Clinical Policy: Skin and Soft Tissue Substitutes

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See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Patients receiving treatment with a skin substitute graft should be under the care of a wound care physician or surgeon and systemic disease should be monitored/treated to ensure adequate healing of the wound site. This policy addresses the medical necessity criteria for skin substitutes for the treatment of wounds..

Skin substitutes range widely in terms of origin, additives, and processing. Processing variations lead to broad differences between products within the same class, with a need for more comparative product studies. The result is that products within the same class vary significantly and the impact on the product's function is indeterminant in many cases.[31] A 2024 systematic review/meta-analysis concluded that "enough evidence is still lacking to determine a statistical difference between broad categories of CAMPs [cellular, acellular and matrix-like products]; hence decision-makers should consider published head-head comparative studies, real-world evidence, and cost-effectiveness evidence between individual CAMPs to decide on which to use in practice."[32]

Medical necessity determinations regarding preferred products when deemed medically necessary are applicable to FDA-labeled indications. Preferred products are subject to change based on new product launches, product approvals, product withdrawals and other market changes. (NOTE: *Per state requirements, any determination that a requested service or item is not medically necessary shall be made by a PHW/Centene Medical Director.)*

Note: For criteria applicable to:

- Medicare plans, please see MC.CP.MP185 Skin and Soft Tissue Substitutes.
- Burn treatment (other than skin substitutes), please see CP.MP.186 Burn Surgery.
- Breast reconstructive procedures, please see CP.MP.31 Cosmetic and Reconstructive Procedures.

Policy/Criteria

I. It is the policy of non-Medicare health plans affiliated with Centene Corporation® that up to four initial applications of skin and soft tissue substitutes/cellular and tissue-based products (CTPs) are **medically necessary** for *diabetic foot ulcers (DFU) or venous leg ulcers (VLU)* when all the following criteria are met, specific to the wound for which the skin substitute/CTP is being requested:

A. Request indicates the specific wound to which the skin and soft tissue substitute/CTP will be applied;
B. The wound is > 1 square centimeter;
C. The wound is not infected and one of the following:
   1. For patients with a DFU, documentation of all the following:

a. Failure to achieve at least 50% ulcer area reduction, despite compliance with standard of care (SOC) wound treatment for a minimum of four weeks, as noted in I.D.;
b. Assessment of type 1 or type 2 diabetes and management history with attention to certain comorbidities (e.g., vascular disease, neuropathy, osteomyelitis);
c. Review of current blood glucose levels/hemoglobin A1c (HbA1c);
d. Diet, nutritional status, and activity level;
e. Updated medication history, including review of pertinent medical problems diagnosed since the previous ulcer evaluation;
f. Physical exam assessing skin, ulcer, and vascular perfusion, as well as off-loading devices or use of appropriate footwear;

2. For patients with a VLU, documentation of all the following:
a. Failure to respond, despite compliance with SOC wound treatment for a minimum of four weeks, as noted in I.D;
b. Assessment of clinical history (prior ulcers, body mass index, history of pulmonary embolism or superficial/deep venous thrombosis, number of pregnancies, and physical inactivity);
c. Updated medication history, including review of pertinent medical problems diagnosed since the previous ulcer evaluation;
d. Physical exam assessing for edema, skin changes and evaluation of vascular competence (including venous reflux and perforator incompetence) and venous thrombosis;
e. Documentation supporting the use of a firm strength compression garment (>20 mmHg) or multi-layered compressive dressing;

D. Documentation that modifiable risk factors, such as diabetes, venous insufficiency, and neuropathy are being addressed adequately to improve likelihood of healing;
E. Documentation of implemented SOC treatment plan demonstrating all the following:
1. Debridement as appropriate to a clean, granular base;
2. Documented evidence of one of the following:
a. Offloading for DFUs;
b. Sustained compression dressings for VLUs;
3. Infection control, with removal of foreign body or nidus of infection, as applicable;
4. Management of exudate with maintenance of a moist environment;
5. One of the following:
a. The member/enrollee is a non-smoker;
b. The member/enrollee has been counseled on the effect of smoking on wound healing and has completed, or is currently enrolled in, smoking cessation therapy;

F. Documentation to support failure to heal or stalled healing with SOC, as applicable, including all the following:
1. Measurements of the initial ulcer;
2. Pre-SOC ulcer measurements;
3. Weekly SOC ulcer measurements;
4. Post-completion SOC ulcer measurements following at least four weeks of SOC treatment;
5. Other interventions, as applicable;

G. Request is for one of the following preferred products:

1. Kerecis Omega3 Margen Shield (A2019);
2. Apligraf (Q4101);
3. Oasis Wound Matrix (Q4102);
4. Integra Bilayer Matrix Wound Dressing (Q4104);
5. Integra dermal regeneration template or Integra Omnigraft dermal regeneration matrix (Q4105);
6. Dermagraft (Q4431)
7. Graftjacket (Q4107);
8. Theraskin (Q4121);
9. Grafix Core and Grafix PL Core (Q4132);
10. Grafix PRIME, GrafixPL; PRIME, Stravix and Stravix PL (Q4133);
11. Kerecis Omega3 (Q4158);
12. Epifix (Q4186)

H. Requested use complies with the requested product's labeled indications;

I. Only one skin and soft tissue substitute/CTP will be simultaneously in place per wound episode with the first skin and soft tissue substitute/CTP application beginning the episode of care.
Note: Product change within the wound episode is allowed, with a total of up to four initially authorized and total applications not to exceed the ten (10)-application limit per wound per 12-week episode of care;

J. The graft will be applied in a single layer without overlay of product or adjacent skin and in compliance with the correct label application techniques for the skin and soft tissue substitute/CTP;

K. The following documentation requirements will be met for each application:
1. Documentation, including the size of the wound at baseline and follow-up, with measurements of wound location, stage, size, depth, duration, and presence of infection;
2. A complete description of the procedure including product used (with identifying package label or National Drug Code [NDC] in the chart) and size of product used;
3. If multiple sizes of a specific product are available, the size that best fits the wound is utilized, with the least amount of wastage;
4. If a portion of a product is discarded, documentation includes all the following:
   a. The amount administered and wasted;
   b. The date, time, and amount of product wasted and the reason for the wastage.
   Note:
   - When a portion of a single use package must be discarded, payment will be made for the portion discarded along with the amount applied up to the amount of the product on the package label.
   - All documentation must be maintained in the member/enrollee's medical record and made available upon request.

II. It is the policy of non-Medicare health plans affiliated with Centene Corporation® that continued treatment beyond the initial four applications and up to a total of ten (10) applications with skin and soft tissue substitutes/cellular and tissue-based products (CTPs) is **medically necessary** for *diabetic foot ulcers (DFU) or venous leg ulcers (VLU)* when all of the following criteria are met, specific to the wound for which the skin substitute/CTP is being requested:

