Title: Bio-Engineered Skin and Soft Tissue Substitutes

See Also: Periodontal Soft Tissue Grafting dental policy

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**DESCRIPTION**
Bio-engineered skin and soft tissue substitutes may be derived from human tissue (autologous or allogeneic), non-human tissue (xenographic), synthetic materials, or a composite of these materials. Bio-engineered skin and soft tissue substitutes are being evaluated for a variety of conditions, including breast reconstruction and to aid healing of lower extremity ulcers and severe burns. Acellular dermal matrix products are also being evaluated in the repair of a variety of soft tissues.
Background
Bio-engineered skin and soft tissue substitutes may be either acellular or cellular. Acellular products (i.e., cadaveric human dermis with cellular material removed) contain a matrix or scaffold composed of materials such as collagen, hyaluronic acid, and fibronectin. 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 (e.g., 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. Tissue-engineered skin substitutes can be used as either temporary or permanent wound coverings.

There are a large number of potential applications for artificial skin products. One large category is non-healing 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, non-healing lower extremity wounds represent an ongoing risk for infection, sepsis, limb amputation and death. Bio-engineered skin and soft tissue substitutes have the potential to improve rates of healing and reduce secondary complications.

Other situations in which bio-engineered skin products might substitute for living skin grafts include certain postsurgical states such as 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 situation in which artificial skin products may substitute for auto- or allografts. Certain primary dermatologic conditions that involve large areas of skin breakdown, such as bullous diseases, may also be conditions in which artificial skin products can be considered as substitutes for skin grafts. Acellular dermal matrix products are also being evaluated in the repair of other soft tissues including rotator cuff repair, following oral and facial surgery, hernias, and a variety of other conditions.

Regulatory Status
There are a large number of artificial skin products that are commercially available or in development. The following summary of commercially available skin substitutes describes those products that have substantial relevant evidence on efficacy. This list demonstrates the wide range of types of products available:

Acellular Dermal Matrix
Allograft acellular dermal matrix products derived from donated human skin tissue are supplied by U.S. AATB-compliant tissue banks using the standards of the American Association of Tissue Banks (AATB) and U.S. Food and Drug Administration's (FDA) guidelines. The processing removes the cellular components (i.e., epidermis and all viable dermal cells) that can lead to rejection and infection. Acellular dermal matrix products from human skin tissue are regarded as minimally processed and not
significantly changed in structure from the natural material; the FDA classifies it as banked human tissue and therefore does not require FDA approval.

- **AlloDerm®** (LifeCell Corporation) is an acellular dermal matrix (allograft) tissue-replacement product that is created from native human skin and processed so that the basement membrane and cellular matrix remain intact. An injectable micronized form of AlloDerm (Cymetra) is also available.

- **AlloMax™ Surgical Graft** (Bard Davol) is an acellular non-cross-linked human dermis allograft. (AlloMax was previously marketed as NeoForm™)

- **DermaMatrix** (Synthes) is an acellular dermal matrix (allograft) derived from donated human skin tissue. DermaMatrix Acellular Dermis is processed by the Musculoskeletal Transplant Foundation® (MTF®).

- **GraftJacket® Regenerative Tissue Matrix** (KCI) is an acellular regenerative tissue matrix that has been processed from screened donated human skin supplied from U.S. tissue banks. The allograft is minimally processed to remove the epidermal and dermal cells, while preserving dermal structure.

PriMatrix (TEI Biosciences) is a xenogeneic acellular dermal matrix processed from fetal bovine dermis. It is indicated through the U.S. Food and Drug Administration’s (FDA) 510(k) process for partial and full-thickness wounds; diabetic, pressure, and venous stasis ulcers; surgical wounds; and tunneling, draining, and traumatic wounds.

**Amniotic Membrane**

Human amniotic membrane, or amnion, is the inner most layer of the 3 layers forming the fetal membrane. It is harvested immediately after birth, cleaned, sterilized, and either fresh frozen or dehydrated. Human amniotic membrane is considered to be minimally processed and not significantly changed in structure from the natural material; the U.S. Food and Drug Administration (FDA) classifies it as banked human tissue and therefore, it does not require FDA approval. Epifix® (MiMedix) is a commercially available source of dehydrated human amniotic membrane.

**Collagen Scaffold**

OASIS™ Wound Matrix (Cook Biotech) is a xenographic collagen scaffold derived from porcine small intestinal mucosa. It was cleared by the FDA’s 510(k) process in 2000 for the management of partial- and full-thickness wounds including pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled undermined wounds, surgical wounds, trauma wounds, and draining wounds.

**Living Cell Therapy**

Apligraf® (Organogenesis) is a bi-layered cell therapy composed of an epidermal layer of living human keratinocytes and a dermal layer of living human fibroblasts. Apligraf® is supplied as needed, in 1 size, with a shelf-life of 10 days. It was FDA approved in 1998 for use in conjunction with compression therapy for the treatment of non-infected, partial- and full-thickness skin ulcers due to venous insufficiency and in 2001 for full-thickness neuropathic diabetic lower extremity ulcers nonresponsive to standard wound therapy.
Dermagraft® (Advanced Tissue Sciences) is composed of cryopreserved human-derived fibroblasts and collagen applied to a bioabsorbable mesh. Dermagraft has been approved by the FDA for repair of diabetic foot ulcers.

Epicel® (Genzyme Biosurgery) is a cultured epithelial autograft and is FDA-approved under a humanitarian device exemption (HDE) for the treatment of deep dermal or full-thickness burns comprising a total body surface area of greater than or equal to 30%. It may be used in conjunction with split-thickness autografts or alone in patients for whom split-thickness autografts may not be an option due to the severity and extent of their burns.

OrCel™ (Forticell Bioscience) (formerly called Composite Cultured Skin) is an absorbable allogeneic bi-layered cellular matrix, made of bovine collagen, in which human dermal cells have been cultured. It was approved by the FDA premarket approval (PMA) for healing donor site wounds in burn victims and under a humanitarian device exemption (HDE) for use in patients with recessive dystrophic epidermolysis bullosa undergoing hand reconstruction surgery to close and heal wounds created by the surgery, including those at donor sites.

**Biosynthetic**

Biobrane®/Biobrane-L (Smith and Nephew) is a biosynthetic wound dressing constructed of a silicon film with a nylon fabric partially imbedded into the film. The fabric creates a complex 3-dimensional structure of tri-filament thread, which chemically binds collagen. Blood/sera clot in the nylon matrix, adhering the dressing to the wound until epithelialization occurs.

Integra® Dermal Regeneration Template (Integra LifeSciences) is a bovine, collagen/glycosaminoglycan dermal replacement covered by a silicone temporary epidermal substitute. It is FDA approved for use in postexcisional treatment of life-threatening full-thickness or deep partial-thickness thermal injury where sufficient autograft is not available at the time of excision or not desirable because of the physiologic condition of the patient. Integra™ Matrix Wound Dressing and Integra™ meshed Bilayer Wound Matrix are substantially equivalent skin substitutes that are FDA 510(k) approved for other indications.

TransCyte™ (Advanced Tissue Sciences) consists of human dermal fibroblasts grown on nylon mesh, combined with a synthetic epidermal layer and was approved by the FDA in 1997. TransCyte is intended to be used as a temporary covering over burns until autografting is possible. It can also be used as a temporary covering for some burn wounds that heal without autografting.
POLICY

Note: Use Q4100 for skin substitutes that do not have a unique code.

A. Breast reconstructive surgery:
   - 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 post-mastectomy skin flaps that are at risk of dehiscence or necrosis, or
   - the infra-mammary fold and lateral mammary folds have been undermined during mastectomy and re-establishment of these landmarks is needed using the following acellular dermal matrix (ADM) may be considered medically necessary.
     1. AlloDerm®* (Q4116)

B. Treatment of chronic, noninfected, full-thickness diabetic lower extremity ulcers using the following tissue-engineered skin substitutes may be considered medically necessary.
   1. Apligraf®** (Q4101)
   2. Dermagraft®** (Q4106)

C. Treatment of chronic, non-infected, partial- or full-thickness lower extremity skin ulcers due to venous insufficiency, which have not adequately responded following a one-month period of conventional ulcer therapy, using the following tissue-engineered skin substitutes may be considered medically necessary.
   1. Apligraf®** (Q4101)
   2. Oasis™ Wound Matrix*** (Q4102)

D. Treatment of dystrophic epidermolysis bullosa using the following tissue-engineered skin substitutes may be considered medically necessary.
   1. 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 FDA)****

E. Treatment of second- and third-degree burns using the following tissue-engineered skin substitutes may be considered medically necessary.
   1. Epicel® (for the treatment of deep dermal or full-thickness burns comprising a total body surface area of greater than or equal to 30% when provided in accordance with the HDE specifications of the FDA)****
   2. Integra Dermal Regeneration Template™**
   3. TransCyte™***

*Banked Human Tissue
**FDA PMA approved
***FDA 510(k) cleared
****FDA-approved under a humanitarian device exemption (HDE)
F. All other uses of the bio-engineered skin and soft tissue substitutes listed above are considered **experimental / investigational**.

G. All other skin and soft tissue substitutes not listed above are considered **experimental / investigational**, including, but not limited to:

1. Acticoat
2. Actisorb
3. Allograft
4. AlloMax
5. Allopatch
6. AlloPatch HD (Q4128)
7. AlloSkin (Q4115)
8. Alloskin AC (Q4141)
9. AlloSkin RT (Q4123)
10. AmnioExCel (Q4137)
11. AmnioFix
12. AminoMatrix (Q4139)
13. Architect Extracellular Matrix (Q4147)
14. Artelon
15. Arthres GraftRope
16. ArthroFlex (FlexGraft) (Q4125)
17. Avaulta Plus
18. Avotermin
19. Biobrane
20. BioDfence/BioDfactor (Q4140)
21. BioDfence Dryflex (Q4138)
22. Biostat Biologx
23. Biotape
24. C-QUR
25. CellerateRX
26. CollaFix
27. Collamend
28. Conexa
29. CorMatrix
30. CorMatrix Patch
31. CRXa
32. Cuffpatch
33. Cymetra
34. Cymetra Injectable Allograft (Q4112)
35. DuraGen Plus
36. Dermacell (Q4122)
37. DermaClose RC Continuous External Tissue Expander
38. DermaMatrix Acellular Dermis
39. Durepair Regeneration Matrix
40. Endoform Dermal Template (C9367)
41. ENDURAgen
42. EpiDex
43. EpiFix (Q4131) (Q4145)
44. Evicel
45. Excellagen (Q4149)
46. E-Z Derm (Q4136)
47. FlexHD Acellular Hydrated Dermis (Q4128)
48. GammaGraft (Q4111)
49. Grafix core (Q4132)
50. Grafix prime (Q4133)
51. GraftJacket (Q4107)
52. GraftJacket Regenerative Tissue Matrix
53. GraftJacket Xpress, injectable (Q4113)
54. hMatrix (Q4134)
55. Hyalomatrix PA (Q4117)
56. Inforce
57. Integra™ Bilayer Wound Matrix (Q4104)
58. Integra Flowable Wound Matrix (Q4114)
59. Integra Neural Wrap
60. Integra Matrix Wound Dressing (Q4108)
61. Matriderm
62. MatriStem Micromatrix (Q4118)
63. MatriStem Wound Matrix (Q4119)
64. MatriStem Burn Matrix (Q4120)
65. Matrix HD
66. Medeor (Q4142)
67. MediHoney
68. Mediskin (Q4135)
69. MemoDerm (Q4126)
70. Meso BioMatrix
71. NEOX 1K (Q4148)
72. Neuragen
73. NeuraWrap
74. Neuroflex
75. NeuroMatrix Collagen Nerve Cuff (C9355)
76. NeuroMend Collagen Nerve Wrap (C9361)
77. NuCel
78. NuShield
79. Oasis Burn Matrix (Q4103)
80. Oasis Ultra Tri-Layer Matrix (Q4124)
81. OrthADAPT Bioimplant
82. Ovation
83. Pelvicol
84. Pelvisoft
85. Peri-Strips Dry
86. Permacol
87. Permacol Biologic Implant (C9364)
88. PTFE felt
89. PriMatrix
90. PriMatrix Acellular Dermal Tissue Matrix (Q4110)
91. Promogran
92. Puracol
93. Repriza (Q4143)
94. Seamguard
95. SportMatrix
96. SportMesh
97. StrataGraft
98. Strattice (xenograft)
99. Strattice Tissue Matrix (Q4130)
100. SurgiMend Collagen Matrix (C9358, C9360)
101. Talymed (Q4127)
102. TenoGlide Tendon Protector Sheet (C9356)
103. TenSI X (Q4146)
104. TheraSkin
105. TheraSkin Unite (Q4121)
106. TissueMend
107. Unite Biomatrix (Q4129)
108. Veritas Collagen Matrix (C9354)
109. X-Repair
110. XenMatrix

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**RATIONALE**
The most recent literature update for this policy was performed through November 2012. Following is a summary of key literature to date.

**Breast Reconstruction**

**AlloDerm**

*Systematic Reviews:* Two systematic reviews from 2012 found an increased rate of complications with acellular dermal matrix-assisted breast reconstruction. One meta-analysis of 16 retrospective studies found a higher likelihood of seroma (pooled odds ratio [OR]: 3.9; 95% CI: 2.4-6.2), infection (pooled OR: 2.7; 95% CI: 1.1-6.4) and reconstructive failure (pooled OR: 3.0; 95% CI: 1.3-6.8) when compared to breast reconstruction using traditional musculofascial flaps. (1) Another meta-analysis that compared 19 studies using acellular dermal matrix (n=2,037) with 35 studies using submuscular reconstruction (n=12,847) found an increased risk of total complications (relative risk [RR]: 2.05; 95% CI: 1.55-2.70), seroma (RR: 2.73; 95% CI: 1.67-4.46), infection (RR: 2.47; 95% CI: 1.71-3.57), and reconstructive failure (RR: 2.80; 95% CI:...
1.76-4.45) with acellular dermal matrix. (2) These meta-analyses are limited by the poor quality of included studies and significant heterogeneity.

**Randomized Controlled Trials:** In 2012, McCarthy et al. reported a multicenter blinded randomized controlled trial of AlloDerm in 2-stage expander/implant reconstruction. (3) Seventy patients were randomized to AlloDerm acellular dermal matrix-assisted tissue expander/implant reconstruction or to submuscular tissue expander/implant placement. There were no significant differences between the groups in the primary outcomes of immediate postoperative pain (54.6 AlloDerm and 42.8 control on a 100-point visual analog score) or pain during the expansion phase (17.0 AlloDerm and 4.6 control), or in the secondary outcome of rate of tissue expansion (91 days AlloDerm and 108 days control) and patient-reported physical well-being. There was no significant difference in adverse events, although the total number of adverse events was small. Phase 2 of the study will evaluate long-term outcomes.

