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Reimbursement Disclaimer

The Grafix 2018 Billing Guide only provides information related to the use of Grafix for the treatment of chronic lower extremity ulcers. Reimbursement guidance included in this billing guide, including coding information, are supplied for informational purposes only and represent no statement, promise or guarantee by Osiris that these codes will be appropriate or that reimbursement will be made. Coding practice will vary by site of care, patient condition, services provided, local payer instructions, and other factors. **The decision as to how to complete a reimbursement form, including amount to bill, is exclusively the responsibility of the provider. The provider is ultimately responsible for verifying coverage with the patient’s payer source and billing appropriately for services provided.**
**Product Description:**
Grafix (viable cryopreserved placental membrane) is available either as a cryopreserved chorion matrix (Grafix CORE®) or as a cryopreserved amnion matrix (Grafix PRIME®). Both products retain the extracellular matrix, growth factors, and endogenous neonatal mesenchymal stem cells and fibroblasts of the native tissue. Grafix, as a placental matrix, can support migration, proliferation and differentiation of several types of cells in the patient (i.e. recipient) known to be involved in the body’s natural tissue repair processes. Note: though well characterized in the scientific literature, the effect of the preservation of these cells in the product on the clinical outcome is unknown.

Grafix is processed from human placental tissue that has been donated by healthy mothers who have undergone full term normal pregnancy and delivered a healthy infant via cesarean section. Grafix is processed aseptically in a controlled clean room environment, following rigorous quality control testing per FDA regulations and the American Association of Tissue Banks (AATB) standards.¹

**Regulatory:**
Grafix is a Human Cells, Tissues, and Cellular Tissue Based Product (HCT/P) as defined in 21 CFR 1271 and Section 361 of the Public Health Service Act.
- Good tissue practice (GTP) compliant per FDA regulations
- Osiris is registered with the U.S. Food and Drug Administration as a tissue establishment for Grafix
- Licensed tissue bank for all required U.S. states
- AATB accreditation

**Indications for Use:**
Grafix may be used to repair acute and chronic wounds, including but not limited to: diabetic foot ulcers, venous leg ulcers, pressure ulcers, dehisced surgical wounds, burns, acute surgical wounds, Pyoderma Gangrenosum, and Epidermolysis Bullosa. Grafix may be used in wounds encompassing both Upper Extremity and Lower Extremity acute and chronic wounds. Grafix naturally conforms to complex anatomies and may be used over exposed bone, tendon, joint capsule, and muscle. Grafix is limited to the homologous use as a wound cover.¹

**Dosage:**
The quantity and size of product used will vary based upon wound size and physician recommendation. Application of Grafix is recommended weekly for up to 12 weeks or until the wound is closed.¹

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1. Osiris Therapeutics, Inc., Grafix PRIME package insert LS27600, Grafix CORE package insert LS27700
Coding Information

Grafix Healthcare Common Procedure Coding System (HCPCS) Codes

HCPCS stands for Healthcare Common Procedure Coding System (HCPCS). For Medicare and other health insurance programs, standardized coding systems are essential to ensure healthcare claims are processed in an orderly and consistent manner. The HCPCS Level II code set is one of the standard code sets used by medical coders and billers for this purpose and is comprised of alphanumeric medical procedure codes used for reporting and billing non-physician services.

Grafix HCPCS Codes and Units Billed:

Grafix is intended for the treatment of one patient and is utilized as single use only. Payers will reimburse for the entire square centimeter piece, however, it is recommended that providers document wastage according to the payer guidelines. Grafix is billed per square centimeter. One billable unit is 1 cm². In the chart below you will find the assigned HCPCS Codes for Grafix and the billable units per product size.

<table>
<thead>
<tr>
<th>Osiris Part #</th>
<th>Product Description</th>
<th>Size in cm²</th>
<th>Billable Units</th>
<th>HCPCS Code</th>
<th>UPC Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>PS60014</td>
<td>Grafix CORE 16 mm disc</td>
<td>2 cm²</td>
<td>2</td>
<td>Q4132</td>
<td>59857-00333-3</td>
</tr>
<tr>
<td>PS12015</td>
<td>Grafix CORE 1.5 cm x 2 cm</td>
<td>3 cm²</td>
<td>3</td>
<td>Q4132</td>
<td>59857-00310-4</td>
</tr>
<tr>
<td>PS12023</td>
<td>Grafix CORE 2 cm x 3 cm</td>
<td>6 cm²</td>
<td>6</td>
<td>Q4132</td>
<td>59857-00305-0</td>
</tr>
<tr>
<td>PS12034</td>
<td>Grafix CORE 3 cm x 4 cm</td>
<td>12 cm²</td>
<td>12</td>
<td>Q4132</td>
<td>59857-00311-1</td>
</tr>
<tr>
<td>PS12055</td>
<td>Grafix CORE 5 cm x 5cm</td>
<td>25 cm²</td>
<td>25</td>
<td>Q4132</td>
<td>59857-00304-3</td>
</tr>
<tr>
<td>PS60013</td>
<td>Grafix PRIME 16 mm disc</td>
<td>2 cm²</td>
<td>2</td>
<td>Q4133</td>
<td>59857-00339-5</td>
</tr>
<tr>
<td>PS11015</td>
<td>Grafix PRIME 1.5 cm x 2 cm</td>
<td>3 cm²</td>
<td>3</td>
<td>Q4133</td>
<td>59857-00338-8</td>
</tr>
<tr>
<td>PS11023</td>
<td>Grafix PRIME 2 cm x 3 cm</td>
<td>6 cm²</td>
<td>6</td>
<td>Q4133</td>
<td>59857-00337-1</td>
</tr>
<tr>
<td>PS11034</td>
<td>Grafix PRIME 3 cm x 4 cm</td>
<td>12 cm²</td>
<td>12</td>
<td>Q4133</td>
<td>59857-00336-4</td>
</tr>
<tr>
<td>PS11055</td>
<td>Grafix PRIME 5 cm x 5 cm</td>
<td>25 cm²</td>
<td>25</td>
<td>Q4133</td>
<td>59857-00335-7</td>
</tr>
</tbody>
</table>

Medically Unlikely Edit (MUE):

A Medically Unlikely Edit (MUE) is a Medicare unit of service claim edit applied to Medical Claims against a procedure code for medical services rendered by one provider or facility to one patient on one day. The MUE is the maximum units of a product reimbursed in one application.

