Skin Substitutes
Clinical Coverage Criteria

Overview

The U.S. Food and Drug Administration (FDA) does not refer to any product or class of products as skin substitutes. Although the term 'skin substitute' has been adopted to refer to this category of products in certain contexts, these products do not actually function like human skin that is grafted onto a wound; they are not a substitute for a skin graft. Instead, these products are applied to wounds to aid wound healing and through various mechanisms of action they stimulate the host to regenerate lost tissue. These products vary in their material composition, intended layer of replacement, and the presence or lack of cellular components (CMS, 2013).

The FDA regulates products commonly referred to as "skin substitutes" under one of four categories, depending on the product's origin and composition: human-derived products regulated as human cells, tissues, and cellular and tissue-based products (HCT/Ps); human- and human/animal-derived products regulated through premarket approval (PMA) or as a Humanitarian Use Device (HUD) obtained through a humanitarian device exemption (HDE); or animal-derived products and synthetic products regulated under the 510(k) process. While some skin substitutes have been approved by FDA as medical devices through the PMA process, including Apligraf, Dermagraft, and the Integra skin substitutes, most skin substitutes are regulated as either 510(k) medical devices or HCT/Ps.

Chronic wounds are wounds that fail to proceed through the normal phases of wound healing in an orderly and timely manner. These wounds usually do not close without interventions. Four weeks of standard of care without achieving a 50% reduction in wound size may signal the need for a change or additional therapies (Fryberg and Banks, 2015). A randomized controlled trial (RCT) in patients with diabetic foot ulcers demonstrated that a 50% reduction in wound area at 4 weeks was a strong predictor of wound healing by 12 weeks when standard of care was used (Sheehan et al., 2003). Complete healing of chronic wounds is marked by epidermis reepithelization and dermis repair. Successful healing of chronic wounds depends on critical factors, such as proper blood flow and nutrition to ensure tissue growth, infection control, maintenance of a moist environment, and removal of dead tissue to allow space for new cells and tissue to fill the wound void (Snyder et al., 2020).

Usual care or standard care for established chronic wounds incorporates common principles that apply to managing all wound types:

- Remove necrotic tissue through debridement
- Maintain moisture balance by selecting the proper wound dressing to control exudate.
- Take measures to prevent or treat wound infections.
- Correct ischemia in the wound area.
- For venous leg ulcers, apply some form of compression.
- For diabetic foot ulcers, apply some form of offloading.

The methods for achieving each of these wound management principles varies among clinical practice guidelines and clinical studies (Snyder et al., 2020). Using saline wet-to-dry gauze on any chronic wound is no longer considered part of standard wound care (Ovington LG., 2002). If

chronic wounds fail to respond to standard of care, skin substitutes may be indicated as an adjunct to established chronic wound care methods to increase the likelihood of complete healing (Nathoo et al., 2014).

In 2012 the Agency for Healthcare Research and Quality (AHRQ) published a technology assessment for Skin Substitutes for Treating Chronic Wounds for the Centers for Medicare & Medicaid Services (CMS). AHRQ identified 57 skin substitute products available in the United States that are used to manage or treat chronic wounds and regulated by FDA. Eighteen RCTs met inclusion criteria. Twelve studies examined diabetic foot ulcers, and six studies examined vascular leg ulcers. One RCT of pressure ulcers was identified but did not meet inclusion criteria. Of the 57 skin substitute products identified for this report, only seven skin substitutes were examined in RCTs that met inclusion criteria. Overall applicability of the evidence base is limited to a small number of skin substitutes used to treat diabetic foot ulcers and venous leg ulcers, and to patients in generally good health. Patients were generally excluded from studies if their health was suboptimal, they were taking medication that would interfere with wound healing, their wounds were infected, or the blood flow to the affected area was poor. Excluding these types of patients means that the outcomes reported in these studies address the efficacy (the capacity to produce a desired effect) of skin substitutes rather than the effectiveness (create an effect in real world practice) of skin substitutes and raises questions about the applicability of the results of these studies to the general population affected by chronic wounds (Carter et al., 2009). All the studies in the evidence base reported some benefit of skin substitutes over the control treatments when number of wounds completely healed was measured between 8 and 16 weeks but the reported results varied widely across studies. Two studies comparing different skin substitutes reported no significant differences in wound healing rates. This is significant given the wide variation in cost for skin substitutes.[1,2] Because of the differences in product components and healing properties, the results obtained from studies of a single product cannot be extrapolated to other skin substitutes. Similarly, results from studies of diabetic foot ulcers cannot be applied to venous leg ulcers or pressure ulcers because of the differences in etiology and pathophysiology (CBER, 2006). Clinical evidence from RCTs demonstrating effectiveness for the majority of the skin substitutes identified in this technology assessment was not available.