**Controlled Studies:** Preminge and colleagues evaluated the impact of AlloDerm on expansion rates in immediate tissue expander/implant reconstruction in a retrospective matched cohort study. (4) Forty-five patients had reconstruction with AlloDerm and 45 had standard reconstruction. Subjects were matched for expander size (+/-100 mL), history of irradiation, and indication for mastectomy. There were no significant differences in initial filling volume, mean number of postoperative expansions, mean rate of postoperative tissue expansion, or in the incidence of postoperative complications. Aesthetic outcomes were not addressed.

In 2008, Colwell and Breuing reported on 10 patients who had mastopexy with dermal slings, 5 patients were given AlloDerm and 5 were given autologous tissue. (5) Patients have maintained projection and breast base width after 6 months to 3 years.

**Uncontrolled Studies:** Salzberg reported results on use of AlloDerm for reconstructive surgery on 76 breasts in 49 patients who underwent immediate reconstructive surgery after mastectomy in 2006. (6) Patients were considered good candidates if they had skin-sparing mastectomies or had adequate soft tissue coverage. The mean follow-up was 18 months (range, 3-52 months). The authors reported that patients had “decreased” postsurgical pain, and that, subjectively, physicians and patients were satisfied with the breast projection and desired symmetry. No serious postoperative complications were reported. Based on biopsies obtained at 2 and 6 months in 2 patients, fibroblast ingrowth and full vascularity were noted.

Breuning and Colwell reported on use of the AlloDerm hammock in 43 patients and 67 breasts in 2007. (7) Indications for reconstructive surgery and use of the allograft were immediate expander-implant reconstruction (N=10), immediate silicone implant reconstruction (N=30), delayed expander-implant reconstruction (N=4), and revisional implant reconstruction for capsular contracture following capsulectomy (N=23). The article indicates that patients were included if AlloDerm was used in association with an implant or expander to reconstruct their breast. The authors reported that the AlloDerm hammock allowed complete coverage of the implant and symmetric positioning of the infra-mammary fold. In delayed reconstructions with existing skin redundancy at the mastectomy site, inferior epigastric tissue was recruited, and tissue expanders filled over 75% of the desired volume, thus decreasing the need for subsequent filling. One patient had implant extrusion and 2 had infections. No capsular contracture, hematoma, or seroma was observed at mean follow-up of approximately 1.5 years (range, 6 months to 3 years). The authors concluded that implant reconstruction with an inferolateral
AlloDerm hammock facilitates positioning of the implant in immediate or revisional breast reconstruction and simplifies expander-implant reconstruction.

Thus, a number of case series have demonstrated that this approach can provide tissue coverage of implants and tissue expanders.

AlloDerm has been reported in nipple reconstructive surgery. (8) This report involves a case series on 30 nipple reconstructive procedures performed at one institution. The authors conclude that use of an AlloDerm graft core is a safe technique for “improving the long-term maintenance of nipple projection.”

Use of AlloDerm has also been reported in a small series (n=3) to correct breast implant-related problems (malposition, symmastia, and rippling). (9)

Other: Liu et al. reported postoperative complications in breast reconstruction with (n=266) or without (n=204) AlloDerm in 2011. (10) Radiation therapy, body mass index (BMI), intraoperative use of tumescent solution, and medical comorbidities were similar between the 2 groups, but there were twice as many smokers and the implants were larger in the AlloDerm group. There was a trend for a higher rate of major infections that required prosthesis removal in the AlloDerm group (4.9% vs. 2.5%, p=0.172) and a statistically significant increase in overall wound infection rate (6.8% vs. 2.5%). The overall surgical complication rate was significantly higher in the AlloDerm group (19.5% vs. 12.3%). Multivariate analysis indicated that the use of acellular dermal matrix, smoking, higher BMI, higher initial volume, and bigger implant size were associated with a higher overall surgical complication rate. This study is limited by the retrospective analysis and differences between groups at baseline.

Bindingnavele et al. reviewed charts of 41 patients (65 breasts) who had staged breast reconstruction with acellular cadaveric dermis to report postoperative complication rates. (11) Rates for wound infection, expander removal, hematoma, and seroma were 3.1%, 1.5%, 1.5%, and 4.6%, respectively. The authors concluded that based on low rates of complications and good cosmetic outcomes, the technology should be in the repertoire of plastic surgeons and that follow-up is required to evaluate long-term outcomes.

**Interpositional Graft after Parotidectomy**

**AlloDerm**

In 2003, Sinha et al. reported the use of AlloDerm acellular human dermal matrix as an interpositional physical barrier to prevent the development of Frey syndrome (gustatory sweating) after parotidectomy. (12) Thirty patients were divided into 3 groups; it was not described if the assignments were randomized. One group underwent superficial parotidectomy with reconstruction of the defect with AlloDerm, a second group had superficial parotidectomy without placement of an interpositional barrier, and the third group underwent deep-plane rhytidectomy without disruption of the parotid fascia. At minimum 1-year follow-up, there was a subjective incidence of Frey syndrome in 1 patient treated with AlloDerm and 5 patients in group 2. The objective incidence of Frey syndrome, measured with the Minor starch-iodine test, was 2 patients treated with AlloDerm and 8 patients in group 2. None of the patients in group 3 who underwent deep-plane rhytidectomy without disruption of the parotid fascia had subjective or objective Frey syndrome. There were no adverse effects.
A 2008 publication from Asia compared use of allogeneic acellular dermal matrix (RENOV) in 168 patients who had superficial or partial parotidectomy. (13) Sixty-four patients received an acellular dermal matrix and 104 patients had superficial or partial parotidectomy alone. The size of the graft depended on the amount of tissue required to restore the normal facial contour. The method of assignment to the 2 groups was not described. At a median follow-up of 16 months (range, 11-27), the subjective incidence of Frey syndrome was 2% in the acellular dermal matrix group compared with 61% in controls. Objective assessment, performed in 30 patients randomly selected from each group, found an incidence of Frey syndrome in 2 patients (7%) treated with acellular dermal matrix and 24 patients (80%) in the control group. One patient in the acellular dermal matrix group and 18 patients in the control group developed a parotid fistula.

**DermaMatrix**

DermaMatrix is an acellular dermal matrix that differs from AlloDerm in several ways; it can be stored at room temperature (vs. refrigerated), it has a shelf-life of 3 years (vs. 2 years), and it can be rehydrated in 3 minutes (vs. 30 minutes).

Athavale et al. evaluated complications of AlloDerm and DermaMatrix in a retrospective review of 100 patients treated between 2001 and 2009 at a single U.S. institution. (14) Exclusion criteria for the study included presence of malignancy on final surgical pathology report, incomplete medical records, previous history of radiation therapy to the head and neck region, and additional procedures to the region of the parotid gland. Initially, only AlloDerm was used; this changed to a 20/80 ratio of AlloDerm/DermaMatrix due to more readily available stock of DermaMatrix. Complications were defined as any outcome that required procedural intervention for resolution (seroma/sialocele formation, infected fluid collection, and/or serosanguinous fluid collection). The authors identified 8 complications in 31 DermaMatrix implants (26%) compared with 5 complications in 69 AlloDerm implants (7%). The complication rate did not differ for total parotidectomies but was higher for DermaMatrix compared to AlloDerm for subtotal parotidectomies (37% vs. 8%). Nearly half of all complications were seroma/sialocele formation.

Randomized, double-blind, controlled trials with longer follow-up are needed to evaluate this procedure.

**Tendon Repair**

**GraftJacket**

In 2012, Barber et al. reported an industry-sponsored multi-center randomized controlled trial of augmentation with GraftJacket acellular human dermal matrix for arthroscopic repair of large (>3 cm) rotator cuff tears involving 2 tendons. (15) Twenty-two patients were randomized to GraftJacket augmentation, and 20 patients were randomized to no augmentation. At a mean follow-up of 24 months (range, 12 to 38 months) the American Shoulder and Elbow Surgeons (ASES) score improved from 48.5 to 98.9 in the GraftJacket group and from 46.0 to 94.8 in the control group (p=0.035). The Constant score improved from 41 to 91.9 in the GraftJacket group and from 45.8 to 85.3 in the control group (p=0.008). The University of California, Los Angeles score was not significantly different between the groups. Gadolinium-enhanced magnetic resonance imaging (MRI) scans showed intact cuffs in 85% of repairs in the GraftJacket group and 40% of repairs in the control group. However, no correlation was found between MRI findings and clinical outcomes. Rotator cuff retears occurred in 3 patients (14%) in the GraftJacket group and 9 patients (45%) in the control group. Although these results are promising, additional study with a larger number of patients is needed.
Fistula Repair

Acellular Dermal Matrix
A study from Asia compared a xenogeneic acellular dermal matrix (J-I type, J.Y. Life Tissue Engineering Co., China) with endorectal advancement flap (ERAF) for the treatment of complex ano-rectal fistula in a randomized study with 90 consecutive patients. (16) Follow-up was performed at 2 days, 2, 4, 6, 12 weeks, and 5 months after surgery. Success was defined as closure of all external opening, absence of drainage without further intervention, and absence of abscess formation. Success was observed in 82.2% of the acellular dermal matrix group. Fistula recurred in 2 (4.45%) patients in the acellular dermal matrix group compared with 13 (28.89%) patients in the ERAF group. Healing time was reduced (7.5 vs. 24.5 days), and quality of life was rated higher in the acellular dermal matrix group (85.9 vs. 65.3). No significant difference was observed in the incontinence and anal deformity rate between the 2 groups. This product is not cleared for marketing in the U.S., although the manufacturing process was reported to be similar to Surgisis AFP.

Surgical Repair of Hernias
A 2011 systematic review included 30 level III and level IV articles on acellular dermal matrix for abdominal wall reconstruction. (17) No randomized controlled trials or high-quality comparative studies (level I or II) were identified. Examples of the level III studies are described below.

AlloDerm
Gupta et al. compared the efficacy and complications associated with the use of AlloDerm and Surgisis bioactive mesh in 74 patients who underwent ventral hernia repair in 2006. (18) The first 41 procedures were performed using Surgisis Gold 8-ply mesh formed from porcine small intestine submucosa, and the remaining 33 patients had ventral hernia repair with AlloDerm. Patients were seen 7-10 days after discharge from the hospital and at 6 weeks. Any signs of wound infection, diastasis, hernia recurrence, changes in bowel habits, and seroma formation were evaluated. The use of the AlloDerm mesh resulted in 8 hernia recurrences (24%). Fifteen of the AlloDerm patients (45%) developed a diastasis or bulging at the repair site. Seroma formation was only a problem in 2 patients.

In 2007, Espinosa-de-los-Monteros and colleagues retrospectively reviewed 39 abdominal wall reconstructions with AlloDerm performed in 37 patients and compared them with 39 randomly selected cases. (19) They reported a significant decrease in recurrence rates when human cadaveric acellular dermis was added as an overlay to primary closure plus rectus muscle advancement and imbrication in patients with medium-sized hernias. However, no differences were observed when adding human cadaveric acellular dermis as an overlay to patients with large-size hernias treated with underlay mesh.

The limited evidence available at this time does not support the use of AlloDerm in hernia repair.

Oral Surgery

AlloDerm
In 2008, Novaes and de Barros described 3 randomized trials from their research group that examined use of acellular dermal matrix in root coverage therapy and alveolar ridge augmentation. (20) Two trials used acellular dermal matrix in both the study and control groups and are not described here. A third trial compared acellular dermal matrix with subepithelial
connective tissue graft in 30 gingival recessions (9 patients). At 6 months postsurgery, the acellular dermal matrix showed recession reduction of 1.83 mm while subepithelial connective tissue graft showed recession reduction of 2.10 mm; these were not significantly different. A nonrandomized cohort study compared Alloderm with the gold standard of split thickness skin grafts in 34 patients who underwent oral cavity reconstruction following surgical removal of tumors. Patients were enrolled after surgical treatment for evaluation at a tertiary care center and divided into 2 cohorts according to the reconstruction method used, which was based on surgeon preference. Twenty-two patients had been treated with Alloderm, and 12 had been treated with split thickness skin grafts. The location of the grafts (Alloderm vs. autograft) were on the tongue (54% vs. 25%), floor of mouth (9% vs. 50%), tongue and floor of mouth (23% vs. 8%), buccal (9% vs. 0%), or other (5% vs. 17%). More patients in the Alloderm group were treated with radiation therapy (45% vs. 17%), and the graft failure rate was higher (14% vs. 0%). Radiation therapy had a significantly negative impact for both groups. Histology on a subset of the patients showed increased inflammation, fibrosis, and elastic fibers with split thickness skin grafts. Functional status and quality of life were generally similar in the 2 groups. Interpretation of these results is limited by the differences between the groups at baseline.

Laryngoplasty
There are several reports with short-term follow-up of micronized AlloDerm (Cymetra) injection for laryngoplasty. In 2005, Milstein et al. reported mean 11.2 month follow-up (range, 1 to 35 months) of Cymetra injection in 20 patients with unilateral vocal-fold paralysis. Pre- and post-operative digital voice samples and video stroboscopy were rated on a 4-point scale by a panel of 3 voice experts who were blinded to the pre- or postoperative status. Compared with preoperative measures, Cymetra improved voice quality (from 3.23 to 1.65), glottal closure (from 3.21 to 1.42), and degree of vocal-fold bowing (from 2.38 to 1.36). Quality-of-life measures and patients' self-perceptions of vocal quality were also improved. In 5 patients (25%), the effect was temporary, and in 8 patients (40%) who had follow-up of 1 year or longer, the improvement was maintained. Longer-term study in a larger number of patients is needed to determine the durability of this procedure and to evaluate the safety of repeat injections.

Tymanoplasty
Vos et al. reported a retrospective non-randomized comparison of AlloDerm versus native tissue grafts for type I tympanoplasty in 2005. Included in the study were 108 patients (25 AlloDerm, 53 fascia reconstruction, and 30 fascia plus cartilage reconstruction) treated between 2001 and 2004. One surgeon had performed 96% of the AlloDerm tympanoplasties. Operative time was reduced in the AlloDerm group (82 minutes for AlloDerm, 114 minutes for fascial cases, and 140 minutes for fascia plus cartilage). There was no significant difference in the success rate of the graft (88% for AlloDerm, 89% for fascia grafts, 96.7% for cartilage plus fascia). There was no significant difference in hearing between the groups at follow-up (time not specified). Longer-term controlled study in a larger number of patients is needed to determine the durability of this procedure.

