SKIN SUBSTITUTE APPLICATION

Guideline Number: MPG286.02 **Approval Date**: February 8, 2017

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- Porcine Skin and Gradient Pressure Dressings (NCD 270.5)

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INSTRUCTIONS FOR USE

This Policy Guideline is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates for health care services submitted on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450), or their electronic comparative. The information presented in this Policy Guideline is believed to be accurate and current as of the date of publication.

This Policy Guideline provides assistance in administering health benefits. All reviewers must first identify member eligibility, any federal or state regulatory requirements, Centers for Medicare and Medicaid Services (CMS) policy, the member specific benefit plan coverage, and individual provider contracts prior to use of this Policy Guideline. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document may differ greatly from the standard benefit plan upon which this Policy Guideline is based. In the event of a conflict, the member specific benefit plan document supersedes this Policy Guideline. Other Policies and Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

UnitedHealthcare follows Medicare coverage guidelines and regularly updates its Medicare Advantage Policy Guidelines to comply with changes in CMS policy. UnitedHealthcare encourages physicians and other healthcare professionals to keep current with any CMS policy changes and/or billing requirements by referring to the CMS or your local carrier website regularly. Physicians and other healthcare professionals can sign up for regular distributions for policy or regulatory changes directly from CMS and/or your local carrier. This Policy Guideline is provided for informational purposes. It does not constitute medical advice.

POLICY SUMMARY

Overview

Tissue-engineered skin substitutes (i.e. human skin equivalents, dermal substitute tissues) are products that use living cells (e.g., fibroblasts and keratinocytes) or other collagen-derived or biologically-derived extracellular matrix in a scaffold of natural, biodegradable or synthetic matrices to foster wound healing. The scaffold provides a stable framework that guides tissue integration and development. The scaffold is also able to bind autologous proteins which influence cell migration and adherence. Skin substitutes are indicated in the treatment of wounds that have not responded to aggressive, conventional wound therapy, or as outlined in the indications given below.

Guidelines

Indications – all covered bioengineered skin substitutes must be:

- Provided in accordance with the material's Food and Drug Administration-(FDA) approved package label.
- Applied to partial or full-thickness wounds (see individual product information for labeled indications).
- Applied to wounds that have demonstrated a failed or insufficient response to no fewer than four weeks of conservative wound-care measures when applied to chronic wounds.
  - Standard wound therapy includes:
    - control of edema, venous hypertension or lymphedema;
    - control of any nidus of infection or colonization with bacterial or fungal elements;
    - elimination of underlying cellulitis, osteomyelitis, foreign body or malignant process;
    - appropriate debridement of necrotic tissue or foreign body (exposed bone or tendon);
    - maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings;
    - optimization of glucose control (when applicable);

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- for diabetic foot ulcers, appropriate non-weight bearing or off-loading;
- assessment of a patient's vascular status and correction of any vascular problems in the affected limb if possible;
- for venous stasis ulcers, compression therapy provided with documented diligent use of multilayer dressings, compression stockings of > 20mmHg pressure, or pneumatic compression;
- provision of wound environment to promote healing (protection from trauma and contaminants, elimination of inciting or aggravating processes); and
- optimization of nutritional status.

- Provided in association with patient care (including home care by patient or other entity) that is consistent with all other accepted standards of medical/surgical wound management (including appropriate physician evaluation/management and supervision of care provided by non-physicians).
- Applied to wounds reasonably expected to heal in the presence of the wound environment, cytokines and growth factors supplied by the skin substitute/replacement and not applied to wounds demonstrating such hostile host environment that destruction of the substitute is highly likely.
- Applied to wounds of reasonable size given the clinical circumstances. For instance, UnitedHealth Care would not expect routine use of graft material in treating small wounds (smaller than 1.0 cm 2 or 1.0 cm in smallest diameter) unless the medical record clearly demonstrates the wound to be refractory to conservative treatment but otherwise healable. Use on small wounds that have demonstrated adequate healing by conservative means is not covered.
- Only applied to wounds with adequate circulation/oxygenation to support tissue growth/wound healing as evidenced by physical examination (presence of acceptable peripheral pulses and/or Doppler toe signals and/or Ankle-Brachial Index (ABI) of no less than 0.60, toe pressure > 30mm Hg).
- Wound healing is impaired by the systemic use of tobacco. Therefore, ideally, patients who have smoked will have ceased smoking or have refrained from systematic tobacco intake for at least 4-6 weeks during conservative wound care and prior to planned bioengineered skin replacement therapy.

