbid events, functional outcomes, quality of life, and treatment-related morbidity. The RCT identified found improved outcomes with the Graftjacket ADM allograft for rotator cuff repair. Although these results were positive, additional study with a larger number of patients is needed to evaluate the consistency of the effect. The evidence is insufficient to determine the effects of the technology on health outcomes.

Surgical Repair of Hernias or Parastomal Reinforcement

For individuals who are undergoing surgical repair of hernias or parastomal reinforcement who receive acellular collagen-based scaffolds, the evidence includes RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, quality of life, and treatment-related morbidity. Several comparative studies including RCTs have shown no difference in outcomes between tissue-engineered skin substitutes and either standard synthetic mesh or no reinforcement. The evidence is sufficient to determine that the technology is unlikely to improve the net health outcome.

Diabetic Lower-Extremity Ulcers

For individuals who have diabetic lower-extremity ulcers who receive AlloPatch, Apligraf, Dermagraft, or Integra, the evidence includes RCTs. Relevant outcomes are disease-specific survival, symptoms, change in disease status, morbid events, and quality of life. RCTs have demonstrated the efficacy of AlloPatch (reticular ADM), Apligraf and Dermagraft (living cell therapy), and Integra (biosynthetic) over the standard of care. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have diabetic lower-extremity ulcers who receive ADM products other than AlloPatch, Apligraf, Dermagraft, or Integra, the evidence includes RCTs. Relevant outcomes are disease-specific survival, symptoms, change in disease status, morbid events, and quality of life. Results from a multicenter RCT showed some benefit of DermACELL that was primarily for the subgroup of patients who only required a single application of the ADM. Studies are needed to further define the population who might benefit from this treatment. Additional study with a larger number of subjects is needed to evaluate the effect of Graftjacket, TheraSkin, DermACELL, Cytal, PriMatrix, and Oasis Wound Matrix, compared with current SOC or other advanced wound therapies. The evidence is insufficient to determine the effects of the technology on health outcomes.

Lower-Extremity Ulcers due to Venous Insufficiency

For individuals who have lower-extremity ulcers due to venous insufficiency who receive Apligraf or Oasis Wound Matrix, the evidence includes RCTs. Relevant outcomes are disease-specific survival, symptoms, change in disease status, morbid events, and quality of life. RCTs have demonstrated the efficacy of Apligraf living cell therapy and xenogenic Oasis Wound Matrix over the standard of care. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome. For individuals who have lower-extremity ulcers due to venous insufficiency who receive bioengineered skin substitutes other than Apligraf or Oasis Wound Matrix, the evidence includes RCTs. Relevant outcomes are disease-specific survival, symptoms, change in disease status, morbid events, and quality of life. In a moderately large RCT, Dermagraft was not shown to be more effective than controls for the primary or secondary end points in the entire population and was only slightly more effective than controls (an 8%-15% increase in healing) in subgroups of patients with ulcer durations of 12 months or less or size of 10 cm or less. Additional study with a larger number of subjects is needed to evaluate the effect of the xenogenic PriMatrix skin substitute vs the current standard of care. The evidence is insufficient to determine the effects of the technology on health outcomes.

Dystrophic Epidermolysis Bullosa

For individuals who have dystrophic epidermolysis bullosa who receive OrCel, the evidence includes case series. Relevant outcomes are symptoms, change in disease status, morbid events, and quality of life. OrCel was approved under a humanitarian drug exemption for use in patients with dystrophic epidermolysis bullosa undergoing hand reconstruction surgery, to close and heal wounds created by the surgery, including those at donor sites. Outcomes have been reported in small series (eg, 5 patients). The evidence is insufficient to determine the effects of the technology on health outcomes.

Deep Dermal Burns

For individuals who have deep dermal burns who receive bioengineered skin substitutes (ie, Epicel, Integra Dermal Regeneration Template), the evidence includes RCTs. Relevant outcomes are disease-specific survival, symptoms, change in disease status, morbid events, functional outcomes, quality of life, and treatment-related morbidity. Overall, few skin substitutes have been approved, and the evidence is limited for each product. Epicel (living cell therapy) has received Food and Drug Administration approval under a humanitarian device exemption for the treatment of deep dermal or full-thickness burns comprising a total body surface area of 30% or more. Comparative studies have demonstrated improved outcomes for biosynthetic skin substitute Integra Dermal Regeneration Template for the treatment of burns. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Clinical Input

Clinical input has been obtained on several occasions. The input considered ADM products to be medically necessary for breast reconstruction under select conditions and for the various products to be similar in efficacy. Input was mixed on the efficacy of xenogenic products for other indications. It was concluded that, based on the extensive data from case series and clinical input on the usefulness of this procedure in providing inferolateral support for breast reconstruction, this procedure was medically necessary for breast reconstruction when there is insufficient tissue expander or implant coverage by the pectoralis major muscle and additional coverage is required; when there is viable but compromised or thin postmastectomy skin flaps that are at risk of dehiscence or necrosis; or when the inframammary fold and lateral mammary folds have been undermined during mastectomy and reestablishment of these landmarks is needed.

Policy History

Date	Action
3/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
1/2019	Clarified coding information.
10/2018	Policy statements on breast reconstructive surgery following cancer treatment using allogeneic acellular dermal matrix products revised. Effective 10/1/2018.
7/2018	BCBSA National medical policy review. New medically necessary indications described: DermACELL, FlexHD Pliable, and Integra Flowable Wound Matrix. New investigational indications described: Biobrane/Biobrane-L, Helicoll, Keramatrix, Kerecis, TransCyte. Effective 7/1/2018.
1/2018	Clarified coding information.
12/2017	BCBSA National medical policy review. Integra Omnigraft deleted from investigational policy statement and added to bullet for Integra® Dermal Regeneration Matrix. Effective 12/1/2017.
11/2017	BCBSA National medical policy review. CellerateRX® (CRXa™) removed from the investigational policy statement. Effective 11/1/2017.
10/2017	Clarified coding information.
6/2017	BCBSA National medical policy review. New and investigational indications described. Clarified coding information. Effective 6/1/2017.
1/2017	Clarified coding information for the 2017 code changes.
12/2016	BCBSA National medical policy review. Acellular dermal matrix products used in breast reconstruction clarified; investigational list updated with new products and name changes; wound dressing products removed from list. References added. Clarified coding information. Effective 12/1/2016.
11/2016	BCBSA National medical policy review. Clinical input reviewed. Integra Dermal Regeneration Template, Biovance and Grafix were added as medically necessary for the treatment of diabetic foot ulcers. TransCyte removed from the medically necessary statement; it is no longer commercially available. List of investigational skin or soft tissue substitutes updated. Clarified coding information. Effective 11/1/2016.
10/2016	Clarified coding information.
1/2016	Clarified coding information.
9/2015	Local Coverage Determination (LCD): Biologic Products for Wound Treatment and Surgical Interventions (L26003) added. 9/2015
4/2015	Coverage for Epifix® for the treatment of diabetic lower extremity ulcers. Clarified coding information. Effective 4/1/2015.
1/2015	Clarified coding information; Local Coverage Determination (LCD): Biologic Products for Wound Treatment and Surgical Interventions (L26003) added.
7/2014	BCBSA National medical policy review.

	Graftjacket RTM removed from investigational statement. Effective 7/1/2014.
6/2014	BCBSA National medical policy review. New medically necessary and investigational indications described. Effective 6/1/2014.
1/2014	Updated to add new HCPCS codes Q4137-Q4149.
11/2013	New medical policy clarifying coverage and non-coverage. Effective 11/1/2013.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.

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Endnotes

¹ Based on expert opinion and MPRM #7.01.113