Diabetic Lower Extremity Ulcers

Apligraf
In 2001, Veves and colleagues reported on a randomized prospective study on the effectiveness of Graftskin (Apligraf), a living skin equivalent, in treating noninfected nonischemic chronic plantar diabetic foot ulcers. The study involved 24 centers in the U.S.; 208 patients were randomly assigned to ulcer treatment either with Graftskin (112 patients) or saline-moistened
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gauze (96 patients, control group). Standard state-of-the-art adjunctive therapy, including extensive surgical debridement and adequate foot off-loading, was provided in both groups. Graftskin was applied at the beginning of the study and weekly thereafter for a maximum of 4 weeks (maximum of 5 applications) or earlier if complete healing occurred. At the 12-week follow-up visit, 63 (56%) Graftskin-treated patients achieved complete wound healing compared with 36 (38%) in the control group (p=0.0042). The Kaplan-Meier median time to complete closure was 65 days for Graftskin, significantly lower than the 90 days observed in the control group (p=0.0026). The rate of adverse reactions was similar between the 2 groups with the exception of osteomyelitis and lower-limb amputations, both of which were less frequent in the Graftskin group. The authors concluded that application of Graftskin for a maximum of 4 weeks resulted in a higher healing rate when compared with state-of-the-art treatment and was not associated with any significant side effects. This study was reviewed in a 2001 TEC Assessment, which concluded that Graftskin (Apligraf), in conjunction with good local wound care, met the TEC criteria for the treatment of diabetic ulcers that fail to respond to conservative management. (25)

In 2010, Steinberg and colleagues reported on a study of 72 subjects from Europe and Australia that assessed the safety and efficacy of Apligraf in the treatment of non-infected diabetic foot ulcers. (26) The design and patient population of this study were similar to the 208-subject United States study (described above) which led to FDA-approval of Apligraf for the treatment of diabetic foot ulcers. For these studies, subjects with a non-infected neuropathic diabetic foot ulcer present for at least 2 weeks were enrolled in these prospective, multicenter, randomized, controlled, open-label studies that compared Apligraf use in conjunction with standard therapy (sharp debridement, standard wound care, and off-loading) against standard therapy alone. Pooling of data was performed because of the similarity and consistency of the 2 studies. Efficacy and safety results were consistent across studies independent of mean ulcer duration that was significantly longer in the European study (21 months, compared to 10 months in the U.S. study). Reported adverse events by 12 weeks were comparable across treatment groups in the 2 studies. Efficacy measures demonstrated superiority of Apligraf treatment over control-treated groups in both studies. Combining the data from both studies, 55.2% (80/145) of Apligraf subjects had complete wound closure by 12 weeks, compared to 34.3% (46/134) of control subjects (p=0.0005), and Apligraf subjects had a significantly shorter time to complete wound closure (p=0.0004). The authors concluded that both the EU and U.S. studies exhibited superior efficacy and comparable safety for subjects treated with Apligraf compared to control subjects, and the studies provide evidence of the benefit of Apligraf in treating diabetic foot ulcer (DFU).

In 2010, Kirsner and colleagues reported on analysis of 2,517 patients with diabetic neuropathic foot ulcers who were treated between 2001 and 2004. (27) The study was a retrospective analysis using a wound-care database; the patients received advanced biological therapy i.e., Apligraf (446 patients), Regranex, or Procuren. In this study, advanced biological therapy was used, on average, within 28 days from the first wound clinic visit and associated with a median time to healing of 100 days. Wounds treated with engineered skin (Apligraf) as the first advanced biological therapy were 31.2% more likely to heal than wounds first treated with topical recombinant growth factor (p<0.001) and 40.0% more likely to heal than those first treated with platelet releasate (p=0.01). Wound size, wound grade, duration of wound, and time to initiation of advanced biological therapy affected the time to healing.
Dermagraft
A pivotal multi-center FDA-regulated trial randomized 314 patients with chronic diabetic ulcers to Dermagraft or control. Over the course of the 12-week study, patients received up to 8 applications of Dermagraft. All patients received pressure-reducing footwear and were encouraged to stay off their study foot as much as possible. At 12 weeks, the median percent wound closure for the Dermagraft group was 91% compared to 78% for the control group. Ulcers treated with Dermagraft closed significantly faster than ulcers treated with conventional therapy. No serious adverse events were attributed to Dermagraft. Ulcer infections developed in 10.4% of the Dermagraft patients compared to 17.9% of the control patients. Together, there was a lower rate of infection, cellulitis, and osteomyelitis in the Dermagraft-treated group (19% vs. 32.5%).

GraftJacket Regenerative Tissue Matrix
Brigido et al. reported a small (n=40) randomized pilot study of GraftJacket compared with conventional treatment for chronic non-healing diabetic foot ulcers in 2004. (28) Control patients received conventional therapy with debridement, wound gel with gauze dressing, and off-loading. GraftJacket patients received surgical application of the scaffold using skin staples or sutures and moistened compressive dressing. A second graft application was necessary after the initial application for all patients in the GraftJacket group. Preliminary 1-month results showed that after a single treatment, ulcers treated with GraftJacket healed at a faster rate than conventional treatment. There were significantly greater decreases in wound length (51% vs. 15%), width (50% vs. 23%), area (73% vs. 34%), and depth (89% vs. 25%). All of the grafts incorporated into the host tissue.

In 2009, Reyzelman et al. reported an industry-sponsored multicenter randomized study that compared a single application of GraftJacket versus standard of care in 86 patients with diabetic foot ulcers. (29) Offloading was performed using a removable cast walker. Ulcer size at presentation was 3.6 cm² in the GraftJacket group and 5.1 cm² in the control group. Eight patients, 6 in the study group and 2 in the control group, did not complete the trial. At 12 weeks, complete healing was observed in 69.6% of the GraftJacket group and 46.2% of controls. After adjusting for ulcer size at presentation, a statistically significant difference in non-healing rate was calculated, with odds of healing 2.0 times higher in the study group. Mean healing time was 5.7 weeks versus 6.8 weeks for the control group. The authors did not report if this difference was statistically significant. The median time to healing was 4.5 weeks for GraftJacket (range, 1-12 weeks) and 7.0 weeks for control (range 2-12 weeks). Kaplan-Meier survivorship analysis for time to complete healing at 12 weeks showed a significantly lower non-healing rate for the study group (30.4%) compared with the control group (53.9%). The authors commented that a single application of GraftJacket, as used in this study, is often sufficient for complete healing. This study is limited by the small study population, differences in ulcer size at baseline, and the difference in the percentage of patients censored in each group. Questions also remain about whether the difference in mean time to healing is statistically or clinically significant. Additional trials with a larger number of subjects are needed to evaluate if GraftJacket Regenerative Tissue Matrix improves health outcomes in this population.

Oasis Wound Matrix
Niezgoda and colleagues compared healing rates at 12 weeks for full-thickness diabetic foot ulcers treated with OASIS Wound Matrix, an acellular wound care product, versus Regranex Gel. (30) This was an industry-sponsored randomized controlled multicenter trial conducted at 9 outpatient wound care clinics and involved 73 patients with at least 1 diabetic foot ulcer. Patients...
were randomized to receive either Oasis Wound Matrix (n=37) or Regranex Gel (n=36) and a secondary dressing. Wounds were cleansed and debrided, if needed, at a weekly visit. The maximum treatment period for each patient was 12 weeks. After 12 weeks of treatment, 18 (49%) Oasis-treated patients had complete wound closure compared with 10 (28%) Regranex-treated patients. Oasis treatment met the non-inferiority margin, but did not demonstrate that healing in the Oasis group was statistically superior (p=0.055). Post-hoc subgroup analysis showed no significant difference in incidence of healing in patients with type 1 diabetes (33% vs. 25%) but a significant improvement in patients with type 2 diabetes (63% vs. 29%). There was also an increased healing of plantar ulcers in the Oasis group (52% vs. 14%). These post-hoc findings are considered hypothesis-generating. Additional study with a larger number of subjects is needed to evaluate the effect of Oasis treatment in comparison with the current standard of care.

PriMatrix
In 2011, Karr published a retrospective comparison of PriMatrix (a xenograft fetal bovine dermal collagen matrix) and Apligraf in 40 diabetic foot ulcers. (31) The first 20 diabetic foot ulcers matching the inclusion and exclusion criteria for each graft were compared. Included were diabetic foot ulcers of 4 weeks’ duration, at least 1 sq cm and depth to subcutaneous tissue, healthy tissue at the ulcer, adequate arterial perfusion to heal, and able to off-load the diabetic ulcer. The products were placed on the wound with clean technique, overlapping the edges of the wound, and secured with sutures or staples. The time to complete healing for PriMatrix was 38 days with 1.5 applications compared to 87 days with 2 applications for Apligraf. Although promising, additional study with a larger number of subjects is needed to evaluate the effect of PriMatrix treatment in comparison with the current standard of care.

Lower Extremity Ulcers due to Venous Insufficiency

Apligraf
Falanga and colleagues reported a multicenter randomized trial of Apligraf (human skin equivalent) in 1998. (32) A total of 293 patients with venous insufficiency and clinical signs of venous ulceration were randomized to compression therapy alone or compression therapy and treatment with Apligraf. Apligraf was applied up to a maximum of 5 (mean 3.3) times per patient during the initial 3 weeks. The primary endpoints were the percentage of patients with complete healing by 6 months after initiation of treatment and the time required for complete healing. At 6 months’ follow-up, the percentage of patients healed was increased with Apligraf (63% vs. 49%), and the median time to complete wound closure was reduced (61 vs. 181 days). Treatment with Apligraf was found to be superior to compression therapy in healing larger (>1,000 mm2) and deeper ulcers and ulcers of more than 6 months’ duration. There were no symptoms or signs of rejection, and the occurrence of adverse events was similar in both groups. This study was reviewed in a 2001 TEC Assessment, which concluded that Apligraf (graftskin), in conjunction with good local wound care, met the TEC criteria for the treatment of venous ulcers that fail to respond to conservative management. (25)

Oasis Wound Matrix
In 2005, Mostow et al. reported an industry-sponsored multicenter (12 sites) randomized trial that compared weekly treatment with Oasis Wound Matrix versus standard of care in 120 patients with chronic ulcers due to venous insufficiency that were not adequately responding to conventional therapy. (33) Healing was assessed weekly for up to 12 weeks, with follow-up performed after 6 months to assess recurrence. After 12 weeks of treatment, there was a
significant improvement in the percentage of wounds healed in the Oasis group (55% vs. 34%). After adjusting for baseline ulcer size, patients in the Oasis group were 3 times more likely to achieve healing than those in the standard care group. Patients in the standard care group whose wounds did not heal by the 12th week were given the option to cross over to Oasis treatment. None of the healed patients treated with Oasis wound matrix and seen for the 6-month follow-up experienced ulcer recurrence.

A research group in Europe has described 2 comparative studies of the Oasis matrix for mixed arterial venous and venous ulcers. In a 2007 quasi-randomized study, Romanelli et al. compared the efficacy of 2 extracellular matrix-based products, Oasis and Hyaloskin (extracellular matrix with hyaluronic acid). (34) A total of 54 patients with mixed arterial/venous leg ulcers were assigned to the 2 arms based on order of entry into the study; 50 patients completed the study. Patients were followed up twice a week, and the dressings were changed more than once a week, only when necessary. After 16 weeks of treatment, complete wound closure was achieved in 82.6% of Oasis-treated ulcers compared with 46.2% of Hyaloskin-treated ulcers. Oasis treatment significantly increased the time to dressing change (mean of 6.4 vs. 2.4 days), reduced pain on a 10-point scale (3.7 vs. 6.2), and improved patient comfort (2.5 vs. 6.7).

In a 2010 trial, Romanelli et al. compared Oasis with a moist wound dressing in 23 patients with mixed arterial/venous ulcers and 27 patients with venous ulcers. (35) The study was described as randomized, but the method of randomization was not described. After the 8-week study period, patients were followed up monthly for 6 months to assess wound closure. Complete wound closure was achieved in 80% of the Oasis-treated ulcers at 8 weeks, compared to 65% of the standard of care group. On average, Oasis-treated ulcers achieved complete healing in 5.4 weeks as compared with 8.3 weeks for the standard of care group. Treatment with Oasis also increased the time to dressing change (5.2 vs. 2.1 days) and the percentage of granulation tissue formed (65% vs. 38%).

PriMatrix

In 2011, Karr published a retrospective comparison of PriMatrix and Apligraf in 28 venous stasis ulcers. (31) The first 14 venous stasis ulcers matching the inclusion and exclusion criteria for each graft were compared. Included were venous stasis ulcers of 4 weeks’ duration, at least 1 sq cm and depth to subcutaneous tissue, healthy tissue at the ulcer, adequate arterial perfusion to heal, and able to tolerate compression therapy. The products were placed on the wound with clean technique, overlapping the edges of the wound, and secured with sutures or staples. The time to complete healing for PriMatrix was 32 days with 1.3 applications compared to 63 days with 1.7 applications for Apligraf. Although promising, additional study with a larger number of subjects is needed to evaluate the effect of PriMatrix treatment in comparison with the current standard of care.

Dystrophic Epidermolysis Bullosa

Dermagraft had been FDA approved by a Humanitarian Device Exemption (HDE) for the treatment of dystrophic epidermolysis bullosa. The manufacturer has since withdrawn Dermagraft from HDE status.

OrCel is approved by an HDE 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.
As this is a rare disorder, it is unlikely that there will be randomized controlled trials to evaluate whether OrCel improves health outcomes for this condition. Dermagraft is no longer considered medically necessary for this indication, due to the withdrawal of HDE status.

In 2003, Fivenson et al. reported the off-label use of Apligraf in 5 patients with recessive dystrophic epidermolysis bullosa who underwent syndactyly release. (36)

Dermagraft, OrCel, and Apligraf are all living cell therapies. Apligraf is a bi-layered cell therapy composed of living human keratinocytes and fibroblasts, while OrCel is a bi-layered cellular matrix made of bovine collagen in which human dermal cells (fibroblasts and keratinocytes) have been cultured. Dermgraft is composed of cryopreserved human-derived fibroblasts and collagen on a bioabsorbable mesh.

**Ocular Burns**

A 2012 Cochrane review evaluated the evidence on amniotic membrane transplantation (AMT) for acute ocular burns. (37) Included in the review was a single randomized controlled trial from India of 68 patients with acute ocular burns who were randomized to treatment with AMT and medical therapy or medical therapy alone. In the subset of 36 patients with moderate ocular burns who were treated within 7 days, 13/20 (65.0%) of control eyes and 14/16 (87.5%) of AMT-treated eyes had complete epithelialization by 21 days. There was a trend (p=0.09) toward a reduced risk ratio of failure of epithelialization in the treatment group. Mean LogMAR [logarithm of the minimum angle of resolution] final visual acuities were 0.06 in the treatment group and 0.38 in the control group. In the subset of patients with severe ocular burns treated within 7 days, 1/17 (5.9%) of AMT-treated eyes and 1/15 (6.7%) control eyes were epithelialized by day 21. Final visual acuity was 1.77 logMAR in the treated eyes and 1.64 in the control group (not significantly different). The risk of bias was considered to be high because of differences between the groups at baseline and because outcome assessors could not be masked to treatment. The review determined that conclusive evidence supporting the treatment of acute ocular surface burns with AMT is lacking. It should also be noted that the amniotic membrane used in this study was fresh frozen and is not commercially available.

**Non-Ocular Burns**

**Epcel**

Epcel is FDA-approved under an HDE for the treatment of deep dermal or full-thickness burns comprising a total body surface area of greater than or equal to 30%. It is unlikely that there will be randomized controlled trials (RCTs) to evaluate whether Epcel® will improve health outcomes for this condition. One case series described the treatment of 30 severely burned patients with Epcel®. (38) The cultured epithelial autografts were applied to a mean 37% of total body surface area. Epcel® achieved permanent coverage of a mean 26% of total body surface area, an area greater than that covered by conventional autografts (a mean 25%). Survival was 90% in these severely burned patients.