In 2020, the Agency for Healthcare Research and Quality (AHRQ) published an update of their previous technology assessment for Skin Substitutes for the Treatment of Chronic Wounds for the Centers for Medicare & Medicaid Services (CMS). This report includes human placental/amniotic membrane products which were not included in the earlier AHRQ report. In the 2020 report, AHRQ identified 76 commercially available skin substitutes. Three systematic reviews and 22 RCTs that met inclusion criteria. Any studies that used saline wet-to-dry gauze as the comparator were excluded. Sixteen skin substitutes were examined in the treatment of diabetic foot ulcers, pressure ulcers, and venous leg ulcers. Of the 22 RCTs, 16 studies compared standard of care to 13 skin substitutes. Seven studies reported statistically significant differences in number of wounds healed and time to heal favoring the intervention over standard of care in the treatment of diabetic foot ulcers. One study reported statistically significant differences in number of wounds healed and time to heal favoring the intervention over standard of care in the treatment of venous leg ulcers. The only RCT examining a skin substitute compared to standard of care in the treatment of pressure ulcers found no statistically significant differences in pressure ulcers healed at 12 weeks or 6 months. The remaining six RCTs compared one skin

[1] In a review of the clinical and cost efficacy of targeted skin substitutes for the treatment of venous leg ulcers, Hankin et al., 2012, found that the most expensive skin substitute for the treatment of venous leg ulcers did not appear to provide the greatest comparative clinical or cost efficacy. Conclusions must be tempered by the small number of studies and limitations in study quality. Given the wide variation in costs for skin substitutes, payers must carefully compare cost efficacy when determining the relative value of these products. More high-quality head-to-head comparisons to guide coverage and reimbursement determinations for these products are needed.

[2] A cost-effectiveness review of three skin substitutes (Oasis Wound Matrix, Apligraf and Dermagraft) conducted by Carter et al., 2014, found that Oasis Wound Matrix was the most cost-effective skin substitute when used in the management of venous leg ulcers as an adjunct to standard care.

substitute with another skin substitute in the treatment of diabetic foot ulcers or venous leg ulcers. Of the six head-to-head comparative studies, findings from five studies did not indicate significant differences between skin substitutes in outcomes measured at the latest follow-up. One head-to-head study in diabetic foot ulcers reported significantly shorter time to healing and significantly higher rate of complete healing at 12 weeks for EpiFix vs. Apligraf (Zelen et al., 2016).

AHRQ concluded that the evidence base remained insufficient to determine whether one skin substitute product is superior to another and that the clearest implications of this assessment are the lack of studies examining the effectiveness of most skin substitute products and the need for better-designed and better-reported studies providing more clinically relevant data (AHRQ, 2020). Clinical evidence for the majority of skin substitutes is lacking. Well-designed studies are needed to determine whether one skin substitute product is superior to another. Trial design should be standardized to facilitate comparisons across studies. Published studies seldom reported wound recurrence which is an important outcome.

Policy

This Policy applies to the following Fallon Health products:

☒ Commercial

☒ Medicare Advantage

☒ MassHealth ACO

☒ NaviCare

☒ PACE

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare does not have an NCD for skin substitutes. National Government Services, Inc. does not have an LCD or LCA skin substitutes. (MCD search 07-02-2021). The Agency for Healthcare Research and Quality completed a Technology Assessment for Skin Substitutes for Treating Chronic Wounds at the request of CMS in 2020 (Snyder et al., 2020). The 2020 Technology Assessment is an update of the 2012 AHRQ Technology Assessment (Snyder et al., 2012),

For plan members enrolled in NaviCare and PACE plans, Fallon Health follows Medicare guidance for coverage determinations. In the event that there is no Medicare guidance or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health will follow guidance published by MassHealth. When there is no Medicare or MassHealth guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members. Each PACE plan member is assigned to an Interdisciplinary Team. When there is no Medicare or MassHealth guidance, the member's Interdisciplinary Team is responsible for coverage determinations.

Prior authorization is required. Documentation in the medical record specifically addressing circumstances as to why the wound has failed to respond to standard wound care treatment of greater than 4 weeks and referencing the specific interventions that have failed is required.

