Clinical Policy: Skin and Soft Tissue Substitutes

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Coding Implications
Revision Log

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

Description

This policy outlines the medical necessity criteria for skin and soft tissue substitutes/cellular and/or tissue-based products (CTPs) in the treatment of wounds and is intended for use by Medicare health plans affiliated with Centene Corporation® in Medicare Administrative Contractors (MAC) jurisdictions with an absence of full coverage criteria provided by the Centers for Medicare and Medicaid Services (CMS) and the applicable MAC.

The policy criteria for diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs) are sourced from Local Coverage Determinations (LCDs) Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities (L36690), Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities (L36377), and Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds (L35041), which are supported by peer-reviewed literature and nationally-recognized guidelines.

The policy criteria for burns are sourced from the practice guidelines from the International Society for Burn Injuries (ISBI) and the American Burn Association (ABA) as well as peer-reviewed scientific literature.[79-86]

The policy criteria for breast reconstruction is sourced from LCDs Cosmetic and Reconstructive Surgery (L39051, L35090, L33428, L39506, and L38914) and the National Coverage Determination: Breast Reconstruction Following Mastectomy (140.2), which are supported by peer-reviewed literature and guidelines. In addition, criteria was also sourced from the Women's Health and Cancer Rights Act (WHCRA) and treatment guidelines from the American Society of Plastic Surgeons.[87-98]

The policy criteria for dystrophic epidermolysis bullosa (DEB) is sourced from treatment guidelines from Wounds International and European Reference Network for Rare and Undiagnosed Skin Diseases and the U.S. Food and Drug Administration (FDA)-approved indications.[99-101]

The policy criteria for post-reconstruction surgery for abdominal wall wounds is sourced from treatment guidelines from the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), the European Hernia Society (EHS), the American Hernia Society (AHS), and the HerniaSurge Group, whose guidelines are endorsed by the EHS, AHS, Asia Pacific Hernia Society (APHS), Afro Middle East Hernia Society (AMEHS), Australasian Hernia Society, International Endo Hernia Society (IEHS), European Association for Endoscopic Surgery and Other Interventional Techniques (EAES).[102-109]

Additionally, criteria related to specific products not considered medically necessary for any indication are supported by a lack of evidence of safety and efficacy in high-quality randomized

controlled trials, prospective cohort studies and nationally recognized clinical professional society guidelines.[8-78]

Standard treatment of chronic lower extremity ulcers or skin loss primarily includes infection and edema control, mechanical offloading, mechanical compression or limb elevation, debridement of necrotic or infected tissue, and management of concomitant and inciting medical issues (blood glucose control, tobacco use). Maintenance of a therapeutic environment with appropriate dressings to preclude further trauma facilitates development of healthy granulation tissue and encourages re-epithelialization. The fundamental basis for non-healing of a wound is of paramount importance and must be corrected prior to consideration of additional therapy, consistent with the criteria below. A failed response is defined as an ulcer or skin deficit that has failed to respond to documented appropriate wound-care measures, has increased in size or depth, or has not changed in baseline size or depth and has no indication that improvement is likely (such as granulation, epithelialization or progress towards closing).[1,2] Application of evidence-based wound care measures helps to ensure patients receive optimal care and progress towards treatment goals, thus minimizing the risks of treatment strategies of uncertain value.

The FDA does not refer to any product or class of products as "skin substitutes." However, products commonly described as CTPs are regulated by the FDA under one of four categories depending on the origin and composition of the product. The specific skin substitute products classified as medically necessary for the treatment of DFUs and/or VLUs have demonstrated safety and effectiveness and, therefore, benefit the patient by promoting healing and accelerating wound closure.[1,2]

Note: For criteria applicable to:

- Non-Medicare plans, please see CP.MP.185 Skin and Soft Tissue Substitutes.
- Burn treatment (other than skin substitutes), please see CP.MP.186 Burn Surgery.
- Breast reconstructive procedures, please see MC. CP.MP.31 Cosmetic and Reconstructive Procedures.

