

**Subject:** Application and Use of Tissue-Engineered/Bioengineered Skin Substitutes

**Medical Policy #:** 35.0

**Original Effective Date:** 11/29/2017

**Status:** Reviewed

**Last Review Date:** 07/26/2023

## Disclaimer

Refer to the member's specific benefit plan and Schedule of Benefits to determine coverage. This may not be a benefit on all plans or the plan may have broader or more limited benefits than those listed in this Medical Policy.

## Description

There are currently a wide variety of bioengineered products available for soft tissue coverage to affect closure. These products may be derived from allogeneic, xenogeneic, synthetic sources or a combination of any or all of these types of materials. However, without the component of the recipient's own distinct epithelium and cellular skin elements, permanent skin replacement or coverage by the graft cannot be accomplished.

## Coverage Determination

Prior Authorization is required. Logon to Pres Online to submit a request: <https://ds.phs.org/preslogin/index.jsp>

### **Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds:** **For Commercial, Medicaid, and Medicare.**

Presbyterian Health Plan follows the Local Coverage Determination ([L35041](#)) for the application of bioengineered skin substitutes to lower extremity for chronic non-healing wounds when standard or conservative measures have failed.

**Note:** The skin substitute graft codes are not to be reported for application of **non-graft wound dressings**. Non-graft wound dressings (e.g., gel, ointment, foam, liquid, powder) or injected skin substitutes (e.g. Q4246 & Q4145) are generally included in standard wound care management; such products may provide value and, in fact, may preclude the need for skin substitute application.<sup>1, 16</sup>

### **Other wound treatment:**

- For more information on negative pressure wound therapy please see [L35125](#)-Wound Care.
- Autologous Platelet Rich Plasma (PRP) used in the treatment of Chronic Non-Healing Wounds, see Platelet-Rich Plasma, Blood Derived Products, and Platelet-Derived Growth Factor Products for the Treatment of Wounds and Other Injuries, MPM 16.16.
- For Porcine skin and Gradient Pressure Dressings see section (Elastic stockings) of the Durable Medical Equipment, Miscellaneous, MPM 4.5.
- For bioengineered skin and soft tissue substitutes of the breast, see Breast Surgical Procedures, MPM 27.0.

## Coding

The coding listed in this medical policy is for reference only. Covered and non-covered codes are within this list.

CPT Codes	Description
15002	Wound prep trk/arm/leg
15003	Wound prep addl 100 cm
15004	Wound prep f/n/hf/g
15005	Wound prep f/n/hf/g addl cm
15040	Harvest cultured skin graft
15050	Skin pinch graft
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

<b>CPT Codes</b>	<b>Description</b>
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)
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)

<b>Codes</b>	<b>Description</b>
C1849	Skin substitute, synthetic, resorbable, per sq cm
C9363	Integra meshed bil wound mat
Q4100	Skin substitute, nos
Q4101	Apligraf
Q4102	Oasis wound matrix
Q4103	Oasis burn matrix
Q4104	Integra bmwd
Q4105	Integra drt or omnigraft
Q4106	Dermagraft

Not every Presbyterian health plan contains the same benefits. Please refer to the member's specific benefit plan and Schedule of Benefits to determine coverage [MPMPPC051001]

