Guidelines for Medical Necessity Determination for Skin Substitutes

This edition of the Guidelines for Medical Necessity Determination (Guidelines) identifies the clinical information that MassHealth needs to determine medical necessity for skin substitutes. These Guidelines are based on generally accepted standards of practice, review of the medical literature, and federal and state policies and laws applicable to Medicaid programs.

Providers should consult MassHealth regulations at 130 CMR 415.000: *Acute Inpatient Hospital Services*, 130 CMR 433.000: *Physician Services*, 130 CMR 410.000: *Outpatient Hospital Services*, 130 CMR 450.000: *Administrative and Billing Regulations*, Subchapter 6 of the *Physician Manual*, and Subchapter 6 of the *Acute Outpatient Hospital Manual* for information about coverage, limitations, service conditions, and other prior-authorization (PA) requirements.

Providers serving members enrolled in a MassHealth-contracted accountable care partnership plan (ACPP), managed care organization (MCO), One Care organization, Senior Care Organization (SCO), or Program of All-inclusive Care for the Elderly (PACE) should refer to the ACPP's, MCO's, One Care organization's, SCO's, or PACE's medical policies, respectively, for covered services.

MassHealth reviews requests for PA for certain skin-substitute products on the basis of medical necessity. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including member eligibility, other insurance, and program restrictions.

1 SECTION I. GENERAL INFORMATION

Skin substitutes are cellular- and tissue-based products that may be derived from human tissue (autologous or allogeneic), nonhuman tissue (xenogeneic), synthetic materials, or a composite of these sources to replicate the functional and structural characteristics of normal skin. They are important adjuncts in the management of acute and chronic wounds, specifically for partial- and full-thickness skin loss in neuropathic diabetic ulcers, chronic venous ulcers, and pressure injuries. They can provide temporary or permanent coverage of open skin wounds following burns or injuries and be used for reconstruction. Skin substitutes have demonstrated benefits (in reduced healing time, pain, and post-operative contractures) when used alone or in addition to the standard of care for these conditions, and in situations where conservative treatment may appear insufficient to provide complete healing.

Specific manufacturing processes vary by company, but generally involve seeding selected cells onto a matrix, where they receive proteins and growth factors necessary to multiply and develop into the desired tissue. Since wound healing tends to be unique to the individual, the choice of skin substitute used needs to be carefully considered. Some factors that may inform decision-making are the type of skin substitutes available; indications; wound type; etiology; skin component that requires replacement; and desired outcomes. These Guidelines apply to the following skin substitutes for individuals with diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs). PA is granted for 16 weeks from the date of approval for a maximum of one unit per week. Please submit a new PA request if additional units are needed.

SKIN SUBSTITUTES FOR ADULTS WITH DIABETIC FOOT ULCERS (DFUS)

1. Prior authorization is NOT required for:
    a. Apligraf (Q4101), one unit per week; OR
    b. Epifix (Q4186), one unit per week; OR
    c. Dermagraft (Q4106), one unit per week.
2. Prior authorization IS required and will cover a maximum of 16 weeks of therapy for:
    a. Grafix prime or Grafixpl prime (Q4133), one unit per week; OR
    b. Amnioband (Q4151), one unit per week; OR
    c. Affinity (Q4159), one unit per week; OR
    d. Puraply (Q4196), one unit per week.

SKIN SUBSTITUTES FOR ADULTS WITH VENOUS LEG ULCERS (VLUS)

1. Prior authorization is NOT required for:
    a. Epifix (Q4186), one unit per week; OR
    b. Apligraf (Q4191), one unit per week.
2. Prior authorization IS required and will cover a maximum of 16 weeks of therapy for:
    a. Grafix prime or Grafixpl prime (Q4133), one unit per week; OR
    b. Amnioband (Q4151), one unit per week; OR
    c. Affinity (Q4159), one unit per week; OR
    d. Puraply (Q4196), one unit per week.

2 SECTION II. CLINICAL GUIDELINES

A. CLINICAL COVERAGE

MassHealth bases its determination of medical necessity for a skin-substitute graft on clinical data and the presence of indicators that would affect the relative risks and benefits of the product. These criteria include, but are not limited to, the following.

1. The presence of a chronic, noninfected DFU or chronic, noninfected VLU has failed to respond to documented standard of care treatment (outlined below) for a minimum of four weeks (defined as 30 days) with documented compliance to prescribed treatment.
    a. Failure to respond to documented standard of care treatment is defined as an ulcer that has increased in size or depth, has had no change in baseline size or depth, and has shown no sign of improvement or indication that improvement is likely (such as granulation, epithelialization, or progress toward closing). Documentation of response requires measurements of the initial

ulcer, measurements at the completion of at least four weeks of standard of care treatment, and measurements immediately before placement of the skin-substitute graft for DFUs and VLUs.