Policy/Criteria

I. It is the policy of Medicare health plans affiliated with Centene Corporation® that up to four initial applications of skin and soft tissue substitutes/CTPs are considered **medically necessary** for diabetic foot ulcers and venous leg ulcers when all the following criteria are met, specific to the wound for which the skin substitute/CTP is being requested:[1-3]

A. Request indicates the specific wound to which the skin substitute will be applied;
B. Wound is chronic, defined as a wound that does not respond to at least four weeks of standard wound treatment as a component of organized, comprehensive, conservative therapy;
C. Wound characteristics and treatment plan are documented;
D. Standard wound care has failed, evidenced by all the following:
   1. The ulcer or skin deficit has been treated with appropriate wound-care measures, including debridement, standard dressings, compression, off-loading;
   2. Wound area has reduced by <50% in four weeks[7];
E. Documentation of effort to cease nicotine use, including from sources other than cigarettes, but excluding nicotine replacement therapy, for at least four weeks during conservative wound care and prior to planned bioengineered skin replacement therapy, or no nicotine use;
F. Wound characteristics, all the following:
   1. Partial- or full-thickness ulcer with a clean, granular base;

2. No involvement of tendon, muscle, joint capsule, or exposed bone or sinus tracts, unless Integra® is used per U.S. Food and Drug Administration (FDA) guidelines;
3. No wound infection;
4. Clean and free of necrotic debris or exudate;

G. Member/enrollee has adequate circulation/oxygenation to support tissue growth/wound healing, as evidenced by physical examination (e.g., Ankle-Brachial Index [ABI] of no less than 0.6 or toe pressure greater than 30 millimeters of mercury [mmHg]);

H. One of the following:

1. Diabetic foot ulcer (DFU), and all the following:
   a. Diagnosis of Type 1 or Type 2 diabetes and medical management for the condition;
   b. Documented conservative wound care for ≥ four weeks;
   c. Wound is without evidence of osteomyelitis or nidus of infection;
   d. One of the following products is requested:
      i. AmnioBand, guardian (Q4151);
      ii. Affinity (Q4159);
      iii. Apligraf (Q4101);
      iv. DermACELL, DermACELL AWM, or DermACELL AWM porous (Q4122);
      v. Derma-Gide (Q4203);
      vi. Dermagraft (Q4431);
      vii. Epicord (Q4187);
      viii. Epifix (Q4186);
      ix. FlexHD or AllopatchHD (Q4128);
      x. Grafix PRIME, GrafixPL PRIME, Stravix and StravixPL (Q4133);
      xi. GraftJacket (Q4107);
      xii. Integra dermal regeneration template or Integra Omniograft dermal regeneration matrix (Q4105);
      xiii. Kerecis Omega 3 (Q4158);
      xiv. Kerecis Omega3 MariGen shield (A2019);
      xv. NuShield (Q4160);
      xvi. Oasis wound matrix (Q4102);
      xvii. PriMatrix (Q4110);
      xviii. Theraskin (Q4121);

2. Venous leg ulcers (VLU), all the following:
   a. A chronic, non-infected VLU has failed to respond to documented conservative wound-care measures for ≥ four weeks with documented compliance;
   b. Completed assessment includes:
      i. History (prior ulcers, thrombosis risks);
      ii. Physical exam (edema, skin changes);
      iii. ABI (Ankle-Brachial Index) and duplex scan to confirm Clinical-Etiology-Anatomy-Pathophysiology (*CEAP);
   c. A venous duplex ultrasound has been completed to assess saphenous vein incompetency/venous reflux and contributory superficial ulcer bed perforators;
   d. One of the following products is requested:
      i. AmnioBand, guardian (Q4151);
      ii. Apligraf (Q4101);
      iii. Dermagraft (Q4431);
      iv. Epifix (Q4186);
      v. Oasis wound matrix (Q4102);

I. Requested use complies with FDA-approved indications for the specific product;
J. Only one skin substitute will be simultaneously in place per wound episode.
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 eight-application limit per wound per 12-week episode of care;
K. 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 substitute graft/CTP;
L. The following documentation requirements will be met for each application:
1. Graphic evidence of ulcer size, depth, and characteristics of the ulcer or photo documentation of the ulcer at baseline and follow-up with measurements of wound including size and depth;
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.

M. None of the following contraindications:
1. Inadequate control of underlying conditions or exacerbating factors (e.g., uncontrolled diabetes, active infection, and active Charcot arthropathy of the ulcer extremity, vasculitis or continued tobacco smoking without physician attempt to effect smoking cessation);
2. Known hypersensitivity to any component of the specific skin substitute graft (e.g., allergy to avian, bovine, porcine, equine products);
3. Partial thickness loss with the retention of epithelial appendages (epithelium will repopulate the deficit).

Note: Treatment of any chronic skin wound will typically last no more than 12 weeks.