**Integra Dermal Regeneration Template**

Branski et al. reported a randomized trial of Integra compared with a standard autograft-allograft technique in 20 children with an average burn size of 73% total body surface area (71% full-thickness burns) in 2007. (39) Once vascularized (about 14-21 days), the Silastic epidemis was stripped and replaced with thin (0.05-0.13 mm) epidermal autograft. There were no significant differences between the Integra group and controls in burn size (70% vs. 74% total body surface area).
area), mortality (40% vs. 30%), and length of stay (41 vs. 39 days - all respectively). Long-term follow-up revealed a significant increase in bone mineral content and density (24 months) and improved scarring in terms of height, thickness, vascularity, and pigmentation (12 months and 18-24 months) in the Integra group. No differences were observed between the groups in the time to first reconstructive procedure, cumulative reconstructive procedures required during 2 years, and the cumulative operating room time required for these procedures. The authors concluded that Integra can be used for immediate wound coverage in children with severe burns without the associated risks of cadaver skin.

In 2003, Heimback and colleagues reported a multicenter (13 U.S. burn care facilities) postapproval study involving 222 burn injury patients (36.5% total body surface area, range 1-95%) who were treated with Integra® Dermal Regeneration Template. (40) Within 2 to 3 weeks, the dermal layer regenerated, and a thin epidermal autograft was placed. The incidence of infection was 16.3%. Mean take rate (absence of graft failure) of Integra was 76.2%; the median take rate was 98%. The mean take rate of epidermal autograft placed over Integra was 87.7%; the median take rate was 95%.

OrCel
There is limited evidence to support the efficacy of OrCel compared to the standard of care for the treatment of split-thickness donor sites. Still et al. examined the safety and efficacy of bilayered OrCel to facilitate wound closure of split-thickness donor sites in 82 severely burned patients. (41) Each patient had 2 designated donor sites that were randomized to receive a single treatment of either OrCel or the standard dressing (Biobrane-L). The healing time for OrCel sites was significantly shorter than for sites treated with a standard dressing, enabling earlier recropping. OrCel sites also exhibited a non-significant trend for reduced scarring. Additional studies are needed to evaluate the effect of this product on health outcomes.

TransCyte
In 2001, Lukish et al. compared 20 consecutive cases of pediatric burns greater than 7% total body surface area that underwent wound closure with TransCyte with the previous 20 consecutive burn cases greater than 7% total body surface area that received standard therapy. (42) Standard therapy consisted of application of antimicrobial ointments and hydrodebridement. Only 1 child in the TransCyte group required autografting (5%), compared with 7 children in the standard therapy group (35%). Children treated with TransCyte had a statistically significant decreased length of stay compared with those receiving standard therapy, 5.9 days versus 13.8 days, respectively.

Amani et al. compared results from 110 consecutive patients with deep partial-thickness burns who were treated with Transcyte with data from the American Burn Association Patient Registry. (43) Significant differences were found in patients who were treated with dermabrasion and Transcyte compared to the population in the Registry. Patients with 0-19.9% total body surface area burn treated with dermabrasion and Transcyte had length of stay of 6.1 days versus 9.0 days (p<0.001). Those with 20-39.9% total body surface area burn had length of stay of 17.5 days versus 25.5 days. Patients who had 40-59.9% total body surface area burn had length of stay of 31 versus 44.6 days. The authors found this new method of managing patients with partial-thickness burns to be more efficacious and to significantly reduce length of stay compared to traditional management.
Biomembrane
A small (n=46) quasi-randomized trial compared treatment with amniotic membrane (Biomembrane) versus polyurethane membrane (Tegaderm) for patients with second- or third-degree burns covering less than 50% total body surface area. (44) Treatment with amniotic membrane significantly reduced occurrence of infection (4.3%) compared to treatment with polyurethane (13.0%). Pain during dressing was reduced in the group treated with amniotic membrane (43.5% vs. 60.9%), while the frequency of healing within the 11-20 day follow-up was greater (47.8% vs. 39.1%). It was not reported if the evaluators in this quasi-randomized study were blinded to treatment condition. In addition, this study did not have a control group treated with medical therapy alone.

Epifix
Although several small trials from the Middle East and Asia have evaluated locally harvested and processed amniotic membrane, no randomized controlled trials were identified with the commercially available Epifix amniotic membrane.

Traumatic Wounds
Use of Integra Dermal Regeneration Template has been reported in small case series (<20 patients) for the treatment of severe wounds with exposed bone, joint and/or tendon. (45-47) No controlled trials were identified.

Other
In addition to indications reviewed above, off-label uses of bio-engineered skin substitutes have included surgical wounds, pressure ulcers, split-thickness skin donor sites, inflammatory ulcers such as pyoderma gangrenosum and vasculitis, scleroderma digital ulcers, post-keloid removal wounds, genetic conditions, and variety of other conditions. (48) In addition, products that have been FDA approved/cleared for one indication (e.g., lower extremity ulcers) have been used off-label in place of other FDA approved/cleared products (e.g., for burns). (49) No controlled trials were identified for these indications. Therefore, they are considered investigational.

Clinical Input Obtained Through Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2008
In response to requests for input on use of AlloDerm in breast reconstruction surgery, input was received from 1 physician specialty society (2 physicians) and 1 academic medical center while this policy was under review in 2008. All reviewers indicated that this procedure should be available for use during breast reconstruction surgery.

2011
In response to requests, input was received from 3 physician specialty societies and 2 academic medical centers while this policy was under review in 2011. A majority of reviewers supported the indications and products as described in this policy. Clinical input was requested regarding the use of an interpositional spacer after parotidectomy. Support for this indication was mixed. Some reviewers suggested use of other products and/or additional indications; however, the input on
these products/indications was not uniform. The reviewers provided references for the additional indications; these were subsequently reviewed.

**Summary**

Bio-engineered skin and soft tissue substitutes are being evaluated for a variety of conditions. Overall, the number of bio-engineered skin and soft-tissue substitutes is large, but the evidence is limited for any specific product. Relatively few products have been compared with the standard of care, and then only for some indications. A few comparative trials have been identified for use in lower extremity ulcers (diabetic or venous) and for treatment of burns. In these trials, there is a roughly 15% to 20% increase in the rate of healing. Several other products/indications are supported by either clinical input or by an FDA HDE.

**Breast Reconstruction**

Given the extensive data from controlled cohorts and case series, as well as the clinical input obtained about the usefulness of this procedure in providing inferolateral support for breast reconstruction, use of AlloDerm may be considered medically necessary in 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 infra-mammary fold and lateral mammary folds have been undermined during mastectomy and re-establishment of these landmarks is needed.

**Interpositional Graft after Parotidectomy**

Two lower quality controlled trials were identified that demonstrated a reduction in the incidence of Frey syndrome with use of an interpositional acellular dermal matrix graft. Neither study described the method of group assignment or blinding of patients and assessors. In addition, clinical input regarding the use of an interpositional spacer after parotidectomy was not uniform. Therefore, bio-engineered skin and soft tissue substitutes are considered investigational to fill in contour defects and prevent Frey syndrome after parotidectomy.

**Tendon Repair**

One small randomized controlled trial was identified that found improved outcomes with GraftJacket acellular human dermal matrix for rotator cuff repair. Although these results are promising, additional study with a larger number of subjects is needed. Therefore, this use is considered investigational.

**Fistula Repair**

One randomized controlled trial was identified that used an acellular dermal matrix product that has not been cleared for marketing in the U.S. Therefore, the use of this product for fistula repair is considered investigational.

**Surgical Repair of Hernias**

The limited evidence available does not support the efficacy of any tissue-engineered skin substitute for surgical repair of hernias. Therefore, this use is considered investigational.

**Oral Surgery**

Use of acellular human dermal matrix (AlloDerm) has been reported for root coverage therapy and oral cavity reconstruction following surgical removal of tumors. Although AlloDerm may
possibly result in less scar contracture, results to date have not shown an improvement over the standard of care. Therefore, this use is considered investigational.

**Laryngoplasty**
The effect of micronized AlloDerm (Cymetra) in laryngoplasty has been reported in case series. Longer-term controlled study in a larger number of patients is needed to determine the durability of this procedure and to evaluate the safety of repeat injections.

**Tympanoplasty**
AlloDerm has been compared with native tissue grafts in a non-randomized controlled study. There was no significant difference in the success rate of the graft (88% for AlloDerm, 89% for fascia grafts, 96.7% for cartilage plus fascia), and there was no significant difference in hearing between the groups at follow-up. Longer-term controlled study in a larger number of patients is needed to determine the durability of this procedure.

**Diabetic Lower Extremity Ulcers**
Randomized controlled trials have demonstrated the efficacy of Apligraf and Dermagraft over the standard of care. Use of these products may be considered medically necessary for the treatment of diabetic lower extremity ulcers. Additional study with a larger number of subjects is needed to evaluate the effect of PriMatrix treatment in comparison with the current standard of care.

**Lower Extremity Ulcers Due to Venous Insufficiency**
Randomized controlled trials have demonstrated the efficacy of Apligraf and Oasis Wound Matrix over the standard of care. Use of these products may be considered medically necessary for lower extremity ulcers due to venous insufficiency. Additional study with a larger number of subjects is needed to evaluate the effect of PriMatrix treatment in comparison with the current standard of care.

**Dystrophic Epidermolysis Bullosa**
OrCel has received approval via a Humanitarian Device Exemption (HDE). As this is a rare disorder and it is unlikely that there will be randomized controlled trials, Orcell is considered medically necessary for this indication.

**Ocular Burns**
Evidence is insufficient to evaluate the efficacy of human amniotic membrane for ocular burns. This is considered investigational.

**Non-Ocular Burns**
Epicel is FDA-approved under a HDE for the treatment of deep dermal or full-thickness burns comprising a total body surface area of greater than or equal to 30%. This treatment may be considered medically necessary according to the HDE indications.

Comparative studies have demonstrated improved outcomes for Integra Dermal Regeneration Template and Transcyte for the treatment of burns; therefore, these are considered medically necessary.
Traumatic Wounds
Use of Integra Dermal Regeneration Template has been reported in small case series (<20 patients) for the treatment of severe wounds with exposed bone, joint, and/or tendon. Controlled trials are needed to evaluate this product/indication.

All other uses of the bio-engineered skin and soft-tissue substitutes are considered investigational.

Practice Guidelines and Position Statements
In 2006, the American Society of Plastic Surgeons (ASPS) endorsed guidelines from the Wound Healing Society on the treatment of arterial insufficiency ulcers. (50) The guidelines state that extracellular matrix replacement therapy appears to be promising for mixed ulcers and may have a role as an adjuvant agent in arterial ulcers, but further study is required. (Level IIIC) “Despite the existence of animal studies, case series, and a small number of random control trials to support biomaterial use for pressure ulcers, diabetic ulcers, and venous ulcers; there are no studies specifically on arterial ulcers. Therefore, studies in arterial ulcers must be conducted before the recommendation can be made.”

The ASPS endorsed guidelines from the Wound Healing Society on the treatment of venous ulcers in 2006. (51) The guidelines state that various skin substitutes or biologically active dressings are emerging that provide temporary wound closure and serve as a source of stimuli (e.g., growth factors) for healing of venous ulcers. Guideline #7b.1 states that there is evidence that a bilayered artificial skin (biologically active dressing), used in conjunction with compression bandaging, increases the chance of healing a venous ulcer compared with compression and a simple dressing (Level I).

The ASPS also endorsed guidelines from the Wound Healing Society on the treatment of diabetic ulcers in 2006. (52) The guidelines state that healthy living skin cells assist in healing diabetic foot ulcers by releasing therapeutic amounts of growth factors, cytokines, and other proteins that stimulate the wound bed. Guideline #7.2.2 states that living skin equivalents may be of benefit in healing diabetic foot ulcers. (Level I)

The 2007 guidelines from the ASPS on chronic wounds of the lower extremity state that maintaining a moist environment, while simultaneously removing soluble factors detrimental to wound healing might logically provide optimal conditions for wound healing. (53) Classic dressings include gauze, foam, hydrocolloid, and hydrogels. Fluid-handling mechanisms include absorption, gelling, retention and vapor transmission. Bioactive dressings include topical antimicrobials, bioengineered composite skin equivalent, bilaminar dermal regeneration template, and recombinant human growth factor.

The 2011 Guidance from the United Kingdom’s National Institute for Health and Clinical Excellence recommends not to use dermal or skin substitutes for the inpatient management of diabetic foot problems, unless part of a clinical trial. (54)

The 2006 guidelines on diabetic foot disorders from the American College of Foot and Ankle Surgeons (ACFAS) state that bioengineered tissues have been shown to significantly increase complete wound closure in venous and diabetic foot ulcers. (55) Tissue-engineered skin substitutes can function both as biologic dressings and as delivery systems for growth factors and extracellular matrix components through the activity of live human fibroblasts contained in their
dermal elements. Currently, two bioengineered tissues have been approved to treat diabetic foot ulcers in the U.S.: Apligraf™ (Organogenesis Inc., Canton, MA), and Dermagraft™ (Smith & Nephew, Inc., London, UK); both have demonstrated efficacy in randomized, controlled trials. Apligraf™ has been shown to significantly reduce the time to complete wound closure in venous and diabetic ulcers. Regenerative tissue matrix (GraftJacket™, Wright, Arlington, TN) is a new therapy used in diabetic foot ulcers, although it had not undergone any randomized clinical trials at the time of this guideline. This allograft skin is minimally processed to remove epidermal and dermal cells while preserving the bioactive components and structure of dermis. This results in a framework that supports cellular repopulation and vascularization.

In 2004, the Infectious Diseases Society of America (IDSA) provided the following information on adjunctive treatments for infected wounds: “Investigators and industry representatives have advocated many types of wound-care treatments, including wound vacuum-drainage systems, recombinant growth factors, skin substitutes, antimicrobial dressings, and maggot (sterile larvae) therapy. Although each treatment likely has some appropriate indications, for infected wounds, available evidence is insufficient to recommend routine use of any of these modalities for treatment or prophylaxis.” (56)

**CODING**

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) 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 of these services as it applies to an individual member.