<b>Codes</b>	<b>Description</b>
Q4107	Graftjacket
Q4108	Integra matrix
Q4110	Primatrix
Q4111	Gammagraft
Q4115	Alloskin, per sq cm
Q4116	AlloDerm, per sq cm
Q4117	HYALOMATRIX, per sq cm
Q4121	TheraSkin, per sq cm
Q4122	Dermacell, awm, porous sq. cm
Q4123	AlloSkin RT, per sq cm
Q4124	OASIS ultra tri-layer wound matrix, per sq cm
Q4126	MemoDerm, DermaSpan, TranZgraft or InteguPly, per sq cm
Q4127	Talymed, per sq cm
Q4128	Flex hd, or allopatch hd, per square centimeter
Q4132	Grafix Core and GrafixPL Core, per sq cm
Q4133	Grafix stravix prime pl sq cm
Q4134	HMatrix, per sq cm
Q4135	Mediskin, per sq cm
Q4136	E-Z Derm, per sq cm
Q4137	Amnioexcel biodexcel 1sq cm
Q4138	Biodfence dryflex, 1cm
Q4140	Biodfence 1cm
Q4141	Alloskin ac, 1 cm
Q4143	Repriza, 1cm
Q4145	EpiFix, injectable, 1 mg
Q4146	Tensix, per sq cm
Q4147	Architect ecm px fx 1 sq. cm
Q4148	Neox Cord 1K, Neox Cord RT, or Clarix Cord 1K, per sq cm
Q4150	Allowrap ds or dry 1 sq. cm
Q4151	Amnioband, guardian 1 sq. cm
Q4152	Dermapure 1 square cm
Q4153	Dermavest, plurivest sq. cm
Q4154	Biovance 1 square cm
Q4156	Neox 100 or Clarix 100, per sq cm
Q4157	Revitalon 1 square cm
Q4158	Kerecis omega3, per sq. cm
Q4159	Affinity1 square cm
Q4160	Nushield 1 square cm
Q4161	Bio-connekt per square cm
Q4163	Woundex, bioskin, per sq. cm
Q4164	Helicoll, per square cm
Q4165	Keramatrix, kerasorb sq. cm
Q4166	Cytal, per square centimeter
Q4167	Truskin, per sq. centimeter
Q4169	Artacent wound, per sq. cm

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<b>Codes</b>	<b>Description</b>
Q4170	Cygnus, per sq. cm
Q4173	PalinGen or PalinGen XPlus, per sq cm
Q4175	Miroderm, per sq cm
Q4176	Neopatch, per sq. centimeter
Q4178	Floweramniopatch, per sq. cm
Q4179	Flowerderm, per sq. cm
Q4180	Revita, per sq. cm
Q4181	Amnio wound, per square cm
Q4182	Transcyte, per sq. centimeter
Q4183	Surgigraft, 1 sq. cm
Q4184	Cellesta or duo per sq. cm
Q4186	Epifix 1 sq. cm
Q4187	Epicord 1 sq. cm
Q4188	Amnioarmor 1 sq. cm
Q4190	Artacent ac 1 sq. cm
Q4191	Restorigin 1 sq. cm
Q4193	Coll-e-derm 1 sq. cm
Q4194	Novachor 1 sq. cm
Q4195	Puraply 1 sq. cm
Q4196	Puraply am 1 sq. cm
Q4197	Puraply xt 1 sq. cm
Q4198	Genesis amnio membrane 1sq cm
Q4199	Cygnus matrix, per sq cm
Q4200	Skin te 1 sq. cm
Q4201	Matrion 1 sq. cm
Q4203	Derma-gide, 1 sq. cm
Q4204	Xwrap 1 sq. cm
Q4205	Membrane graft or wrap sq. cm
Q4208	Novafix per sq. cm
Q4209	Surgraft per sq. cm
Q4210	Axolotl graf dualgraf sq. cm
Q4211	Amnion bio or axobio sq. cm
Q4214	Cellesta cord per sq. cm
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, surederm sq. cm
Q4221	Amniowrap2 per sq. cm
Q4222	Progenamatrix, per sq. cm
Q4226	Myown harv prep proc sq. cm
Q4227	Amniocore per sq. cm
Q4229	Cogenex amnio memb per sq. cm
Q4232	Corplex, per sq. cm

