

OHCA Guidelines

Medical Procedure Class:	Wound Care and Skin Substitutes
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<p>* This document is not a contract, and these guidelines do not reflect or represent every conceivable situation. Although all items contained in these guidelines may be met, this does not reflect, or imply, any responsibility of this agency or department to change the plan provision to include the stated service as an eligible benefit.</p>	

New Criteria

Revision of Existing Criteria

Summary	
Purpose:	To provide guidelines to assure medical necessity and consistency in the prior authorization process.

Definitions

- Acellular** – Not composed of or having cells
- Allogeneic** – Tissues or cells that are genetically different making them immunologically incompatible.
- Allograft** – Tissue graft or organ between genetically different individuals of the same species.
- Ankle-brachial index (ABI)** – The ankle to arm ratio of systolic blood pressure which is useful in diagnosing peripheral arterial disease.
- Autograft** – Tissue graft transplanted within the same individual, usually from one location to another.
- Autologous** – Tissues or cells that are re-implanted in the same individual from which they were harvested.
- Biological** – In medicine, refers to a substance made from a living organism or its products.
- Bioengineered** – The design and manufacturing of aids (i.e., artificial limbs, organs) to rectify defective body functions.
- Bovine** – Relating to cow or cattle.
- Cellular** – Made up of living cells.
- Cellulitis** – Inflammation of the tissue just below the skin surface.
- Charcot arthropathy** – Neuropathic joint disease caused by diminished proprioceptive sensation, with gradual destruction of the joint by repeated injury.
- Chronic** – Lasting for a long period of time or marked by frequent recurrence.
- Coagulum** – Any coagulated mass, clump, or clot.
- Collagen** – Protein component of bone, cartilage, tendon and other connective tissue.
- Composite** – Made by combining two or more existing things.
- Compression therapy** – Support garments such as: socks, sleeves, or stockings, that are designed to apply pressure and support the veins in order to improve circulation.
- Cryopreserved** – To preserve cells or tissue by freezing at very low temperatures.
- Diabetes Mellitus** – A disorder of carbohydrate metabolism, caused by a deficiency of insulin, characterized by excessive thirst and urination.
- Debridement** – Surgical removal of foreign material or dead damaged or infected tissue from a wound.

Dehydrated – To remove water from; make anhydrous.

Eschar – A dry scab or slough formed on the skin as a result of a burn or gangrene.

Exudate – Any fluid of semisolid that has oozed out of a tissue or its capillaries because of injury or inflammation. Is characteristically high in protein and white blood cells.

Fibroblasts – Cells that are commonly known as the healing cells that are the precursors of bone, collagen and other connective tissue cells.

Foreskin – Fold of skin that covers the penis and is removed in circumcision.

Harvest – To remove tissues or cells from a living or dead body for the purposes of transplantation.

HbA1C – Glycosylated hemoglobin-also called hemoglobin A1C which is a common lab value to determine glucose intolerance in diabetes. The percentage of hemoglobin that is glycosylated can be assessed over a long period of time.

Immunology – The bodily distinction of self from non-self.

Keratinocytes – Cells found in the epidermis that produce keratin.

Matrices – Plural for matrix.

Matrix – Something within or from which something else originates, develops or takes form; the extracellular substance in which tissue cells are embedded.

Necrotic – Death of tissue in response to disease or injury.

Osteomyelitis – Inflammation of bone and bone marrow caused by infection.

Porcine – Relating to swine or a pig.

Proprioceptive – Awareness of one's own self. Pertaining to awareness of posture and sensations of body movements. Being able to orient self in space without visual clues.

Regeneration – Regrowth of cells, tissues, organs or limbs.

Skin substitute – A material used to cover wounds or burns where extensive areas of skin are missing, to promote healing.

Sinus tract – A narrow, elongated channel in the body that allows the escape of fluid.

Synthetic – A substance that is produced by an artificial rather than a natural process.

Tunnel – An elongated passageway, usually open at both ends.