**CPT/HCPCS**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>15040</td>
<td>Harvest of skin for tissue cultured skin autograft, 100 sq cm or less</td>
</tr>
<tr>
<td>15050</td>
<td>Pinch graft, single or multiple, to cover small ulcer, tip of digit, or other minimal open area (except on face), up to defect size 2 cm diameter</td>
</tr>
<tr>
<td>15100</td>
<td>Split-thickness autograft, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children (except 15050)</td>
</tr>
<tr>
<td>15101</td>
<td>Split-thickness autograft, trunk, arms, legs; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>15110</td>
<td>Epidermal autograft, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children</td>
</tr>
<tr>
<td>15111</td>
<td>Epidermal autograft, trunk, arms, legs; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>15115</td>
<td>Epidermal autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children</td>
</tr>
<tr>
<td>15116</td>
<td>Epidermal autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>-------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>15120</td>
<td>Split-thickness autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children (except 15050)</td>
</tr>
<tr>
<td>15121</td>
<td>Split-thickness autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>15130</td>
<td>Dermal autograft, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children</td>
</tr>
<tr>
<td>15131</td>
<td>Dermal autograft, trunk, arms, legs; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>15135</td>
<td>Dermal autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children</td>
</tr>
<tr>
<td>15136</td>
<td>Dermal autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>15150</td>
<td>Tissue cultured skin autograft, trunk, arms, legs; first 25 sq cm or less</td>
</tr>
<tr>
<td>15151</td>
<td>Tissue cultured skin autograft, trunk, arms, legs; additional 1 sq cm to 75 sq cm (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>15152</td>
<td>Tissue cultured skin autograft, trunk, arms, legs; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>15155</td>
<td>Tissue cultured skin autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 25 sq cm or less</td>
</tr>
<tr>
<td>15156</td>
<td>Tissue cultured skin autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; additional 1 sq cm to 75 sq cm (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>15157</td>
<td>Tissue cultured skin autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>15271</td>
<td>Application of skin substitutes graft to trunk, arms, legs total wound surface area up to 100 sq cm; first 24 sq cm or less wound surface area</td>
</tr>
<tr>
<td>15272</td>
<td>Application of skin substitutes 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)</td>
</tr>
<tr>
<td>15273</td>
<td>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</td>
</tr>
<tr>
<td>15274</td>
<td>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)</td>
</tr>
<tr>
<td>15275</td>
<td>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</td>
</tr>
</tbody>
</table>
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)

C9354 Acellular pericardial tissue matrix of nonhuman origin (Veritas), per sq cm
C9355 Collagen nerve cuff (NeuroMatrix), per 0.5 cm length
C9356 Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix (TenoGlide Tendon Protector Sheet), per sq cm
C9358 Dermal substitute, native, nonenatured collagen, fetal bovine origin (SurgiMend Collagen Matrix), per 0.5 sq cm
C9360 Dermal substitute, native, nonenatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 sq cm
C9361 Collagen matrix nerve wrap (NeuroMend Collagen Nerve Wrap), per 0.5 cm length
C9363 Skin substitute (Integra Meshed Bilayer Wound Matrix), per square cm
C9364 Porcine implant, Permacol, per sq cm
Q4100 Skin substitute, not otherwise specified
Q4101 Apligraf, per sq cm
Q4102 Oasis wound matrix, per sq cm
Q4103 Oasis burn matrix, per sq cm
Q4104 Integra bilayer matrix wound dressing (BMWD), per sq cm
Q4105 Integra dermal regeneration template (DRT), per sq cm
Q4106 Dermagraft, per sq cm
Q4107 GRAFTJACKET, 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 express, injectable, 1cc
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, PSMX, RS, or PSM, per sq cm
Q4120 MatriStem burn matrix, per sq cm
Q4121 TheraSkin, per sq cm
Q4122 DermACELL, per square centimeter
Bio-Engineered Skin and Soft Tissue Substitutes

Q4123 Alloskin RT, per square centimeter
Q4124 Oasis Ultra Tri-Layer Matrix, per square centimeter
Q4125 Arthroflex, per square centimeter
Q4126 MemoDerm, DermaSpan, TranZgraft or InteguPly, per sq cm
Q4127 Talymed per square centimeter
Q4128 FlexHD, AllopatchHD, or Matrix HD, per sq cm
Q4129 Unite Biomatrix, per square centimeter
Q4130 Strattice TM, per square centimeter
Q4131 EpiFix, per sq cm
Q4132 Grafix core, per sq cm
Q4133 Grafix prime, per sq cm
Q4134 hMatrix, per sq cm
Q4135 Mediskin, per sq cm
Q4136 E-Z Derm, per sq cm
Q4137 AmnioExCel per square centimeter
Q4138 BioDfence Dryflex per square centimeter
Q4139 AmnioMatrix or BioDMatrix, injectable, 1 cc
Q4140 BioDfense, per square centimeter
Q4141 Alloskin AC, per square centimeter
Q4142 XCM Biologic Tissue Matrix, per square centimeter
Q4143 Repriza, per square centimeter
Q4145 Epifix, injectable, 1 mg
Q4146 TenSIX, per square centimeter
Q4147 Architect Extracellular Matrix, per square centimeter
Q4148 NEOX 1K, per square centimeter
Q4149 Excellagen, 0.1 cc

Application of skin replacements and skin substitutes is reported with CPT codes 15040-15278.
- Codes 15040-5261 are specific to autografts and tissue-cultured autografts.
- Codes 15271-15278 are specific to skin substitutes.
- Effective in 2012 there is a specific add-on CPT code for the use of these materials as an implant: 15777.
- The HCPCS codes for these products that are used in outpatient and office settings are listed in the code table. There are also HCPCS modifiers to indicate whether the skin substitute is or is not used as a graft (i.e., surface use vs. use as an implant):
  -JC: Skin substitute used as a graft
  -JD: Skin substitute not used as a graft

ICD-9 Diagnoses
174.0-174.9 Malignant neoplasm of female breast
233.0 Carcinoma in situ of breast
250.60-250.63 Diabetes with neurological manifestations
250.80-250.83 Diabetes with other specified manifestations
454.0-454.2 Varicose veins of lower extremities with ulcer / inflammation
459.81 Venous (peripheral) insufficiency, unspecified
707.00-707.09 Decubitus ulcer
707.10-707.19 Ulcer of the lower limbs, except decubitus
707.20-707.25 Pressure ulcer stages
707.8 Chronic ulcer of other specified sites
707.9 Chronic ulcer of unspecified sites
757.39 Other specified anomalies of skin (epidermolysis bullosa)
941.20-941.59 Burn of face, head, and neck, second or third degree
942.20-942.59 Burn of trunk, second or third degree
943.20-943.59 Burn of upper limb, second or third degree
944.20-944.58 Burn of wrist(s) and hand(s), second or third degree
945.20-945.59 Burn of lower limb(s), second or third degree
946.2-946.5 Burn of multiple specified sites, second or third degree
948.00-948.99 Burn classified according to extent of body surface involved (specified as second or third degree)
949.2-949.5 Burn, unspecified, second or third degree
V10.3 Personal history of malignant neoplasm, breast
V45.71 Acquired absence of breast and nipple
V84.01 Genetic susceptibility to malignant neoplasm of breast

ICD-10 Diagnoses (Effective October 1, 2014)
C50.011 Malignant neoplasm of nipple and areola, right female breast
C50.012 Malignant neoplasm of nipple and areola, left female breast
C50.111 Malignant neoplasm of central portion of right female breast
C50.112 Malignant neoplasm of central portion of left female 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
C50.311 Malignant neoplasm of lower-inner quadrant of right female breast
C50.312 Malignant neoplasm of lower-inner quadrant of left female 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
C50.511 Malignant neoplasm of lower-outer quadrant of right female breast
C50.512 Malignant neoplasm of lower-outer quadrant of left female breast
C50.611 Malignant neoplasm of axillary tail of right female breast
C50.612 Malignant neoplasm of axillary tail of left female breast
C50.811 Malignant neoplasm of overlapping sites of right female breast
C50.812 Malignant neoplasm of overlapping sites of left female breast
D05.01 Lobular carcinoma in situ of right breast
D05.02 Lobular carcinoma in situ of left breast
D05.11 Intraductal carcinoma in situ of right breast
D05.12 Intraductal carcinoma in situ of left breast
D05.81 Other specified type of carcinoma in situ of right breast
D05.82 Other specified type of carcinoma in situ of left breast
E10.40 Type 1 diabetes mellitus with diabetic neuropathy, unspecified
E10.41 Type 1 diabetes mellitus with diabetic mononeuropathy
E10.42 Type 1 diabetes mellitus with diabetic polyneuropathy
E10.43 Type 1 diabetes mellitus with diabetic autonomic (poly)neuropathy
E10.44 Type 1 diabetes mellitus with diabetic amyotrophy
E10.49 Type 1 diabetes mellitus with other diabetic neurological complication
E10.610 Type 1 diabetes mellitus with diabetic neuropathic arthropathy
E10.618 Type 1 diabetes mellitus with other diabetic arthropathy
E10.621 Type 1 diabetes mellitus with foot ulcer
E10.69 Type 1 diabetes mellitus with other specified complication
E11.40 Type 2 diabetes mellitus with diabetic neuropathy, unspecified
E11.41 Type 2 diabetes mellitus with diabetic mononeuropathy
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E11.42</td>
<td>Type 2 diabetes mellitus with diabetic polyneuropathy</td>
</tr>
<tr>
<td>E11.43</td>
<td>Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy</td>
</tr>
<tr>
<td>E11.44</td>
<td>Type 2 diabetes mellitus with diabetic amyotrophy</td>
</tr>
<tr>
<td>E11.49</td>
<td>Type 2 diabetes mellitus with other diabetic neurological complication</td>
</tr>
<tr>
<td>E11.610</td>
<td>Type 2 diabetes mellitus with diabetic neuropathic arthropathy</td>
</tr>
<tr>
<td>E11.618</td>
<td>Type 2 diabetes mellitus with other diabetic arthropathy</td>
</tr>
<tr>
<td>E11.621</td>
<td>Type 2 diabetes mellitus with foot ulcer</td>
</tr>
<tr>
<td>E11.69</td>
<td>Type 2 diabetes mellitus with other specified complication</td>
</tr>
<tr>
<td>E13.40</td>
<td>Other specified diabetes mellitus with diabetic neuropathy, unspecified</td>
</tr>
<tr>
<td>E13.41</td>
<td>Other specified diabetes mellitus with diabetic mononeuropathy</td>
</tr>
<tr>
<td>E13.42</td>
<td>Other specified diabetes mellitus with diabetic polyneuropathy</td>
</tr>
<tr>
<td>E13.43</td>
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<td>E13.49</td>
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<td>E13.610</td>
<td>Other specified diabetes mellitus with diabetic neuropathic arthropathy</td>
</tr>
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<td>E13.618</td>
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</tr>
<tr>
<td>E13.621</td>
<td>Other specified diabetes mellitus with foot ulcer</td>
</tr>
<tr>
<td>E13.69</td>
<td>Other specified diabetes mellitus with other specified complication</td>
</tr>
<tr>
<td>I83.011</td>
<td>Varicose veins of right lower extremity with ulcer of thigh</td>
</tr>
<tr>
<td>I83.012</td>
<td>Varicose veins of right lower extremity with ulcer of calf</td>
</tr>
<tr>
<td>I83.013</td>
<td>Varicose veins of right lower extremity with ulcer of ankle</td>
</tr>
<tr>
<td>I83.014</td>
<td>Varicose veins of right lower extremity with ulcer of heel and midfoot</td>
</tr>
<tr>
<td>I83.015</td>
<td>Varicose veins of right lower extremity with ulcer other part of foot</td>
</tr>
<tr>
<td>I83.018</td>
<td>Varicose veins of right lower extremity with ulcer other part of lower leg</td>
</tr>
<tr>
<td>I83.021</td>
<td>Varicose veins of left lower extremity with ulcer of thigh</td>
</tr>
<tr>
<td>I83.022</td>
<td>Varicose veins of left lower extremity with ulcer of calf</td>
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<td>I83.023</td>
<td>Varicose veins of left lower extremity with ulcer of ankle</td>
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<td>Varicose veins of left lower extremity with ulcer of heel and midfoot</td>
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<tr>
<td>I83.025</td>
<td>Varicose veins of left lower extremity with ulcer other part of foot</td>
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<tr>
<td>I83.028</td>
<td>Varicose veins of left lower extremity with ulcer other part of lower leg</td>
</tr>
<tr>
<td>I83.11</td>
<td>Varicose veins of right lower extremity with inflammation</td>
</tr>
<tr>
<td>I83.12</td>
<td>Varicose veins of left lower extremity with inflammation</td>
</tr>
<tr>
<td>I83.211</td>
<td>Varicose veins of right lower extremity with both ulcer of thigh and inflammation</td>
</tr>
<tr>
<td>I83.212</td>
<td>Varicose veins of right lower extremity with both ulcer of calf and inflammation</td>
</tr>
<tr>
<td>I83.213</td>
<td>Varicose veins of right lower extremity with both ulcer of ankle and inflammation</td>
</tr>
<tr>
<td>I83.214</td>
<td>Varicose veins of right lower extremity with both ulcer of heel and midfoot and inflammation</td>
</tr>
<tr>
<td>I83.215</td>
<td>Varicose veins of right lower extremity with both ulcer other part of foot and inflammation</td>
</tr>
<tr>
<td>I83.218</td>
<td>Varicose veins of right lower extremity with both ulcer of other part of lower extremity and inflammation</td>
</tr>
<tr>
<td>I83.221</td>
<td>Varicose veins of left lower extremity with both ulcer of thigh and inflammation</td>
</tr>
<tr>
<td>I83.222</td>
<td>Varicose veins of left lower extremity with both ulcer of calf and inflammation</td>
</tr>
<tr>
<td>I83.223</td>
<td>Varicose veins of left lower extremity with both ulcer of ankle and inflammation</td>
</tr>
<tr>
<td>I83.224</td>
<td>Varicose veins of left lower extremity with both ulcer of heel and midfoot and inflammation</td>
</tr>
<tr>
<td>I83.225</td>
<td>Varicose veins of left lower extremity with both ulcer other part of foot and inflammation</td>
</tr>
<tr>
<td>I83.228</td>
<td>Varicose veins of left lower extremity with both ulcer of other part of lower extremity and inflammation</td>
</tr>
<tr>
<td>I87.2</td>
<td>Venous insufficiency (chronic) (peripheral)</td>
</tr>
<tr>
<td>L89.010</td>
<td>Pressure ulcer of right elbow, unstageable</td>
</tr>
<tr>
<td>L89.012</td>
<td>Pressure ulcer of right elbow, stage 2</td>
</tr>
<tr>
<td>L89.013</td>
<td>Pressure ulcer of right elbow, stage 3</td>
</tr>
<tr>
<td>L89.014</td>
<td>Pressure ulcer of right elbow, stage 4</td>
</tr>
</tbody>
</table>
Pressure ulcer of left elbow, unstageable
Pressure ulcer of left elbow, stage 2
Pressure ulcer of left elbow, stage 3
Pressure ulcer of left elbow, stage 4
Pressure ulcer of right upper back, unstageable
Pressure ulcer of right upper back, stage 2
Pressure ulcer of right upper back, stage 3
Pressure ulcer of right upper back, stage 4
Pressure ulcer of left upper back, unstageable
Pressure ulcer of left upper back, stage 2
Pressure ulcer of left upper back, stage 3
Pressure ulcer of left upper back, stage 4
Pressure ulcer of right lower back, unstageable
Pressure ulcer of right lower back, stage 2
Pressure ulcer of right lower back, stage 3
Pressure ulcer of right lower back, stage 4
Pressure ulcer of left lower back, unstageable
Pressure ulcer of left lower back, stage 2
Pressure ulcer of left lower back, stage 3
Pressure ulcer of left lower back, stage 4
Pressure ulcer of sacral region, unstageable
Pressure ulcer of sacral region, stage 2
Pressure ulcer of sacral region, stage 3
Pressure ulcer of sacral region, stage 4
Pressure ulcer of right hip, unstageable
Pressure ulcer of right hip, stage 2
Pressure ulcer of right hip, stage 3
Pressure ulcer of right hip, stage 4
Pressure ulcer of left hip, unstageable
Pressure ulcer of left hip, stage 2
Pressure ulcer of left hip, stage 3
Pressure ulcer of left hip, stage 4
Pressure ulcer of right buttock, unstageable
Pressure ulcer of right buttock, stage 2
Pressure ulcer of right buttock, stage 3
Pressure ulcer of right buttock, stage 4
Pressure ulcer of left buttock, unstageable
Pressure ulcer of left buttock, stage 2
Pressure ulcer of left buttock, stage 3
Pressure ulcer of left buttock, stage 4
Pressure ulcer of contiguous site of back, buttock and hip, stage 2
Pressure ulcer of contiguous site of back, buttock and hip, stage 3
Pressure ulcer of contiguous site of back, buttock and hip, stage 4
Pressure ulcer of right ankle, unstageable
Pressure ulcer of right ankle, stage 2
Pressure ulcer of right ankle, stage 3
Pressure ulcer of right ankle, stage 4
Pressure ulcer of left ankle, unstageable
Pressure ulcer of left ankle, stage 2
Pressure ulcer of left ankle, stage 3
L89.524  Pressure ulcer of left ankle, stage 4
L89.610  Pressure ulcer of right heel, unstageable
L89.612  Pressure ulcer of right heel, stage 2
L89.613  Pressure ulcer of right heel, stage 3
L89.614  Pressure ulcer of right heel, stage 4
L89.620  Pressure ulcer of left heel, unstageable
L89.622  Pressure ulcer of left heel, stage 2
L89.623  Pressure ulcer of left heel, stage 3
L89.624  Pressure ulcer of left heel, stage 4
L89.810  Pressure ulcer of head, unstageable
L89.812  Pressure ulcer of head, stage 2
L89.813  Pressure ulcer of head, stage 3
L89.814  Pressure ulcer of head, stage 4
L97.112  Non-pressure chronic ulcer of right thigh with fat layer exposed
L97.122  Non-pressure chronic ulcer of left thigh with fat layer exposed
L97.212  Non-pressure chronic ulcer of right calf with fat layer exposed
L97.222  Non-pressure chronic ulcer of left calf with fat layer exposed
L97.312  Non-pressure chronic ulcer of right ankle with fat layer exposed
L97.322  Non-pressure chronic ulcer of left ankle with fat layer exposed
L97.412  Non-pressure chronic ulcer of right heel and midfoot with fat layer exposed
L97.422  Non-pressure chronic ulcer of left heel and midfoot with fat layer exposed
L97.512  Non-pressure chronic ulcer of other part of right foot with fat layer exposed
L97.522  Non-pressure chronic ulcer of other part of left foot with fat layer exposed
L97.812  Non-pressure chronic ulcer of other part of right lower leg with fat layer exposed
L97.822  Non-pressure chronic ulcer of other part of left lower leg with fat layer exposed
L97.912  Non-pressure chronic ulcer of unspecified part of right lower leg with fat layer exposed
L97.922  Non-pressure chronic ulcer of unspecified part of left lower leg with fat layer exposed
L98.412  Non-pressure chronic ulcer of buttock with fat layer exposed
L98.422  Non-pressure chronic ulcer of back with fat layer exposed
L98.492  Non-pressure chronic ulcer of skin of other sites with fat layer exposed
Q81.2   Epidermolysis bullosa dystrophica
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
T20.22xA  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
T20.311A  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
T20.32xA  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
T20.611A  Corrosion of second degree of right ear [any part, except ear drum], initial encounter
T20.611D  Corrosion of second degree of right ear [any part, except ear drum], subsequent encounter
T20.611S  Corrosion of second degree of right ear [any part, except ear drum], sequela
T20.62xA  Corrosion of second degree of lip(s), initial encounter
T20.62xD  Corrosion of second degree of lip(s), subsequent encounter
T20.62xS  Corrosion of second degree of lip(s), sequela
T20.63xA  Corrosion of second degree of chin, initial encounter
T20.63xD  Corrosion of second degree of chin, subsequent encounter
T20.63xS  Corrosion of second degree of chin, sequela
T20.64xA  Corrosion of second degree of nose (septum), initial encounter
T20.64xD Corrosion of second degree of nose (septum), subsequent encounter
T20.64xS Corrosion of second degree of nose (septum), sequela
T20.65xA Corrosion of second degree of scalp [any part], initial encounter
T20.65xD Corrosion of second degree of scalp [any part], subsequent encounter
T20.65xS Corrosion of second degree of scalp [any part], sequela
T20.66xA Corrosion of second degree of forehead and cheek, initial encounter
T20.66xD Corrosion of second degree of forehead and cheek, subsequent encounter
T20.66xS Corrosion of second degree of forehead and cheek, sequela
T20.67xA Corrosion of second degree of neck, initial encounter
T20.67xD Corrosion of second degree of neck, subsequent encounter
T20.67xS Corrosion of second degree of neck, sequela
T20.69xA Corrosion of second degree of multiple sites of head, face, and neck, initial encounter
T20.69xD Corrosion of second degree of multiple sites of head, face, and neck, subsequent encounter
T20.69xS Corrosion of second degree of multiple sites of head, face, and neck, sequela
T20.711A Corrosion of third degree of right ear [any part, except ear drum], initial encounter
T20.711D Corrosion of third degree of right ear [any part, except ear drum], subsequent encounter
T20.711S Corrosion of third degree of right ear [any part, except ear drum], sequela
T20.712A Corrosion of third degree of left ear [any part, except ear drum], initial encounter
T20.712D Corrosion of third degree of left ear [any part, except ear drum], subsequent encounter
T20.712S Corrosion of third degree of left ear [any part, except ear drum], sequela
T20.72xA Corrosion of third degree of lip(s), initial encounter
T20.72xD Corrosion of third degree of lip(s), subsequent encounter
T20.72xS Corrosion of third degree of lip(s), sequela
T20.73xA Corrosion of third degree of chin, initial encounter
T20.73xD Corrosion of third degree of chin, subsequent encounter
T20.73xS Corrosion of third degree of chin, sequela
T20.74xA Corrosion of third degree of nose (septum), initial encounter
T20.74xD Corrosion of third degree of nose (septum), subsequent encounter
T20.74xS Corrosion of third degree of nose (septum), sequela
T20.75xA Corrosion of third degree of scalp [any part], initial encounter
T20.75xD Corrosion of third degree of scalp [any part], subsequent encounter
T20.75xS Corrosion of third degree of scalp [any part], sequela
T20.76xA Corrosion of third degree of forehead and cheek, initial encounter
T20.76xD Corrosion of third degree of forehead and cheek, subsequent encounter
T20.76xS Corrosion of third degree of forehead and cheek, sequela
T20.77xA Corrosion of third degree of neck, initial encounter
T20.77xD Corrosion of third degree of neck, subsequent encounter
T20.77xS Corrosion of third degree of neck, sequela
T20.79xA Corrosion of third degree of multiple sites of head, face, and neck, initial encounter
T20.79xD Corrosion of third degree of multiple sites of head, face, and neck, subsequent encounter
T20.79xS Corrosion of third degree of multiple sites of head, face, and neck, 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