2. Member is 18 years of age or older.
3. Member has a wound index of 1 to 25 cm^2.
4. Member has no ulcer within 3 cm of index ulcer.
5. Member has an Ankle Brachial Index (ABI) level between 0.7 and 1.2.
6. For members with a DFU:
    a. Member has been assessed of Type 1 vs. Type 2 diabetes and management history with attention to certain comorbidities (e.g., vascular disease, neuropathy, osteomyelitis).
    b. Member has an Hba1c level of less than 12% within 90 days of PA submission.
    c. Member has a serum creatinine level of less than 3.0 mg/dL.
    d. Member's diet, nutritional status, and activity level have been assessed.
    e. Member's use of off-loading device or appropriate footwear has been assessed.
7. For members with a VLU:
    a. Member's clinical history (prior ulcers, thrombosis risks) and physical exam(s) (edema, skin changes) have been assessed.
    b. Member has had diagnostic testing to verify superficial or deep venous reflux, perforator incompetence, and chronic (or acute) venous thrombosis or evidence of varicosities, lipodermatosclerosis, venous dermatitis, or other clinical signs of a VLU.
    c. Member's standard of care treatment must continue for no less than four weeks and include ongoing compression therapy.
8. The implemented treatment demonstrates all the following:
    a. debridement as appropriate;
    b. form of offloading for DFUs;
    c. form of compression for VLUs;
    d. infection control; and
    e. management of exudate—maintenance of a moist environment (moist saline gauze, other classic dressings, bioactive dressing, etc.) and evaluation by an experienced wound clinician.
9. Member has documentation of smoking history and has received counseling on the effect of smoking on surgical outcomes and treatment for smoking cessation.
    a. Member is a nonsmoker; OR
    b. should have refrained from smoking for at least six weeks before treatment; OR
    c. is undergoing treatment for smoking cessation.

10. Member is able to follow the treatment plan.

11. Ulcer improves significantly over six weeks of treatment with skin substitutes, with continued significant improvement every six weeks required for coverage of ongoing applications.

If the member is pregnant, provide informed consent as these products have largely not been tested in this population.

B. NON-COVERAGE

MassHealth does not provide coverage for a skin-substitute graft to be medically necessary under certain circumstances. Examples of such circumstances include, but are not limited to, the following.

1. Member is younger than 18.

2. Member has an ulcer penetrating into muscle, tendon, or bone.

3. Member shows signs of ulcer infection, bone infection, active Charcot arthropathy, or active vasculitis of the ulcer extremity.

4. Member has an ulcer located on the dorsum of the foot.

5. Member has more than 50% of the ulcer below the malleolus.

6. Member has received negative pressure wound therapy or hyperbaric oxygen therapy in the last 7 days or treatment with other advanced wound care products within the past 30 days.

7. Member has an uncontrolled infection, such as bacteremia or osteomyelitis.

8. Member is receiving immunosuppressants or corticosteroids.

9. Member is taking COX-2 inhibitors.

10. Member has wounds of greater severity than Wagner II; in other words, these products are not covered for ulcers with deep bone involvement or gangrene.

11. Member has had more than manufacturer's recommended application procedures within the episode of skin replacement surgery.

12. Member has had repeat applications of skin-substitute grafts when a previous application was unsuccessful. Unsuccessful treatment is defined as an ulcer that has increased in size or depth, has had no change in baseline size or depth, and has shown no sign of improvement or indication that improvement is likely (such as granulation, epithelialization, or progress toward closing).

13. Wound duration beyond 104 weeks/2 years.

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SECTION III: SUBMITTING CLINICAL DOCUMENTATION

A. Some skin substitutes require PA from a MassHealth-enrolled surgeon and must be accompanied by clinical documentation that supports the medical necessity for this procedure. Clinical documentation includes, but is not limited to, documentation demonstrating that the member meets the clinical criteria for coverage of the intended procedure, as described in Section II.

B. A summary of the member's medical history must include all of the following:

   a. the primary diagnosis name and HCPCS code specific to the condition requiring the procedure;

   b. the date the member was diagnosed with the medical condition requiring the procedure; and

   c. the past treatment course and current plan of care.

C. Documentation of recent clinical evaluations must include all of the following:

   a. diagnostic studies and laboratory tests—results of studies and tests deemed relevant to the type of procedure being requested and that have been conducted in the last year;

   b. medication regimen—the type and name of prescription and over-the-counter drugs the member has received within the last three-to-six months;

   c. risk factors—description of all current medical or comorbid conditions (e.g., neurologic disease, obesity, cardiovascular disease, diabetes, HIV), surgeries or procedures, or functional status;

      i. past and present substance misuse (e.g., alcohol, tobacco, marijuana, opiates, cocaine), including date or period of time since last use. Serial blood and urine testing can be used to verify abstinence from substances that are of concern;

      ii. active tobacco use, which is a contraindication for wound healing and has been shown to be related to increased postoperative complications and poorer clinical outcomes. Provide documentation of tobacco-cessation efforts, including testing for abstinence, if clinically indicated; and

      iii. Any other non-coverage circumstances listed in Section II.B.

   d. Clinical photography with measurements of each subsequent submission, including prior photos.

CLINICAL INFORMATION

Clinical information must be submitted by the MassHealth-enrolled surgeon who is performing the procedure.

Providers must electronically submit PA requests and all supporting documentation using the Provider Online Service Center (POSC), unless the provider has a currently approved electronic claims waiver (hereinafter, "waiver"). Please see All Provider Bulletin 369 for further waiver information. If you have questions about POSC access, contact MassHealth at (800) 841-2900, TDD/TTY: 711.

For PA requests that are not submitted using the POSC, providers with currently approved waivers must include the MassHealth Prior Authorization Request (PA-1 Form) and all supporting documentation. The PA-1 Form can be found at mass.gov/prior-authorization-for-masshealth-providers.

Select References

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These Guidelines are based on review of the medical literature and current standards of care in the use of skin substitutes. MassHealth reserves the right to review and update the contents of these Guidelines and cited references as new clinical evidence and medical technology emerge.

This document was prepared for medical professionals to assist them in submitting documentation supporting the medical necessity of the proposed treatment, products, or services. Some language used in this communication may be unfamiliar to other readers; in this case, those readers should contact their health care provider for guidance or explanation.

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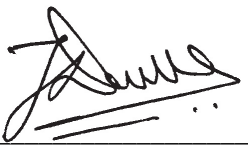
Approved by: 

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