Initial coverage for skin substitutes will be authorized for up to 5 applications. Continued coverage for skin substitutes is contingent upon evidence documented in the plan member's medical record that the wound is improving in response to the wound care being provided. Since it is neither reasonable nor medically necessary to continue a given type of wound care in the absence of wound improvement, it is expected that the wounds response to treatment will be documented in

the medical record at least once every 30 days for each episode of wound treatment and made available to the contractor upon request.

I. Diabetic foot ulcers:
   1. The following skin substitute graft products may be considered medically necessary for the treatment of chronic full-thickness neuropathic diabetic foot ulcers that have not adequately responded to 4 weeks of standard care with documented compliance[3]:
      a. Apligraf (PMA 950032) Q4101, or
      b. Dermagraft (PMA P000036) Q4106, or
      c. Integra Dermal Regeneration Template, marketed as Integra Omnigraft Dermal Regeneration Matrix (PMA P900033) Q4105.

      AND
   2. All of the following criteria are met:
      a. There is adequate circulation to the affected area[4],
      b. There is no sign of clinical infection in the ulcer,
      c. The plan member has adequate glycemic control (HbA1C < 12%),
      d. The plan member is willing and able to maintain the required schedule of dressing changes and offloading, and
      e. The plan member is a nonsmoker, or has refrained from smoking for at least 6 weeks prior to planned treatment with a skin substitute, or has received counseling on the effects of smoking on wound healing and surgical outcomes and treatment for smoking cessation.

In addition to the skin substitutes for the treatment of diabetic foot ulcers listed above, MassHealth members have coverage for the following:
- Oasis Wound Matrix (Q4102)
- Integra Bilayer Matrix Wound Dressing (Q4104)
- GraftJacket (Q4107)
- Integra Matrix (Q4108)
- PriMatrix (Q4110)
- TheraSkin (Q4121)
- Grafix Core (Q4132)
- Grafix Prime (Q4133)
- Bio-Connekt wound matrix (Q4161)
- AmnioPro Flow, BioSkin Flow, BioRenew Flow, WoundEx Flow, Amniogen-A, Amniogen-C (Q4162)
- AmnioPro, BioSkin, BioRenew, WoundEx, Amniogen-45, Amniogen-200 (Q4163)
- Helicoll (Q4164)
- Keramatrix (Q4165)
- EpiFix (Q4186)
- EpiCord (Q4187)

II. Venous leg ulcers:
   1. The following skin substitute graft products may be considered medically necessary for the treatment of chronic partial and full-thickness venous leg ulcers that have not adequately responded to 4 weeks of standard care with documented compliance[5]:

[3] The standard of care in diabetic foot ulcers is sharp debridement, daily wound care dressings, offloading and infection control (Snyder et al., 2010). During the two-week run-in period prior to randomization, 17% of eligible patients (22 of 126) achieved > 20% wound healing with daily dressing changes performed by the patient using collagen-alginate dressings and Camboot offloading and were excluded from the study (Zelen et al., 2016).

[4] For ABI </=0.90, referral should be made to a vascular specialist for further arterial evaluation including comprehensive lower extremity arterial Doppler study, arterial imaging, and possible revascularization consideration before therapy (O'Donnell et al., 2014).

a. Apligraf (PMA 950032) Q4101, or
b. Oasis Wound Matrix (510(k) K061711) Q4102.

AND

2. All of the following criteria are met:
   a. There is adequate circulation to the affected area,[6]
   b. There is no sign of clinical infection in the ulcer,
   c. The plan member has adequate glycemic control (HbA1c < 12%),
   d. The plan member is will and able to maintain the required schedule of dressing changes and compression, and
   e. The plan member is a nonsmoker, or has refrained from smoking for at least 6 weeks prior to planned treatment with a skin substitute, or has received counseling on the effects of smoking on wound healing and surgical outcomes and treatment for smoking cessation.

In addition to the skin substitutes listed above for the treatment of venous leg ulcers, MassHealth members have coverage for the following:

- Integra bilayer matrix wound dressing (Q4104)
- Integra dermal regeneration template (Q4105)
- Dermagraft (Q4106)
- GraftJacket (Q4107)
- Integra Matrix (Q4108)
- PriMatrix (Q4110)
- AlloSkin (Q4115)
- TheraSkin (Q4121)
- Grafix Core (Q4132)
- Grafix Prime (Q4133)
- Bio-Connekt wound matrix (Q4161)
- AmnioPro, BioSkin, BioRenew, WoundEx, Amniogen-45, Amniogen-200 (Q4163)
- Helicoll (Q4164)
- Keramatrix (Q4165)
- EpiFix (Q4186)
- EpiCord (Q4187)

RCTs examining skin substitutes in the treatment of pressure ulcers have not demonstrated a clinically significant benefit over standard of care, therefore the use of skin substitutes in the treatment of pressure ulcers is considered investigational.