II. It is the policy of Medicare health plans affiliated with Centene Corporation® that continued treatment beyond the initial four applications and up to a total of eight 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 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 substitute will be applied;
B. Request is for one of the following:
1. For DFU, one of the following products is requested:
a. AmnioBand, guardian (Q4151);
b. Affinity (Q4159);
c. Apligraf (Q4101);
d. DermACELL, DermACELL AWM, or DermACELL AWM porous (Q4122);
e. Derma-Gide (Q4203);

f. Dermagraft (Q4431);
g. Epicord (Q4187);
h. Epifix (Q4186);
i. FlexHD or AllopatchHD (Q4128);
j. Grafix PRIME, GrafixPL PRIME, Stravix and StravixPL (Q4133);
k. GraftJacket (Q4107);
l. Integra dermal regeneration template or Integra Omniograft dermal regeneration matrix (Q4105);
m. Kerecis Omega 3 (Q4158);
n. Kerecis Omega3 MariGen shield (A2019);
o. NuShield (Q4160);
p. Oasis wound matrix (Q4102);
q. PriMatrix (Q4110);
r. Theraskin (Q4121);

2. For VLU, one of the following products is requested:
   a. AmnioBand, guardian (Q4151);
   b. Apligraf (Q4101);
   c. Dermagraft (Q4431);
   d. Epifix (Q4186);
   e. Oasis wound matrix (Q4102);

C. Requested use complies with labeled indications;
D. 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 VLU, 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. Graphic evidence of ulcer size, depth, and characteristics of the ulcer or photo documentation of the ulcer at baseline and follow-up with measurements of wound including size and depth;
      c. The skin and soft tissue substitute/CTP is 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;
      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;
E. 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 eight-application limit per wound per 12-week episode of care;

F. 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 Medicare health plans affiliated with Centene Corporation that skin and soft tissue substitutes/CTPs for diabetic foot ulcers and venous leg ulcers are **not medically necessary** for the following indications or scenarios:[1-3]

A. Partial thickness loss with the retention of epithelial appendages, as epithelium will repopulate the deficit from the appendages, negating the benefit of overgrafting;
B. Simultaneous use of more than one product for the episode of wound;
C. Repeat or alternative applications of skin substitute grafts when a previous full course of applications was unsuccessful. 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) for a period of four weeks past start of therapy;
D. Retreatment of healed ulcers- those showing greater than 75% size reduction and smaller than 0.5 square cm;
E. Re-treatment within one year of any given course of skin substitute treatment for a venous stasis ulcer or (diabetic) neuropathic foot ulcer.

Note:

- It is expected that when multiple sizes of a specific product are available, the size that best fits the wound with the least amount of wastage will be utilized.[4,5]
- Repeat use of surgical preparation services in conjunction with skin substitute application codes will be considered not reasonable and necessary. It is expected that each wound will require the use of appropriate wound preparation code at least once at initiation of care prior to placement of the skin substitute graft.[1-3]
- The following documentation requirements apply, and all documentation must be maintained in the medical chart and made available upon request:[4,5]
  - Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service(s)). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
  - The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed.
  - Medical record documentation must support the medical necessity of the services as directed in this policy.
  - The documentation must support that the service was performed and must be included in the patient's medical record. This information is normally found in the history and physical, office/progress notes, hospital notes, and/or procedure report.
  - The medical record must clearly show that the criteria above have been met as well as the appropriate diagnosis and response to treatment.

- The documentation must support the need for cellular and/or tissue-based product (CTP) application and the product used.
- A description of the wound(s) must be documented at baseline (prior to beginning conservative treatment) relative to size, location, stage, duration, and presence of infection, in addition to type of treatment given and response.
- All information must be updated in the medical record throughout treatment.
- Wound description must also be documented pre and post treatment with the skin substitute graft being used.
- If obvious signs of worsening or lack of treatment response are noted, continuing treatment with the skin substitute would not be considered medically reasonable and necessary without documentation of a reasonable rationale for doing so.
- Documentation of smoking history, and that the patient has received counseling on the effects of smoking on surgical outcomes and treatment for smoking cessation (if applicable) as well as outcome of counselling must be in the medical record.
- The amount of utilized and wasted skin and soft tissue substitute/CTP must be clearly documented in the procedure note with the following minimum information:
  - Date, time and location of ulcer treated;
  - Name of skin and soft tissue substitute/CTP and how product supplied;
  - Amount of product unit used;
  - Amount of product unit discarded;
  - Reason for the wastage;
  - Manufacturer's serial/lot/batch or other unit identification number of graft material. When manufacturer does not supply unit identification, record must document such.