Limitations
Timing, frequency and number of reapplications of bioengineered skin substitutes should be appropriate for the material used and clinical condition of the patient. UnitedHealth Care does not expect to see routine application of maximally allowed numbers of skin substitutes/replacements per wound and will monitor and evaluate claim data regarding numbers of applications per patient and per wound.

During a course of treatment, repeat applications of skin substitutes/replacements are not indicated when applications heretofore were unsuccessful. Unsuccessful treatment is defined in this situation as increase in size or depth of a wound or ulcer, or no change in baseline size or depth and no sign of improvement or indication that improvement is likely (such as granulation or epithelialization and no progress toward closing) since the previous application.

Retreatment of healed ulcers is not indicated. Retreatment with the same skin substitute product is not indicated for ulcers for which an initial course of treatment with skin substitutes was unsuccessful. An unsuccessful course of treatment is defined in this case as incomplete healing following maximal numbers of applications and/or maximal duration of treatment time indicated by the FDA label of the individual product and/or this LCD.

Skin substitutes/replacements must not be provided to patients with known hypersensitivity to any component of the specific skin substitute/replacement material, inadequate control of underlying condition or exacerbating factors, or other contraindication (e.g., allergy to bovine, uncontrolled diabetes, active infection, active Charcot's arthropathy of the ulcer extremity, vasculitis, uncontrolled rheumatoid arthritis or rheumatoid ulcers, radiation and/or chemotherapy within one month immediately preceding application of skin substitute/replacement, ongoing use of high-dose corticosteroids or immunosuppressants).

Note: UnitedHealth Care may make payment only for those services performed by persons with appropriate education, knowledge, skill and competence. UnitedHealth Care may make payment for physician services performed by persons licensed by the state to perform them. Because applications of Apligraf®, Integra®, Dermagraft®, GraftJacket®, PriMatrix™, TheraSkin®, and Epifix®, as well as any subsequently accepted similar product, are physician (surgical) services, UnitedHealth Care payment for the products and their applications will be made only to licensed physicians and qualified non-physician practitioners who are licensed to perform these physician services (nurse practitioners, clinical nurse specialists and physician assistants).

Bioengineered Skin Substitutes (BSS)
Apligraf® (Q4101): Apligraf is supplied as a living, bilayered, skin substitute. The epidermal layer is formed by human keratinocytes and has a well-differentiated stratum corneum. The dermal layer is composed of human fibroblasts in a bovine Type 1 collagen lattice. While matrix proteins and cytokines found in human skin are present in Apligraf, it does not contain Langerhans cells, melanocytes, macrophages, lymphocytes, blood vessels, or hair follicles.

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Apligraf is supplied sealed in a heavy gauge polyethylene bag intended for single use as a circular disk approximately 7.5 centimeters (cm) in diameter. It is approved for diabetic foot ulcer and venous stasis ulcer. Additionally, diabetic ulcers of the ankle and calf are covered. In vitro and in vivo histology studies have shown that Apligraf either degrades or its cell viability is reduced when the device is exposed to the following cytotoxic agents: Dakin's solution, Mafenide acetate, Scarlet red dressing, Tincoban, Zinc sulfate, Povodine-iodine solution, Chlorhexidine, or Polymixin/Nystatin. The use of Apligraf with these solutions will be considered not medically reasonable and necessary.

Integra® (Q4105): Integra DRT is a bilayer membrane system for skin replacement. The dermal replacement layer is made of a porous matrix of fibers of cross-linked bovine tendon collagen and glycosaminoglycan (chondroitin-6-sulfate) that is manufactured with a controlled porosity and defined degradation rate. The temporary epidermal substitute layer is made of synthetic polysiloxane polymer (silicone) and functions to control moisture loss from the wound. The collagen dermal replacement layer serves as a matrix for the infiltration of fibroblasts, macrophages, lymphocytes, and capillaries derived from the wound bed. It is approved for the treatment of deep partial-thickness or full-thickness thermal injury to the skin. Formation of the neodermis typically takes 14-21 days. The epidermal autograft can be applied immediately after the neodermis has formed. Hemostasis must be achieved prior to applying Integra DRT. Inadequate control of bleeding will interfere with the incorporation of this product. Integra DRT should be applied on the day of excision.