- MUE for Grafix CORE Q4132 = 50 units
- MUE for Grafix PRIME Q4133 = 113 units

Modifiers:

Please check with the patient’s insurer or Medicare Administrative Contractor (MAC) to inquire if modifiers are required with HCPCS Q4132 or Q4133 and/or the CPT codes used (15271—15278). Some of the modifiers will impact reimbursement while others are informational only. Common modifiers may include:

- JC: skin substitute used as a graft
- JW: wastage
- KX: requirements in the medical policy have been met
CPT Coding*

The Common Procedural Terminology (CPT®) code set describes medical, surgical, and diagnostic services and is designed to communicate uniform information about medical services and procedures among physicians, coders, patients, accreditation organizations, and payers for administrative, financial, and analytical purposes.

***IMPORTANT***

Wound Location: Determining the wound location and surface area is important in order to select the appropriate CPT code. Please reference the CPT descriptors below to ensure accurate billing.

Modifiers: Please check with the patient’s insurer or Medicare Administrative Contractor to inquire if modifiers are required with the CPT codes used. Common modifiers may include:

- JC: skin substitute used as a graft
- JW: wastage
- KX: requirements in the medical policy have been met

Add-on Codes: The + symbol signifies an add-on code. An add-on code cannot be used alone but must be billed with the initial code above it. Please check the CPT 2018 coding book for further instructions.

<table>
<thead>
<tr>
<th>CPT</th>
<th>Descriptions for Application of Skin Substitutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>15271</td>
<td>Application of skin substitute graft to trunk, arms, legs, total wound surface area of up to 100 sq. cm; first 25 sq. cm or less of wound surface area</td>
</tr>
<tr>
<td>+15272</td>
<td>Each additional 25 sq. cm up to 100 sq. cm wound surface area, or part thereof. List separately in addition to code 15271 for primary procedure.</td>
</tr>
<tr>
<td>15273</td>
<td>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</td>
</tr>
<tr>
<td>+15274</td>
<td>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 15273 for primary procedure.</td>
</tr>
<tr>
<td>15275</td>
<td>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 cm or less wound surface area</td>
</tr>
<tr>
<td>+15276</td>
<td>Each additional 25 sq. cm wound surface area, or part thereof. List separately in addition to code 15275 for primary procedure.</td>
</tr>
<tr>
<td>15277</td>
<td>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</td>
</tr>
<tr>
<td>+15278</td>
<td>Each additional 100 sq. cm wound surface area, or part thereof. List separately in addition to code 15277 for primary procedure.</td>
</tr>
</tbody>
</table>

CPT Codes 15271-15278:

- Billing Units = 1 unit per service for CPT 15271, 15273, 15275 and 15277 (daily limitations apply)
- Add-on codes 15272, 15274, 15276 and 15278 are billed as 1 unit for each additional amount of graft material as specified; either each additional 25 cm² or 100 cm² applied

*CPT® is a registered trademark of the American Medical Association®.

The CPT codes supplied above are for informational purposes only and do not represent a statement, promise, or guarantee that these codes will be appropriate or that reimbursement will be made. Coding practice will vary by site of care, patient condition, range of service provided, local payer instructions, and other factors. The decision as to how to complete a reimbursement form, including codes used and amount to bill, is exclusively the responsibility of the provider. The provider is ultimately responsible for verifying coverage with the patient’s payer source.
MEDICARE - National Average Reimbursement

Medicare Area Contractors (MAC)
The Centers for Medicare and Medicaid Services (CMS) contracts with regional Medicare Area Contractors (MACs) to administer the Medicare program. Each MAC establishes its own set of guidelines for the coverage of services. The coverage guidelines are published by each MAC as a Local Coverage Determination, or LCD.

Hospital Outpatient Department (HOPD) / Ambulatory Service Center (ASC)
Effective January 1, 2014, CMS updated reimbursement for skin substitutes by bundling payment into assigned high and low cost bundle amounts in the Outpatient Prospective Payment System (OPPS). In 2018, CMS assigned Grafix CORE and Grafix PRIME to the high-cost bundle for Medicare-only patients. Customers are advised to continue to bill the 1527X series for the application of Grafix. The rates detailed below represent the National average of the Medicare allowable.

***IMPORTANT***

Bundled Payments: Medicare does not separately reimburse for most skin substitute products, including Grafix. Therefore, when Grafix is applied in the hospital outpatient setting, Medicare reimburses the CPT code national average payment amounts listed below only; there is no separate reimbursement for skin substitutes, including Grafix. CMS identifies products for the High and Low bundle by the HCPCS code, therefore the product specific HCPCS code must still be listed on the claim. The high bundle payment is the same regardless of the product HCPCS code or the amount of graft product applied (i.e. billing units in cm²).

Coinsurance/Deductibles: As with all products and services paid for under Medicare Part B, Medicare reimburses 80 percent of the allowable amount. The patient, or secondary/supplemental plan, is responsible for the remaining 20 percent coinsurance amount. The appropriate annual deductibles also apply.

Sequestration: Since April 1, 2013, all Medicare claims with a date-of-service on or after April 1, 2013 are subjected to a 2 percent sequestration amount, which remains in effect in the U.S. budget until 2022. Please note, the 2 percent is deducted from the 80 percent allowable amount paid by Medicare and not the coinsurance amount.