Ulcer – A break in skin or mucous membrane with loss of surface tissue, disintegration, necrosis of epithelial tissue and often pus.

Venous – Refers to the veins; the vessels leading back to the heart.

Viable – Capable of growing or developing.

WNL – Within normal limits

Xenograft – A graft in which the donor and recipient are of different species (i.e., bovine or porcine).

Description

A wound is an injury resulting in division of tissue or rupture of the integument or mucous membranes due to an external force or as a result from a disease process. Wounds are classified as acute or chronic. A chronic wound is defined as a wound that has not healed in an expected amount of time based on a patient's age, disease process, comorbidities, and wound etiology. Typically, chronic wounds are those that have not healed within 30 days. Commonly, chronic wounds are those of the lower extremity, such as, venous leg ulcers and diabetic foot ulcers.

Wound treatment depends on the type of wound, the location of the wound, and the wound size. All wounds should be free from infection, coagulum, sinus tracts, tunnels, cellulitis, eschar and necrotic tissue. There should be no exposure of joints, tendons, ligaments, or bone. Standard wound care therapy is comprised of wound cleansing, debridement if indicated, utilization of appropriate wound care product, management of infection and edema, initiating non-weight bearing measures (i.e., off-loading), compression therapy if appropriate, and management of underlying disease processes.

For the sake of this guideline, Diabetes Mellitus management (Type I or II), should reflect a hemoglobin A1C (HbA1C) level of 10.0% or less, in order to maximize optimal wound healing. A patient's nutritional status should reflect normal albumin & pre-albumin levels. Adequate blood supply to the affected area should be evidenced by palpable pedal pulses or an ankle-brachial index (ABI) of ≥ 0.70 . For patients with hypertension, appropriate management of blood pressure is essential and should be well documented in the record. Patients who smoke need to be made aware that wound healing is impaired by the systemic use of tobacco. If the patient is a smoker, counseling on the effects of smoking and wound healing should be documented in the medical record, as well as the smoking cessation treatments offered. Ideally, patients who smoke should cease smoking during wound treatment and prior to any skin substitute therapy.

Bioengineered skin substitutes and cellular and tissue based products (CTP's), may be indicated for chronic wounds that have not responded to standard wound therapy as stated above. There are a variety of skin substitution products available that are marketed for multiple indications. Common types of products available may be classified as human skin allografts (bioengineered from human skin or tissue components), allogeneic matrices (derived from human neonatal fibroblasts of the foreskin), composite matrices (derived from human keratinocytes and fibroblasts supported by a scaffold), and acellular matrices (derived from other than human skin {allogeneic or xenogeneic collagen, membrane, or cellular remnants} and include the majority of skin substitutes).

There are a number of skin substitutes currently available on the market with new products emerging every day. OHCA has chosen to open coverage on a limited number of products at this time and will consider the skin substitutes to be used as an adjunct to standard wound care. These products come in a variety of sizes, however, OHCA will only be covering those sizes that are the most cost effective. It is expected that where there are multiple sizes of a specific product available, the size that best fits the wound with the least amount of wastage, at the lesser cost, will be utilized. Combination therapy of skin substitutes is not allowable.

**CPT Codes Covered requiring PA: Standard wound care supplies A6010—A6407
Skin Substitute Products Q4101, Q4102, Q4106, Q4107, Q4132, Q4133, Q4186**

****See HCPCS Book for full definition of codes****

Non-covered items: Requests that do not meet medical necessity

Approval Criteria:

I. GENERAL

- A. Medical Necessity must be met. All documentation submitted to request services or substantiate previously provided services must demonstrate through adequate objective medical records, evidence sufficient to justify the member's needs for the service, in the most cost-effective manner, in accordance with the OAC 317:30-3.
- B. Standard wound care supplies (i.e., gauze pads, dressings) that exceed the set monthly limits without authorization will require a prior authorization and will require physician review to determine medical necessity.
- C. Documentation requirements as follows:
 - 1. A copy of a current signed prescription for supplies or skin substitute from a contracted qualified health care professional (M.D., D.O., P.A., C.N.P., or A.R.N.P) that includes:
 - a. Date of order;
 - b. Name of prescriber;
 - c. Name and address of member;

