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1.0 Description of the Procedure, Product, or Service

Bioengineered skin or graftskin (living skin equivalent) is used to treat chronic wounds, burns, and rare skin conditions such as recessive dystrophic epidermolysis bullosa. These products promote the growth of new skin, or serve as a temporary cover until other grafts can be placed. Bioengineered skin consists of a dermal layer and/or an epidermal layer which is embedded into a cellular matrix forming the skin substitute.

It is thought that bioengineered skin accelerates wound healing by introducing living cells, which are "smart", to reestablish the condition needed for repair.

Skin ulcers are a diverse and complex group of disorders with a variety of apparent causes. They are a source of major disability, morbidity, and carry an increased risk of mortality. Skin ulcers can result from venous insufficiency, diabetic neuropathy and/or peripheral arterial disease, pressure sores, acute surgical wounds such as those caused by excision of skin cancer, and/or burn injuries.

Management of skin wounds is designed with attention to each recipient's particular set of characteristics and causal factors. Treatment strategies incorporate common principles that apply to the management of all wounds. While there is no universally agreed upon standard of care, there are a number of accepted components of what is considered optimal local care. Principles of good wound care include optimized tissue perfusion, a moist wound environment, antimicrobial therapy where appropriate, aggressive wound debridement, pressure relief, and adequate nutrition.

Treatment for each category of ulcers has components that are indication-specific and should be used in addition to the common principles of good wound care. For example, venous ulcers combine good wound care with compression treatment. This decreases the venous pressure and improves the blood return to the heart. Diabetic neuropathic ulcers often require extensive debridement, weight off-loading, and aggressive control of blood glucose. Diabetic ulcers can be particularly difficult to heal and may require additional interventions for healing.

In the absence of complications, most acute wounds tend to heal within eight (8) weeks or so with standard care. However, a minority of wounds will not heal and become refractory. Refractory skin wounds are characterized by lack of healing, prolonged treatment courses, and frequent recurrences. In some cases of prolonged non-healing ulcers, skin grafting can be attempted.

Bioengineered skin has been shown to improve the management and healing in the treatment of severe burns. Bioengineered skin is used when there is limited amount of the recipient's own skin to use for grafts or they are too ill to have more wound sites created.

Another use for bioengineered skin is for a condition called epidermolysis bullosa (EB). EB is a rare disease that is usually inherited. These recipients suffer from extremely fragile skin with recurrent painful blister formation that can develop into open sores or ulcers. An exacerbation of this disease can be caused by just minor skin friction or trauma.

Tissue-engineered skin substitutes have emerged as a potential alternative to skin grafting in cases of refractory, non-healing skin ulcers and burns. Various manufacturers produce bio-engineered skin substitutes including: Apligraf®, Integra®, Epicel®, Dermagraft®, AlloDerm®, OrCel®, and TransCyte. Each product is different and requires FDA approval for specific indications.

Apligraf® (graftskin) is a culture-derived human skin equivalent (HSE). Like human skin it has two (2) layers. The upper epidermal layer is made of living human keratinocytes. The bottom dermal layer consists of human fibroblasts combined with bovine collagen to produce a matrix of proteins. This living skin construct is similar in cell proliferation to human skin.

Integra is a bilayered (two layers) membrane system made of a porous matrix of fibers that cross-link bovine tendon collagen and glycosaminoglycan. The epidural substitute layer is made of a thin poly silicone layer to control moisture.

Epicel® uses autologous keratinocytes from a recipient's healthy skin tissue that are cultured to form cultured epidermal autografts (CEA). The autografts are processed into sheets that are attached to a petrolatumgauze backing using stainless steel surgical clips. The autograft is applied directly to the burn wound.

Dermagraft® is a single layer biosynthetic dermal substitute made of human fibroblasts. The fibroblasts are obtained from neonatal foreskin and cultured on a bioabsorbable polyglactin mesh for several weeks. Matrix proteins are secreted during the culture period that includes human dermal collagens and soluble factors which creates a three-dimensional matrix that is used as a dermal replacement or temporary skin substitute.

OrCel ®(formally known as composite cultured skin) is a living skin equivalent. This bilayered cellular matrix is made of human dermal cells cultured in bovine collagen sponge. The absorbable matrix is used as a wound dressing.

Alloderm® is skin tissue donated from cadavers to make an acellular dermal matrix that has been freeze dried after processing. It is used to serve as a scaffold for normal tissue remodeling. The collagen framework provides strength to the skin and contains no cells that can cause rejection or irritation. Alloderm has been researched as a support mechanism for breast reconstruction, difficult hernia repairs and after parotidectomy to avoid Frey's syndrome.

Transcyte® is a bilaminate skin substitute made of human fibroblasts cultured on a silicone-covered nylon mesh and combined with a synthetic epidermal layer. This biosynthetic skin substitute is cryopreserved and used for temporary wound coverage.

EZ Derm™ is a porcine (pig) derived xenograft (non-human skin graft) of collagen that has been chemically crosslinked with aldehyde (non-human skin graft) to provide strength and durability. This skin substitute has the reliability of a long shelf life at room temperature. It is designed as a biosynthetic temporary wound covering.

Oasis® is an acellular skin substitute made from porcine small intestine. The matrix is composed of submucosa acellular collagen and acts as a wound covering. It accommodates the remodeling of host tissue by providing an acellular dermal scaffold for tissue growth.

PriMatrix™(formerly known as DressSkin) is an acellular collagen dermal tissue matrix made from fetal bovine skin. It is cell-friendly, strong and vascularizes quickly to provide a scaffold for new tissue development. It was developed to be used in the management of skin ulcers, second-degree burns, surgical wounds, and trauma wounds.