A. Request indicates the specific wound to which the skin and soft tissue substitute/CTP will be applied;

B. The wound is > 1 square centimeter;
C. Request is for one of the following preferred products:
   1. Kerecis Omega3 Margen Shield (A2019);
   2. Apligraf (Q4101);
   3. Oasis Wound Matrix (Q4102);
   4. Integra Bilayer Matrix Wound Dressing (Q4104);
   5. Integra dermal regeneration template or Integra Omnigraft dermal regeneration matrix (Q4105);
   6. Dermagraft (Q4431);
   7. Graftjacket (Q4107);
   8. Theraskin (Q4121);
   9. Grafix Core and Grafix PL Core (Q4132);
   10. Grafix PRIME, GrafixPL; PRIME, Stravix and Stravix PL (Q4133);
   11. Kerecis Omega3 (Q4158);
   12. Epifix (Q4186).
D. Requested use complies with the requested product's labeled indications;
E. Documentation includes all the following:
   1. Explanation of why extended time or additional applications (beyond the initial four) are medically necessary for the specific member/enrollee's wound;
   2. That the treatment plan regarding the initial four applications has resulted in wound healing and expectation that the wound will continue to heal with this plan;
   3. Estimated time for extended treatment, number of additional applications anticipated, and plan of care if healing is not achieved as planned;
   4. Modifiable risk factors, such as diabetes, venous insufficiency, and neuropathy, are being addressed adequately to improve likelihood of healing;
   5. For venous leg ulcers, appropriate consultation and management for the diagnosis and stabilization of any venous-related disease;
   6. Additional documentation from each of the initial four applications, and for all subsequent applications, includes all the following:
      a. A complete description of the procedure including product used (with identifying package label or NDC in the chart) and size of product used;
      b. Documentation, including the size of the wound at baseline and follow-up, with measurements of the wound location, stage, size, depth, duration, and presence of infection;
      c. The skin and soft tissue substitute/CTP is applied in a single layer without overlay of product or adjacent skin and in compliance with the correct label application techniques for the skin and soft tissue substitute/CTP;
      d. When multiple sizes of a specific product are available, the size that best fits the wound with the least amount of wastage is utilized;
F. Only one skin and soft tissue substitute/CTP will be simultaneously in place per wound episode with the first skin and soft tissue substitute/CTP application beginning the episode of care;
   Note: Product change within the wound episode is allowed; total applications not to exceed the ten (10) application limit per wound per 12-week episode of care;
G. When a portion of a product was discarded, the medical record clearly demonstrates the amount administered and wasted, in addition to the date, time, amount of product wasted and the reason for the wastage.
   Note:

- When a portion of a single-use package must be discarded, payment will be made for the portion discarded along with the amount applied up to the amount of the product on the package label.
- All documentation must be maintained in the member/enrollee's medical record and made available upon request.

III. It is the policy of non-Medicare health plans affiliated with Centene Corporation that skin and soft tissue substitutes/CTPs for *diabetic foot ulcers (DFU) and venous leg ulcers (VLU)* are **not medically necessary** for the following indications or scenarios:

A. Any usage not listed in section I. or II. of the policy;
B. Greater than ten applications of a skin and soft tissue substitute/CTP within an episode of care (up to twelve weeks);
C. Repeat applications of skin and soft tissue substitute/CTP when a previous application was unsuccessful. Unsuccessful treatment is defined as increase in size or depth of an ulcer, no measurable change from baseline, and no sign of improvement or indication that improvement is likely (such as granulation, epithelialization, or progress towards closure);
D. Inadequate control of underlying conditions or exacerbating factors, or other contraindications (e.g., active infection, progressive necrosis, active Charcot arthropathy of the ulcer extremity, active vasculitis, or ischemia);
E. Use of surgical preparation services (e.g., debridement), with routine, simple, or repeat skin replacement surgery with a skin and soft tissue substitute/CTP;
F. Use of liquid or gel skin and soft tissue substitute/CTP for ulcer care;
G. Placement of skin and soft tissue substitute/CTP on an infected, ischemic, or necrotic wound bed.

IV. It is the policy of non-Medicare health plans affiliated with Centene Corporation that *burn treatment* with skin and soft tissue substitutes/CTPs (including the procedure, product, service) is considered **medically necessary** when meeting all the following, specific to the wound for which the skin substitute/CTP is being requested:

A. Request indicates the specific wound to which the skin and soft tissue substitute/CTP will be applied;
B. Request is for four weeks of treatment at a time;
C. The wound is > 1 square centimeter;
D. Sufficient autograft is not available at the time of excision or is not feasible due to the physiological condition of the member/enrollee;
E. No evidence of burn wound infection;
F. Burn is either deep partial-thickness or full-thickness;
G. Documentation of all the following:
    1. Modifiable risk factors for impaired wound healing are being addressed adequately to improve likelihood of healing;
    2. Review of current blood glucose levels/hemoglobin A1c (HbA1c), if member/enrollee has history of prediabetes or diabetes;
    3. Diet, nutritional status, and activity level;
    4. Updated medication history and review of pertinent medical problems diagnosed;
    5. One of the following:
        a. The member/enrollee is a non-smoker;
        b. The member/enrollee has been counseled on the effect of smoking on wound healing and has completed, or is currently enrolled in, smoking cessation therapy;
H. Treatment with any of the following skin replacement/substitutes:
    1. Allograft (human cadaver);
    2. Xenograft (porcine);

3. Tissue-engineered skin and soft tissue substitute/CTP:
   a. Biobrane® (A2043);
   b. Biobrane® Glove (A2044);
   c. Transcyte® (Q4182);
   d. Integra® Wound Matrix (Q4108);
   e. Integra® meshed Bilayer Wound Matrix (C9363);
   f. Integra® bilayer matrix wound dressing (Q4104);
   g. Integra® Dermal Regeneration Template (Q4105);
   h. Suprathel (A2012);
   i. Epicel® (C9399) if used per the U.S. Food and Drug Administration (FDA) Humanitarian Device Exemption (HDE);

I. Only one skin and soft tissue substitute/CTP will be simultaneously in place per wound episode with the first skin and soft tissue substitute/CTP application beginning the episode of care;
J. The graft will be applied in a single layer without overlay of product or adjacent skin and in compliance with the correct label application techniques for the skin and soft tissue substitute/CTP;
K. The following documentation requirements will be met for each application:
   1. Documentation, including the size of the wound at baseline and follow-up, with measurements of wound location, stage, size, depth, duration, and presence of infection;
   2. A complete description of the procedure including product used (with identifying package label or National Drug Code [NDC] in the chart) and size of product used;
   3. If multiple sizes of a specific product are available, the size that best fits the wound is utilized, with the least amount of wastage;
   4. If a portion of a product is discarded, documentation includes all the following:
      a. The amount administered and wasted;
      b. The date, time, and amount of product wasted and the reason for the wastage.

      Note:
      - When a portion of a single use package must be discarded, payment will be made for the portion discarded along with the amount applied up to the amount of the product on the package label.
      - All documentation must be maintained in the member/enrollee's medical record and made available upon request.

V. It is the policy of non-Medicare health plans affiliated with Centene Corporation that treatment with skin and soft tissue substitutes/CTPs for *breast reconstruction* are considered **medically necessary** when meeting all of the following, specific to the wound for which the skin substitute/CTP is being requested:
A. Request indicates the specific wound to which the skin and soft tissue substitute/CTP will be applied;
B. Request is for up to four weeks of treatment at a time;
C. The wound is > 1 square centimeter;
D. Post-mastectomy breast reconstruction;
E. No evidence of wound infection;
F. Documentation of all the following:
   1. Modifiable risk factors for impaired wound healing are being addressed adequately to improve likelihood of healing;
   2. Review of current blood glucose levels/hemoglobin A1c (HbA1c), if member/enrollee has history of prediabetes or diabetes;
   3. Diet, nutritional status, and activity level;
   4. Updated medication history and review of pertinent medical problems diagnosed;

5. One of the following:
   a. The member/enrollee is a non-smoker;
   b. The member/enrollee has been counseled on the effect of smoking on wound healing and has completed, or is currently enrolled in, smoking cessation therapy;

G. Treatment with any of the following skin and soft tissue substitutes/CTPs:
   1. AlloDerm® (Q4116);
   2. Cortiva® (Q4433);
   3. DermaCell® (Q4122);
   4. FlexHD or AllopatchHD (Q4128);

H. Only one skin and soft tissue substitute/CTP will be simultaneously in place per wound episode with the first skin and soft tissue substitute/CTP application beginning the episode of care;

I. The graft will be applied in a single layer without overlay of product or adjacent skin in compliance with the correct label application techniques for the skin and soft tissue substitute/CTP;

J. The following documentation requirements will be met for each application:
   1. Documentation including the size of the wound at baseline and follow-up, with measurements of wound location, stage, size, depth, duration, and presence of infection;
   2. A complete description of the procedure including product used (with identifying package label or National Drug Code [NDC] in the chart) and size of product used;
   3. If multiple sizes of a specific product are available, the size that best fits the wound is utilized, with the least amount of wastage;
   4. If a portion of a product is discarded, documentation includes all the following:
      a. The amount administered and wasted;
      b. The date, time, and amount of product wasted and the reason for the wastage.