IV. It is the policy of 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 criteria, [79-86] specific to the wound for which the skin substitute/CTP is being requested:

A. Request indicates the specific wound to which the skin substitute will be applied;
B. Sufficient autograft is not available at the time of excision or is not feasible due to the physiological condition of the member/enrollee;
C. No evidence of burn wound infection;
D. Burn is either deep partial-thickness or full-thickness;
E. Documentation of all the following:[1-3]
   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;
F. 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);

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; [1-4]

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;[1-4]

I. The following documentation requirements will be met for each application:
   1. Graphic evidence of ulcer size, depth, and characteristics of the ulcer or photo documentation of the ulcer at baseline and follow-up with measurements of wound including size and depth;
   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 Medicare health plans affiliated with Centene Corporation that skin and soft tissue substitutes/CTPs for *breast reconstruction* are considered **medically necessary** when meeting all the following criteria,[87-98] specific to the wound for which the skin substitute/CTP is being requested:

A. Request indicates the specific wound to which the skin substitute will be applied;

B. Post-mastectomy breast reconstruction;

C. No evidence of wound infection;

D. Documentation of all of the following:[1-3]
   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;

E. 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);

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;[1-4]

G. 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; [1-4]

H. The following documentation requirements will be met for each application:
   1. Graphic evidence of ulcer size, depth, and characteristics of the ulcer or photo documentation of the ulcer at baseline and follow-up with measurements of wound including size and depth;
   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 Medicare health plans affiliated with Centene Corporation that OrCel™ is **medically necessary** as treatment for mitten hand deformities due to *dystrophic epidermolysis bullosa* when meeting all the following criteria,[99-101, 110] specific to the wound for which the skin substitute/CTP is being requested:

A. Request indicates the specific wound to which the skin substitute will be applied;

B. Used according to the U.S. Food and Drug Administration (FDA) Humanitarian Device Exemption (HDE);

C. No evidence of wound infection;

D. Documentation of all of the following:[1-3]
   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;

E. 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.[1-4]

F. The following documentation requirements will be met for each application:

1. Graphic evidence of ulcer size, depth, and characteristics of the ulcer or photo documentation of the ulcer at baseline and follow-up with measurements of wound including size and depth;
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 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,[102-109, 110] specific to the wound for which the skin substitute/CTP is being requested:

A. Request indicates the specific wound to which the skin substitute will be applied;
B. Repair of hernias or for surgical repair of complex abdominal wall wounds;
C. No evidence of wound infection;
D. Documentation of all of the following:[1-3]
   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;
E. Treatment with any of the following skin and soft tissue substitutes/CTPs:
   1. Alloderm (Q4116);
   2. Phasix ST (C1781);
   3. Strattice (Q4130);
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; [1-4]
G. 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; [1-4]
H. The following documentation requirements will be met for each application:
   1. Graphic evidence of ulcer size, depth, and characteristics of the ulcer or photo documentation of the ulcer at baseline and follow-up with measurements of wound including size and depth;
   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 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:[1-3]

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).

IX. It is the policy of 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

Centers for Medicare & Medicaid Services[1-3]

According to the Centers for Medicare & Medicaid Services (CMS), chronic wounds of the lower extremities, including venous stasis ulcers (VSU), venous leg ulcers (VLU), diabetic foot ulcers (DFU) and pressure sores, are major public health problems. While lower extremity ulcers have numerous causes, such as burns, trauma, mixed venous-arterial disease, immobility and vasculitis, nutritional or other neuropathy, over 90% of the lesions in the United States are related to venous stasis disease and diabetic neuropathy.

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. A wound that has not healed within one to three months may be considered a chronic wound and can be a challenge to treat effectively. Even with advancements in various synthetic occlusive dressings, some ulcers fail to heal and may benefit from a skin substitute.

Autologous skin grafts, also referred to as autografts, are permanent covers that use skin from different parts of the individual's body. These grafts consist of the epidermis and a dermal component of variable thickness. A split-thickness skin graft (STSG) includes the entire epidermis and a portion of the dermis. A full-thickness skin graft (FTSG) includes all layers of the skin. Although autografts are the optimal choice for full thickness wound coverage, areas for skin harvesting may be limited, particularly in cases of large burns or venous stasis ulceration. Harvesting procedures are painful, disfiguring and require additional wound care.

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.