Wage Index: The referenced amounts below are based on the National average payment amounts listed by Medicare. The actual amount a hospital or provider receives is also adjusted on the area wage index. Wage index is one of the factors used by Medicare to determine prospective payment to hospitals for the patient care they provide to Medicare recipients. It is intended to account for regional differences in the cost of wages in the Medicare reimbursement formula.

HOPD and ASC National Average Payment Amounts
Both Grafix CORE and PRIME are included in the high bundle.

<table>
<thead>
<tr>
<th>CPT</th>
<th>APC Assignment</th>
<th>HOPD Bundle Rate</th>
<th>ASC Bundle Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>15271/15275/15277</td>
<td>APC 5054 Level 4 Skin Procedure</td>
<td>$1,568.32</td>
<td>$817.15</td>
</tr>
<tr>
<td>15273</td>
<td>APC 5055 Level 5 Skin Procedure</td>
<td>$2,710.30</td>
<td>$1,412.16</td>
</tr>
</tbody>
</table>

Note: Payment rates can be found on the CMS website under the 2018 Final Rule. The referenced amounts above are based on the unadjusted national average payment amounts listed by CMS and do not include copayments/deductible, sequestration, or wage index adjustments. All codes provided herein are for information purposes only and shall not be construed as a statement, promise or guarantee that these codes are accurate, or reimbursement will be received.
**MEDICARE - Physician Services Reimbursement**

**Physician Services Payment for Application of Grafix in a HOPD or ASC:**
If Grafix is used in the outpatient department, the physician will bill separately for the application procedure on the CMS-1500 claim form. *(Refer to page 14 of this Billing Guide)*

**MEDICARE - 2018 National Average Physician Service Payments**

Detailed below are the national average payment rates per CPT for the physician service when the physician applies a skin substitute in the hospital/ASC place of service.

<table>
<thead>
<tr>
<th>CPT</th>
<th>Descriptor for Application of Skin Substitutes</th>
<th>Physician Rate in HOPD</th>
</tr>
</thead>
<tbody>
<tr>
<td>15271</td>
<td>Application of skin substitute graft to trunk, arms, legs, total wound surface area of up to 100 sq. cm; first 25 sq. cm or less of wound surface area</td>
<td>$87.48</td>
</tr>
<tr>
<td>+15272</td>
<td>Each additional 25 sq. cm up to 100 sq. cm wound surface area, or part thereof (list separately in addition to code for primary procedure)</td>
<td>$18.36</td>
</tr>
<tr>
<td>15273</td>
<td>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</td>
<td>$211.68</td>
</tr>
<tr>
<td>+15274</td>
<td>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)</td>
<td>$47.88</td>
</tr>
<tr>
<td>15275</td>
<td>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 area</td>
<td>$99.00</td>
</tr>
<tr>
<td>+15276</td>
<td>Each additional 25 sq. cm wound surface, or part thereof (list separately in addition to code for primary procedure)</td>
<td>$26.28</td>
</tr>
<tr>
<td>15277</td>
<td>Application of skin substitute graft to face, scalp, eyelids, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq. cm wound area, or 1% of infants and children</td>
<td>$238.68</td>
</tr>
<tr>
<td>+15278</td>
<td>Each additional 100 sq. cm wound surface area, or part thereof, (list separately in addition to code for primary procedure)</td>
<td>$60.12</td>
</tr>
</tbody>
</table>

**Critical Access Hospitals (CAHs)**

“Critical Access Hospital” is a designation given to certain rural hospitals by the CMS. This designation was created by Congress in the 1997 Balanced Budget Act.

The CAH designation is designed to reduce the financial vulnerability of rural hospitals and improve access to healthcare by keeping essential services in rural communities. This is accomplished through cost-based Medicare reimbursement.

CAHs are paid for most inpatient and outpatient services to Medicare patients at 101 percent of reasonable costs. CAH services are subject to the Medicare Part A and Part B deductible and coinsurance amounts. CAHs are not subject to the Inpatient Prospective Payment System (IPPS) or the Hospital Outpatient Prospective Payment System (OPPS). Billing and reimbursement for CAHs is based on the choice of two payment methods (standard and optional).

Reimbursement for CAHs is beyond the scope of this Billing Guide. For more information visit the CMS website or contact your local Medicare Area Contactor (MAC).

*Note: Check rates in your geographic service area*
ICD-10 Diagnosis Codes

ICD-10 is the 10th revision of the International Statistical Classification of Disease and Related Health Problems (ICD) published by the World Health Organization (WHO). It contains codes for diseases, signs and symptoms, abnormal findings, complaints, social circumstances, and external causes of injury or diseases. CMS publishes Clinical Modification (ICD-10-CM), modified guidelines for ICD-10 for use in the United States. The ICD-10-CM is a morbidity classification for classifying diagnoses (diagnosis coding) and the reason for visits in all health care settings.

ICD-10-CM consists of two parts:
- ICD-10-CM Diagnosis Coding for use in all health care settings
- ICD-10-PCS Procedure Coding System for use in hospital in-patient procedure coding

ICD-10-CM for Etiology and Manifestation:
Certain conditions have both an underlying etiology and multiple body system manifestations due to the underlying etiology. For such conditions, the ICD-10-CM coding rule requires the underlying condition (e.g. Type II diabetes mellitus) be sequenced first, if applicable, followed by the manifestation (e.g. a chronic ulcer). Wherever such a combination exists, there is a "use additional code" note at the etiology code, and a "code first" note at the manifestation code. These instructional notes indicate the proper sequencing order of the codes as etiology followed by manifestation. Please note that the insurer may verify and require that the diagnosis codes are in the proper order on claim forms.

ICD-10-CM Coding for Chronic Ulcers:
While many clinicians may interchange the terms "ulcer" and "wound" as if they are synonyms, they are not synonyms when it comes to ICD-10-CM coding. Wounds that become chronic are categorized as "ulcers" in ICD-10 Code language. There are specific ICD-10-CM code series for chronic ulcers. (See pages 15-16).