The expectation is that one specific skin substitute graft product will be used for the entire episode of wound care. The rare clinical circumstance necessitating switching to a different product must be clearly supported.

Exclusions

- Skin substitute are not considered reasonable and necessary in patients with inadequate control of underlying conditions or exacerbating factors including but not limited to any of the following:
  - Use of skin substitutes in wounds with signs of clinical infection.
  - Use of skin substitutes when there is not adequate circulation to the affected area.

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[5] Compression therapy is the standard care for the treatment of venous leg ulcers. The use of a skin substitute in addition to compression therapy is recommended for the treatment of venous leg ulcers that have failed to show signs of healing after standard therapy for 4 to 6 weeks (O'Donnell et al., 2014).

[6] Mostow et al., 2005 excluded patients with an ankle-brachial index (ABI) <0.80 in the RCT of Oasis Wound Matrix with compression vs. compression alone for the treatment of venous leg ulcers. Falanga et al., 1998 excluded patients with an ABI </= 65 in the RCT of Apligraf with compression vs. compression alone for the treatment of venous leg ulcers.

- Use of skin substitutes in wounds with exposed bone, tendon, or fascia.
- Use of skin substitutes in plan members with HbA1c >12%.
- Use of skin substitutes in plan members with active Charcot arthropathy of the ulcer extremity

- Continued use of skin substitutes after 6 weeks in any patient whose wound has failed to heal by >/= 50% is not medically necessary
- Treatment with skin substitutes beyond 12 weeks is not typically medically necessary.

Coding

Acute Outpatient Hospital and Ambulatory Surgical Center Billing
In the acute outpatient hospital or ambulatory surgical center setting, payment for skin substitutes is packaged into the payment for the associated skin substitute application procedure.

Under Medicare reimbursement methodology (used by Fallon Health for commercial and Medicare members), skin substitute products are divided into two groups for payment purposes:

1. High cost skin substitute products
2. Low cost skin substitute products

High cost skin substitute products should be billed in combination with the performance of one of the skin application procedures described by CPT codes 15271-15278.
Low cost skin substitute products should be billed in combination with the performance of one of the skin application procedures described by HCPCS code C5271-C5278.

The high cost versus low cost assignment is determined by CMS and published annually in the Update of the Ambulatory Surgical Center (ASC) Payment System transmittal. For calendar year 2021, see Table 9 in Transmittal 10557 available at:
https://www.cms.gov/files/document/r10557cp.pdf#page=19.

Excerpt from Table 9 in Transmittal 10557:

Calendar Year (CY) 2021 HCPCS Code	CY 2021 Sort Descriptor	CY 2020 High/Low Cost Assignment	CY 2020 High/Low Cost Assignment
Q4101	Apligraf	High	High
Q4102	Oasis Wound Matrix	Low	Low
Q4105	Integra DRT or OmniGraft	High	High
Q4106	Dermagraft	High	High

For MassHealth members, acute outpatient hospitals and ambulatory surgical centers should report the application of skin substitute graft using CPT code range 15271 through 15278. HCPCS code C5271-C5278 are not reimbursable for MassHealth members. Payment for skin substitutes is packaged into the payment for the associated skin substitute application procedure.

Physician Billing
Physicians report the application of skin substitute grafts in the CPT code range 15271 through 15278. In the office setting, skin substitute products are reimbursed separately. If the CMS quarterly ASP Drug Pricing File (available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice) does not contain pricing for a skin substitute code that is within the Q41XX-Q42XX range, the claim must include the invoice or acquisition cost. Enter the invoice price or acquisition cost and the total amount of product used loop 2400 segment NTE on the electronic claim. If the code is defined as per square centimeter, the units billed must match the size billed in square centimeters. For example, Q4101 is coded as per square centimeter. If you have a product that is 4x4 square centimeters, you would enter as 16

units. Providers must maintain an invoice copy within the patient's file and it must be made available to Fallon Health upon request.

***Application of skin substitute grafts**:*

To be properly performed, every surgical procedure in this CPT/HCPCS code range requires the use of a skin substitute. These surgical procedures include preparation of the wound and application of the skin substitute product through suturing or various other techniques. The skin substitutes themselves are identified by a HCPCS code in the range Q4101-Q42XX. Claims reporting skin substitute grafts must contain the presence of an appropriate surgical procedure CPT or HCPCS code.