Dermagraft® (Q4106): Dermagraft is a cryopreserved dermal substitute composed of human fibroblasts, extracellular matrix, and a bioabsorbable scaffold. During the manufacturing process, the human fibroblasts are seeded into a bioabsorbable polyglactin mesh scaffold. The fibroblasts proliferate to fill the interstices of this scaffold and secrete human dermal collagen, matrix proteins, growth factors and cytokines to create a three-dimensional human dermal substitute containing metabolically active, living cells. It is approved for treatment of full-thickness diabetic foot ulcers. Additionally, diabetic ulcers of the ankle and calf are covered. Any topical agents, cytotoxic cleansing solutions, or medications (e.g., lotions, ointments, creams, or gels) on an ulcer being treated with Dermagraft may reduce the viability of the product. The use of Dermagraft in conjunction with these solutions will not be considered reasonable and necessary. The use of Dermagraft in the treatment of full thickness diabetic ulcers has not been studied in patients children under the age of 18, pregnant women, patients with ulcers over a Charcot's deformity of the midfoot or patient receiving immunosuppressive or cytotoxic agents, and is not indicated when these conditions are present.

GraftJacket® (Q4107): is a human dermal collagen template that is readily incorporated into the body. The GRAFTJACKET Matrix provides a scaffold for host cell repopulation, revascularization and, ultimately, conversion to host tissue. It is approved for full-thickness diabetic foot ulcers. Additionally, diabetic ulcers of the ankle and calf are covered.

PriMatrix™ (Q4110): PriMatrix Dermal Scaffold is an acellular collagen matrix derived from fetal bovine dermis. PriMatrix provides an environment that supports cell repopulation and revascularization for wound healing. Designed to deliver and incorporate collagen into the wound bed to stimulate tissue granulation and support native collagen production. It is approved for use in the treatment of venous ulcers, diabetic foot ulcers, and lower extremity full thickness wounds with or without exposed bone and/or exposed tendon.

TheraSkin® (Q4121): TheraSkin is a biologically active, cryopreserved real human skin allograft, composed of living cells, fibroblasts and keratinocytes, and a fully developed extra cellular matrix (ECM) in its epidermis and dermis layers. TheraSkin provides, upon application, an "at ready" supply of growth factors/cytokines, and a collagen scaffold to jumpstart healing in a recalcitrant, non-healing chronic wound. It is approved for use in the treatment of venous stasis ulcer and neuropathic diabetic foot ulcers

Talymed® (Q4127): Talymed is a sterile advanced wound matrix comprised of shortened fibers of poly-N-acetylglucosamine, isolated from microalgae. It is indicated for the management of wounds including: diabetic ulcers, venous ulcers, pressure wounds, ulcers caused by mixed vascular etiologies, full thickness and partial thickness wounds, second degree burns, surgical wounds-donor sites/grafts, post-Mohs surgery, post-laser surgery, and other bleeding surface wounds, abrasions, lacerations, traumatic wounds healing by secondary intention, chronic vascular ulcers, dehisced surgical wounds. It is approved for treatment of diabetic foot ulcer and venous stasis ulcer.

Epifix® (Q4131): Epifix is an amniotic membrane allograft used in the treatment of chronic and acute wounds. It is approved for diabetic foot ulcer and venous stasis ulcer. Additionally, diabetic ulcers of the ankle and calf are covered.

Grafix® (Q4132) (Q4133): Grafix is a living skin substitute allograft comprised of a biologic membrane with native mesenchymal stem cells used as a covering to promote healing and tissue repair in chronic wounds

CPT codes 15002, 15003, 15004, and 15005 are used to report excision of non-viable tissue in preparation of a clean and viable wound surface for initial skin graft, flap, and negative pressure wound therapy or substitute graft

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application. UnitedHealthcare Medicare & Retirement does not expect to be billed for CPT codes 15002, 15003, 15004, and 15005 in conjunction with routine, simple and/or repeat application of skin substitutes/replacements.