Bioengineered Skin and Cultured Epidermal Autografts (CEA) are autografts derived from the patient's own skin cells grown or cultured from very small amounts of skin or hair follicle. Production time is prolonged. One such product is grown on a layer of irradiated mouse cells, displaying some components of a xenograft. Widespread usage has not been available due to limited availability or access to the technology.

Cellular and/or tissue-based products (CTPs) were developed to address problems with autografts, allografts, and xenografts. These consist of biologic covers for refractory wounds with full thickness skin loss secondary to third degree burns, diabetic neuropathic ulcers and the skin loss of chronic venous stasis or venous hypertension. The production of these biologic CTPs varies by company and product but generally involves the creation of immunologically inert biological products containing protein, hormones or enzymes seeded into a matrix which may provide protein or growth factors intended to stimulate or facilitate healing or promote epithelization. There are currently a broad range of bioengineered products available for soft tissue coverage to affect closure. Sufficient data is available to establish distinct inferiority to human skin autografts and preclude their designation as skin equivalence.

Current evidence does not provide sufficient support for the use of skin and soft tissue substitutes/CTPs for specific indications. In these cases, the following were considered: current, widely-used treatment guidelines developed by organizations representing clinical medical specialties; reports from peer reviewed medical literature meeting any of the following: large, randomized controlled trials, prospective cohort studies with clear results specifically designed to answer the relevant clinical question, large systematic reviews or meta-analyses summarizing the literature of the specific clinical question; professional standards of safety and effectiveness recognized in the United States for diagnosis, care, or treatment; nationally recognized drug compendia resources such as Facts & Comparisons®, DRUGDEX®; and government-funded or independent entities that assess and report on clinical care decisions and technology such as Agency for Healthcare Research and Quality (AHRQ) and National Institute for Health and Care Excellence (NICE), etc.

Skin Substitute Product Evidence Assessment

Diabetic Foot Ulcers (DFUs):

- *Affinity*: One randomized controlled trial (RCT) with a sample size of 76 reported wound closure at 16 weeks of 63% in Affinity arm and 38% in standard of care (SOC) arm (n=38).[8]

- *AmnioBand, guardian*: One RCT with a sample size of 60 reported a healing rate at 12 weeks was 90% for the AmnioBand group versus 40% for the Apligraf group.[9] Another RCT with a sample size of 40 reported at 12 weeks 85% of the DFU in the AmnioBand group healed compared with 25% in the SOC group.[10] Additionally, a RCT with a sample size of 80 reported at 12 weeks 85% of the DFUs in the AmnioBand group achieved healing compared with 33% of the DFUs in the SOC group.[11]
- *Apligraf*: One RCT with a sample size of 208 reported wound closure at 12 weeks of 56% for the Apligraf group and 28% for the SOC group,[12] another RCT with a sample size of 72 reported on wound closure at 12 weeks of 55.2% for Apligraf and 34.3% for SOC,[13] and another RCT with a sample size of 82 reported on wound healing at 12 weeks of 51.5% for Apligraf and 26.3% for SOC.[14] One RCT with a sample size of 60 reported on wound closure at 6 weeks of 95% for EpiFix, 45% for Apligraf, and 35% for SOC.[15]
- *DermACELL, awm, porous*: One RCT with a sample size of 168 reported the healing rate at 16 weeks was 67.9% in the DermACELL arm, 48.1% in the SOC arm, 47.8% in the GraftJacket arm.[16,17] Further, a prospective study with a sample size of 61 of large complex wounds treated with DermACELL reported 24.6% closure at 16 weeks.[18]
- *Derma-Gide*: One RCT with a sample size of 40 reported wound closure at 12 weeks of 85% of the Derma-Gide group and 30% of the SOC group (interim analysis).[19] Another RCT with a sample size of 105 reported wound closure at 12 weeks of 83% of the Derma-Gide group and 45% of the SOC group,[20] and there are further retrospective case series and a bench report.[21-23]
- *Dermagraft*: One RCT with a sample size of 314 reported wound closure at 12 weeks of 30% of the Dermagraft group and 18.3% in the SOC group.[24] Another RCT with a sample size of 50 reported on wound closure at 12 weeks with 50% for the Dermagraft and 8% in the SOC group.[25] Additionally, one RCT with a sample size of 23 reported wound closure at 20 weeks with 90.91% in the Theraskin group and 66.67% in the Dermagraft group.[26]
- *Epicord*: One RCT with a sample size of 155 reported wound closure at 12 weeks of 70% for EpiCord and 48% for SOC.[27]
- *Epifix*: One RCT with a sample size of 25 reported wound healing at six weeks in the EpiFix group of 92% and 8% in the SOC group.[28] Another RCT with a sample size of 60 reported on wound closure at 6 weeks of 95% for EpiFix, 45% for Apligraf and 35% for SOC.[29] Further, one RCT with a sample size of 104 reported wound closure at 12 weeks of 73% for Apligraf, 97% for EpiFix and 51% for SOC,[30] and another RCT with a sample size of 110 reported on wound closure at 12 weeks of 70% EpiFix and 50% SOC in the intention-to-treat (ITT) analysis.[31]
- *FlexHD or AllopatchHD*: One RCT with a sample size of 40 reported a wound healing at 12 weeks of 80% for AlloPatch and 20% for SOC;[32] an additional 40 participants enrolled and reported similar results.[33] There is literature also in breast reconstruction, rotator cuff repair, hernia repair, lab research,[34-36] and a retrospective report.[32]
- *Grafix stravix prime pl*: One RCT with a sample size of 97 reported wound closure at 12 weeks was 62% in the Grafix group and 21% in the SOC group.[37] There was also a retrospective report with a sample size of 441.[38]
- *GraftJacket*: One RCT with a sample size of 40 reported on wound healing at 12 weeks with a 67.4% reduction with GraftJacket and 34% with SOC.[39] Another RCT with a sample size of 28 reported on wound closure at 16 weeks of 85.71% in the GraftJacket arm and 28.57% in SOC, [40] and one RCT with a sample size of 86 reported on mean wound healing time of 12 weeks was 30.4% with GraftJacket and 53.9% with SOC.[41] Additionally, one RCT with a sample size of 168 reported on wound closure at 16 weeks of 67.9% for DermACELL, 47.8% for GraftJacket, and 48.1% for SOC.[42,43] These studies