TissueMend® is an acellular soft tissue matrix (scaffold) made from fetal bovine dermis. Fetal dermis has minimal hair and hair follicles and has highly regenerative capabilities. Over time parallel collagen fibers develop and new tissue becomes integrated with the host matrix at the margins of the original wound. It assists the repair and reinforcement of soft tissue. It is indicated for wounds with poor tissue quality and insufficient tendon length such as rotator cuff repair as reinforcement.

Celaderm® is an allograft that contains active keratinocytes made from epithelial cells of the foreskin. Although metabolically active they are not capable of proliferating. The product has not received FDA approval at this time.

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

- a. Apligraf® bioengineered skin for the treatment of skin ulcers is covered when it is determined to be medically necessary because the following criteria have been met:
 1. The application of Apligraf® for the following indications:
 - (a) Treatment of venous ulcers when **ALL** of the following criteria are met.
 - (i) When used in conjunction with standard therapy;
 - (ii) The ulcers have not healed by at least 50% after clinically appropriate therapy;
 - (iii) The ulcers intended for treatment are partial or full thickness venous stasis ulcers; **AND**
 - (iv) The recipient has adequate arterial blood supply to the involved limb.
 - (b) Treatment of chronic diabetic neuropathic foot ulcers when **ALL** of the following criteria are met:
 - (i) when used in conjunction with clinically appropriate diabetic foot ulcer care;
 - (ii) the ulcers have persisted for three weeks or longer;
 - (iii) the ulcers have not healed by 50% after 3 weeks of standard treatment;

- (iv) the recipient has adequate arterial blood supply to the involved foot;
AND
 - (v) the ulcers intended for treatment are full-thickness neuropathic diabetic foot ulcers, but do not go down to the tendon, muscle, capsule, or bone.
- b. The application of Dermagraft® is covered for the treatment of full-thickness diabetic foot ulcers when **ALL** of the following criteria are met:
- 1. when used in conjunction with clinically appropriate diabetic foot ulcer care protocols;
 - 2. the ulcers have persisted for six weeks or longer;
 - 3. the ulcers have not healed by 50% after 3 weeks of standard treatment;
 - 4. the ulcers intended for treatment are full-thickness neuropathic diabetic foot ulcers, but do not extend down to the tendon, muscle, joint capsule, or bone;
AND
 - 5. the recipients have adequate blood supply to the involved foot.
- c. Alloderm® (an acellular allograft) may be considered medically necessary for use in breast reconstruction surgery.
- d. Bioengineered skin may be considered medically necessary in the treatment of burns and rare skin conditions such as recessive epidermolysis bullosa when all of the following criteria are met.
- 1. When the product has full FDA approval **AND**
 - 2. When the product is used in the scope of the FDA indications.

3.3 Policy Guidelines

- a. Currently there is insufficient evidence to determine the efficacy for uses of certain bioengineered skin other than those indicated above as covered.
- b. The use Alloderm® in breast reconstruction can be particularly useful in women who have insufficient tissue expander or implant coverage by the pectoralis major muscle and additional coverage is required, or when there is viable but compromised or thin post-mastectomy 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 are needed.

4.0 When the Procedure, Product, or Service Is Not Covered

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;

- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

4.2 Specific Criteria

- a. Bioengineered skin is not covered for indications other than those listed in **Subsection 3.2**.
- b. Apligraf® is contraindicated for use in the following situations:
 - 1. The wounds are infected.
 - 2. The recipient has a known allergy to bovine collagen.
 - 3. The recipient has a known hypersensitivity to components in the product's agarose shipping medium.
 - 4. The application of Apligraf® has not been proven medically effective and is therefore considered investigational for all other applications including: burns, pressure sores and acute surgical wounds. The NC Health Choice Program does not cover investigational services.
- c. Dermagraft® is contraindicated for use in the following situations:
 - 1. Ulcers that have signs of clinical infection
 - 2. Ulcers that have sinus tracts.
 - 3. Recipients with known hypersensitivity to bovine products.
 - 4. For any indications other than those listed in **Subsection 3.2.b**.
- d. Alloderm® is considered investigational for all indications except as indicated in **Subsection 3.2.c** including: parotidectomy and recurrent hernia repair or other major abdominal cavity reconstruction.
- e. Other Graftskin products have not been proven medically effective and are therefore considered investigational for all other applications.
- f. EZ Derm® and Mediskin®
- g. Oasis®, Surgis®
- h. Acticoat®
- i. GraftJacket
- j. PriMatrix™(formerly known as DressSkin)
- k. TissueMend®
- l. Celaderm®.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is not required for bioengineered skin.

5.2 Application Limits

- a. Apligraf® applications will be limited to no more than four (4) per wound when the criteria in **Subsection 3.2a** are met.
- b. Dermagraft® applications will be limited to no more than eight (8) weekly per wound when the criteria in **Subsection 3.2b** are met.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

7.0 Additional Requirements

7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010		Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 “NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY.

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

CPT Codes				
15150	15151	15152	15155	15156
15157	15170	15171	15175	15176
15300	15301	15320	15321	15330
15331	15335	15336	15340	15341
15360	15361	15365	15366	
HCPCS Codes				
Q4100	Q4101	Q4106	Q4112	Q4113
Q4116	Q4104	Q4105	Q4106	Q4114
Q4111				

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

F. Place of Service

Inpatient Hospital, Outpatient Hospital, and Office

G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services.

H. Reimbursement

Providers must bill their usual and customary charges.