Wound cleansing and removal of exudates, existing skin replacement graft material and/or nominal amounts of devitalized tissue are included with the skin replacement application procedure. UnitedHealth Care expects separate reporting of surgical debridement with application of skin replacements only when gross contamination requiring extended cleansing and removal of appreciable amounts of devitalized tissue are performed and documented. UnitedHealth Care expects that most repeat applications of skin replacement materials will not require separate debridement procedures.

Product Wastage
UnitedHealth Care provides payment for the amount of the BSS product that is reasonable and necessary to treat the patient's ulcer. If the physician has made good faith efforts to minimize the unused portion of the BSS product in how patients are scheduled and how he/she ordered, accepted, stored and used the product, and made good faith efforts to minimize the unused portion of the product in how it is supplied, the program will cover the amount of product discarded along with the amount used to treat the ulcer.

Documentation Requirements
- Documentation supporting medical necessity should be legible, maintained in the patient's medical record and made available to UnitedHealthcare upon request.
- Medical record documentation must confirm and support characteristics of the ulcer, the presence of qualifying or disqualifying conditions, and the nature of and the duration of pretreatment conservative/conventional management.
- The exact location of each ulcer treated must be included in the medical record.
- Documentation of response, or lack thereof, to conservative therapy requires documentation of the measurements (depth, width and length or circumference) of the ulcer at initial presentation and following conservative or conventional management to be included in the medical record.
- Documentation must include measurement (width and length or circumference and depth) of the ulcer immediately prior to all applications of skin substitutes/replacements.
- The record must document that wound treatments with bioengineered skin substitutes are accompanied by appropriate adjunctive wound care measures such as dressing changes during the healing period, appropriate compressive dressings, appropriate off-loading, etc.
- Documentation must show that the skin substitute product was appropriately handled, applied, and immobilized in accordance with manufacturer's label instructions.
- Medical record documentation must clearly document the medical necessity of, performance of and the extent of site preparation procedures reported with bioengineered skin substitute application services.
- Documentation of smoking history, and that the patient has received counseling on the effects of smoking on surgical outcomes and treatment for smoking cessation (if applicable) as well as outcome of counselling must be in the medical record.
- Any amount of wasted material must be clearly documented in the medical record with the following information:
  - Date, time and location of ulcer treated.
  - Approximate amount of product unit used.
  - Approximate amount of product unit discarded.
  - Reason for the wastage.
  - Manufacturer's serial/lot/batch or other unit identification number of graft material. When manufacturer does not supply unit identification, record must document such.

APPLICABLE CODES

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

Coding Clarification: Local Coverage Determinations (LCDs) and/or Articles may vary in coverage per jurisdiction.

CPT Code	Description
15002	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, legs; first 100 sq cm or 1% of body area of infants and children

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CPT Code	Description
15003	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, legs; first 100 sq cm or 1% of body area of infants and children
15004	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet and/or multiple digits; first 100 sq cm or 1% of body area of infants and children
15005	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet and/or multiple digits; each additional 100 sq cm, or part thereof, or each additional 1% of body area of infants and children (List separately in addition to code for primary procedure)
15271	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
15272	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)
15273	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
15274	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)
15275	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
15276	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)
15277	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
15278	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)

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HCPCS Code	Description
Porcine Skin Substitutes: See the Medicare Advantage Policy Guideline Porcine Skin and Gradient Pressure Dressing (NCD 270.5) for porcine HCPCS codes	
J3590	Unclassified Biologics
Q4100	Skin Substitute, not otherwise specified
Q4101	Apligraf®, per square centimeter
Q4104	Integra® Bilayer Matrix Wound Dressing (BMWD), per square centimeter
Q4105	Integra Dermal Regeneration Template® (DRT), per square centimeter
Q4106	Dermagraft®, per square centimeter
Q4107	Graftjacket®
Q4108	Integra® Matrix, per square centimeter