Use of surgical preparation services in conjunction with skin substitute application codes will be considered not reasonable and necessary.

Note: These procedures are not to be reported for application injected skin substitutes.

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)
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 *Not covered for MassHealth members*
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 *Not covered for MassHealth members*
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 *Not covered for MassHealth members*
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 *Not covered for MassHealth members*
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 *Not covered for MassHealth members*
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 *Not covered for MassHealth members*
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 *Not covered for MassHealth members*
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 *Not covered for MassHealth members*

Skin substitutes covered for the treatment of diabetic foot ulcers:

Code	Description
Q4101	Apligraf, per sq cm
Q4105	Integra dermal regeneration template, per sq cm
Q4106	Dermagraft, per sq cm

Skin substitutes covered for the treatment of venous leg ulcers:

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

Skin substitutes considered investigational (except as indicated):

Q4100	Skin substitute, not otherwise specified
Q4103	Oasis burn matrix, per sq cm
Q4104	Integra bilayer matirx wound dressing (BMWD), per sq cm *Covered for MassHealth members*
Q4107	GraftJacket, per sq cm *Covered for MassHealth members*
Q4108	Integra Matrix, per sq cm *Covered for MassHealth members*
Q4110	PriMatrix, per sq cm *Covered for MassHealth members*
Q4111	GammaGraft
Q4112	Cymetra, Injectable, 1 cc
Q4113	GraftJacket Xpress, Injectable, 1 cc
Q4114	Integra flowable wound matrix, Injectable, 1 cc
Q4115	AlloSkin, per sq cm
Q4116	AlloDerm, per sq cm
Q4117	HyaloMatrix, per sq cm

Q4118	MatriStem micromatrix, 1 mg
Q4119	MatriStem wound matrix, per sq cm
Q4120	MatriStem burn matrix, per sq cm
Q4121	TheraSkin, per sq cm *Covered for MassHealth members*
Q4122	DermACELL, per sq cm
Q4123	AlloSkin RT, per sq cm
Q4124	Oasis ultri tri-layer wound matrix, per sq cm
Q4125	ArthroFlex, per sq cm
Q4126	MemoDerm, DermaSpan, TranZgraft or IntéguPly, per sq cm
Q4127	Talymed, per sq cm
Q4128	FlexHD, AlloPatchHD, or MatrixHD, per sq cm
Q4129	Unite biomatrix, per sq cm
Q4130	Strattice TM, per sq cm
Q4131	EpiFix, per sq cm
Q4132	Grafix Core, per sq cm *Covered for MassHealth members*
Q4133	Grafix Prime, per sq cm *Covered for MassHealth members*
Q4134	Hmatrix, per sq cm
Q4135	Mediskin, per sq cm
Q4136	E-Z Derm, per sq cm
Q4137	AmnioExcel or BioDExCel, per sq cm
Q4138	BioDFence, DryFlex, per sq cm
Q4139	AmnioMatrix or BioDMatrix, Injectable, 1 cc
Q4140	BioDFence, per sq cm
Q4141	AlloSkin AC, per sq cm
Q4142	XCM biologic tissue matrix, per sq cm
Q4143	Repriza, per sq cm
Q4145	EpiFix, Injectable, 1 mg
Q4146	Tensix, per sq cm
Q4147	Architect, Architect PX, Architect FX, extracellular matrix, per sq cm
Q4148	Neox 1k, per sq cm
Q4149	Excellagen, 0.1cc
Q4150	AlloWrap DS or dry, per sq cm
Q4151	AmnioBand or Guardian, per sq cm
Q4152	DermaPure, per sq cm
Q4153	Dermavest and plurivest, per sq cm
Q4154	Biovance, per sq cm
Q4155	Neox Flo or Clarix Flo 1 mg
Q4156	Neox 100, per sq cm
Q4157	Revitalon, per sq cm
Q4158	Marigen, per sq cm