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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
T21.25xS Burn of second degree of buttock, sequela
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
T21.31xA 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
T21.61xA Corrosion of second degree of chest wall, initial encounter
T21.61xD Corrosion of second degree of chest wall, subsequent encounter
T21.61xS Corrosion of second degree of chest wall, sequela
T21.62xA Corrosion of second degree of abdominal wall, initial encounter
T21.62xD Corrosion of second degree of abdominal wall, subsequent encounter
T21.62xS Corrosion of second degree of abdominal wall, sequela
T21.63xA Corrosion of second degree of upper back, initial encounter
T21.63xD Corrosion of second degree of upper back, subsequent encounter
T21.63xS Corrosion of second degree of upper back, sequela
T21.64xA Corrosion of second degree of lower back, initial encounter
T21.64xD Corrosion of second degree of lower back, subsequent encounter
T21.64xS Corrosion of second degree of lower back, sequela
T21.65xA Corrosion of second degree of buttock, initial encounter
T21.65xD  Corrosion of second degree of buttock, subsequent encounter
T21.65xS  Corrosion of second degree of buttock, sequela
T21.66xA  Corrosion of second degree of male genital region, initial encounter
T21.66xD  Corrosion of second degree of male genital region, subsequent encounter
T21.67xA  Corrosion of second degree of female genital region, initial encounter
T21.67xD  Corrosion of second degree of female genital region, subsequent encounter
T21.67xS  Corrosion of second degree of female genital region, sequela
T21.69xA  Corrosion of second degree of other site of trunk, initial encounter
T21.69xD  Corrosion of second degree of other site of trunk, subsequent encounter
T21.69xS  Corrosion of second degree of other site of trunk, sequela
T21.71xA  Corrosion of third degree of chest wall, initial encounter
T21.71xD  Corrosion of third degree of chest wall, subsequent encounter
T21.71xS  Corrosion of third degree of chest wall, sequela
T21.72xA  Corrosion of third degree of abdominal wall, initial encounter
T21.72xD  Corrosion of third degree of abdominal wall, subsequent encounter
T21.72xS  Corrosion of third degree of abdominal wall, sequela
T21.73xA  Corrosion of third degree of upper back, initial encounter
T21.73xD  Corrosion of third degree of upper back, subsequent encounter
T21.73xS  Corrosion of third degree of upper back, sequela
T21.74xA  Corrosion of third degree of lower back, initial encounter
T21.74xD  Corrosion of third degree of lower back, subsequent encounter
T21.74xS  Corrosion of third degree of lower back, sequela
T21.75xA  Corrosion of third degree of male genital region, initial encounter
T21.76xA  Corrosion of third degree of male genital region, initial encounter
T21.76xD  Corrosion of third degree of male genital region, subsequent encounter
T21.76xS  Corrosion of third degree of male genital region, sequela
T21.77xA  Corrosion of third degree of female genital region, initial encounter
T21.77xD  Corrosion of third degree of female genital region, subsequent encounter
T21.77xS  Corrosion of third degree of female genital region, sequela
T21.79xA  Corrosion of third degree of other site of trunk, initial encounter
T21.79xD  Corrosion of third degree of other site of trunk, subsequent encounter
T21.79xS  Corrosion of third degree of other site of trunk, 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
T22.221A  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
T22.231A  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
<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>T22.232D</td>
<td>Burn of second degree of left upper arm, subsequent encounter</td>
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<td>Burn of second degree of left upper arm, sequela</td>
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<tr>
<td>T22.241A</td>
<td>Burn of second degree of right axilla, initial encounter</td>
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<td>T22.241D</td>
<td>Burn of second degree of right axilla, subsequent encounter</td>
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<td>T22.242A</td>
<td>Burn of second degree of left axilla, initial encounter</td>
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<td>Burn of second degree of left axilla, sequela</td>
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<td>T22.251A</td>
<td>Burn of second degree of right shoulder, initial encounter</td>
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<td>T22.251D</td>
<td>Burn of second degree of right shoulder, subsequent encounter</td>
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<td>T22.252A</td>
<td>Burn of second degree of left shoulder, initial encounter</td>
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<td>Burn of second degree of left shoulder, subsequent encounter</td>
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<td>T22.252S</td>
<td>Burn of second degree of left shoulder, sequela</td>
</tr>
<tr>
<td>T22.261A</td>
<td>Burn of second degree of right scapular region, initial encounter</td>
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<td>T22.261D</td>
<td>Burn of second degree of right scapular region, subsequent encounter</td>
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<td>T22.262A</td>
<td>Burn of second degree of left scapular region, initial encounter</td>
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<td>T22.262D</td>
<td>Burn of second degree of left scapular region, subsequent encounter</td>
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<tr>
<td>T22.291A</td>
<td>Burn of second degree of multiple sites of right shoulder and upper limb, except wrist and hand, initial encounter</td>
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<tr>
<td>T22.291D</td>
<td>Burn of second degree of multiple sites of right shoulder and upper limb, except wrist and hand, subsequent encounter</td>
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<td>T22.291S</td>
<td>Burn of second degree of multiple sites of right shoulder and upper limb, except wrist and hand, sequela</td>
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<tr>
<td>T22.292A</td>
<td>Burn of second degree of multiple sites of left shoulder and upper limb, except wrist and hand, initial encounter</td>
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<td>T22.292D</td>
<td>Burn of second degree of multiple sites of left shoulder and upper limb, except wrist and hand, subsequent encounter</td>
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<td>Burn of second degree of multiple sites of left shoulder and upper limb, except wrist and hand, sequela</td>
</tr>
<tr>
<td>T22.311A</td>
<td>Burn of third degree of right forearm, initial encounter</td>
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<td>T22.311D</td>
<td>Burn of third degree of right forearm, subsequent encounter</td>
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<td>Burn of third degree of left forearm, subsequent encounter</td>
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<td>Burn of third degree of right elbow, initial encounter</td>
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<td>Burn of third degree of right elbow, subsequent encounter</td>
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<td>Burn of third degree of left elbow, initial encounter</td>
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<td>T22.322D</td>
<td>Burn of third degree of left elbow, subsequent encounter</td>
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<td>Burn of third degree of right upper arm, initial encounter</td>
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<td>T22.331D</td>
<td>Burn of third degree of right upper arm, subsequent encounter</td>
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<td>Burn of third degree of left upper arm, initial encounter</td>
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<tr>
<td>T22.341A</td>
<td>Burn of third degree of right axilla, initial encounter</td>
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<tr>
<td>Code</td>
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<td>Burn of third degree of right axilla, subsequent encounter</td>
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<td>Burn of third degree of right axilla, sequela</td>
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<td>Burn of third degree of left axilla, sequela</td>
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<td>Burn of third degree of right shoulder, sequela</td>
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<td>Burn of third degree of left shoulder, initial encounter</td>
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<td>Burn of third degree of left shoulder, subsequent encounter</td>
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<td>Burn of third degree of left shoulder, sequela</td>
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<tr>
<td>T22.361A</td>
<td>Burn of third degree of right scapular region, initial encounter</td>
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<td>T22.361D</td>
<td>Burn of third degree of right scapular region, subsequent encounter</td>
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<td>T22.361S</td>
<td>Burn of third degree of right scapular region, sequela</td>
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<td>T22.362A</td>
<td>Burn of third degree of left scapular region, initial encounter</td>
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<td>Burn of third degree of left scapular region, subsequent encounter</td>
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<td>Burn of third degree of left scapular region, sequela</td>
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<td>T22.391A</td>
<td>Burn of third degree of multiple sites of right shoulder and upper limb, except wrist and hand, initial encounter</td>
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<td>Burn of third degree of multiple sites of right shoulder and upper limb, except wrist and hand, subsequent encounter</td>
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<td>Burn of third degree of multiple sites of right shoulder and upper limb, except wrist and hand, sequela</td>
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<td>Burn of third degree of multiple sites of left shoulder and upper limb, except wrist and hand, sequela</td>
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<tr>
<td>T22.611A</td>
<td>Corrosion of second degree of right forearm, initial encounter</td>
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<td>Corrosion of second degree of right forearm, subsequent encounter</td>
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<td>Corrosion of second degree of right elbow, initial encounter</td>
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<td>Corrosion of second degree of left elbow, initial encounter</td>
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<td>Corrosion of second degree of left elbow, sequela</td>
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<tr>
<td>T22.631A</td>
<td>Corrosion of second degree of right upper arm, initial encounter</td>
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<td>Corrosion of second degree of right upper arm, subsequent encounter</td>
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<td>Corrosion of second degree of right upper arm, sequela</td>
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<td>T22.632A</td>
<td>Corrosion of second degree of left upper arm, initial encounter</td>
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<td>Corrosion of second degree of left upper arm, subsequent encounter</td>
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<td>Corrosion of second degree of left upper arm, sequela</td>
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<td>T22.641A</td>
<td>Corrosion of second degree of right axilla, initial encounter</td>
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<td>Corrosion of second degree of right axilla, sequela</td>
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<td>Corrosion of second degree of left axilla, initial encounter</td>
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T22.642D  Corrosion of second degree of left axilla, subsequent encounter
T22.642S  Corrosion of second degree of left axilla, sequela
T22.651D  Corrosion of second degree of right shoulder, subsequent encounter
T22.651S  Corrosion of second degree of right shoulder, sequela
T22.652A  Corrosion of second degree of left shoulder, initial encounter
T22.652D  Corrosion of second degree of left shoulder, subsequent encounter
T22.652S  Corrosion of second degree of left shoulder, sequela
T22.661A  Corrosion of second degree of right scapular region, initial encounter
T22.661D  Corrosion of second degree of right scapular region, subsequent encounter
T22.661S  Corrosion of second degree of right scapular region, sequela
T22.662A  Corrosion of second degree of left scapular region, initial encounter
T22.662D  Corrosion of second degree of left scapular region, subsequent encounter
T22.662S  Corrosion of second degree of left scapular region, sequela
T22.691A  Corrosion of second degree of multiple sites of right shoulder and upper limb, except wrist and hand, initial encounter
T22.691D  Corrosion of second degree of multiple sites of right shoulder and upper limb, except wrist and hand, subsequent encounter
T22.691S  Corrosion of second degree of multiple sites of right shoulder and upper limb, except wrist and hand, sequela
T22.692A  Corrosion of second degree of multiple sites of left shoulder and upper limb, except wrist and hand, initial encounter
T22.692D  Corrosion of second degree of multiple sites of left shoulder and upper limb, except wrist and hand, subsequent encounter
T22.692S  Corrosion of second degree of multiple sites of left shoulder and upper limb, except wrist and hand, sequela
T22.711A  Corrosion of third degree of right forearm, initial encounter
T22.711D  Corrosion of third degree of right forearm, subsequent encounter
T22.711S  Corrosion of third degree of right forearm, sequela
T22.712A  Corrosion of third degree of left forearm, initial encounter
T22.712D  Corrosion of third degree of left forearm, subsequent encounter
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T22.721A  Corrosion of third degree of right elbow, initial encounter
T22.721D  Corrosion of third degree of right elbow, subsequent encounter
T22.721S  Corrosion of third degree of right elbow, sequela
T22.722A  Corrosion of third degree of left elbow, initial encounter
T22.722D  Corrosion of third degree of left elbow, subsequent encounter
T22.722S  Corrosion of third degree of left elbow, sequela
T22.731A  Corrosion of third degree of right upper arm, initial encounter
T22.731D  Corrosion of third degree of right upper arm, subsequent encounter
T22.731S  Corrosion of third degree of right upper arm, sequela
T22.732A  Corrosion of third degree of left upper arm, initial encounter
T22.732D  Corrosion of third degree of left upper arm, subsequent encounter
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T22.741A  Corrosion of third degree of right axilla, initial encounter
T22.741D  Corrosion of third degree of right axilla, subsequent encounter
T22.741S  Corrosion of third degree of right axilla, sequela
T22.742A  Corrosion of third degree of left axilla, initial encounter
T22.742D  Corrosion of third degree of left axilla, subsequent encounter
T22.742S  Corrosion of third degree of left axilla, sequela
T22.751A  Corrosion of third degree of right shoulder, initial encounter
T22.751D Corrosion of third degree of right shoulder, subsequent encounter
T22.751S Corrosion of third degree of right shoulder, sequela
T22.752D Corrosion of third degree of left shoulder, subsequent encounter
T22.752S Corrosion of third degree of left shoulder, sequela
T22.761A Corrosion of third degree of right scapular region, initial encounter
T22.761D Corrosion of third degree of right scapular region, subsequent encounter
T22.761S Corrosion of third degree of right scapular region, sequela
T22.762A Corrosion of third degree of left scapular region, initial encounter
T22.762D Corrosion of third degree of left scapular region, subsequent encounter
T22.762S Corrosion of third degree of left scapular region, sequela
T22.791A Corrosion of third degree of multiple sites of right shoulder and upper limb, except wrist and hand, initial encounter
T22.791D Corrosion of third degree of multiple sites of right shoulder and upper limb, except wrist and hand, subsequent encounter
T22.791S Corrosion of third degree of multiple sites of right shoulder and upper limb, except wrist and hand, sequela
T22.792A Corrosion of third degree of multiple sites of left shoulder and upper limb, except wrist and hand, initial encounter
T22.792D Corrosion of third degree of multiple sites of left shoulder and upper limb, except wrist and hand, subsequent encounter
T22.792S Corrosion of third degree of multiple sites of left shoulder and upper limb, except wrist and hand, 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
T23.221A 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
T23.231A 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
T23.241A 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
T23.242A 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
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T23.251D Burn of second degree of right palm, subsequent encounter
T23.251S Burn of second degree of right palm, sequela
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<td>Burn of second degree of back of left hand, sequela</td>
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<td>Burn of second degree of right wrist, initial encounter</td>
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<td>T23.291A</td>
<td>Burn of second degree of multiple sites of right wrist and hand, initial encounter</td>
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<td>Burn of second degree of multiple sites of right wrist and hand, subsequent encounter</td>
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<td>Burn of second degree of multiple sites of right wrist and hand, sequela</td>
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<td>Burn of second degree of multiple sites of left wrist and hand, initial encounter</td>
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<td>Burn of second degree of multiple sites of left wrist and hand, subsequent encounter</td>
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<td>T23.311A</td>
<td>Burn of third degree of right thumb (nail), initial encounter</td>
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<td>Burn of third degree of right thumb (nail), subsequent encounter</td>
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<td>Burn of third degree of right thumb (nail), sequela</td>
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<td>Burn of third degree of single right finger (nail) except thumb, initial encounter</td>
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<td>Burn of third degree of single right finger (nail) except thumb, subsequent encounter</td>
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<td>Burn of third degree of single right finger (nail) except thumb, sequela</td>
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<td>Burn of third degree of multiple right fingers (nail), not including thumb, initial encounter</td>
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<td>Burn of third degree of multiple sites of right wrist and hand, initial encounter</td>
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<td>Burn of third degree of multiple sites of left wrist and hand, sequela</td>
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<td>T23.611A</td>
<td>Corrosion of second degree of right thumb (nail), initial encounter</td>
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<td>Corrosion of second degree of right thumb (nail), subsequent encounter</td>
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<td>Corrosion of second degree of right thumb (nail), sequela</td>
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<td>Corrosion of second degree of left thumb (nail), sequela</td>
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<td>T23.621A</td>
<td>Corrosion of second degree of single right finger (nail) except thumb, initial encounter</td>
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T23.752D Corrosion of third degree of left palm, subsequent encounter
T23.752S Corrosion of third degree of left palm, sequela
T23.761A Corrosion of third degree of back of right hand, initial encounter
T23.761D Corrosion of third degree of back of right hand, subsequent encounter
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T23.771S Corrosion of third degree of right wrist, sequela
T23.772A Corrosion of third degree of left wrist, initial encounter
T23.772D Corrosion of third degree of left wrist, subsequent encounter
T23.772S Corrosion of third degree of left wrist, sequela
T23.791A Corrosion of third degree of multiple sites of right wrist and hand, initial encounter
T23.791D Corrosion of third degree of multiple sites of right wrist and hand, subsequent encounter
T23.791S Corrosion of third degree of multiple sites of right wrist and hand, sequela
T23.792A Corrosion of third degree of multiple sites of left wrist and hand, initial encounter
T23.792D Corrosion of third degree of multiple sites of left wrist and hand, subsequent encounter
T23.792S Corrosion of third degree of multiple sites of left wrist and hand, 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
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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
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T24.232S Burn of second degree of left lower leg, sequela
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T24.291D Burn of second degree of multiple sites of right lower limb, except ankle and foot, subsequent encounter
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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
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T24.311D Burn of third degree of right thigh, subsequent encounter
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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
T24.321A  Burn of third degree of right knee, initial encounter
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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
T24.331A  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
T24.391A  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
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T24.392S  Burn of third degree of multiple sites of left lower limb, except ankle and foot, sequela
T24.611A  Corrosion of second degree of right thigh, initial encounter
T24.611D  Corrosion of second degree of right thigh, subsequent encounter
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T24.621A  Corrosion of second degree of right knee, initial encounter
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T24.691A  Corrosion of second degree of multiple sites of right lower limb, except ankle and foot, initial encounter
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T24.711A Corrosion of third degree of right thigh, initial encounter
T24.711D Corrosion of third degree of right thigh, subsequent encounter
T24.711S Corrosion of third degree of right thigh, sequela
T24.712A Corrosion of third degree of left thigh, initial encounter
T24.712D Corrosion of third degree of left thigh, subsequent encounter
T24.712S Corrosion of third degree of left thigh, sequela
T24.721A Corrosion of third degree of right knee, initial encounter
T24.721D Corrosion of third degree of right knee, subsequent encounter
T24.721S Corrosion of third degree of right knee, sequela
T24.722A Corrosion of third degree of left knee, initial encounter
T24.722D Corrosion of third degree of left knee, subsequent encounter
T24.722S Corrosion of third degree of left knee, sequela
T24.731A Corrosion of third degree of right lower leg, initial encounter
T24.731D Corrosion of third degree of right lower leg, subsequent encounter
T24.731S Corrosion of third degree of right lower leg, sequela
T24.732A Corrosion of third degree of left lower leg, initial encounter
T24.732D Corrosion of third degree of left lower leg, subsequent encounter
T24.732S Corrosion of third degree of left lower leg, sequela
T24.791A Corrosion of third degree of multiple sites of right lower limb, except ankle and foot, initial encounter
T24.791D Corrosion of third degree of multiple sites of right lower limb, except ankle and foot, subsequent encounter
T24.791S Corrosion of third degree of multiple sites of right lower limb, except ankle and foot, sequela
T24.792A Corrosion of third degree of multiple sites of left lower limb, except ankle and foot, initial encounter
T24.792D Corrosion of third degree of multiple sites of left lower limb, except ankle and foot, subsequent encounter
T24.792S Corrosion of third degree of multiple sites of left 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
T25.221A 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
T25.231A 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
T25.291A 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
T25.311A  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
T25.321A  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
T25.331A  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
T25.391A  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
T25.611A  Corrosion of second degree of right ankle, initial encounter
T25.611D  Corrosion of second degree of right ankle, subsequent encounter
T25.611S  Corrosion of second degree of right ankle, sequela
T25.612A  Corrosion of second degree of left ankle, initial encounter
T25.612D  Corrosion of second degree of left ankle, subsequent encounter
T25.612S  Corrosion of second degree of left ankle, sequela
T25.621A  Corrosion of second degree of right foot, initial encounter
T25.621D  Corrosion of second degree of right foot, subsequent encounter
T25.621S  Corrosion of second degree of right foot, sequela
T25.622A  Corrosion of second degree of left foot, initial encounter
T25.622D  Corrosion of second degree of left foot, subsequent encounter
T25.622S  Corrosion of second degree of left foot, sequela
T25.631A  Corrosion of second degree of right toe(s) (nail), initial encounter
T25.631D  Corrosion of second degree of right toe(s) (nail), subsequent encounter
T25.631S  Corrosion of second degree of right toe(s) (nail), sequela
T25.632A  Corrosion of second degree of left toe(s) (nail), initial encounter
T25.632D  Corrosion of second degree of left toe(s) (nail), subsequent encounter
T25.632S  Corrosion of second degree of left toe(s) (nail), sequela
T25.691A  Corrosion of second degree of right ankle and foot, initial encounter
T25.691D  Corrosion of second degree of right ankle and foot, subsequent encounter
T25.691S  Corrosion of second degree of right ankle and foot, sequela
T25.692A  Corrosion of second degree of left ankle and foot, initial encounter
T25.692D  Corrosion of second degree of left ankle and foot, subsequent encounter
T25.692S  Corrosion of second degree of left ankle and foot, sequela
T25.711A  Corrosion of third degree of right ankle, initial encounter
T25.711D  Corrosion of third degree of right ankle, subsequent encounter

