NGS Medicare Policy Primer

Medicare Jurisdiction (JK & J6)
NY, MA, ME, VT, CT, RI, NH, MN, WI & IL
Retired skin substitute LCD effective 9/1/16

Indications

Apligraf®

Non-infected partial and full-thickness skin ulcers due to VSU of greater than 1 month duration and which have not adequately responded to conventional ulcer therapy.

Full-thickness neuropathic DFU of greater than 3 weeks duration which have not adequately responded to conventional ulcer therapy and which extend through the dermis but without tendon, muscle, capsule or bone exposure.

Dermagraft®

In the treatment of full-thickness diabetic foot ulcers of greater than 6 weeks duration which extend through the dermis but without tendon, muscle, capsule or bone exposure.

PuraPly™

Indicated for the management of wounds including:

- Partial and full-thickness wounds
- Venous ulcers
- Diabetic ulcers
- Drainage wounds
- Pressure ulcers
- Chronic vascular ulcers
- Trauma wounds (abrasions, lacerations, second-degree burns, skin tears)
- Surgical wounds (donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence)

PuraPly™ AM

Indicated for the management of wounds as an effective barrier to resist microbial colonization within the dressing and reduce microbes penetrating through the dressing:

- Partial and full-thickness wounds
- Pressure ulcers
- Venous ulcers
- Diabetic ulcers
- Chronic vascular ulcers
- Tunneled/undermined wounds
- Surgical wounds (donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence)
- Trauma wounds (abrasions, lacerations, second-degree burns, skin tears)
- Drainage wounds

Affinity®

Affinity is a fresh (i.e. not dehydrated, not frozen) amniotic membrane allograft consisting of an epithelial layer, basement membrane, stromal layer, and spongy layer. Affinity contains a well preserved extracellular matrix, several types of viable cells native to the tissue, and multiple growth factors, cytokines. Affinity is minimally processed to retain the natural benefits of the tissue and is hypothermically maintained to preserve the structural integrity and viability of the amniotic tissue for 42 days. Affinity provides an optimal environment for the repair and restoration of wound tissue and supports the body's natural ability to heal.

Affinity can be applied to a variety of partial- and full-thickness, acute and chronic wounds, including, but not limited to:

- Diabetic foot ulcers
- Venous leg ulcers
- Arterial ulcers
- Pressure ulcers
- Surgical wounds
- Trauma wounds

NuShield®

NuShield is a sterilized, dehydrated placental allograft membrane containing all of the layers of both the amnion and chorion. NuShield contains an extracellular matrix maintained in its native configuration along with many different growth factors and cytokines present in amniotic tissue. NuShield is minimally processed to take advantage of the tissue's natural biologic and physical properties for ease of use, while preserving the native protein content and may be stored at ambient conditions for up to 5 years. NuShield is intended for homologous use to support the repair, reconstruction and replacement of damaged tissue.

NuShield can be applied to a variety of partial- and full-thickness, acute and chronic wounds, including, but not limited to:

- Diabetic foot ulcers
- Venous leg ulcers
- Arterial ulcers
- Pressure ulcers
- Surgical wounds
- Trauma wounds

Limitations

- **Apligraf:** The safety and effectiveness of Apligraf have not been established for patients receiving greater than 5 device applications
- **Dermagraft:** has not been studied in patient receiving greater than 8 device applications

Coding

HCPCS Codes:

- **Q4101:** Apligraf, per square centimeter
- **Q4106:** Dermagraft, per square centimeter
- **Q4172:** PuraPly, PuraPly Antimicrobial per square centimeter
- **Q4159:** Affinity, per square centimeter
- **Q4160:** NuShield, per square centimeter

JW Modifier:

Effective January 1, 2017 in Physician Office Setting, Place of service 11- claims for discarded drug or biological amount not administered to any patient, shall be submitted using the JW modifier. This modifier, billed on a separate line, will provide payment for the amount of discarded drug or biological. Providers must document the discarded drugs or biologicals in patient's medical record.

CPT Codes:

Application Codes for Leg, Arm or Trunk:

- **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
- **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 (List separately in addition to code for primary procedure)

Application Codes for Foot, face, scalp, etc.:

- **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
- **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 (List separately in addition to code for primary procedure)

NGS Medicare Sample Model Documentation

Medicare Jurisdiction (JK & J6)

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Pre-Treatment

1. Duration of ulcer: _____ weeks
2. Exact location of ulcer
3. Describe adequate treatment of the underlying disease process contributing to the ulcer
4. Diagnosis of patient

Treatment

5. Document measurement of ulcer (width and length or circumference and depth) immediately prior to application of the skin substitute _____ sq cm
6. Document whether this is an initial application of skin substitute or a reapplication
7. For skin substitute reapplications, document that applications have been successful (e.g. decrease in size or depth, increase in granulation tissue)
8. Document the wound dressing changes and the standard conservative measures accompanying the wound treatment with the skin substitute
9. Document how the wound site was prepared, and how the skin substitute was fixated on the wound
10. Product Wastage Documentation Requirements:
    - Date and time
    - Location of ulcer
    - Approximate amount of product unit used
    - Approximate amount of product unit discarded
    - Reason for the wastage
    - Manufacture's serial/lot/batch number

Modifiers

JW: Skin substitute not applied to wound, wastage