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HCPCS Code	Description
Q4110	Primatrix™
Q4111	Gammagraft®, per square centimeter
Q4115	Alloskin™, per square centimeter
Q4116	Alloderm®, per square centimeter
Q4117	Hyalomatrix, per square centimeter
Q4121	Theraskin®, per square centimeter
Q4122	Dermacell®, per square centimeter
Q4123	Alloskin™ RT, per square centimeter
Q4125	Arthroflex®, per square centimeter
Q4126	Memoderm®, Dermaspan, Tranzgraft or Integuply, per square centimeter
Q4127	Talymed®, per square centimeter
Q4128	Flex HD®, Allopatch HD™, or Matrix HD®, per square centimeter
Q4129	Unite Biomatrix™, per square centimeter **(Deleted 12/31/2016 – No code referenced)**
Q4131	Epifix®, per square centimeter
Q4132	Grafix® core, per sq cm
Q4133	Grafix® prime, per sq cm
Q4134	HMatrix®, per square centimeter
Q4137	Amnioexcel® or Biodexcel®, per square centimeter
Q4138	Biodfence® Dryflex, per square centimeter
Q4140	Biodfence®, per square centimeter
Q4141	Alloskin™ AC, per square centimeter
Q4143	Repriza®, per square centimeter
Q4145	Epifix® injectable, 1 MG
Q4146	Tensix™, per square centimeter
Q4147	Architect®, Architect® PX, or Architect® FX, Architect Extracellular Matrix®, per square centimeter
Q4148	Neox® 1K, per square centimeter
Q4150	Allowrap® DDS or dry, per square centimeter
Q4151	Amnioband or Guardian, per square centimeter
Q4152	Dermapure™, per square centimeter
Q4153	Dermavest®, per square centimeter
Q4154	Biovance®, per square centimeter
Q4155	Neox® FLO or Clarixflo®, 1 mg
Q4156	Neox® 100, per square centimeter
Q4157	Revitalon™, per square centimeter
Q4158	Marigen™, per square centimeter
Q4159	Affinity, per square centimeter
Q4160	Nushield™, per square centimeter
Q4161	Bio-ConneKt wound matrix, per sq cm
Q4162	AmnioPro Flow, BioSkin Flow, BioRenew Flow, WoundEx Flow, Amniogen-A, Amniogen-C, 0.5 cc
Q4163	AmnioPro, BioSkin, BioRenew, WoundEx, Amniogen-45, Amniogen-200, per sq cm
Q4164	Helicoll, per sq cm
Q4165	Keramatrix, per sq cm
Q4167	Truskin, per sq cm **(Effective 01/01/2017)**
Q4168	AmnioBand, 1 mg **(Effective 01/01/2017)**
Q4169	Artacent wound, per sq cm **(Effective 01/01/2017)**

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HCPCS Code	Description
Q4170	Cygnus, per sq cm **(Effective 01/01/2017)**
Q4171	Interfyl, 1 mg **(Effective 01/01/2017)**
Q4173	PalinGen or PalinGen XPlus, per sq cm **(Effective 01/01/2017)**
Q4174	PalinGen or ProMatrX, 0.36 mg per 0.25 cc **(Effective 01/01/2017)**

Modifier	Description
JC	Skin substitute used as a graft
JD	Skin substitute not used as graft
KX	Requirements specified in the medical policy have been met

QUESTIONS AND ANSWERS

1	Q:	Are all HCPCS codes listed in this policy covered?
	A:	No, you must review the Local Coverage Determination (LCD) and/or Article for your jurisdiction for coverage of each code.

REFERENCES

CMS National Coverage Determinations (NCDs)
NCD 270.5 Porcine Skin and Gradient Pressure Dressing

CMS Local Coverage Determinations (LCDs)

LCD	HHH	Medicare Part A	Medicare Part B
L34285 (Surgery: Bioengineered Skin Substitutes (BSS) for the Treatment of Diabetic and Venous Stasis Ulcers of the Lower Extremities) Cahaba		AL, GA, TN	AL, GA, TN
L36466 (Application of Skin Substitutes) Palmetto	NC, SC, VA, WV	NC, SC, VA, WV	NC, SC, VA, WV
L35041 (Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds) Novitas		AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
L36377 (Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities) First Coast		FL, PR, VI	FL, PR, VI
L36690 Would Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities, CGS		OH, KY	OH, KY
L33391 (Biologic Products for Wound Treatment and Surgical Interventions) NGS **Retired 09/01/2016**		CT, IL, MA, ME, MN, NH, NY, RI, VT, WI	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
L34053 (Application of Cellular and/or Tissue Based Products (CTPs) for Wounds of Lower Extremities) CGS **Retired 10/09/2016**		OH, KY	OH, KY