Contains Public Information
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T31.62 Burns involving 60-69% of body surface with 20-29% third degree burns
T31.63 Burns involving 60-69% of body surface with 30-39% third degree burns
T31.64 Burns involving 60-69% of body surface with 40-49% third degree burns
T31.65 Burns involving 60-69% of body surface with 50-59% third degree burns
T31.66 Burns involving 60-69% of body surface with 60-69% third degree burns
T31.70 Burns involving 70-79% of body surface with 0% to 9% third degree burns
T31.71 Burns involving 70-79% of body surface with 10-19% third degree burns
T31.72 Burns involving 70-79% of body surface with 20-29% third degree burns
T31.73 Burns involving 70-79% of body surface with 30-39% third degree burns
T31.74 Burns involving 70-79% of body surface with 40-49% third degree burns
T31.75 Burns involving 70-79% of body surface with 50-59% third degree burns
T31.76 Burns involving 70-79% of body surface with 60-69% third degree burns
T31.77 Burns involving 70-79% of body surface with 70-79% third degree burns
T31.80 Burns involving 80-89% of body surface with 0% to 9% third degree burns
T31.81 Burns involving 80-89% of body surface with 10-19% third degree burns
T31.82 Burns involving 80-89% of body surface with 20-29% third degree burns
T31.83 Burns involving 80-89% of body surface with 30-39% third degree burns
T31.84 Burns involving 80-89% of body surface with 40-49% third degree burns
T31.85 Burns involving 80-89% of body surface with 50-59% third degree burns
T31.86 Burns involving 80-89% of body surface with 60-69% third degree burns
T31.87 Burns involving 80-89% of body surface with 70-79% third degree burns
T31.88 Burns involving 80-89% of body surface with 80-89% third degree burns
T31.90 Burns involving 90% or more of body surface with 0% to 9% third degree burns
T31.91 Burns involving 90% or more of body surface with 10-19% third degree burns
T31.92 Burns involving 90% or more of body surface with 20-29% third degree burns
T31.93 Burns involving 90% or more of body surface with 30-39% third degree burns
T31.94 Burns involving 90% or more of body surface with 40-49% third degree burns
T31.95 Burns involving 90% or more of body surface with 50-59% third degree burns
T31.96 Burns involving 90% or more of body surface with 60-69% third degree burns
T31.97 Burns involving 90% or more of body surface with 70-79% third degree burns
T31.98 Burns involving 90% or more of body surface with 80-89% third degree burns
T31.99 Burns involving 90% or more of body surface with 90% or more third degree burns
T32.0 Corrosions involving less than 10% of body surface
T32.10 Corrosions involving 10-19% of body surface with 0% to 9% third degree corrosion
T32.11 Corrosions involving 10-19% of body surface with 10-19% third degree corrosion
T32.20 Corrosions involving 20-29% of body surface with 0% to 9% third degree corrosion
T32.21 Corrosions involving 20-29% of body surface with 10-19% third degree corrosion
T32.22 Corrosions involving 20-29% of body surface with 20-29% third degree corrosion
T32.30 Corrosions involving 30-39% of body surface with 0% to 9% third degree corrosion
T32.31 Corrosions involving 30-39% of body surface with 10-19% third degree corrosion
T32.32 Corrosions involving 30-39% of body surface with 20-29% third degree corrosion
T32.33 Corrosions involving 30-39% of body surface with 30-39% third degree corrosion
T32.40 Corrosions involving 40-49% of body surface with 0% to 9% third degree corrosion
T32.41 Corrosions involving 40-49% of body surface with 10-19% third degree corrosion
T32.42 Corrosions involving 40-49% of body surface with 20-29% third degree corrosion
T32.43 Corrosions involving 40-49% of body surface with 30-39% third degree corrosion
T32.44 Corrosions involving 40-49% of body surface with 40-49% third degree corrosion
T32.50 Corrosions involving 50-59% of body surface with 0% to 9% third degree corrosion
T32.51 Corrosions involving 50-59% of body surface with 10-19% third degree corrosion
T32.52 Corrosions involving 50-59% of body surface with 20-29% third degree corrosion
T32.53 Corrosions involving 50-59% of body surface with 30-39% third degree corrosion