Q4159	Affinity, per sq cm
Q4160	Nushield, per sq cm
Q4161	Bio-Connekt wound matrix, per sq cm *Covered for MassHealth members*
Q4162	AmnioPro Flo, BioSkin Flow, BioRenew Flow, WoundEx Flow, Amniogen-A, Amniogen-C, 0.5 cc *Covered for MassHealth members*
Q4163	AmnioPro, BioSkin, BioRenew, WoundEx, Amniogen-45, Amniogen-200, per sq cm *Covered for MassHealth members*
Q4164	Helicoll, per sq cm *Covered for MassHealth members*
Q4165	Keramatrix, per sq cm *Covered for MassHealth members*
Q4166	Cytal, per sq cm
Q4167	Truskin, per sq cm
Q4168	AmnioBand, 1 mg
Q4169	Artacent wound, per sq cm
Q4170	Cygnus, per sq cm
Q4171	Interfyl, 1 mg
Q4172	Puraply or puraply am, per sq cm
Q4173	Palingen or pallingen xplus, per sq cm
Q4174	Palingen or promatrix, 0.36 mg per 0.25 cc
Q4175	Miroderm, per sq cm
Q4176	NeoPatch or therion, per sq cm
Q4177	Flolweramnioflo, 0.1 cc
Q4178	Floweramniopatch, per sq cm
Q4179	Flowerderm, per sq cm
Q4180	Revita, per sq cm
Q4181	Amnio wound, per sq cm
Q4182	Transcyte, per sq cm
Q4183	Surgigraft, per sq cm
Q4184	Cellesta or cellesta duo, per sq cm
Q4185	Cellesta flowable amnion (25 mg per cc); per 5 cc
Q4186	EpiFix, per sq cm
Q4187	EpiCord, per sq cm *Covered for MassHealth members*
Q4188	Amnioarmor, per sq cm
Q4189	Artacent ac, 1 mg
Q4190	Artacent ac, per sq cm
Q4191	Restorigin, per sq cm
Q4192	Restoragin, 1 cc
Q4193	Coll-e-derm, per sq cm
Q4194	Novachor, per sq cm
Q4195	Puraply, per sq cm

Q4196	Puraply am, per sq cm
Q4197	Puraply xt, per sq cm
Q4198	Genesis amniotic membrane, per sq cm
Q4200	Skin te, per sq cm
Q4201	Matrion, per sq cm
Q4202	Keroxx (2.5g/cc), 1 cc
Q4203	Derma-gide, per sq cm
Q4204	Swrap, per sq cm
Q4205	Membrane graft or wrap sq cm
Q4206	Fluid flow or fluid gf, 1 cc
Q4208	Novafix, per sq cm
Q4209	Surgigraft, per sq cm
Q4210	Axolotl graft or axolotl dualgraft, per sq cm
Q4211	Amnio bio or axobiomembrane, per sq cm
Q4212	Allogen, per cc
Q4213	Ascent, 0.5mg
Q4214	Cellest cord, per sq cm
Q4215	Axolotl ambient or axolotl cryp, 0.1mg
Q4216	Artacent cord, per sq cm
Q4217	Woundfix, biowound, woundfix plus, biowound plus, woundfix xplus, biowound xplus, per sq cm
Q4218	Surgicord, per sq cm
Q4219	Surgigraft-dual, per sq cm
Q4220	Bellacell HD or surederm, per sq cm
Q4221	Amniowrap2, per sq cm
Q4222	Progenamatrix, per sq cm
Q4226	Myown harv prep proc sq cm
Q4227	Amniocore, per sq cm
Q4228	Bionextpatch, per sq cm
Q4229	Cogenex amniotic membrane, per sq cm
Q4230	Cogenex flowable amnio, per 0.5 cc
Q4231	Corplex p, per cc
Q4232	Corplex, per sq cm
Q4233	Surfactor or nudyn, per 5 cc
Q4234	Xcellerate, per sq cm
Q4235	Amniorepair or altiply, per sq cm
Q4236	Carepatch, per sq cm
Q4237	Cryo-cord, per sq cm
Q4238	Derm-maxx, per sq cm
Q4239	Amnio-maxx or amnio-maxx lite, per sq cm
Q4240	Corecyte, for topical use only, per 5 cc
Q4241	Polycyte, for topical use only, per 5 cc

Q4242	Amniocyte plus, per 0.5 cc
Q4244	Procenta, per 22 mg
Q4245	Amniotext, per cc
Q4246	Coretext or protext, per cc
Q4247	Amniotext patch, per sq cm
Q4248	Dermacyte amniotic membrane allograft, per sq cm
Q4249	Amniply, per sq cm
Q4250	AmnioAMP-MP per sq cm
Q4254	Novafix dl per sq cm
Q4255	Reguard, topical use per sq

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Policy history

Origination date:	06/01//2021
Approval(s):	Technology Assessment Committee: 12/08/2020 (policy origination)
	07/10/2021 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.