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<b>Codes</b>	<b>Description</b>
Q4234	Xcellerate, per sq. cm
Q4235	Amniorepair or altiply sq. cm
Q4237	cryo-cord, per sq. cm
Q4238	Derm-maxx, per sq. cm
Q4239	Amnio-maxx or lite per sq. cm
Q4247	Amniotext patch, per sq. cm
Q4248	Dermacyte Amn mem allo sq. cm
Q4249	Amniply, per sq cm
Q4250	AmnioAMP-MP per sq cm
Q4251	Vim, per square centimeter
Q4252	Vendaje, per square centimeter
Q4253	Zenith amniotic membrane, per square centimeter
Q4254	Novafix dl per sq cm
Q4255	Reguard, topical use per sq cm
A2011	Supra SDRM, per sq cm
A2012	Suprathel, per sq cm
A2013	Innovamatrix FS, per sq cm
A4100	Skin substitute, FDA-cleared as a device, not otherwise specified
Q4224	Hhf10-p per sq cm
Q4225	Amniobind, per sq cm
Q4256	Mlg complet, per sq cm
Q4257	Relese, per sq cm
Q4258	Enverse, per sq cm
<b>A2001</b>	Innovamatrix ac, per sq cm
<b>A2002</b>	Mirragen adv wnd mat per sq cm
<b>A2005</b>	Microlyte matrix, per sq cm
<b>A2006</b>	Novosorb synpath per sq cm
<b>A2007</b>	Restrata, per sq cm
<b>A2008</b>	Theragenesis, per sq cm
<b>A2009</b>	Symphony, per sq cm
<b>A2010</b>	Apis, per square centimeter
A2015	Phoenix wound matrix, per sq cm
A2016	PermeaDerm B, per sq cm
A2017	PermeaDerm glove, each
A2018	PermeaDerm C, per sq cm
A2020	AC5 Advanced Wound System (AC5)
Q4259	Celera per sq cm
Q4260	Signature apatch, per sq cm
Q4261	Tag, per square centimeter
Q4246	CoreText or ProText, per cc
Q4265	Neostim tl, per square centimeter
Q4266	Neostim membrane, per square centimeter
Q4267	Neostim dl, per square centimeter
Q4268	Surgraft ft, per square centimeter
Q4269	Surgraft xt, per square centimeter

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Codes	Description
Q4270	Complete sl, per square centimeter
Q4271	Complete ft, per square centimeter
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
Q4277	WoundPlus membrane or E-Graft, per sq cm
Q4278	EPIEFFECT, per sq cm
Q4280	Xcell Amnio Matrix, per sq cm
Q4281	Barrera SL or Barrera DL, per sq cm
Q4282	Cygnus Dual, per sq cm
Q4283	Biovance Tri-Layer or Biovance 3L, per sq cm
Q4284	DermaBind SL, per sq cm
A2022	InnovaBurn or InnovaMatrix XL, per sq cm
A2024	Resolve Matrix, per sq cm
Q4285	NuDYN DL or NuDYN DL MESH, per sq cm
Q4286	NuDYN SL or NuDYN SLW, per sq cm

Codes	The following codes may be used in the Non-facility (i.e. provider's office setting). (Not an all-inclusive list)
A2001	InnovaMatrix AC, per sq cm
A2002	Mirragen Advanced Wound Matrix, per sq cm
A2005	Microlyte Matrix, per sq cm
A2006	NovoSorb SynPath dermal matrix, per sq cm
A2007	Restrata, per sq cm
A2008	TheraGenesis, per sq cm
A2009	Symphony, per sq cm
A2010	Apis, per sq cm
Q4101	Apligraf

## Reviewed by / Approval Signatures

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**Senior Medical Director:** [David Yu MD](#)

**Medical Director:** [Ana Maria Rael MD](#)

**Date Approved:** 07/26/2023

## References

1. Novitas, Local Coverage Determination (LCD): Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds (L35041), Revision Date: 09/26/2019, Revision #R19. There has been no change in content to the LCD. Accessed 05/19/2023.
2. Novitas, Local Coverage Article (LCA): Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds (A54117), Revision Date:08/13/2020, R21. Accessed 05/19/2023
3. MCG Health, Ambulatory Care 27<sup>th</sup> Edition, Skin Substitute, Tissue-Engineered (Human Cellular), for Diabetic Foot Ulcer and Venous Ulcer, (A-0326), last updated: 2/1/2023. Accessed 05/19/2023

Not every Presbyterian health plan contains the same benefits. Please refer to the member's specific benefit plan and Schedule of Benefits to determine coverage [MPMPPC051001]