Contains Public Information
REVISIONS

08-03-2010 In the Policy section:

- Added additional indication under B. Apligraf:
  3. Patients with vasculitis.
- Updated Integra name to Integra Bilayer Matrix.
- Revised wording in D. Integra (second paragraph):
  From "burns" To "wounds"

Contains Public Information
- Added medical necessity criteria for Oasis Wound Matrix
  F. Oasis Wound Matrix (Q4102)
  Oasis Wound Matrix is considered medically necessary for treatment of venous stasis ulcer.
  Oasis Wound matrix is considered experimental / investigational for all other applications.
- Added medical necessity criteria for Trancyte
  G. TransCyte (Q4100)
  TransCyte is a biosynthetic skin substitute containing layers of synthetic materials like silicone, nylon, or polygactin.
  TransCyte is considered medically necessary as a temporary wound veering to treat second and third degree burns.
  TransCyte is considered experimental / investigational for all other applications
- Added Oasis Burn Matrix to skin substitutes list that is experimental / investigational.

In the Coding section:
- Removed HCPCS Codes not effective after 12-31-2008:  J7340, J7342, J7343, J7344
- Added HCPCS Codes effective 01-01-2009:  Q4100, Q4101, Q4102, Q4103, Q4104, Q4105, Q4106, Q4107, Q4108, Q4109, Q4110, Q4111, Q4112, Q4113, Q4114
- Added HCPCS Codes effective 07-01-2009:  Q4115, Q4116

Updated References.

02-01-2012
Title changed from “Wound Care: Skin Substitutes and Growth Factors” to “Tissue-Engineered Skin Substitutes”

Added reference to another policy: “See Also: Periodontal Soft Tissue Grafting dental policy”

Description section updated

In Policy section:
- Added the notation: “Use Q4100 for skin substitutes that do not have a unique code.”
- Added medically necessary indication for B AlloMax - AlloMax is considered medically necessary when used for hernia reconstruction in a contaminated field
- Added medically necessity indication for C 1 a Apligraft - for the treatment of chronic, non-infected, partial- or full-thickness lower extremity skin ulcers due to venous insufficiency which have not adequately responded following a one month period of conventional ulcer therapy (standard dressing changes and compression)**
- Added E/I language for C 2 Apligraf - Apligraf is considered experimental/investigational when used beyond five applications, for infected wounds, and for all other applications
- Added medically necessary indication for E Epicel - Epicel is considered medically necessary for the treatment of second- and third-degree burns
- Added medically necessary indication for F 2 Integra Bilayer Matrix - for the treatment of second- and third-degree burns**
- Added medically necessary indication for G Oasis Wound Matrix - Oasis Wound Matrix is considered medically necessary for chronic, non-infected, partial- or full-thickness lower extremity skin ulcers due to venous insufficiency which have not
adequately responded following a one month period of conventional ulcer therapy
(standard dressing changes and compression)***

- Added medically necessary indications for H OrCel - OrCel is considered
  medically necessary: 1. for the treatment of dystrophic epidermolysis bullosa,
  2. 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 FDA****

- Added to the E/I list the following skin substitutes: Actisorb - Silvercoated wound
dressings, Allograft, Allopatch, AlloPatch HD (Q4128), AlloSkin (Q4115), AlloSkin RT
(Q4123), Artelon, Arthres GraftRope, ArthroFlex (FlexGraft) (Q4125), Avaulta Plus,
Avotemin, Biocrine, BioDfence/BioDFactor, Biostat Biologx, Biotape, CellerateRX,
Conexa, CorMatrix, CorMatrix Patch, CRx, Cymetra, Cymetra Injectable Allograft
(Q4112), DuraGen Plus, DermaCELL (Q4122), DermaClose RC Continuous External
Tissue Expander, DermaMatrix Acellular Dermal, Durepair Regeneration Matrix,
Endoform Dermal Template (C9367), ENDURAgens, Evicel, E-Z Derm, FlexHD
(Q4128), GammaGraft (Q4111), Hyalomatrix PA (Q4117), Integra Flowable Wound
Matrix (Q4114), Integra Dermal Regeneration Template (Q4105), Integra Neural
Wrap, Integra Matrix (Q4108), Matristem Micromatrix (Q4118), Matristem Wound
Matrix (Q4119), Matristem Burn Matrix (Q4120), Matrix HD, MediHoney, Mediskin,
MemoDerm (Q4126), NeuroForm, NeuroMatrix Collagen Nerve Cuff (C9355),
NeuroMend Collagen Nerve Wrap (C9361), Oasis Ultra Tri-Layer Matrix (Q4124),
OrthoADAPT Bioimplant, Permacol, Permacol Biologic Implant (C9364), PriMatrix,
PriMatrix Acellular Dermal Tissue Matrix (Q4110), Repriza, Strattice (xenograft),
Strattic Tissue Matrix (Q4130), SurgiMend Collagen Matrix (C9358, C9360),
Talymed (Q4127), TenoGlide Tendon Protector Sheet (C9356), TheraSkin,
TheraSkin Unite (Q4121), TissueMend, Unite Biomatrix (Q4129), Veritas Collagen
Matrix (C9354)

- Removed policy language concerning Recombinant platelet-derived growth
factor (Regranex) (S0157)

  - Regranex Gel actively stimulates angiogenesis and granulation tissue
    formation.
  - Demonstrates biological activity similar to that of endogenous platelet-derived
    growth factor.
  - Promoted recruitment and proliferation of chemotactic cells, including
    monocytes and fibroblasts, necessary for stimulation of a variety of wound
    healing processes and aiding in the creation of granulation tissue.
  - The first and only prescription growth factor clinically proven to actively
    stimulate granulation tissue formation and enhance natural wound healing.

Regranex is considered medically necessary for either of the following indications:

1. When used according to the FDA labeled indication for neuropathic diabetic
ulcers extending into the subcutaneous tissue. Candidates for treatment should
meet all of the following three criteria:

   - Adequate tissue oxygenation as measured by transcutaneous partial pressure
     of oxygen; and
   - Full thickness ulcer; and
   - Participation in a wound management program (debridement, off loading, infection control)  OR

2. As treatment of pressure ulcers extending into the subcutaneous tissues.
Candidates for treatment should meet all of the following criteria:
- Full thickness ulcer; and
- Ulcers in locations that can be off loaded; and
- Albumin concentration greater than 2.5 dL; and
- Total lymphocyte count greater than 1000

Patients are typically treated daily for up to 20 weeks or until complete healing.
- Removed policy language concerning E/I growth factors of Autologel and SafeBlood.

Rationale section updated

In Coding section:
- Added CPT and HCPCS codes that are effective 01/01/12: 15271, 15272, 15273, 15274, 15275, 15276, 15277, 15278, 15777, Q4122, Q4123, Q4124, Q4125, Q4126, Q4127, Q4128, Q4129, Q4130
- Added CPT and HCPCS codes that were previously effective and appropriate for the policy: 15040, 15050, 15100, 15101, 15110, 15111, 15115, 15116, 15120, 15121, 15130, 15131, 15135, 15136, 15150, 15151, 15152, 15155, 15156, 15157, C9354, C9355, C9356, C9358, C9360, C9361, C9363, C9364, C9367, Q4117, Q4118, Q4119, Q4120, Q4121
- Revised HCPCS codes nomenclature: Q4101, Q4102, Q4103, Q4104, Q4105, Q4106, Q4107, Q4108, Q4110, Q4111, Q4112, Q4113, Q4115, Q4116

- Removed CPT and HCPCS codes: 15330, 15331, 15335, 15336, 15340, 15341, 15360, 15361, 15365, 15366, Q4109, S0157
- Added CPT and HCPCS codes: 15330, 15331, 15335, 15336, 15340, 15341, 15360, 15361, 15365, 15366, Q4109, S0157
- Added Diagnosis codes: 233.0, V45.71, V84.01

References updated

01-15-2013

In Policy section:
- Added the following skin substitutes to K. All other skin substitutes not listed above are considered experimental / investigational, including, but not limited to:
  "26. EpiFix (Q4131), 31. Grafix core (Q4132), 32. Grafix prime (Q4133), 35. hMatrix (Q4134)"
- Added HCPCS codes Q4135 to Mediskin and Q4136 to E-Z Derm

In Coding section:
- Added HCPCS Codes: Q4131, Q4132, Q4133, Q4134, Q4135, Q4136 (effective 01-01-2013)
- Updated coding instructions

12-12-2013

Title changed from “Tissue-Engineered Skin Substitutes” to Bio-Engineered Skin and Soft Tissue-Substitutes"

Description section updated

In Policy section:
- Revised wording for Item A FROM: "AlloDerm is considered medically necessary when used for post-mastectomy breast reconstruction*." TO: "Breast reconstructive surgery:
-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 post-mastectomy skin flaps that are at risk of dehiscence or necrosis, or
-the infra-mammary fold and lateral mammary folds have been undermined during mastectomy and re-establishment of these landmarks is needed using the following acellular dermal matrix (ADM) may be considered medically necessary.
1. AlloDerm®* (Q4116)"
- Revised AlloMax from being medically necessary, "...when used for hernia
reconstruction in a contaminated field." to being experimental / investigational.

- Revised wording for Apligraf, Dermagraft, and Oasis Wound Matrix FROM:
  1. Apligraf is considered medically necessary:
     a. for the treatment of chronic, non-infected, partial- or full-thickness lower extremity skin ulcers due to venous insufficiency which have not adequately responded following a one month period of conventional ulcer therapy (standard dressing changes and compression)**.
     b. in conjunction with standard diabetic foot ulcer care (surgical debridement, off loading, etc) for ulcers of greater than three weeks duration**.
  2. Apligraf is considered experimental/investigational when used beyond five applications, for infected wounds, and for all other applications." and
  "1. Dermagraft is considered medically necessary for the treatment of:
     a. full thickness diabetic foot ulcers of greater than six weeks duration that extend through the dermis but without tendon, muscle, joint capsule or bone exposure**.
     b. Wounds as a result of dystrophic epidermolysis bullosa****.
  2. Dermagraft is contraindicated for infected ulcers and ulcers with sinus tracts." and
  "Oasis Wound Matrix is considered medically necessary for chronic, non-infected, partial- or full-thickness lower extremity skin ulcers due to venous insufficiency which have not adequately responded following a one month period of conventional ulcer therapy (standard dressing changes and compression)***." TO:
  "Treatment of chronic, noninfected, full-thickness diabetic lower extremity ulcers using the following tissue-engineered skin substitutes may be considered medically necessary.
  1. Apligraf®** (Q4101)
  2. Dermagraft®** (Q4106)"

- Revised wording for OrCel FROM:
  "OrCel is considered medically necessary:
  1. for the treatment of dystrophic epidermolysis bullosa.
  2. 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 FDA****.
  TO:
  "Treatment of dystrophic epidermolysis bullosa using the following tissue-engineered skin substitutes may be considered medically necessary.
  1. 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 FDA)****"
1. in the post excisional treatment of full thickness or deep partial thickness wounds when autografting is not feasible.
2. for the treatment of second- and third-degree burns**." and "TransCyte is considered medically necessary for the treatment of second- and third-degree burns**." 

TO:
"Treatment of second- and third-degree burns using the following tissue-engineered skin substitutes may be considered medically necessary.
1. Epitel® (for the treatment of deep dermal or full-thickness burns comprising a total body surface area of greater than or equal to 30% when provided in accordance with the HDE specifications of the FDA)****
2. Integra Dermal Regeneration Template™***
3. TransCyte™**

- Added: "F. All other uses of the bio-engineered skin and soft tissue substitutes listed above are considered experimental / investigational."
- Removed Neuroform from the policy.

Rationale section updated

In Coding section:
- Removed CPT / HCPCS codes: 15170, 15171, 15175, 15176, C9367
- Updated nomenclature for HCPCS codes: Q4119, Q4126, Q4128
- Added ICD-10 Codes (Effective October 1, 2014)

Revision section
- Removed Revision details for 05-21-2008.

References updated

01-01-2014 In Policy section:
- In Item G added the following experimental / investigational skin substitutes: Alloskin AC, per square centimeter (Q4141); AmnioExCel per square centimeter (Q4137); Architect Extracellular Matrix, per square centimeter (Q4147); BioDfence Dryflex per square centimeter (Q4138); Epifix, injectable, 1 mg (Q4145); Excellagen, 0.1 cc (Q4149); NEOX 1K, per square centimeter (Q4148); TenSI, per square centimeter (Q4146)

In Coding Section:
- Added HCPCS Codes to existing E/I skin substitutes: Q4139, Q4140, Q4142, Q4143 (Eff 01-01-2014)
REFERENCES


Other References: