Grafix®

BILLING GUIDE 2017

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**Grafix®**

**Product Description:**
Grafix (cryopreserved placental membrane) is available either as a cryopreserved chorion matrix (Grafix CORE®) or as a cryopreserved amnion matrix (Grafix PRIME® and Grafix XC®). 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, preservation of these cells in the product may not be indicative of clinical outcome.

Grafix is processed from donated 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.

**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.

**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.

**Grafix Healthcare Common Procedure Coding System (HCPCS) Codes**
HCPCS stands for Healthcare Common Procedure Coding System (HCPCS). For Medicare, and other health insurance programs, to ensure health care claims are processed in an orderly and consistent manner, standardized coding systems are essential. 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.
codes used for reporting and billing non-physician services. The other, HCPCS Level I coding set is comprised of CPT® (Current Procedural Terminology), which is copyrighted by the American Medical Association (AMA).

- The HCPCS codes included in this billing guide 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.

**Grafix Units Billed:**
Please note billable units. Grafix is intended for 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. One billable unit is 1 cm².

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Billable Units</th>
<th>HCPCS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grafix CORE 16 mm (2 mm²)</td>
<td>2</td>
<td>Q4132 Grafix CORE, per square centimeter</td>
</tr>
<tr>
<td>Grafix CORE 1.5x2 cm (3 cm²)</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Grafix CORE 2x3 cm (6 cm²)</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Grafix CORE 3x4 cm (12 cm²)</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>Grafix CORE 5x5 cm (25 cm²)</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>Grafix PRIME 16 mm (2 mm²)</td>
<td>2</td>
<td>Q4133 Grafix PRIME, per square centimeter</td>
</tr>
<tr>
<td>Grafix PRIME 1.5x2 cm (3 cm²)</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Grafix PRIME 2x3 cm (6 cm²)</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Grafix PRIME 3x4 cm (12 cm²)</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>Grafix PRIME 5x5 cm (25 cm²)</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>Grafix XC 7.5x15 cm (113 cm²)</td>
<td>113</td>
<td></td>
</tr>
</tbody>
</table>

**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
ICD-10 Diagnosis Codes*

Effective October 1, 2015, the International Classification of Diseases, 9th edition, Clinical Modification (ICD-9) code sets used to report medical diagnoses and inpatient procedures was replaced by the International Classification of Diseases, 10th edition, Clinical Modification (ICD-10). ICD-10 consists of two parts:

- ICD-10-CM **diagnosis coding** for use in all U.S. health care settings
- ICD-10-PCS **in-patient procedure coding** for use in U.S. hospital settings

ICD-10 impacts diagnosis and in-patient procedure coding for everyone covered by the Health Insurance Portability Accountability Act (HIPAA), not just those who submit Medicare or Medicaid claims. The ICD-10-CM/PCS system also provides significant improvements through greater detailed information and the ability to expand to capture additional advancements in clinical medicine. ICD-10-CM/PCS improvements include:

- Coding to higher level of specificity with proper medical documentation will result in improved ability to measure health care services
- Updated medical terminology and classification of diseases
- Increased sensitivity when refining grouping and reimbursement methodologies
- Enhanced ability to conduct public health surveillance
- Codes that allow comparison of mortality and morbidity data

ICD-10 codes must be coded to the highest level of specificity. The following table is provided for informational purposes. For specific codes to use in practice, please consult the ICD-10-CM Guidelines for Coding and Report in the AAPC 2017 ICD-10 CM coding books for additional coding guidelines. Please note that the insurer may verify and require that the diagnosis codes are in the proper order on claim forms.