4. Hayes, Health Technology Assessment, Acellular Skin Substitutes for Chronic Foot Ulcers in Adults with Diabetes Mellitus. Annual review: May 10, 2023. Accessed 05/19/2023.
5. Hayes, Skin Substitutes for Venous Leg Ulcers in Adults, Health Technology Assessment Jul 23, 2020 | Annual Review: Aug 16, 2022. Accessed 05/19/2023
6. CMS Manual System, Pub 100-04 Medicare Claims Processing, [Transmittal 10224](#), Date: July 15, 2020. (For New Skin Substitute Products Low Cost/High cost Group Assignment. [Cited 06/04/2021])
7. CMS Manual System, Pub 100-04 Medicare Claims Processing, [Transmittal R10557CP, CR 12129](#), Date: January 08, 2021 for Effective Date Jan 01, 2021 (Table 9-Skin Substitute Assignments for High Cost and Low Cost Groups for CY2021. [Cited 06/04/2021])
8. CMS, Manual System, Pub 100-04 Medicare claims Processing, Transmittal 11150, Change Request [12552](#), Date: December 10, 2021. (January 2022 Update of the Hospital Outpatient Prospective Payment System (OPPS)). [Cited 12/27/2021]
9. CMS Manual System, Pub 100-04 Medicare claims Processing, Transmittal **11305**, Change Request [12666](#), Date: March 24 2022, [Cited 06/17/2022]
10. Federal Register, CMS, Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; and Provider and Supplier Prepayment and Post-Payment Medical Review Requirements, Publication date 11/19/2021, Effective 01/01/2022, [document citation: 86 FR 64996](#). [Accessed 05/20/2022]
11. CMS Manual System, Pub 100-04 Medicare claims Processing, [Transmittal 11457, Change Request 12761](#), June 15, 2022 [Cited 06/17/2022]
12. CMS, Manual System, Pub 100-04 Medicare Claims Processing, [Transmittal 11149, Change Request 12533](#), (for all non-OPPS providers), December 10, 2021 [Cited 01/01/2022]
13. [Novitas, Solutions, Billing for skin substitute codes](#), (when applied in a non-facility setting), last modified: 04/20/2023. [Cited 05/19/2023]
14. CMS Manual System, Pub 100-04 Medicare claims Processing, [Transmittal 10997, Change Request 12436](#), September 16, 2021, Implementation date: 10/04/ 2021 [Cited 11/14/2022]
15. CMS Manual System, Pub 100-04 Medicare claims Processing, [Transmittal 11594, Change Request 12885](#), September 09, 2022, Implementation date: 10/01/ 2022 [Cited 11/14/2022]
16. CPT Assistant, October 2017, Frequently Asked Questions, Micronized/powdered form of human allograft applications, correct reporting. CPT® Assistant copyright 1990-2022 American Medical Association. All rights reserved. [Cited 12/21/2022]
17. CMS Manual System, Pub 100-04 Medicare claims Processing, [Transmittal 11903, Change Request 13143](#), March 16, 2023. [Cited 04/18/2023]
18. CMS Manual System, Pub 100-04 Medicare claims Processing, Transmittal 11738, [Change Request 12998](#), Date: January 10, 2023.
19. CMS, Pub 100-04 Medicare Claims Processing, Transmittal 12122, [Change Request 13216](#), Date July 05, 2023. [Cited 07/19/2023]
20. CMS, Pub 100-04 Medicare Claims Processing, [CMS Transmittal 12227](#), Date August 31, 2023 [10/15/2023]