      Note:
      - When a portion of a single use package must be discarded, payment will be made for the portion discarded along with the amount applied up to the amount of the product on the package label.
      - All documentation must be maintained in the member/enrollee's medical record and made available upon request.

VI. It is the policy of non-Medicare health plans affiliated with Centene Corporation that OrCel™ is **medically necessary** for up to four weeks of treatment for mitten hand deformities due to *dystrophic epidermolysis bullosa* when meeting all the following, specific to the wound for which the skin substitute/CTP is being requested:

A. Request indicates the specific wound to which the skin and soft tissue substitute/CTP will be applied;
B. Request is for up to four weeks of treatment at a time;
C. The wound is > 1 square centimeter;
D. Used according to FDA HDE;
E. No evidence of wound infection;
F. Documentation of all of the following:
   1. Modifiable risk factors for impaired wound healing are being addressed adequately to improve likelihood of healing;
   2. Review of current blood glucose levels/hemoglobin A1c (HbA1c), if member/enrollee has history of prediabetes or diabetes;
   3. Diet, nutritional status, and activity level;
   4. Updated medication history and review of pertinent medical problems diagnosed;
   5. One of the following:
      a. The member/enrollee is a non-smoker;

b. The member/enrollee has been counseled on the effect of smoking on wound healing and has completed, or is currently enrolled in, smoking cessation therapy;

G. Only one skin and soft tissue substitute/CTP will be simultaneously in place per wound episode with the first skin and soft tissue substitute/CTP application beginning the episode of care;
H. The graft will be applied in a single layer without overlay of product or adjacent skin in compliance with the correct label application techniques for the skin and soft tissue substitute/CTP;
I. The following documentation requirements will be met for each application:
   1. Documentation including the size of the wound at baseline and follow-up, with measurements of wound location, stage, size, depth, duration, and presence of infection;
   2. A complete description of the procedure including product used (with identifying package label or National Drug Code [NDC] in the chart) and size of product used;
   3. If multiple sizes of a specific product are available, the size that best fits the wound is utilized, with the least amount of wastage;
   4. If a portion of a product is discarded, documentation includes all the following:
      a. The amount administered and wasted;
      b. The date, time, and amount of product wasted and the reason for the wastage.

      Note:
      - When a portion of a single use package must be discarded, payment will be made for the portion discarded along with the amount applied up to the amount of the product on the package label.
      - All documentation must be maintained in the member/enrollee's medical record and made available upon request.

VII. It is the policy of non-Medicare health plans affiliated with Centene Corporation that skin and soft tissue substitutes/CTPs for *post-reconstruction surgery of abdominal wall wounds* are considered **medically necessary** when meeting all the following, specific to the wound for which the skin substitute/CTP is being requested:
A. Request indicates the specific wound to which the skin and soft tissue substitute/CTP will be applied;
B. Request is for up to four weeks of treatment at a time;
C. The wound is > 1 square centimeter;
D. Repair of hernias or for surgical repair of complex abdominal wall wounds;
E. No evidence of wound infection;
F. Documentation of all the following:
   1. Modifiable risk factors for impaired wound healing are being addressed adequately to improve likelihood of healing;
   2. Review of current blood glucose levels/hemoglobin A1c (HbA1c), if member/enrollee has history of prediabetes or diabetes;
   3. Diet, nutritional status, and activity level;
   4. Updated medication history and review of pertinent medical problems diagnosed;
   5. One of the following:
      a. The member/enrollee is a non-smoker;
      b. The member/enrollee has been counseled on the effect of smoking on wound healing and has completed, or is currently enrolled in, smoking cessation therapy;
G. Treatment with any of the following skin and soft tissue substitutes/CTPs:
   1. Alloderm (Q4116);
   2. Phasix ST (C1781);
   3. Strattice (Q4130);

H. Only one skin and soft tissue substitute/CTP will be simultaneously in place per wound episode with the first skin and soft tissue substitute/CTP application beginning the episode of care;
I. The graft will be applied in a single layer without overlay of product or adjacent skin in compliance with the correct label application techniques for the skin and soft tissue substitute/CTP;
J. The following documentation requirements will be met for each application:
    1. Documentation including the size of the wound at baseline and follow-up, with measurements of wound location, stage, size, depth, duration, and presence of infection;
    2. A complete description of the procedure including product used (with identifying package label or National Drug Code [NDC] in the chart) and size of product used;
    3. If multiple sizes of a specific product are available, the size that best fits the wound is utilized, with the least amount of wastage;
    4. If a portion of a product is discarded, documentation includes all the following:
        a. The amount administered and wasted;
        b. The date, time, and amount of product wasted and the reason for the wastage.

        Note:
        - When a portion of a single use package must be discarded, payment will be made for the portion discarded along with the amount applied up to the amount of the product on the package label.
        - All documentation must be maintained in the member/enrollee's medical record and made available upon request.

VIII. It is the policy of non-Medicare health plans affiliated with Centene Corporation that skin and soft tissue substitutes/CTPs for any indication listed in sections IV to VII above are considered **not medically necessary** for any of the following:
A. Treatment longer than twelve weeks;
B. Repeat applications when initial treatment was unsuccessful for a period of four weeks past the start of therapy (unsuccessful treatment is defined as increase in size or depth of an ulcer or no change in baseline size or depth and no sign of improvement or indication that improvement is likely such as granulation, epithelialization or progress towards closing);
C. Retreatment of healed wounds (those showing greater than 75% size reduction and smaller than 0.5 square cm).
D. Re-treatment within one year of any given course of skin substitute treatment for the same wound.

IX. It is the policy of non-Medicare health plans affiliated with Centene Corporation that **current evidence does not support** the use of skin and soft tissue substitutes/cellular and tissue-based products (CTPs) for either of the following:
A. Indications other than those listed as medically necessary above, including but not limited to, pressure ulcers;
B. Any skin and soft tissue substitute/CTP product not listed as medically necessary for the respective indications in sections I to VII above.
Note: Please see HCPCS Code Table 3 for a list of products not considered medically necessary for any indication (not all-inclusive).

Background
Standard care for lower extremity wounds and ulcers includes infection control, management of edema, mechanical offloading of the affected limb, mechanical compression, limb elevation, debridement of necrotic tissue, management of systemic disease and counseling on the risk of continued tobacco use. Additionally, maintenance of a therapeutic wound environment with appropriate dressings can facilitate

development of healthy granulation tissue and re-epithelialization. Dressings are essential to wound management because the appropriate dressing not only maintains the moisture balance within the wound, but the dressing also controls exudate, which protects the wound from additional trauma.[1-8]

The Centers for Medicare & Medicaid Services (CMS), define a chronic wound as a wound A wound that is physiologically impaired due to a disruption of the wound healing cycle because of impaired angiogenesis, innervation, or cellular migration, or other deficits for 4 weeks or longer. Even with advancements in standard wound care and synthetic occlusive dressings, some ulcers fail to heal and may benefit from a skin substitute.[1-8] The United Kingdom's National Institute for Health and Care Excellence (NICE) recommends consideration of dermal or skin substitutes as an adjunct to standard care when treating diabetic wounds that are not healing.[29] Skin substitutes promote wound healing by replacing extracellular matrix.[20] Skin substitutes are categorized based on the composition of epidermal, dermal, and composite skin present.[20] They are heterogeneous and can be largely separated into two primary categories: cellular (comprised of living cells); or acellular (composed of synthetic materials or tissue from which living cells have been removed).[21,22] The categories are further split based on composition and source of material, including xenograft, acellular allograft, cellular allograft, autograft and synthetic skin substitute choices.[20] Allografts, which use skin from another human (e.g., cadaver), and xenografts, which use skin from another species (e.g., porcine or bovine), may also be employed as temporary skin replacements. However, they are contraindicated in patients with known hypersensitivity to any component of the specific skin substitute graft (e.g., allergy to avian, bovine, porcine, equine products) and must later be replaced by an autograft or the ingrowth of the patient's own skin.[1-3]