Chronic ulcers are categorized as either a "pressure ulcer" or a "non-pressure ulcer".

According to ICD-10-CM guidelines, it is recommended to provide an etiology code as the primary code, and a chronic ulcer code as the secondary code. Providers and billers should refer to specific payer guidelines for proper code sequencing.

Etiology Codes:
Information on diagnosis codes for conditions related to etiologies and diagnosis of chronic ulcers can be found in the FY 2018 ICD-10-CM Official Guidelines for Coding and Reporting¹ as listed below:
- Chapter 4, pages 34-36: Endocrine, Nutritional and Metabolic Disorders (E00-E99)
- Chapter 9, pages 43-49: Diseases of the Circulatory System (I00-I99)
- Chapter 12, pages 51-54: Diseases of the Skin and Subcutaneous Tissue (L00-L99)

Common etiologies may include diabetic ulcer, pressure ulcer, venous stasis ulcer, or arterial ulcer. Chronic ulcers may also originate from other conditions. The provider must use appropriate ICD-10-CM diagnosis codes for the causation of the ulcer and support the diagnosis with documentation in the patient's medical record.

Indications (etiologies) that are covered vary by each payer's medical policies and individual patient benefits. Providers should verify the covered indications with each patient’s specific benefits plan.

Chronic Ulcer (Manifestation) Codes:
Coding and documentation for non-pressure chronic ulcers was expanded with ICD-10-CM. Ulcer codes are required to document the specific anatomic location, severity and laterality (when applicable), in addition to the causation (as previously detailed). Providers should follow the coverage guidelines and diagnosis coding requirements for their local Medicare LCD and medical policies for each payer.

Many chronic ulcer codes, such as the L97 series for “non-pressure chronic ulcers”, are considered manifestation codes and have a “code first” note, recommending that a code for the underlying etiology (causation) be listed first as the “principal” diagnosis. Etiology codes (such as E11.621 – Type 2 diabetes mellitus with foot ulcer) have a “use additional code” note, requiring a manifestation code.

Examples of etiology and manifestation codes used in combination are listed below:
Primary Code: E10.621 – Type 1 diabetes mellitus with foot ulcer
Secondary Code: L97.422 – Non-pressure chronic ulcer of the right heel and midfoot with fat layer exposed

For more information on ICD-10-CM codes related to chronic ulcers, please consult the FY 2018 ICD-10-CM Guidelines for Coding and Reporting¹. You may also consult the AAPC 2018 ICD-10-CM coding books for additional coding guidelines².

2. http://www.sccma-mcms.org/Portals/19/assets/docs/Non-PressureChronicUlcers_ICD-10-CM.pdf

For reference, pages 15-16 of this Billing Guide provide a list of ICD-10-CM codes related to common etiologies and manifestations for chronic ulcers of the lower extremity. These codes are provided for information only and are not a statement or guarantee of reimbursement. The provider is ultimately responsible for verifying coverage with the patient’s payer source.

Unspecified Codes:
Unspecified code options, which indicate to the payer that the documentation was incomplete, and may lead to claim adjudication issues, including denials or review of documentation. Documentation of medical necessity is generally required when treating with skin substitutes, therefore it is recommended to avoid use of unspecified codes when billing for Grafix, or any other skin substitute product.

Examples of unspecified ICD-10-CM codes are:
L97.40 – Non-pressure chronic ulcer of unspecified heel and midfoot
L97.509 – Non-pressure chronic ulcer of the other part of the foot with unspecified severity
***BILLING REMINDERS***

**HCPCS Units Billed:**
Check units billed for Grafix HCPCS on the claim form. Billable units is equal to the size of the graft in square cm (cm$^2$). Grafix is used for single use only and should be billed accordingly as to size. It is recommended that providers document wastage as warranted.

Example: Grafix PRIME 3 cm x 4 cm (Q4133) is billed as 12 units (12 cm$^2$ of graft applied)

**Medically Unlikely Edit (MUE):** A Medically Unlikely Edit (MUE) is a Medicare unit of service claim edit applied to Medical Claims against a procedure code for medical services rendered by one provider or facility to one patient on one day. The MUE is the maximum units of a product reimbursed in one application.
- MUE for Grafix CORE Q4132 = 50 units
- MUE for Grafix PRIME Q4133 = 113 units

**CPT Codes:**
In the hospital outpatient department the fee for application of Grafix is based on the CPT procedure code series 15271-15278 for the application of a skin substitute. Use the appropriate CPT code specific to the location applied. Under Medicare, the CPT code payment and payment for Grafix product used is bundled together as one payment. Physicians may receive payment for their services using the same CPT code, and is paid separately from the facility.

**Debridement:**
Debridement is considered a component code of skin substitute CPT application codes and is not typically separately reimbursed. Many insurers have specific guidelines on debridement services. Check with the insurer for insurer-specific guidance.

**ICD-10-CM Diagnosis Code(s) Order:**
For the treatment of chronic ulcers, a primary ICD-10 code to document the etiology (causation), and a secondary ICD-10 code to document the specific location, severity and laterality (if applicable) of the chronic ulcer (manifestation) are required. Check with the insurer to ensure diagnoses are in the proper primary and secondary order on claims forms.

**Product Wastage Documentation Requirements:**
Any amount of wasted material should be clearly documented in the medical record with the following information. Please check with the patient’s insurer on specific documentation requirements.
- Approximate amount of product unit used, and approximate amount of product unit discarded
- Reason for the wastage

**Modifiers:**
Check to see if modifiers are required with HCPCS Q4132 or Q4133 and/or the CPT codes used. Common modifiers may include:
- JC: skin substitute used as a graft
- JW: wastage
- KX: requirements in the medical policy have been met

**Ulcer Size:**
Determining the ulcer location and surface area is important in order to select the appropriate CPT and ICD-10-CM codes. Please reference the CPT and ICD-10-CM descriptions. Ulcer size, as measured according to acceptable practice standards, should be documented in the medical record weekly, including the Length (L), Width (W) and Depth (D) in cm. Initial coverage is typically based on documentation that the wound is not improving, or reducing in size over time, and has become a chronic ulcer.
Medical Necessity Documentation

How do I determine if Grafix is considered reasonable and necessary for my patient’s condition?
It is recommended that the provider review clinical evidence for Grafix with respect to appropriate diagnoses, application, frequency, etc. If there is an applicable LCD or medical policy for Grafix, all requirements and guidelines must be met in order for the patient to be covered.