were included in a meta-analysis[44] and GraftJacket in another.[45]

- *Integra or Omniograft dermal regeneration template*: One RCT with a sample size of 307 reported wound closure at 16 weeks of 51% in the Integra group and 32% in the SOC group.[46]
- *Kerecis Omega3/Kerecis omega3, MariGen shield*: One RCT with a sample size of 170 was conducted for healing in the punch biopsy site.[47] One RCT with a sample size of 49 reported wound closure at 12 weeks of 67% for Kerecis and 32% for SOC,[48] and another RCT with a sample size of 102 reported 56.9% wound closure by 12 weeks in the Kerecis group and 31.4% in the SOC group.[49] Further, another RCT with a sample size of 255 reported wound closure by 16 weeks of 44% in Kerecis group and 26% in SOC.[50]
- *NuShield*: One RCT with a sample size of 218 reported on wound closure at 12 weeks with 50% closure for NuShield and 35% for SOC alone.[51] Additional literature is a case report,[52] retrospective report with 50 wounds,[53] and literature in talar dome lesions.
- *Oasis wound matrix*: One RCT with a sample size of 26 reported no difference in closure time for Dermagraft (84.6%) or Oasis Wound Matrix (76.9%).[54] Another RCT with a sample size of 73 reported on wound healing at 12 weeks of 49% for Oasis wound matrix and 28% for Regranex gel.[55]
- *Primatrix*: One RCT with a sample size of 161 reported wound closure at 12 weeks of 59.5% for the PrimMatrix arm and 35.4% for the SOC arm.[56] Further evidence includes a prospective trial with a sample size of 55[57], retrospective[58,59] and lab trials.[60]
- *Theraskin*: One RCT with a sample size of 50 reported on wound healing at 12 weeks was 76% for TheraSkin and 36% for SOC.[61] Another RCT with a sample size of 23 reported wound closure at 20 weeks with 90.91% in the Theraskin group and 66.67% in the Dermagraft group.[62] Further evidence includes a small prospective study with a sample size of 29,[63] retrospective cohort studies,[64,65] and a lab study.[66]

Venous Leg Ulcers (VLUs):