Diabetic Foot Ulcers (DFUs) and Venous Leg Ulcers (VLUs)
For a VLU, an evaluation for the presence of saphenous vein reflux is essential prior to consideration of skin substitutes. If there is significant saphenous vein incompetency and reflux (valve closure time defined as > 500 milliseconds), or if ulcer bed veins are identified as contributory on ultrasound, a referral to a vascular surgeon or interventional radiologist is required. Endovascular laser or radiofrequency ablation can enhance rates of healing compared to other treatments for significant saphenous vein reflux. Without significant reflux, sclerotherapy may also be more beneficial.[17]

According to a 2016 Cochrane review, the overall therapeutic outcome of skin grafts and tissue replacements used with standard wound care demonstrated an increase in the healing rate of foot ulcers and slightly fewer amputations in patients with diabetes compared with standard wound care alone.[23] The Wound Healing Society updated their guidelines in 2016, indicating that cellular and acellular skin equivalents positively affect healing in diabetic ulcers by "releasing therapeutic amounts of growth factors, cytokines, and other proteins that stimulate the wound bed."[24] A health technology assessment of skin substitutes conducted for adults with neuropathic diabetic foot ulcers and venous leg ulcers found that adults with difficult to heal neuropathic diabetic ulcers and difficult to heal venous leg ulcers who used skin substitutes were more likely to experience complete wound healing than those who used standard care alone.[27] A systematic review of 17 trials using several skin substitutes to treat diabetic foot ulcers noted that completed closure of diabetic ulcers was significantly improved when compared to standard care alone.[26]

Outlined in a 2020 technical brief prepared for the Agency for Healthcare Research and Quality (AHRQ) are the various products commercially available in the United States that may be considered skin substitutes and identifies and assesses the clinical literature evaluating skin substitutes and their efficacy. Synder et al. (2020) conducted a systematic review of the published literature, grey literature and scientific packets received from manufacturers. The authors searched for systematic reviews/meta-

analyses, randomized controlled trials (RCTs), and prospective nonrandomized comparative studies examining commercially available skin substitutes. The authors identified 76 commercially available skin substitutes and categorized them based on the Davison-Kotler classification system. Sixty-eight (68%) were categorized as acellular dermal substitutes, mostly replacements from human placental membranes and animal tissue sources. Three systematic reviews and 22 RCTs examined use of 16 distinct skin substitutes, including acellular dermal substitutes, cellular dermal substitutes, and cellular epidermal and dermal substitutes in diabetic foot ulcers, pressure ulcers, and venous leg ulcers. Of the 22 included RCTs, 16 studies compared a skin substitute with standard of care (e.g., debridement, glucose control, compression bandages for venous leg ulcers, daily dressing changes with moisture-retentive dressing, such as an alginate or hydrocolloid). Twenty-one ongoing clinical trials (all RCTs) examined an additional nine skin substitutes with similar classifications. The authors found that the studies rarely reported clinical outcomes, such as amputation, wound recurrence at least two weeks after treatment ended, or patient-related outcomes, such as return to function, pain, exudate, and odor. The authors concluded that there is a lack of studies examining the efficacy of most skin substitute products and the need for better-designed and -reported studies providing more clinically relevant data. Before findings can be relied upon, more data are needed on hospitalization, pain reduction, need for amputation, exudate and odor control, and return to baseline activities of daily living and function.[19]

Burns[20,23]

A burn is defined as a traumatic injury to the skin or other organic tissue primarily caused by heat or exposure to electrical discharge, friction, chemicals, and radiation. Burns are classified in terms or degrees. First-degree burns, also called superficial partial thickness, only involve the outer layer of skin, the epidermis. These burns are red and painful but remain dry and without blisters. First-degree burns typically heal within about one week. Second degree, or partial thickness burns, extend deeper into the dermis, include blisters, and have a wet appearance. Second-degree burns are extremely painful and can take two to three weeks to heal. Third-degree, or full thickness, burns have a white or leathery appearance and are dry to the touch. These burns are often without sensation due to nerve damage. They extend the full depth of the skin. Skin grafts are typically required for healing third-degree burns. The most severe burns are called fourth-degree or are classified as with extension to deep tissues. These burns will extend to the muscles, tendons, and/or bone. Skin grafting and even more intensive surgeries or amputations may be required for healing.

Breast Reconstruction[29-35]

Reconstructive surgery is performed to restore and improve function and correct any deformities or abnormal structures of the body that have been caused by congenital defects, developmental abnormalities, trauma, infection, tumors or disease. Reconstructive breast surgery is designed to restore the normal appearance of a breast after a medically necessary mastectomy for breast cancer or other medical condition, injury or congenital abnormality, or unilateral hypertrophy resulting in symptoms following contralateral mastectomy.

Dystrophic Epidermolysis Bullosa (DEB)[41,42]

Inherited epidermolysis bullosa is a group of rare genetic disorders characterized by skin fragility and mechanically induced blistering. It comprises of four main types: epidermolysis bullosa simplex, junctional epidermolysis bullosa, dystrophic epidermolysis bullosa, and Kindler syndrome. Skin blistering on sites of mechanical trauma is the main clinical feature of epidermolysis bullosa. Blisters may be superficial, or they may be more profound and lead to ulcerations. Blisters may be generalized, disseminated to different body sites, or localized to the extremities.

In 2001, OrCel was approved under a Humanitarian Device Exception (HDE) by the U.S. Food and Drug Administration (FDA) for use in individuals with mitten hand deformities due to recessive DEB as

an adjunct to standard autograft procedures for covering wounds and donor sites created after surgical release of hand contractures.

Post-Reconstruction Surgery of Abdominal Wall Wounds[45,53-57]
A hernia occurs when internal organs or tissues bulge outwards through a weak spot in the abdominal wall muscles. Abdominal wall hernias are generally classified by location or etiology, such as ventral hernias, groin hernias, and incisional hernias. Hernia management and treatment is dependent on a multitude of factors, with specific hernia sites requiring distinctive management.

Coding Implications
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2025, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT Code Table 1: Procedure codes that support medical necessity criteria

CPT Codes	Description
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)

HCPCS Code Table 1: HCPCS codes that support medical necessity criteria

HCPCS Codes	Description
G0681	Application of a premarket approval (PMA), 510(k), 361 human cells, tissues or cellular and tissue-based products (HCT/P) nonsheet form skin substitute for a wound surface area up to 100 sq cm; first 25 sq cm or less of wound surface area
G0682	Application of a premarket approval (PMA), 510(k), 361 human cells, tissues or cellular and tissue-based products (HCT/P) nonsheet form skin substitute for a wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof
G0683	Application of a premarket approval (PMA), 510(k), 361 human cells, tissues or cellular and tissue-based products (HCT/P) nonsheet form skin substitute graft for a wound surface greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
G0684	Application of a premarket approval (PMA), 510(k), 361 human cells, tissues or cellular and tissue-based products (HCT/P) nonsheet form skin substitute graft for a wound surface 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