Definition of Reasonable and Necessary:
• Safe
• In accordance with generally accepted standards of medical practice
• Clinically appropriate in terms of type, frequency, extent, site and duration
• Ordered and furnished by qualified personnel

Suggested Documentation Requirements based on current wound care standards:
• Duration of ulcer (# of days or weeks)
• Prior conservative treatments that have failed to induce significant healing
• Exact location of ulcer
• Baseline measurements (LxWxD) immediately prior to initiation of treatment
• Ulcer is free of wound infection and osteomyelitis; past history of osteomyelitis has been treated successfully
• Adequate treatment of the underlying disease contributing to the ulcer
• Appropriate wound dressing changes, adequate wound debridement and patient compliance
• Appropriate off-loading / compression (if applicable), and patient compliance
• Adequate blood flow / perfusion; documentation of tests used to assess perfusion
• Patient’s nutritional status is adequate for healing
• If patient is a smoker, cessation counseling and resources for smoking cessation are documented
• Measurement of the wound progression (length and width or circumference and depth)
• Application number and improvement since last treatment
• Amount of Grafix used and amount discarded (wastage)
• Physician’s choice of fixation

For your convenience, a pre-treatment checklist can be found on page 17. Please note that coverage guidelines vary by payer and this checklist may not represent an appropriate checklist for a specific payer.

Osiris does not guarantee reimbursement or payment for Grafix. *Always refer to the insurer-specific coverage policy or contact the insurer for instructions. The Medical Necessity Documentation Checklist supplied is for informational purposes only and represent no statement, promise, or guarantee by Osiris that using this checklist will be appropriate or that reimbursement will be made. The decision as to how to complete a reimbursement form, including amount to bill, is exclusively the responsibility of the provider. The provider is ultimately responsible for verifying coverage with the patient’s payer source.
The Osiris Reimbursement Hotline

Osiris Reimbursement Hotline: 866-988-3491
FAX Numbers: 866-304-6692 • 443-472-4274 • 443-545-1705

The Osiris Reimbursement Hotline is a HIPAA compliant service comprised of a specialized team experienced in wound care reimbursement to support providers and customers in a variety of ways, such as provider education on coverage, coding, and payment mechanisms for Grafix.

Osiris Reimbursement Hotline staff provides assistance with the following:
- Coding, coverage, and reimbursement support
- Patient-specific insurance verifications
- Payer policy and Medicare Local Coverage Determination (LCD) information
- Prior authorization & Pre-determination support
- Individual claims support
- General product and service questions

Reimbursement Hotline staff can also provide you with information about procedure codes and modifiers and assist providers by reviewing individual payer policies to determine if other codes or modifiers are required.

Hotline staff can provide pre-populated payer prior authorization forms and/or a template letter of medical necessity, as well as submit materials on behalf of the physician and track outcomes until a final reimbursement decision is obtained.

Provider Responsibility:
The provider is responsible for verifying individual contract or reimbursement rates with each payer. The Osiris Reimbursement Hotline staff is not able to and will not confirm the contracted or reimbursable rates on your behalf.

Before Osiris will provide any reimbursement services, the practitioner or facility must:
(a) Submit a fully completed Insurance Verification Request Form, with a signed practitioner authorization and
(b) Enter into a Business Associate Agreement with Osiris

Before Osiris will provide any individualized reimbursement support services, which requires access to Protected Health Information, the health care facility (covered entity) and Osiris must enter into a Business Associate Agreement (BAA). Upon request, the Osiris template Business Associate Agreement is available from the Hotline.

HOW TO GET STARTED WITH THE HOTLINE?
- Complete the Insurance Verification Request Form (IVR) and fax to 866-304-6692 (or any fax number above)
- Call the Osiris Reimbursement Hotline between the hours of 8 am – 7 pm EST: 866-988-3491
Osiris Reimbursement Hotline Insurance Verification Request Form
Fax Numbers: 866-304-6692 • 443-472-4274 • 443-545-1705
Phone: 866-988-3491

REQUIRED INFORMATION INDICATED BY *
☐ New Wound ☐ Additional Application ☐ Re-verification ☐ New Insurance

PATIENT AND PAYER INFORMATION
* Patient Name: ___________________________ Date of Birth: ___________ ☐ Female ☐ Male
Address: ___________________________ City: ___________ State: ___________ Zip Code: ___________
Phone: ___________________________

* Is the patient currently in a Skilled Nursing Facility or Nursing Home? ☐ Yes ☐ No
If YES, how many days has the patient been admitted to the Skilled Nursing Facility or Nursing Home? ___________

Primary Insurance: ___________________________ Secondary Insurance: ___________________________
Payer Phone #: ___________________________ Payer Phone #: ___________________________
Policy Number: ___________________________ Policy Number: ___________________________
Subscriber Name: ___________________________ Subscriber Name: ___________________________

PHYSICIAN AND FACILITY INFORMATION
*Physician Name: ___________________________ Specialty: ___________________________
*Physician ID #s NPI: ___________________________ Tax ID: ___________________________ Medicaid Provider #: ___________________________
*Facility Name: ___________________________
Address: ___________________________ City: ___________ State: ___________ Zip Code: ___________
*Facility's ID #s NPI: ___________________________ Tax ID: ___________________________
Facility Contact: ___________________________ Phone #: ___________________________ Fax #: ___________________________
Email Address: ___________________________

*Treatment Setting: ☐ Hospital Based Outpatient Wound Department/Clinic (HOPD) ☐ Physician Office
Osiris does not verify benefits for procedures performed in the operating room setting.