- d. Member's Medicaid ID#;
 - e. Item(s) to be dispensed, including anticipated frequency and duration;
 - f. Prescriber's signature.
2. Descriptive documentation of each wound requiring treatment to include:
 - a. Baseline characteristics and appearance;
 - b. Area measurements that include length, width, and depth;
 - c. Drainage amount, color, and consistency;
 - d. Presence of tunneling or undermining;
 - e. Presence of slough or necrotic tissue and documentation of debridement as indicated;
 - f. Wound response to treatment.
 3. Documentation of previous care provided to wound and specific products used. For skin substitute usage—document amount of product used, amount wasted, reason for waste, and the manufacturer's serial/lot/batch number associated with the product.
 4. Documentation of offloading and pressure relief support devices being used.
 5. Documentation of compression garments or bandages applied (if applicable and if not contraindicated).
 6. Documentation of member's nutritional status as evidenced by laboratory reports reflecting Albumin and Pre-Albumin levels that are WNL.
 7. Documentation of adequate circulation to affected area to support tissue growth and healing.
 8. Documentation of compliance with diabetes management as evidenced by laboratory reports reflecting HbA1C levels of 10.0% or below.
 9. Documentation of tobacco cessation and counseling prior to administration of a skin substitute product.
 10. Documentation of a comprehensive treatment plan for each wound(s). For non-healing wounds, documentation needs to reflect why the wound(s) have not responded to standard wound care therapy and must reference specific interventions performed.
 11. Documentation of medical management of disease processes and any underlying, exacerbating factors pertinent to care.

II. INDICATIONS

- A. Skin substitutes may be medically indicated for wounds that have failed to respond to standard wound care therapy for greater than 4 weeks, as evidenced by documentation substantiating the lack of wound improvement. Records may reflect no change in wound status from initial baseline, increase in size or depth of the wound, or no signs of developing granulation, epithelialization, or progress towards closing (less than 20% decrease in wound area); **AND**
- B. The wound does not involve tendon, muscle, joint capsule or exhibit exposed bone or sinus tracts, with a clean granular base; **AND**
- C. The wound is clean and free of necrotic debris or exudate; **AND**
- D. The wound is free from infection, surrounding cellulitis, and underlying osteomyelitis; **AND**
- E. The wound is at least 1.0 sq cm in size; **AND**
- F. The wound has adequate circulation to support tissue growth as evidenced by physical exam, palpable pedal pulses, and/or an ABI \geq 0.70; **AND**
- G. Current HbA1C (if applicable) does not exceed 10.0%; **AND**
- H. Current Albumin and Pre-Albumin levels are WNL; **AND**
- I. Documentation of current smoking cessation if member is a smoker.

****If any of the above indications are not met, the use of a skin substitute or cellular tissue product will not have an ideal environment for success. Therefore, the use of skin substitutes or cellular tissue products will be denied as not medically necessary.**

III. LIMITATIONS:

- A. A typical episode of wound care when utilizing skin substitutes will last no longer than 12 weeks. Applications of skin substitutes beyond 12 weeks are not considered medically necessary **regardless** of wound status.
- B. Skin substitutes shall be used according to the products specific guidelines. See the "Limitations" column in the table below for the maximum number of applications allowed per product.
- C. Simultaneous use of more than one skin substitute during an episode of wound care is not covered. Product change may be allowed within the episode (if necessary), but the maximum number of total applications shall not exceed 10, within the 12 week time frame. (For example, during an episode, one product may be utilized for four applications and then the provider may decide to change to another product which may have a maximum number of applications > than the original product. However, only 10 applications, combined total, will be allowed).
- D. Repeat or alternative applications are not considered medically necessary when a previous full course of applications was unsuccessful. Unsuccessful treatment is evidenced by: no change in the wound from initial baseline, an increase in size or depth of the wound, or there are no signs of developing granulation, epithelialization, or progress towards closing.
- E. Re-treatment within one (1) year of any course of a skin substitute is considered treatment failure and does not meet reasonable and necessary criteria.
- F. Any requests for additional product applications, beyond the maximum product limitations, should include documentation demonstrating medical necessity and shall be forwarded to the medical director for review.
- G. Duration of a prior authorization for skin substitutes shall be 4 weeks (in order to track number of applications). Additional prior authorizations must be requested for continued treatment of the wound within the wound care episode.
- H. Skin substitutes are contraindicated and are not considered reasonable and necessary in patients with inadequate control of underlying conditions or exacerbating factors such as, uncontrolled diabetes, active infection, vasculitis, active Charcot arthropathy, or continued tobacco smoking without physician attempt to affect smoking cessation.