HCPCS Code Table 2: HCPCS codes that support medical necessity criteria

HCPCS Codes	Description
A2012	SUPRATHEL, per sq cm
A2019	Kerecis Omega3 MariGen Shield, per sq cm
A2043	BIOBRANE, per sq cm
A2044	BIOBRANE Glove, each
A4100*	Nonsheet form skin substitute, FDA-cleared as a device, not otherwise specified [OrCel]
C1781*	Mesh (implantable) [Phasix ST or Alloderm]
C9363	Skin substitute (Integra Meshed Bilayer Wound Matrix), per sq cm
C9399*	Unclassified drugs or biologicals [Epicel]
Q4101	Apligraf, per sq cm
Q4102	Oasis wound matrix, per sq cm
Q4104	Integra bilayer matrix wound dressing (BMWD), per sq cm
Q4105	Integra dermal regeneration template (DRT) or Integra Omnigraft dermal regeneration matrix, per sq cm
Q4107	Graftjacket, per sq cm
Q4108	Integra matrix, per sq cm
Q4116	AlloDerm, per sq cm
Q4121	TheraSkin, per sq cm
Q4122	DermACELL, DermACELL AWM or DermACELL AWM Porous, per sq cm
Q4128	FlexHD, or AllopatchHD, per sq cm
Q4130	Strattice, per sq cm
Q4132	Grafix Core and GrafixPL Core, per sq cm
Q4133	Grafix PRIME, GrafixPL PRIME, Stravix and StravixPL, per sq cm
Q4158	Kerecis Omega3, per sq cm
Q4182	TransCyte, per sq cm
Q4186	Epifix, per sq cm

HCPCS Codes	Description
Q4431*	PMA skin substitute product, not otherwise specified [Dermagraft]
Q4433*	361 HCT/P skin substitute product, not otherwise specified [Allomax/Cortiva]

***Note**: The product must be specified as noted in the table.

HCPCS Code Table 3: HCPCS codes that do not support medical necessity criteria for any indication

HCPCS Codes	Description
A2001	InnovaMatrix AC, per sq cm
A2002	Mirragen Advanced Wound Matrix, per sq cm
A2004	XCelliStem, 1 mg
A2005	Microlyte Matrix, per sq cm
A2006	NovoSorb SynPath dermal matrix, per sq cm
A2007	Restrata, per sq cm
A2008	TheraGenesis, per sq cm
A2009	Symphony, per sq cm
A2010	Apis, per sq cm
A2011	Supra SDRM, per sq cm
A2013	Innovamatrix FS, per sq cm
A2014	Omeza Collagen Matrix, per 100 mg
A2015	Phoenix Wound Matrix, per sq cm
A2016	PermeaDerm B, per sq cm
A2017	PermeaDerm Glove, each
A2018	PermeaDerm C, per sq cm
A2020	AC5 Advanced Wound System (AC5)
A2021	NeoMatriX, per sq cm
A2022	InnovaBurn or InnovaMatrix XL, per sq cm
A2023	InnovaMatrix PD, 1 mg
A2024	Resolve Matrix or XenoPatch, per sq cm
A2025	Miro3D, per cu cm
A2026	Restrata MiniMatrix, 5 mg
A2027	MatriDerm, per sq cm
A2028	MicroMatrix Flex, per mg
A2029	MiroTract Wound Matrix Sheet, per cc
A2030	Miro3D fibers, per mg
A2031	MiroDry Wound Matrix, per sq cm
A2032	Myriad Matrix, per sq cm
A2033	Myriad Morcells, 4 mg
A2034	Foundation DRS Solo, per sq cm
A2035	Corplex P or Theracor P or Allacor P, per mg
A2036	Cohealyx Collagen Dermal Matrix, per sq cm
A2037	G4Derm Plus, per ml
A2038	MariGen Pacto, per sq cm
A2039	InnovaMatrix FD, per sq cm
A2040	Microlyte PainGuard, per sq cm
A2041	Foundation DRS+ Duo, per sq cm
A2042	Foundation DRS+ Solo, per sq cm

HCPCS Codes	Description
A2045	NovaShield or NovoGen Wound Matrix, per sq cm
A4175	Miroderm, per sq cm
C8002	Preparation of skin cell suspension autograft, automated, including all enzymatic processing and device components
C9250	Human plasma fibrin sealant, vapor-heated, solvent-detergent (Artiss), 2 ml
C9358	Dermal substitute, native, nondenatured collagen, fetal bovine origin (SurgiMend Collagen Matrix), per 0.5 sq cm
C9360	Dermal substitute, native, nondenatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 sq cm
C9364	Porcine implant, Permacol, per sq cm
Q4103	Oasis burn matrix, per sq cm
Q4110	PriMatrix, per sq cm
Q4111	GammaGraft, per sq cm
Q4112	Cymetra, injectable, 1 cc
Q4113	GRAFTJACKET XPRESS, injectable, 1 cc
Q4114	Integra flowable wound matrix, injectable, 1 cc
Q4115	AlloSkin, per square centimeter
Q4117	HYALOMATRIX, per sq cm
Q4118	MatriStem micromatrix, 1 mg
Q4123	AlloSkin RT, per sq cm
Q4124	Oasis ultra tri-layer wound matrix, per sq cm
Q4125	ArthroFlex, per sq cm
Q4126	MemoDerm, DermaSpan, TranZgraft or Integuply, per sq cm
Q4127	Talymed, per sq cm
Q4134	Hmatrix, per sq cm
Q4135	Mediskin, per sq cm
Q4136	EZ Derm, per sq cm
Q4137	AmnioExcel, AmnioExcel Plus or BioDExcel, per sq cm
Q4138	BioDFence DryFlex, per sq cm
Q4139	AmnioMatrix or BioDMatrix, injectable, 1 cc
Q4140	BioDFence, per sq cm
Q4141	AlloSkin AC, per square centimeter
Q4142	XCM biologic tissue matrix, per sq cm
Q4143	Repriza, per sq cm
Q4145	EpiFix, injectable, 1 mg
Q4146	Tensix, per sq cm
Q4147	Architect, Architect PX, or Architect FX, extracellular matrix, per sq cm
Q4148	Neox Cord 1K, Neox Cord RT, or Clarix Cord 1K, per sq cm
Q4149	Excellagen, 0.1 cc
Q4150	AlloWrap DS or dry, per sq cm
Q4151	AmnioBand or Guardian, per sq cm
Q4152	DermaPure, per sq cm
Q4153	Dermavest and Plurivest, per sq cm
Q4154	Biovance, per sq cm

HCPCS Codes	Description
Q4155	Neox Flo or Clarix Flo 1 mg
Q4156	Neox 100 or Clarix 100, per sq cm
Q4157	Revitalon, per sq cm
Q4159	Affinity, per sq cm
Q4160	NuShield, per sq cm
Q4161	Bio-connekt wound matrix, per sq cm
Q4162	WoundEx Flow, BioSkin Flow, 0.5 cc
Q4163	Woundex, bioskin, per sq cm
Q4164	Helicoll, per sq cm
Q4165	Keramatrix or Kerasorb, per sq cm
Q4166	Cytal, per sq cm
Q4167	Truskin, per sq cm
Q4168	AmnioBand, 1 mg
Q4169	Artacent wound, per sq cm
Q4170	Cygnus, per square centimeter
Q4171	Interfyl, 1 mg
Q4173	PalinGen or PalinGen XPlus, per sq cm
Q4174	PalinGen or ProMatrX, 0.36 mg per 0.25 cc
Q4175	Miroderm, per square centimeter
Q4176	Neopatch or therion, per sq cm
Q4177	FlowerAmnioFlo, 0.1 cc
Q4178	FlowerAmnioPatch, per sq cm
Q4179	FlowerDerm, per sq cm
Q4180	Revita, per sq cm
Q4181	Amnio Wound, per sq cm
Q4183	surgiGRAFT, per sq cm
Q4184	Cellesta or Cellesta Duo, per sq cm
Q4185	Cellesta Flowable Amnion (25 mg per cc); per 0.5 cc
Q4187	Epicord, per sq cm
Q4188	AmnioArmor, per sq cm
Q4189	Artacent AC, 1 mg
Q4190	Artacent AC, per sq cm
Q4191	Restorigin, per sq cm
Q4192	Restorigin, 1 cc
Q4193	Coll-e-Derm, per sq cm
Q4194	Novachor, per sq cm
Q4195	PuraPly, per sq cm
Q4196	PuraPly AM, per sq cm
Q4197	PuraPly XT, per sq cm
Q4198	Genesis Amniotic Membrane, per sq cm
Q4199	Cygnus matrix, per sq cm
Q4200	SkinTE, per sq cm
Q4201	Matrion, per sq cm
Q4202	Keroxx (2.5 g/cc), 1 cc