RESEARCH INFORMATION
☐ Q4132 Grafix CORE® ☐ Q4133 Grafix PRIME® ☐ Diabetes ☐ Vascular ☐ Other
*ICD-10 Diagnosis Codes: (Related to Grafix® treatment)
Primary: ___________________________ Secondary: ___________________________ Tertiary: ___________________________
Known Comorbidities: ___________________________

*Application Codes: ☐ 15271 ☐ 15275 ☐ Other, please specify: ___________________________
Anticipated Treatment Start Date: ___________________________ Frequency: ___________________________ Number of Applications: ___________________________

If the payer requires a Prior Auth or Pre-Determination for the Osiris Product applications, would you like assistance? Yes ☐ No ☐
If yes, please attach a minimum of 4 weeks of clinical notes.

*I certify that I have obtained a valid authorization from the patient listed on this form permitting me to (a) release the patient’s protected health information (PHI), to Osiris Therapeutics, Inc. as necessary to research insurance coverage regarding Osiris products and (b) authorizing the payer to disclose PHI to Osiris for purposes of determining benefit coverage.

Physician Signature: ___________________________ Date: __________________________

Please fax this form along with a copy of the front and back of the patient’s insurance card.
Sample Letter of Medical Necessity

(Please refer to this example when drafting your letter on your letterhead)

Date

Insurer Name
Insurer Address
City, State, Zip Code

RE: Letter of Medical Necessity for Grafix®

Patient’s Name
Policy Number
Group Number
Date of Birth

Dear [Insurance Contact Name]:

I am writing to notify you of my intent to treat Mr./Ms. <Patient’s Name> with Grafix which is a biological skin substitute used to treat <name of type of wound: i.e. pressure wounds/diabetic foot ulcers/venous stasis ulcers, etc.>. The patient’s medical history is as follows:<include relevant medical history>

Grafix is an allograft tissue matrix manufactured by Osiris Therapeutics, Inc, and regulated by the FDA under 21 CFR Part 1271 Human Cells, Tissue, and Cellular and Tissue-based Products (HCT/Ps), and section 361 of the Public Health Service Act (PHS Act). Osiris Therapeutics, Inc. is registered with the FDA as a tissue establishment and is accredited by the American Association of Tissue Banks (AATB).

Grafix is a cryopreserved placental membrane retaining the extracellular matrix, growth factors, and endogenous neonatal stem cells, fibroblasts, and epithelial cells of the native tissue. Grafix, as a placental matrix, can support migration, proliferation, and differentiation of several types of cells in the patient (i.e., recipient) known to be involved in the body’s natural repair process. Grafix is an alternative to skin grafting that eliminates the pain, comorbidities, and procedure time associated with obtaining autologous grafts.

My patient has not responded to conservative care for <time frame> and has not responded to more advanced therapy including <product name(s) & type(s) of products>. More aggressive treatment is medically necessary to prevent further damage and <list risk(s) of non-closure>. I believe my patient will benefit from this therapy.

I have enclosed the product information and published data regarding the clinical utility of Grafix.

Please feel free to contact me if additional information is required to process my request for coverage.

Sincerely,
### SAMPLE CLAIM EXAMPLES

**HOPD or Hospital-Affiliated ASC:**
This example represents the application of Grafix PRIME, 3 cm x 4 cm (12 cm²), to an area on the foot, conducted in the HOPD or hospital-affiliated ASC, and the HOPD/ASC is billing for facility services rendered and Grafix. HOPD and the hospital-affiliated ASC use the UB04 (also known as the CMS-1450) claim form. **Note:** Use site of service 19 (off-campus) or 22 (on-campus) for HOPD or 24 for ASC.

<table>
<thead>
<tr>
<th>Description</th>
<th>CPT Code</th>
<th>Amount</th>
<th>Units</th>
<th>Total Charges</th>
<th>NDC Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grafix prime, (3 x 4) per sq cm</td>
<td>Q4133</td>
<td>12</td>
<td>XXX</td>
<td>XXX</td>
<td></td>
</tr>
<tr>
<td>Application</td>
<td>15275</td>
<td>1</td>
<td>XXX</td>
<td>XXX</td>
<td></td>
</tr>
</tbody>
</table>

**Physician Services in HOPD:**
Example of a physician service claim for procedures conducted in the hospital outpatient department. Physician services are billed on the CMS-1500 claim form. **Note:** Use site of service 22 for physician services in the HOPD.
Common ICD-10-CM codes associated with chronic lower extremity ulcers

The ICD-10-CM codes listed below represent some of the etiology diagnosis codes commonly associated with causes of lower extremity chronic ulcers. **This is not meant to be an exhaustive list.** The below list of codes includes an edit to use an additional ICD-10-CM manifestation code from the L97 non-pressure chronic ulcer code series as a secondary diagnosis. See page 16 for a list of specific L97 codes.