HCPCS Code	PRODUCT	PACKAGED	INDICATIONS	TYPE OF SKIN SUBSTITUTE	LIMITATIONS	CPT Application Codes
Q4101	Apligraf (Graftskin)	44 sq cm (~7.5x5.8)	Venous Ulcers Diabetic Foot Ulcers	Bioengineered, bilayered, living cell based product. Contains neonatal keratinocytes and fibroblasts embedded in a bovine collagen matrix	Initial application followed by additional applications at one week intervals up to a maximum of four in a 12 week period (Maximum 5 applications) **Applications beyond 12 weeks are considered not medically necessary regardless of wound status**	15271-15278
Q4106	Dermagraft	37.5 sq cm (~7.5x5)	Diabetic Foot Ulcers	Bioengineered, cryopreserved neonatal fibroblasts seeded on a bio-absorbable scaffold that produce proteins and growth factors (newborn foreskin)	Initial application followed by additional applications up to a maximum of eight in a 12 week period (Maximum 8 applications) **Applications beyond 12 weeks are considered not medically necessary regardless of wound status**	15275-15278
Q4186	Epifix	14 mm 18 mm 2x2 sq cm 2x3 sq cm 2x4 sq cm 3x4 sq cm 4x4 sq cm 5x6 sq cm 7x7 sq cm	Venous Ulcers Diabetic Foot Ulcers	Dehydrated human amnion/chorion membrane (dhacm) allograft (human placenta) that contains extracellular matrix proteins, growth factors, cytokines, and other specialty proteins	Initial application followed by additional applications at one week intervals up to a maximum of four in a 12 week period (Maximum 5 applications) **Applications beyond 12 weeks are considered not medically necessary regardless of wound status**	15271-15278
Q4102	Oasis	3x3.5 sq cm 3x7 sq cm	Venous Ulcers Diabetic Foot Ulcers	Extra cellular matrix (ECM) derived from porcine small-intestine with growth factors	Initial application followed by additional applications at one week intervals up to a maximum of four in a 12 week period (Maximum 5 applications) **Applications beyond 12 weeks are considered not medically necessary regardless of wound status**	15271-15278
Q4132 Q4133	Grafix Core and Grafix Prime	<u>Core (Chorion)</u> 16 mm 1.5x2 sq cm 2x3 sq cm 3x4 sq cm 5x5 sq cm <u>PRIME</u> 16 mm 1.5x2 sq cm 2x3 sq cm 3x4 sq cm 5x5 sq cm	Venous Ulcers Diabetic Foot Ulcers	Cryopreserved placental membrane comprised of extracellular matrix containing collagen, growth factors, fibroblasts, mesenchymal stem cells, and epithelial cells	Initial application followed by additional applications at one week intervals up to a maximum of four in a 12 week period (Maximum 5 applications) **Applications beyond 12 weeks are considered not medically necessary regardless of wound status**	15275-15278
Q4107	Graftjacket	2x4 sq cm 4x4 sq cm 4x8 sq cm 2x12 sq cm	Diabetic Foot Ulcers	Regenerative tissue matrix, acellular, crosslinked and cryopreserved human (cadaveric) dermal matrix	One application is considered medically necessary	15275-15278

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