- *AmnioBand, guardian*: One randomized controlled trial (RCT) with a sample size of 60 reported healing rates at 12 weeks were 75% in the two AmnioBand groups and 30% in the standard of care (SOC) group.[67]
- *Apligraf*: One RCT with a sample size of 275 reported on wound closure at six months of 63% for Apligraf and 49% for SOC.[68] Another RCT with a sample size of 120 reported on wound closure at 24 weeks of 47% for Apligraf and 19% for SOC,[69] and another RCT with a sample size of 31 reported on wound healing at 12 weeks of 93.3% for Theraskin and 75% for Apligraf.[70]
- *Dermagraft*: One RCT with a sample size of 366 reported on wound closure at 12 weeks of 34% for Dermagraft and 31% for SOC.[71]
- *Epifix*: One RCT with a sample size of 53 reported on wound reduction in four weeks for 62% for EpiFix and 32% for SOC.[72] Another RCT with a sample size of 109 reported wound closure at 16 weeks for VLU was 71% for EpiFix and 44% for SOC.[73] The follow-up report included intention-to-treat (ITT) analysis reported similar results with 50% in the EpiFix group and 31% in SOC.[74]
- *Oasis wound matrix*: One RCT with a sample size of 48 reported wound closure at eight weeks of 80% for Oasis wound matrix and 65% for SOC.[75] Another RCT with a sample size of 120 reported on wound healing at 12 weeks of 55% in Oasis group and 34% in SOC.[76] Further, a RCT with a sample size of 89 reported on wound closure at 12 weeks with 47.1% for Dermagraft, 73.7% for Oasis, and 57.9% for SOC,[77] and another RCT with a sample size of 84 reported on wound closure at 12 weeks of 71% Oasis and 46% SOC.[78]

Burns[79]
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[5]
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)[99-101]
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 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[102-104,111]
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

HCPCS Codes	Description
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
Q4110	PriMatrix, 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
Q4133	Grafix PRIME, GrafixPL PRIME, Stravix and StravixPL, per sq cm
Q4151	AmnioBand or Guardian, per sq cm
Q4158	Kerecis Omega3, per sq cm
Q4159	Affinity, per sq cm
Q4160	NuShield, per sq cm
Q4182	TransCyte, per sq cm
Q4186	Epifix, per sq cm
Q4187	Epicord, per sq cm
Q4203	Derma-Gide, per sq cm
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

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
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

HCPCS Codes	Description
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
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 sq cm
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 IntéguPly, per sq cm
Q4127	Talymed, per sq cm
Q4132	Grafix Core and GrafixPL Core, 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 sq cm
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
Q4152	DermaPure, per sq cm
Q4153	Dermavest and Plurivest, per sq cm
Q4154	Biovance, per sq cm
Q4155	Neox Flo or Clarix Flo 1 mg
Q4156	Neox 100 or Clarix 100, per sq cm
Q4157	Revitalon, 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
Q4166	Cytal, per sq cm

HCPCS Codes	Description
Q4167	Truskin, per sq cm
Q4168	AmnioBand, 1 mg
Q4169	Artacent wound, per sq cm
Q4170	Cygnus, per sq cm
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
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
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
Q4213	Ascent, 0.5 mg
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

HCPCS Codes	Description
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
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

HCPCS Codes	Description
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(TM), 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
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

HCPCS Codes	Description
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
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

HCPCS Codes	Description
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
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

HCPCS Codes	Description
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
Q4435	Renati Membrane, per sq
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 developed.	03/24	
Annual review. Update to background with no impact on criteria. Updated verbiage in criteria II.A. for clarity. Removed prior criteria II.B. Updated verbiage in now criteria II.B. for clarity. Removed previous criteria II.D. Updated verbiage in now criteria II.C. and D. Removed previous criteria II.G. through I. Updated verbiage in now criteria II.E. for clarity. Added note to new criteria I.G. to see Table 2, HCPCS codes that support medical necessity criteria… Added not regarding documentation requirements under criteria II. Moved HCPCS codes A2009 and Q4304 from table of HCPCS codes that *do not* support medical necessity to HCPCS codes that *do* support medical necessity. References reviewed and updated. Reviewed by external specialist.	04/25	04/25
Annual review. Updated Description with no clinical significance. Added I.F.1.d. concerning list of requested products for DFUs. Added I.F.2.d. concerning list of requested products for VLUs. Updated wording in I.G., II.C., and Note under II.E. with no clinical significance. Updated wording in Background and added "Skin Substitute Product Evidence Assessment" section regarding skin substitute products for treatment of DFUs and	08/25	