## Publication History

- 11-29-17      Approved by CQUMC on 11/29/2017
- 03/27/19      Update policy
- 07/22/20      Annual review. Reviewed by PHP Medical Policy Committee on 07/03 & 07/16/2020. Agreed to continue following LCD L35041 for all LOBs. New HCPCS codes added: C9363, Q4116, Q4138, Q4143, Q4150, Q4167, Q4170, Q4176, Q4177, Q4179, Q4181, Q4182, Q4183, Q4184, Q4186, Q4187, Q4188, Q4190, Q4191, Q4193, Q4194, Q4195, Q4196, Q4197, Q4198, Q4200, Q4201, Q4203, Q4204, Q4205, Q4206, Q4208, Q4209, Q4210, Q4211, Q4214, Q4216, Q4217, Q4218, Q4219, Q4220, Q4221, Q4222, Q4226, Q4227, Q4228, Q4229, Q4232, Q4234, Q4235, Q4236, Q4237, Q4238, Q4239, Q4247, & Q4248. No prior authorization will be required for ALL the listed Q-Codes, except Q4145. Prior authorization will continue to remain but will also be applied to this policy for codes Q4145, 15271, 15272, 15273, and 15274. \*The reporting of skin substitutes represented by a Q code must contain the presence of an appropriate application CPT code. HCPCS codes Q4177 and Q4206 are exceptions and do not require an application code. The skin substitute products are divided into two groups for packaging purposes: 1) high cost skin substitute products and 2) low cost skin substitute products. High cost skin substitute products should only be utilized in combination with the performance of one of the skin application procedures described by CPT codes 15271-15278. Low cost skin substitute products should only be utilized in combination with the performance of one of the skin application procedures described by HCPCS code C5271-C5278.
- 07/28/21      Annual review. Reviewed by PHP Medical Policy committee on 06/09/2021. No change, continue to follow: L35041 for all LOB and continue PA for applications CPT codes 15271, 15272, 15273, 15274, 15275, 15276, 15277, 15278, C5271, C5272, C5273, C5274, C5275, C5276, C5277, C5278, Q4145. Codes review: pass-through payment expired for Q4195, Q4196 as of Sept 2020 and are now Status Indicator -N-. New codes added: C1849, Q4249, Q4250, Q4254, Q4255. These codes are recognized as either high-cost skin substitute products or low-cost skin substitute products for packaging purposes per CMS, Transmittal # R10557CP as of January 08, 2021. Also, CMS has moved the following codes to "high-cost" category: Q4167, Q4182, Q4188,

Q4190, Q4193, Q4200, Q4209, Q4211, Q4219, Q4222, Q4227, Q4232, Q4237, Q4238, and Q4239. All of these codes are OPSS status Indicator -N- and will be set to not pay per Addendum B, April 2021.

12-27-2021: Update only for Skin Substitute Product Low Cost Group/High Cost Group Assignment Effective January 1, 2022 per CR 12552, date Dec 10, 2021. Code **Q4199 is a new code for CY 2022** with Status Indicator -N- assigned as "Low" cost skin substitute. The overall change from CY 2021 to Final CY 2022 the following changed from "Low" to "High" cost skin substitute: Q4167, Q4182, Q4188, Q4190, Q4193, Q4198, Q4200, Q4201, Q4209, Q4211, Q4219, Q4222, Q4227, Q4232, Q4237, Q4238, Q4239 and Q4249. These Q-codes were deleted as of 10-01-2021: Q4228 and Q4236. These Q-codes were deleted as of 10-01-2021: Q4228 and Q4236. New codes for 01/01/2022 (A2001, A2002, A2003, A2004, A2005, A2006, A2007, A2008 and A2009) were mentioned in the policy under column three to say these A-codes are not yet classified by CMS. Codes Q4145, Q4177 and Q4206 are not listed by CMS as low/high group, but are listed as status indicator -N- per OPSS.

04-08-2022-Update to add codes effective April 1, 2022 (A2011, A2012, A2013, A4100, Q4224, Q4225, Q4256, Q4257 and Q4258) per CMS, Pub 1 00-04 Medicare Claims Processing, TN 11303, [CR 12679](#), Date: March 24, 2022.

07/27/22

Annual review. Reviewed by PHP Medical Policy committee on 07/08/2022. Continue to follow the LCD (L35041) that is still current as of 07/08/2022. Continue PA for 15271, 15272, 15273, 15274, 15275, 15276, 15277, 15278, C5271, C5272, C5273, C5274, C5275, C5276, C5277, C5278, Q4145. According to Change Request 12666, TN# 11305 (date: 03-24-22) the following has changed: Code A2003 was created in error; code Q4199, has been reassigned from the low cost to high cost group as of April 1, 2022. Code A2004 no longer a skin substitute product effective from 01/01/22 thru 06/30/2022, per TN#11457-CR#12761. Codes A2005, A2006, A2008, A2009, A2010 reassigned to SI-N and classified as Low-Cost effect April 01, 2022. Code A2007 reassigned to SI-N and classified as to High Cost effective 04/01/2022. According to Change Request 12761, TN#11457 (06-15-22) the following has been updated: Codes A2001 changed from Low Cost to High Cost and to be retro to 04/01/2022. Codes (A2001, A2002, Q4229, Q4258) changed from Low Cost to High Cost, effective 07/01/2022. New codes (Q4259, Q4260, Q4261) added to Low Cost effective 07/01/2022. Policy updated with language about non-facility guidelines provided by Novitas that providers who bill for CPT 15271-15278 can bill separately for skin substitute codes A2001, A2002, A2005, A2006, A2007, A2008, A2009 and A2010. These same codes A2001 thru A2010 can also be used in the OPSS setting and are classified as SI-N for OPSS. These A-codes and other "A & Q-codes" listed within the policy will not require PA.