HCPCS Codes	Description
Q4203	Derma-Gide, per sq cm
Q4204	XWRAP, per sq cm
Q4205	Membrane Graft or Membrane Wrap, per sq cm
Q4206	Fluid Flow or Fluid GF, 1 cc
Q4208	Novafix, per sq cm
Q4209	SurGraft, per sq cm
Q4211	Amnion Bio or AxoBioMembrane, per sq cm
Q4212	AlloGen, per cc
Q4214	Cellesta Cord, per sq cm
Q4215	Axolotl Ambient or Axolotl Cryo, 0.1 mg
Q4216	Artacent Cord, per sq cm
Q4217	WoundFix, BioWound, WoundFix Plus, BioWound Plus, WoundFix Xplus or BioWound Xplus, per sq cm
Q4218	SurgiCORD, per sq cm
Q4219	SurgiGRAFT-DUAL, per sq cm
Q4220	BellaCell HD or Surederm, per sq cm
Q4221	Amnio Wrap2, per sq cm
Q4222	ProgenaMatrix, per sq cm
Q4224	Human Health Factor 10 Amniotic Patch (HHF10-P), per sq cm
Q4225	AmnioBind or DermaBind TL, per sq cm
Q4226	MyOwn Skin, includes harvesting and preparation procedures, per sq cm
Q4227	AmnioCore TM, per sq cm
Q4229	Cogenex Amniotic Membrane, per sq cm
Q4230	Cogenex Flowable Amnion, per 0.5 cc
Q4232	Corplex, per sq cm
Q4233	SurFactor or NuDyn, per 0.5 cc
Q4234	Xcellerate, per sq cm
Q4235	AMNIOREPAIR or AltiPly, per sq cm
Q4236	carePATCH, per sq cm
Q4237	Cryo-Cord, per sq cm
Q4238	Derm-Maxx, per sq cm
Q4239	Amnio-Maxx or Amnio-Maxx Lite, per sq cm
Q4240	CoreCyte, for topical use only, per 0.5 cc
Q4241	PolyCyte, for topical use only, per 0.5 cc
Q4242	AmnioCyte Plus, per 0.5 cc
Q4245	AmnioText, per cc
Q4246	CoreText or ProText, per cc
Q4247	Amniotext patch, per sq cm
Q4248	Dermacyte Amniotic Membrane Allograft, per sq cm
Q4249	AMNIPLY, for topical use only, per sq cm
Q4250	AmnioAmp-MP, per sq cm
Q4251	Vim, per sq cm
Q4252	Vendaje, per sq cm
Q4253	Zenith Amniotic Membrane, per sq cm

HCPCS Codes	Description
Q4254	Novafix DL, per sq cm
Q4255	REGUaRD, for topical use only, per sq cm
Q4256	MLG-Complete, per sq cm
Q4257	Relese, per sq cm
Q4258	Enverse, per sq cm
Q4259	Celera Dual Layer or Celera Dual Membrane, per sq cm
Q4260	Signature Apatch, per sq cm
Q4261	TAG, per sq cm
Q4262	Dual Layer Impax Membrane, per sq cm
Q4263	SurGraft TL, per sq cm
Q4264	Cocoon Membrane, per sq cm
Q4265	NeoStim TL, per sq cm
Q4266	NeoStim Membrane, per sq cm
Q4267	NeoStim DL, per sq cm
Q4268	SurGraft FT, per sq cm
Q4269	SurGraft XT, per sq cm
Q4270	Complete SL, per sq cm
Q4271	Complete FT, per sq cm
Q4272	Esano A, per sq cm
Q4273	Esano AAA, per sq cm
Q4274	Esano AC, per sq cm
Q4275	Esano ACA, per sq cm
Q4276	ORION, per sq cm
Q4278	EPIEFFECT, per sq cm
Q4279	Vendaje AC, per sq cm
Q4280	Xcell Amnio Matrix, per sq cm
Q4281	Barrera SL or Barrera DL, per sq cm
Q4282	Cygnus Dual, per sq cm
Q4283	Biovance Tri-Layer or Biovance 3L, per sq cm
Q4284	DermaBind SL, per sq cm
Q4285	NuDYN DL or NuDYN DL MESH, per sq cm
Q4286	NuDYN SL or NuDYN SLW, per sq cm
Q4287	DermaBind DL, per sq cm
Q4288	DermaBind CH, per sq cm
Q4289	RevoShield+ Amniotic Barrier, per sq cm
Q4290	Membrane Wrap-Hydro, per sq cm
Q4291	Lamellas XT, per sq cm
Q4292	Lamellas, per sq cm
Q4293	Acesso DL, per sq cm
Q4294	Amnio Quad-Core, per sq cm
Q4295	Amnio Tri-Core Amniotic, per sq cm
Q4296	Rebound Matrix, per sq cm
Q4297	Emerge Matrix, per sq cm
Q4298	AmniCore Pro, per sq cm

HCPCS Codes	Description
Q4299	AmniCore Pro+, per sq cm
Q4300	Acesso TL, per sq cm
Q4301	Activate Matrix, per sq cm
Q4302	Complete ACA, per sq cm
Q4303	Complete AA, per sq cm
Q4304	GRAFIX PLUS, per sq cm
Q4305	American Amnion AC Tri-Layer, per sq cm
Q4306	American Amnion AC, per sq cm
Q4307	American Amnion, per sq cm
Q4308	Sanopellis, per sq cm
Q4309	VIA Matrix, per sq cm
Q4310	Procenta, per 100 mg
Q4311	Acesso, per sq cm
Q4312	Acesso AC, per sq cm
Q4313	Dermabind Fm, per sq cm
Q4314	Reeva Ft, per sq cm
Q4315	Regenelink Amniotic Membrane Allograft, per sq cm
Q4316	Amchoplast, per sq cm
Q4317	Vitograft, per sq cm
Q4318	E-Graft, per sq cm
Q4319	Sanograft, per sq cm
Q4320	Pellograft, per sq cm
Q4321	Renograft, per sq cm
Q4322	Caregraft, per sq cm
Q4323	alloPLY, per sq cm
Q4324	AmnioTX, per sq cm
Q4325	ACApatch, per sq cm
Q4326	WoundPlus, per sq cm
Q4327	DuoAmnion, per sq cm
Q4328	MOST, per sq cm
Q4329	Singlay, per sq cm
Q4330	TOTAL, per sq cm
Q4331	Axolotl Graft, per sq cm
Q4332	Axolotl Dualgraft, per sq cm
Q4333	ArdeoGraft, per sq cm
Q4334	AmnioPlast 1, per sq cm
Q4335	AmnioPlast 2, per sq cm
Q4336	Artacent C, per sq cm
Q4337	Artacent Trident, per sq cm
Q4338	Artacent Velos, per sq cm
Q4339	Artacent Vericlen, per sq cm
Q4340	SimpliGraft, per sq cm
Q4341	SimpliMax, per sq cm
Q4342	TheraMend, per sq cm