<table>
<thead>
<tr>
<th>CODE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>E10.621</td>
<td>Type 1 diabetes mellitus with foot ulcer</td>
</tr>
<tr>
<td>E10.622</td>
<td>Type 1 diabetes mellitus with other skin ulcer</td>
</tr>
<tr>
<td>E11.621</td>
<td>Type 2 diabetes mellitus with foot ulcer</td>
</tr>
<tr>
<td>E11.622</td>
<td>Type 2 diabetes mellitus with other skin ulcer</td>
</tr>
<tr>
<td>E13.621</td>
<td>Other specified diabetes mellitus with foot ulcer</td>
</tr>
<tr>
<td>E13.621</td>
<td>Other specified diabetes mellitus with other skin ulcer</td>
</tr>
<tr>
<td>I83.012</td>
<td>Varicose veins of right lower extremity with ulcer of calf</td>
</tr>
<tr>
<td>I83.013</td>
<td>Varicose veins of right lower extremity with ulcer of ankle</td>
</tr>
<tr>
<td>I83.014</td>
<td>Varicose veins of right lower extremity with ulcer of heel &amp; midfoot</td>
</tr>
<tr>
<td>I83.015</td>
<td>Varicose veins of right lower extremity with ulcer of other part of foot</td>
</tr>
<tr>
<td>I83.018</td>
<td>Varicose veins of right lower extremity with ulcer of other part of lower leg</td>
</tr>
<tr>
<td>I83.022</td>
<td>Varicose veins of left lower extremity with ulcer of calf</td>
</tr>
<tr>
<td>I83.023</td>
<td>Varicose veins of left lower extremity with ulcer of ankle</td>
</tr>
<tr>
<td>I83.024</td>
<td>Varicose veins of left lower extremity with ulcer of heel &amp; midfoot</td>
</tr>
<tr>
<td>I83.025</td>
<td>Varicose veins of left lower extremity with ulcer of other part of foot</td>
</tr>
<tr>
<td>I83.028</td>
<td>Varicose veins of left lower extremity with ulcer of other part of lower leg</td>
</tr>
<tr>
<td>I83.212</td>
<td>Varicose veins of right lower extremity with both ulcer of calf and inflammation</td>
</tr>
<tr>
<td>I83.213</td>
<td>Varicose veins of right lower extremity with both ulcer of ankle and inflammation</td>
</tr>
<tr>
<td>I83.214</td>
<td>Varicose veins of right lower extremity with both ulcer of heel &amp; midfoot and inflammation</td>
</tr>
<tr>
<td>I83.215</td>
<td>Varicose veins of right lower extremity with both ulcer of other part of foot and inflammation</td>
</tr>
<tr>
<td>I83.218</td>
<td>Varicose veins of right lower extremity with both ulcer of other part of lower extremity and inflammation</td>
</tr>
<tr>
<td>I83.222</td>
<td>Varicose veins of left lower extremity with both ulcer of calf and inflammation</td>
</tr>
<tr>
<td>I83.223</td>
<td>Varicose veins of left lower extremity with both ulcer of ankle and inflammation</td>
</tr>
<tr>
<td>I83.224</td>
<td>Varicose veins of left lower extremity with both ulcer of heel &amp; midfoot and inflammation</td>
</tr>
<tr>
<td>I83.225</td>
<td>Varicose veins of left lower extremity with both ulcer of other part of foot and inflammation</td>
</tr>
<tr>
<td>I83.228</td>
<td>Varicose veins of left lower extremity with both ulcer of other part of lower extremity and inflammation</td>
</tr>
<tr>
<td>I87.2</td>
<td>Venous Insufficiency (chronic peripheral)</td>
</tr>
<tr>
<td>I87.311</td>
<td>Chronic venous hypertension (idiopathic) with ulcer of right lower extremity</td>
</tr>
<tr>
<td>I87.312</td>
<td>Chronic venous hypertension (idiopathic) with ulcer of left lower extremity</td>
</tr>
<tr>
<td>I87.313</td>
<td>Chronic venous hypertension (idiopathic) with ulcer of bilateral lower extremity</td>
</tr>
<tr>
<td>I87.331</td>
<td>Chronic venous hypertension (idiopathic) with ulcer and inflammation of right lower extremity</td>
</tr>
<tr>
<td>I87.332</td>
<td>Chronic venous hypertension (idiopathic) with ulcer and inflammation of left lower extremity</td>
</tr>
<tr>
<td>I87.333</td>
<td>Chronic venous hypertension (idiopathic) with ulcer and inflammation of bilateral lower extremity</td>
</tr>
</tbody>
</table>
Common ICD-10-CM codes associated with chronic lower extremity ulcers

The ICD-10-CM codes listed below are specific manifestation diagnosis codes commonly associated with non-pressure chronic ulcers of the lower extremity. This is not meant to be an exhaustive list.