Reviews, Revisions, and Approvals	Revision Date	Approval Date
VLUs and skin substitute products considered not medically necessary. Coding tables reviewed. Replaced original Table 2 ("HCPCS codes that support medical necessity criteria") with new Table 2 ("HCPCS codes that support medical necessity criteria for diabetic foot ulcers [DFUs]") and added Table 3 ("HCPCS codes that support medical necessity criteria for venous leg ulcers [VLUs]"). Original Table 3 updated to Table 4. Added the following HCPCS codes to Table 4: A2001, A2002, A2004, A2005, A2008, A2009, A2020, A2021, A2022, A2023, A2024, A2025, A2027, A4175, C9364, Q4103, Q4104, Q4108, Q4111, Q4115, Q4116, Q4117, Q4118, Q4123, Q4124, Q4126, Q4127, Q4132, Q4134, Q4136, Q4137, Q4140, Q4141, Q4142, Q4146, Q4147, Q4148, Q4150, Q4152, Q4153, Q4154, Q4156, Q4157, Q4161, Q4163, Q4166, Q4169, Q4170, Q4173, Q4176, Q4178, Q4180, Q4188, Q4195, Q4196, Q4197, Q4201, Q4213, Q4215, Q4232, Q4236, Q4253, Q4254, Q4262, Q4267, Q4268, Q4269, Q4270, Q4271, Q4272, Q7273, Q4274, Q4275, Q4276, Q4278, Q4280, Q4281, Q4282, Q4283, Q4284, Q4285, Q4286, Q4304, Q4305, Q4306, Q4307, Q4308, Q4309. References reviewed and updated.		
Description updated. Added "up to four initial applications of" to policy statement I. Added medically necessary product types for DFU in I.F.1.d. and for VLU in I.F.2.d. In I.G., removed that applications should not exceed 10 and the note regarding coding tables. In I.H., noted that up to four applications are initially approved, up to a total of eight. Added requirements in I.I and I.J. Added section II and moved section II. non-medically necessary criteria under section III. Updated background with evidence for specific product types. Updated coding tables to reflect medically necessary product types for DFU and VLU, and those considered not medically necessary for either. References updated.	10/25	10/25
Title changed to "Skin and Soft Tissue Substitutes for Diabetic Foot Ulcers and Venous Leg Ulcers." Specified that policy statements I. and III. apply to DFU and VLU. Removed full-thickness skin loss ulcers as an indication in I.F.3.	11/25	11/25
In the policy description, noted the policy intention is "for use by Medicare health plans affiliated with Centene Corporation® in Medicare Administrative Contractor (MAC) jurisdictions with an absence of full coverage criteria provided by the Centers for Medicare and Medicaid Services (CMS) and the applicable MAC."	12/25	12/25
Annual review. Changed policy name to "Skin and Soft Tissue Substitutes." Description section updated to include criteria sources for new indications. In Notes section, added additional bullet points to refer to CP.MP.186 and MC.CP.MP.31, as applicable. In I.H.1.d.vi., I.H.2.d.iii., II.B.1.f. and II.B.2.c., deleted code Q4106 was replaced with code Q4431. In Note in I.H. and II.D., removed "16." Added criteria IV. regarding skin substitute use for burn treatment, with IV.B. through 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.	03/26	03/26

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Added criteria VIII. regarding indications considered not medically necessary. Added criteria IX. regarding indications not supported by current evidence. Throughout criteria section, replaced all skin substitute verbiage to "skin and soft tissue substitute/CTP". Minor wording updates throughout without clinical significance. Background section updated and includes 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. Combined previous Table 2 and Table 3 into HCPCS Code Table 2. To HCPCS Code Table 2, added the following: A2012, A2043, A2044, A4100, C1781, C9363, C9399, Q4104, Q4108, Q4116, Q4130, Q4182, Q4431, and Q4433. From HCPCS Code Table 2, removed Q4106. To HCPCS Code Table 3, added the following codes: A2026, A2028 to A2039, A2040, A2041, A2042, A2045, C8002, C9250, Q4135, Q4175, Q4310 to Q4373, Q4375 to Q4380, Q4382 to Q4417, Q4418, Q4419, Q4420, Q4421, Q4422, Q4423, Q4424, Q4425, Q4426, Q4427, Q4428, Q4429, Q4432, Q4435, Q4436, Q4437, Q4438, Q4439, and Q4440. To HCPCS Code Table 3, removed the following codes: A2012, C9363, Q4104, Q4108, Q4116, Q4130, Q4182, Q4210, Q4231, and Q4244. References reviewed and updated. Reviewed by internal specialists. Reviewed by external specialist.		
In policy statements IV. to VIII., corrected "non-Medicare health plans" to "Medicare health plans". Corrected the 03/26 revision log to note that code Q4432 was added to HCPCS code table 3.	05/26	05/26

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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: 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.