HCPCS Codes	Description
Q4343	Dermacyte AC Matrix Amniotic Membrane Allograft, per sq cm
Q4344	Tri-Membrane Wrap, per sq cm
Q4345	Matrix HD Allograft Dermis, per sq cm
Q4346	Shelter DM Matrix, per sq cm
Q4347	Rampart DL Matrix, per sq cm
Q4348	Sentry SL Matrix, per sq cm
Q4349	Mantle DL Matrix, per sq cm
Q4350	Palisade DM Matrix, per sq cm
Q4351	Enclose TL Matrix, per sq cm
Q4352	Overlay SL Matrix, per sq cm
Q4353	Xceed TL Matrix, per sq cm
Q4354	PalinGen Dual-Layer Membrane, per sq cm
Q4355	Abiomend Xplus Membrane and Abiomend Xplus Hydromembrane, per sq cm
Q4356	Abiomend Membrane and Abiomend Hydromembrane, per sq cm
Q4357	XWRAP Plus, per sq cm
Q4358	XWRAP Dual, per sq cm
Q4359	ChoriPly, per sq cm
Q4360	AmchoPlast FD, per sq cm
Q4361	EPIXPRESS, per sq cm
Q4362	CYGNUS Disk, per sq cm
Q4363	Amnio Burgeon Membrane and Hydromembrane, per sq cm
Q4364	Amnio Burgeon Xplus Membrane and Xplus Hydromembrane, per sq cm
Q4365	Amnio Burgeon Dual-Layer Membrane, per sq cm
Q4366	Dual Layer Amnio Burgeon X-Membrane, per sq cm
Q4367	AmnioCore SL, per sq cm
Q4368	AmchoThick, per sq cm
Q4369	AmnioPlast 3, per sq cm
Q4370	AeroGuard, per sq cm
Q4371	NeoGuard, per sq cm
Q4372	AmchoPlast EXCEL, per sq cm
Q4373	Membrane Wrap-Lite, per sq cm
Q4375	duoGRAFT AC, per sq cm
Q4376	Duograft AA, per sq cm
Q4377	triGRAFT FT, per sq cm
Q4378	Renew FT Matrix, per sq cm
Q4379	AmnioDefend FT Matrix, per sq cm
Q4380	AdvoGraft One, per sq cm
Q4382	Advograft Dual, per sq cm
Q4383	Axolotl Graft Ultra, per sq cm
Q4384	Axolotl DualGraft Ultra, per sq cm
Q4385	Apollo FT, per sq cm
Q4386	Acesso TrifACA, per sq cm
Q4387	NeoThelium FT, per sq cm
Q4388	NeoThelium 4L, per sq cm

HCPCS Codes	Description
Q4389	NeoThelium 4L Plus, per sq cm
Q4390	Ascendion, per sq cm
Q4391	AmnioPlast Double, per sq cm
Q4392	GRAFIX Duo, per sq cm
Q4393	SurGraft AC, per sq cm
Q4394	SurGraft ACA, per sq cm
Q4395	Acelagraft, per sq cm
Q4396	Natalin, per sq cm
Q4397	Summit AAA, per sq cm
Q4398	Summit AC, per sq cm
Q4399	Summit FX, per sq cm
Q4400	Polygon3 Membrane, per sq cm
Q4401	Absolv3 Membrane, per sq cm
Q4402	XWRAP 2.0, per sq cm
Q4403	XWRAP Dual Plus, per sq cm
Q4404	XWRAP Hydro Plus, per sq cm
Q4405	XWRAP Fenestra Plus, per sq cm
Q4406	XWRAP Fenestra, per sq cm
Q4407	XWRAP Tribus, per sq cm
Q4408	XWRAP Hydro, per sq cm
Q4409	AmniomatrixF3X, per sq cm
Q4410	AmchoMatrixDL, per sq cm
Q4411	AmniomatrixF4X, per sq cm
Q4412	CHORIOFIX, per sq cm
Q4413	Cygnus Solo, per sq cm
Q4414	SimpliChor, per sq cm
Q4415	AlexiGuard SL-T, per sq cm
Q4416	AlexiGuard TL-T, per sq cm
Q4417	AlexiGuard DL-T, per sq cm
Q4418	BioLab Membrane Wrap Flow, per sq cm
Q4419	BioLab Membrane Wrap Lite Flow, per sq cm
Q4420	NuForm, per sq cm
Q4421	BioLab Membrane Wrap Solo, per sq cm
Q4422	A/C Wrap, per sq cm
Q4423	BioLab Tri-Membrane Wrap Flow, per sq cm
Q4424	Revive FT, per sq cm
Q4425	Revive TL, per sq cm
Q4426	DermaBind TL + or DermaBind TL X, per sq cm
Q4427	DermaBind DL N, DermaBind DL +, or DermaBind DL X, per sq cm
Q4428	DermaBind SL N, DermaBind SL +, or DermaBind SL X, per sq cm
Q4429	DermaBind CH N or DermaBind CH X, per sq cm
Q4432	510(k) skin substitute product, not otherwise specified (list in addition to primary procedure)
Q4435	Renati Membrane, per sq

HCPCS Codes	Description
Q4436	Renati AC Membrane, per sq cm
Q4437	Revival AC, per sq cm
Q4438	Pretect, per sq cm
Q4439	InstaGraft, per sq cm
Q4440	CuraMatrix, per sq cm

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy adapted from WellCare's HS433 Skin Substitutes policy. Removed description information about identification of MD managing chronic conditions. Removed requirement for MD review of all requests. Rearranged some not medically necessary indications into the contraindications section. In I.D, changed requirement for no nicotine use for at least 4 weeks to documentation of effort to cease nicotine use, or no nicotine use for at least 4 weeks. In the diabetic foot ulcer criteria, removed requirement of neuropathy. In I.I.1, changed contraindication of "active Charcot arthropathy of the ulcer extremity" to "active Charcot arthropathy of the ulcer surface." In DFU section, removed documentation of assessment of physical activity, nutrition, physical exam, check of prosthetics, and history of diabetes management, including comorbidities. Changed requirement of HbA1c ≤7% to ≤8%, or with documented improvement of blood glucose in last 4 weeks. Changed HbA1c contraindication to >8% or with no document improvement of blood glucose in last 4 weeks. Reworded some extraneous language with no clinical significance. Removed criteria stating that switching products during an episode of wound care is not allowed. Removed not medically necessary language about repeated billing of surgical preparation services. Revised name of the policy to Skin Substitutes for Chronic Wounds.	04/20	04/20
Annual review completed. References reviewed and updated. Changed "Review Date" in the header to "Date of Last Revision" and "Date" in the revision log header to "Revision Date." Added "type 2 diabetes" to I.A. Reworded some extraneous language with no clinical significance. Added to I.F.2. "unless Integra® is used per FDA guidelines". Removed I.J.3. "Concurrent treatment with hyperbaric oxygen therapy". Background section updated with no additional impact to criteria. Added the following HCPCS codes: A2001-A2010, Q4199, Q4201, Q4232 and Q4254. Removed Q4119, Q4174. Added reference CMS A56696. Specialist reviewed.	04/22	04/22
Updated description for code Q4128.	10/22	
Annual review completed. Changed policy title and statements in I. and II. to reflect the inclusion of soft tissue substitutes for chronic wounds. Added note specifying that requests for skin and soft tissue substitutes other than for the indications noted in the policy is outside of the scope	04/23	04/23