**Update on 09-28-22:** HCPCS code Q4246 will require prior authorization for all LOB. Currently, there is insufficient evidence in the published peer reviewed scientific literature to support the efficacy of the extracellular matrix (ECM) allografts derived from human umbilical cord tissue, including the epithelial layer and the Wharton's Jelly (the product called CoreText or ProText) for all indications. Also, Q4246 is injectable and is not part of CMS high/low designated code. Update on 11-16-22: Add codes Q4251, Q4252, and Q4253 (TN#10997/CR#12436-effective 10/01/2021); and codes A2015, A2016, A2017, and A2018 (TN#11594/CR#12885-effective 10-01-2022). Payment methodology will apply based on CMS fee schedules for both facility and non-facility and/or physician for these codes and all other skin substitute codes listed in this policy. Removed codes Q4177 and Q4206 which are not part of CMS High/Low square centimeter but are injectable. All previously configured Skin Substitute codes for ALOB were corrected and moved into production on 12/18/2022. Commercial will follow Medicare (OPPs & MPFS) fee schedule. Codes found on the DME fee schedule include: Q4101, Q4102, Q4106, Q4110, Q4111, Q4121, Q4133, Q4137, Q4151, Q4159, Q4160, Q4163, Q4186, Q4187, Q4195, Q4196; and codes denoted as SI-C- on the MPFS include: A2001, A2002, A2005, A2006, A2007, A2008, A2009, and A2010, A2011, A2012, A2013 and A4100. For Medicaid both OPSS Fee Schedule and Fee for Service (HCPCS) were reviewed to allow for facility and professional. Update of references for other wound treatment option. The coverage determination guideline language removed from policy and reformatted to only include LCD weblink(s).

**Updated on May 24, 2023:** Skin substitute HCPCS codes effective as of April 1, 2023: Q4265, Q4266, Q4267, Q4268, Q4269, Q4270, and Q4271 were added to policy. These newly released codes will be config according to fee schedules to determine if payment is allowable for the different locations. Per TN (11927), CR (13143), Date: March 24, 2023, are assigned as "low" cost skin substitute product. The policy will no longer manage the information regarding appropriate billing of skin substitute in terms of payment packaging purposes, when the skin substitute products are divided by 1) high-cost skin substitute products and 2) low cost skin substitute products.

07-26-23

Annual review. Reviewed by PHP Medical Policy committee on 05-1-2023 and 07-21-2023. Continue to follow L35041 for all LOB. Pending pricing review for A2001, A2002, A2005, A2006, A2007, A2009, and A2010 for physician services in the office setting. The newly released skin substitute codes, effective July 01, 2023: Q4272, Q4273, Q4274, Q4275, Q4276, Q4277, Q4278, Q4280, Q4281, Q4282, Q4283, and Q4284 were added to policy which will be config according to the applicable fee schedules. Code Q4101 will be allowed in POS-11 for ALOB. **Updated on 11-03-2023:** Added the new codes (A2022, A2024, Q4285 and Q4286) effective 10/01/2023 to policy which will be configured the same manner as other skin substitute products that were previously configured based on status indicators (SI) from all applicable fee schedules.

*This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such.*

Not every Presbyterian health plan contains the same benefits. Please refer to the member's specific benefit plan and Schedule of Benefits to determine coverage [MPMPPC051001]



*For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available online at: [Click here for Medical Policies](#)*

**Web links:**

*At any time during your visit to this policy and find the source material web links has been updated, retired or superseded, PHP is not responsible for the continued viability of websites listed in this policy.*

*When PHP follows a particular guideline such as LCDs, NCDs, MCG, NCCN etc., for the purposes of determining coverage; it is expected providers maintain or have access to appropriate documentation when requested to support coverage. See the References section to view the source materials used to develop this resource document.*