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LCD	HHH	Medicare Part A	Medicare Part B
L34886 (Non-Covered Services) Noridian **Retired 07/14/2016**		AK, AZ ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ ID, MT, ND, OR, SD, UT, WA, WY

CMS Articles

Article	HHH	Medicare Part A	Medicare Part B
A54117 (Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds) Novitas		AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
A55035 (Billing Requirements for Application of Skin Substitutes (Part B Services Only)) Palmetto	NC, SC, VA, WV		NC, SC, VA, WV
A55375 (Application of SKIN SUBSTITUTE grafts for treatment of DFU and VLU of lower extremities overpayments resulting from claims processing issue) First Coast		FL, PR, VI	FL, PR, VI
A55389 (Application of Skin Substitute grafts clarification of billing when services are performed in the hospital outpatient setting) First Coast		FL, PR, VI	FL, PR, VI
A52387 (Dermagraft® – Related to LCD L33391) NGS **Retired 09/01/2016**	CT, MA, ME, NH, NY, RI, VT	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
A52388 (EpiFix® - Related to LCD L33391) NGS **Retired 09/01/2016**	CT, MA, ME, NH, NY, RI, VT	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
A52389 (Apligraf® – Related to LCD L33391) NGS **Retired 09/01/2016**	CT, MA, ME, NH, NY, RI, VT	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
A52396 (PriMatrix™ Dermal repair Scaffold - Related to LCD L33391) NGS **Retired 09/01/2016**	CT, MA, ME, NH, NY, RI, VT	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
A52401 (AlloDerm® Regenerative Tissue Matrix - Related to LCD L33391) NGS **Retired 09/01/2016**	CT, MA, ME, NH, NY, RI, VT	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
A52410 (GRAFTJACKET® Regenerative Tissue Matrix-Ulcer Repair and GRAFTJACKET® XPRESS Flowable Soft Tissue Scaffold – Related to LCD L33391) NGS **Retired 09/01/2016**	CT, MA, ME, NH, NY, RI, VT	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI

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Article	HHH	Medicare Part A	Medicare Part B
A52411 (TheraSkin® – Related to LCD L33391) NGS **Retired 09/01/2016**	CT, MA, ME, NH, NY, RI, VT	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
A52418 (Integra® Dermal Regeneration Template (IDRT)Integra® Omnigraft™ Dermal Regeneration Matrix (Omnigraft™) and Integra® Bilayer Wound Dressing - Related to LCD L33391) NGS **Retired 09/01/2016**	CT, MA, ME, NH, NY, RI, VT	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
A54057 (Grafix® - Related to LCD L33391) NGS **Retired 09/01/2016**	CT, MA, ME, NH, NY, RI, VT	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI

CMS Claims Processing Manual
Chapter 17; § 40 Discarded Drugs and Biologicals

CMS Transmittals
Transmittal 2425, Change Request 7754, Dated 03/16/2012 (Billing for Skin Substitutes)
Transmittal 2845, Change Request 8572, Dated 12/27/2013, (January 2014 Update of the Hospital Outpatient Prospective Payment System (OPPS))

MLN Matters
Article MM8548, January 2014 Integrated Outpatient Code Editor (I/OCE) Specifications Version 15.0
Article MM8575, January 2014 Update of the Ambulatory Surgical Center (ASC) Payment System, HCPCS coding and dosage descriptors
Article MM9014, Drugs, Biologicals, and Radiopharmaceuticals, (pages 10-19)
Article MM9486, January 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS) Table 10 Skin Substitute Product Assignment to High Cost/Low Cost Status CY 2016

UnitedHealthcare Commercial Policies
Omnibus Codes

GUIDELINE HISTORY/REVISION INFORMATION

Date	Action/Description
02/08/2017	• Annual review

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