<table>
<thead>
<tr>
<th>ICD-10-CM</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>L97 SERIES</td>
<td>NON-PRESSURE CHRONIC ULCER OF LOWER LIMB</td>
</tr>
<tr>
<td>L97.211</td>
<td>Non-Pressure Chronic Ulcer of Right calf limited to breakdown of skin</td>
</tr>
<tr>
<td>L97.212</td>
<td>Non-Pressure Chronic Ulcer of Right calf with fat layer exposed</td>
</tr>
<tr>
<td>L97.213</td>
<td>Non-Pressure Chronic Ulcer of Right calf with necrosis of muscle</td>
</tr>
<tr>
<td>L97.214</td>
<td>Non-Pressure Chronic Ulcer of Right calf with necrosis of bone</td>
</tr>
<tr>
<td>L97.221</td>
<td>Non-Pressure Chronic Ulcer of Left calf limited to breakdown of skin</td>
</tr>
<tr>
<td>L97.222</td>
<td>Non-Pressure Chronic Ulcer of Left calf with fat layer exposed</td>
</tr>
<tr>
<td>L97.224</td>
<td>Non-Pressure Chronic Ulcer of Left calf with necrosis of bone</td>
</tr>
<tr>
<td>L97.311</td>
<td>Non-Pressure Chronic Ulcer of Right ankle limited to breakdown of skin</td>
</tr>
<tr>
<td>L97.312</td>
<td>Non-Pressure Chronic Ulcer of Right ankle with fat layer exposed</td>
</tr>
<tr>
<td>L97.313</td>
<td>Non-Pressure Chronic Ulcer of Right ankle with necrosis of muscle</td>
</tr>
<tr>
<td>L97.314</td>
<td>Non-Pressure Chronic Ulcer of Right ankle with necrosis of bone</td>
</tr>
<tr>
<td>L97.321</td>
<td>Non-Pressure Chronic Ulcer of Left ankle limited to breakdown of skin</td>
</tr>
<tr>
<td>L97.322</td>
<td>Non-Pressure Chronic Ulcer of Left ankle with fat layer exposed</td>
</tr>
<tr>
<td>L97.323</td>
<td>Non-Pressure Chronic Ulcer of Left ankle with necrosis of bone</td>
</tr>
<tr>
<td>L97.324</td>
<td>Non-Pressure Chronic Ulcer of Left ankle with necrosis of muscle</td>
</tr>
<tr>
<td>L97.411</td>
<td>Non-Pressure Chronic Ulcer of Right heel &amp; midfoot limited to breakdown of skin</td>
</tr>
<tr>
<td>L97.412</td>
<td>Non-Pressure Chronic Ulcer of Right heel &amp; midfoot with fat layer exposed</td>
</tr>
<tr>
<td>L97.413</td>
<td>Non-Pressure Chronic Ulcer of Right heel &amp; midfoot with necrosis of muscle</td>
</tr>
<tr>
<td>L97.414</td>
<td>Non-Pressure Chronic Ulcer of Right heel &amp; midfoot with necrosis of bone</td>
</tr>
<tr>
<td>L97.421</td>
<td>Non-Pressure Chronic Ulcer of Left heel &amp; midfoot limited to breakdown of skin</td>
</tr>
<tr>
<td>L97.422</td>
<td>Non-Pressure Chronic Ulcer of Left heel &amp; midfoot with fat layer exposed</td>
</tr>
<tr>
<td>L97.423</td>
<td>Non-Pressure Chronic Ulcer of Left heel &amp; midfoot with necrosis of muscle</td>
</tr>
<tr>
<td>L97.424</td>
<td>Non-Pressure Chronic Ulcer of Left heel &amp; midfoot with necrosis of bone</td>
</tr>
<tr>
<td>L97.511</td>
<td>Non-Pressure Chronic Ulcer of Other part of right foot limited to breakdown of skin</td>
</tr>
<tr>
<td>L97.512</td>
<td>Non-Pressure Chronic Ulcer of Other part of right foot with fat layer exposed</td>
</tr>
<tr>
<td>L97.513</td>
<td>Non-Pressure Chronic Ulcer of Other part of right foot with necrosis of muscle</td>
</tr>
<tr>
<td>L97.514</td>
<td>Non-Pressure Chronic Ulcer of Other part of right foot with necrosis of bone</td>
</tr>
<tr>
<td>L97.521</td>
<td>Non-Pressure Chronic Ulcer of Other part of left foot limited to breakdown of skin</td>
</tr>
<tr>
<td>L97.522</td>
<td>Non-Pressure Chronic Ulcer of Other part of left foot with fat layer exposed</td>
</tr>
<tr>
<td>L97.523</td>
<td>Non-Pressure Chronic Ulcer of Other part of left foot with necrosis of muscle</td>
</tr>
<tr>
<td>L97.524</td>
<td>Non-Pressure Chronic Ulcer of Other part of left foot with necrosis of bone</td>
</tr>
<tr>
<td>L97.811</td>
<td>Non-Pressure Chronic Ulcer of Other part of right lower leg limited to breakdown of skin</td>
</tr>
<tr>
<td>L97.812</td>
<td>Non-Pressure Chronic Ulcer of Other part of right lower leg with fat layer exposed</td>
</tr>
<tr>
<td>L97.813</td>
<td>Non-Pressure Chronic Ulcer of Other part of right lower leg with necrosis of muscle</td>
</tr>
<tr>
<td>L97.814</td>
<td>Non-Pressure Chronic Ulcer of Other part of right lower leg with necrosis of bone</td>
</tr>
<tr>
<td>L97.821</td>
<td>Non-Pressure Chronic Ulcer of Other part of left lower leg limited to breakdown of skin</td>
</tr>
<tr>
<td>L97.822</td>
<td>Non-Pressure Chronic Ulcer of Other part of left lower leg with fat layer exposed</td>
</tr>
<tr>
<td>L97.823</td>
<td>Non-Pressure Chronic Ulcer of Other part of left lower leg with necrosis of muscle</td>
</tr>
<tr>
<td>L97.824</td>
<td>Non-Pressure Chronic Ulcer of Other part of left lower leg with necrosis of bone</td>
</tr>
</tbody>
</table>
Advanced Wound Therapy Pre-Treatment Checklist

Provider has documentation of the following in the patient’s medical record:

- Diagnosis of a chronic wound and the causation or etiology (i.e. Type II Diabetes)
  - Primary (etiology) and Secondary (chronic ulcer) ICD-10 codes

- Failure to respond to good standard wound care for ≥4 weeks (Be specific about modalities such as debridement, advanced dressings, collagen, etc.)

- Underlying disease or condition is being treated by licensed physician and is under control:
  - Diabetes – HbA1c <12%
  - Venous stasis – Compression therapy

- Blood perfusion is adequate (ABI ≥0.65 or Toe pressure ≥30 mmHg)

- Patient is compliant with off-loading or compression (document type)

- Absence of wound infection or osteomyelitis – must state in the record.
  - If the patient has a history of osteomyelitis, recent x-rays are negative for active osteomyelitis and the patient’s chart documents stating the osteomyelitis is not active

- Weekly wound measurements taken; wound size ≥1 cm² when initiating therapy

- Smoking Status – smokers counselled to stop and provided cessation resources to curb smoking

- The patient is adequately nourished to support wound healing

- Documented treatment plan; to include the use of advanced therapies (Grafix)

Disclaimer: The information provided on this checklist is not a guarantee of coverage or reimbursement for Grafix now or in the future. Coverage and reimbursement varies by payer and patient benefits. It is the provider’s responsibility to verify the coverage policy and treatment guidelines for each payer. The decision to treat with Grafix is the sole responsibility of the provider and Osiris Therapeutics disclaims liability for payment of any claims, benefits or costs.

GR18003/REV00