Reviews, Revisions, and Approvals	Revision Date	Approval Date
of the policy. Updated policy statement I. to include full thickness skin-loss ulcers. Revised criteria I.G. In I.H clarified that the request complies with FDA-approved indications and application limits. Removed criteria II.A. Reworded extraneous language and background updated with no clinical significance. Removed deleted HCPCS code A2003. Labeled HCPCS Table 1 to note support of medical necessity. Added HCPCS Table 2 of codes that do not support medical necessity. Moved the following codes from the previous code reference table to table 2, HCPCS codes that do not support medical necessity: A2002, A2005, A2006, A2007, A2009, A2010, Q4184, Q4199, Q4237, Q4238, Q4239, Q4262, Q4263, and Q4264 Added new codes Q4253, Q4262, Q4263 and Q4264 to HCPCS table 1. Added additional codes to not medically necessary table, Table 2. References reviewed and updated.		
Annual review. In note and policy statements I and II, specified that this policy applies to non-Medicare plans. Removed language related to venous stasis ulcers. Removed criteria 1.A Age ≥ 18 years, or diabetic (Type 1 or Type 2). Removed "including silver dressings in C.1. Replaced C2 "wound has increased in size or depth or has not changed… with "Wound area has reduced <50% in four weeks". Updated description for HCPCS code A4225. Removed the following codes from HCPCS codes that do not support medical necessity criteria and added to table for HCPCS codes that support medical necessity criteria: A2002, Q4236, and Q4262. Added HCPCS code Q4278 to table for HCPCS codes that support medical necessity criteria. Added the following codes to table for HCPCS codes that do not support medical necessity criteria: Q4279 and Q4287 through Q4304. Coding reviewed. References reviewed and updated. Reviewed by external specialist.	03/24	03/24
Annual review. Removed note under description to refer to MC.CP.MP.185 for Medicare plans. Updated and replaced previous criteria I.A. through I. with new criteria I.A. through G. Also updated and replaced previous criteria II.A. through C. with new criteria I.A. through G. Description and Background reviewed and updated. Coding updated to reflect addition of preferred product list in criteria I.E. References reviewed and updated. Reviewed by external specialist.	03/25	03/25
Added the following codes to the "HCPCS codes that do not support medical necessity criteria" table: A2026, A2027, A2028, A2029, C8002, Q4280, Q4311, Q4312, Q4313, Q4314, Q4315, Q4316, Q4317, Q4318, Q4319, Q4320, Q4321, Q4322, Q4323, Q4324, Q4325, Q4326, Q4327, Q4328, Q4329, Q4330, Q4331, Q4332, Q4333, Q4334, Q4335, Q4336, Q4337, Q4338, Q4339, Q4340, Q4341, Q4342, Q4343, Q4344, Q4345, Q4346, Q4347, Q4348, Q4349, Q4350, Q4351, Q4352, Q4353, Q4368, Q4369, Q4370, Q4371, Q4372, Q4373, Q4375, Q4376, Q4377, Q4378, Q4379, Q4380, Q4382.	06/25	06/25

Reviews, Revisions, and Approvals	Revision Date	Approval Date
In policy statement I., specified that criteria is applicable to "up to four initial applications…". Under criteria I.F. removed "FDA approved" and replaced with "labeled". Added criteria I.G.-I.I. Created new policy statement II. and criteria for "beyond the initial four applications and up to a total of eight …". In III.A., added that non medically necessary indications include usage not listed in section II. of the policy. Added the following to the table of HCPCS codes that do not support medical necessity:A2036, A2037, A2038, A2039, Q4383, Q4384, Q4385, Q4386, Q4387, Q4388, Q4389, Q4390, Q4391, Q4392, Q4393, Q4394, Q4395, Q4396, Q4397. Removed Q4104 and Q4106 from list of codes not supported by medical necessity criteria, as they are on the preferred product list.	10/25	10/25
Changed policy title to "Skin and Soft Tissue Substitutes for Diabetic Foot Ulcers and Venous Leg Ulcers" and specified that policy statement III. applies to DFU and VLU.	11/25	
Annual review. Changed policy name to "Skin and Soft Tissue Substitutes." In Notes section, added additional bullet points to refer to MC.CP.MP 185, CP.MP.186, and CP.MP.31, as applicable. In policy statements I and II, noted that the medical necessity requirements are "specific to the wound for which the skin substitute/CTP is being requested" and added as the first criterion that the "request indicates the specific wound to which the skin and soft tissue substitute/CTP will be applied." Reworded I.D.5 to more clearly require that member/enrollees who smoke participate in smoking cessation therapy. In criteria I.E., updated product list for DFUs/VLUs. In I.F.6. and II.B.6., deleted code Q4106 was replaced with code Q4431. In the Note in I.H. and II.E., removed "16." In II.B., updated product list for DFUs/VLUs. Added criteria IV. regarding skin substitute use for burn treatment, with IV.B. thru IV.D. and IV.F. moved from CP.MP.186. Added criteria V. regarding skin substitute use for breast reconstruction. Added criteria VI. regarding skin substitute use for dystrophic epidermolysis bullosa. Added criteria VII. regarding skin substitute use for post-reconstructive surgery of abdominal wall wounds. Added criteria VIII. regarding indications considered not medically necessary. Added criteria IX. regarding indications of which evidence that does not support. Background section updated to include new sections on burns, breast reconstruction, dystrophic epidermolysis, and post-reconstruction surgery of abdominal wall wounds. Updated titles of coding tables. Coding reviewed and updated. Added HCPCS Code Table 1. To HCPCS Code Table 1, added codes G0681, G0682, G0683, and G0684. Added Note under HCPCS Code Table 2. To HCPCS Code Table 2, added the following: A2012, A2043, A2044, A4100, C1781, C9363, C9399, Q4108, Q4116, Q4122, Q4130, Q4182, Q4431, and Q4433.	03/26	03/26

Reviews, Revisions, and Approvals	Revision Date	Approval Date
From HCPCS Code Table 2, removed the following: Q4106, Q4110, Q4111, Q4115, Q4117, Q4118, Q4124, Q4137, Q4141, Q4146, Q4148, Q4151, Q4152, Q4154, Q4156, Q4159, Q4160, Q4166, Q4170, Q4175, Q4178, Q4187, Q4188, Q4195, Q4196, Q4197, Q4201, Q4203, Q4236, Q4253, Q4262. For HCPCS Code Table 3, added the following codes: A2004, A2008, A2040, A2041, A2042, A2045, A4175, C9250, Q4110, Q4111, Q4115, Q4117, Q4118, Q4124, Q4137, Q4141, Q4146, Q4148, Q4151, Q4152, Q4154, Q4156, Q4159, Q4160, Q4166, Q4170, Q4175, Q4178, Q4187, Q4188, Q4195, Q4196, Q4197, Q4201, Q4203, Q4236, Q4253, Q4262, Q4398, Q4399, Q4400, Q4401, Q4402, Q4403, Q4404, Q4405, Q4406, Q4407, Q4408, Q4409, Q4410, Q4411, Q4412, Q4413, Q4414, Q4415, Q4416, Q4417, Q4418, Q4419, Q4420, Q4421, Q4422, Q4423, Q4424, Q4425, Q4426, Q4427, Q4428, Q4429, Q4432, Q4435, Q4436, Q4437, Q4438, Q4439, and Q4440. For HCPCS Code Table 3, removed the following codes: A2012, C9363, Q4100, Q4108, Q4116, Q4122, Q4130, Q4182, Q4210, Q4231, and Q4244. References reviewed and updated. Reviewed by internal specialists. Reviewed by external specialist.		
In I.B.,, II.B., IV.C., V.C., VI.C., and VII.C., added that wound must be greater than 1 square centimeter. Added to IV.B., V.B., VI.B. and VII.B. that the request is for up to four weeks of treatment at a time. In I.K., II.E.6.b., IV.K.1., V.J.1., VI.I.1., and VII.J.1., noted that photographic evidence of wound size, including with a ruler for scale, is required. In V.H., added that "the graft will be applied in a single layer…" Corrected 03/26 revision log to note that codes Q4110, Q4188, and Q4432 were added to HCPCS code table 3. **Added state coverage statement and reviewed by specialist.**	04/2026	6/8/2026

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and

limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, member/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

- Note: *Per state requirements, any determination that a requested service or item is not medically necessary shall be made by a PHW/Centene Medical Director.*

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.