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E10.621- E10.622</td>
<td>Type 1 diabetes mellitus with foot ulcer - Type 1 diabetes mellitus with other skin ulcer</td>
</tr>
<tr>
<td>E11.621 - E11.622</td>
<td>Type 2 diabetes mellitus with foot ulcer - Type 2 diabetes mellitus with other skin ulcer</td>
</tr>
<tr>
<td>E13.621 - E13.622</td>
<td>Other specified diabetes mellitus with foot ulcer - Other specified diabetes mellitus with other skin ulcer</td>
</tr>
<tr>
<td>I83.002 - I83.008</td>
<td>Varicose veins of unspecified lower extremity with ulcer of calf - Varicose veins of unspecified lower extremity with ulcer other part of lower leg</td>
</tr>
<tr>
<td>I83.012 - I83.018</td>
<td>Varicose veins of right lower extremity with ulcer of calf - Varicose veins of right lower extremity with ulcer other part of lower leg</td>
</tr>
<tr>
<td>I83.022 - I83.028</td>
<td>Varicose veins of left lower extremity with ulcer of calf - Varicose veins of left lower extremity with ulcer other part of lower leg</td>
</tr>
<tr>
<td>I83.202 - I83.208</td>
<td>Varicose veins of unspecified lower extremity with both ulcer of calf and inflammation - Varicose veins of unspecified lower extremity with both ulcer of other part of lower extremity and inflammation</td>
</tr>
<tr>
<td>I83.212 - I83.218</td>
<td>Varicose veins of right lower extremity with both ulcer of calf and inflammation - Varicose veins of right lower extremity with both ulcer of other part of lower extremity and inflammation</td>
</tr>
<tr>
<td>I83.222 - I83.228</td>
<td>Varicose veins of left lower extremity with both ulcer of calf and inflammation - Varicose veins of left lower extremity with both ulcer of other part of lower extremity and inflammation</td>
</tr>
<tr>
<td>I87.311 - I87.313</td>
<td>Chronic venous hypertension (idiopathic) with ulcer of right lower extremity - Chronic venous hypertension (idiopathic) with ulcer of bilateral lower extremity</td>
</tr>
<tr>
<td>I87.331 - I87.333</td>
<td>Chronic venous hypertension (idiopathic) with ulcer and inflammation of right lower extremity - Chronic venous hypertension (idiopathic) with ulcer and inflammation of bilateral lower extremity</td>
</tr>
</tbody>
</table>

*Always refer to the insurer-specific coverage policy or contact the insurer for instructions.* The ICD-10 and HCPCS codes 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, range of service 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.
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 enquire 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 2017 coding book for further instructions.

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</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 are 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

Hospital Outpatient Department (HOPD) / Ambulatory Service Center (ASC)
Effective January 1, 2014, the Centers for Medicare & Medicaid Services (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 2017, 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. The only exception is if a new product has applied and received pass-through status from Medicare.

Copayments/Deductibles: As with all products and services, Medicare reimburses 80 percent of this allowable amount and the patient, or secondary/supplemental plan, is responsible for the remaining 20 percent copayment amount. The appropriate 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 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 copayment 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.

### Hospital Outpatient (HOPD) National Average Payment Amounts

Both Grafix Core and Prime are included in the high bundle

<table>
<thead>
<tr>
<th>CPT</th>
<th>High Bundle Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>15271, 15275, 15277</td>
<td>$1,427.16</td>
</tr>
<tr>
<td>15273</td>
<td>$2,503.63</td>
</tr>
</tbody>
</table>

### Ambulatory Service Center (ASC)

<table>
<thead>
<tr>
<th>CPT</th>
<th>ASC Bundle Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>15271, 15275, 15277</td>
<td>$771.98</td>
</tr>
<tr>
<td>15273</td>
<td>$1,354.26</td>
</tr>
</tbody>
</table>

**Note:** The referenced amounts above are based on the National average payment amounts listed by CMS and do not include copayments/deductible, sequestration, or wage index adjustments.

1. The Final Rule is also available in PDF form at the following link: [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1656-FC.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1656-FC.html)
**MEDICARE - Physician Services Reimbursement**

**Grafix Product Reimbursement:**
If Grafix is used in the outpatient department, payment for the product is included in the bundled payment to the facility (HOPD or ASC). The physician rendering services in HOPD or ASC, will bill separately for services rendered on the CMS-1500 claim form.

When a physician submits a CMS-1500 claim for utilization of Grafix in his/her office, the CMS-1500 claim form should include billing for both the product and procedure on date services were rendered.

In the physician’s office, Grafix is not currently included on the Medicare Part B Average Sales Price (ASP) list published quarterly by CMS. Grafix is paid based on submitted invoice cost when administered in the physician’s office. However, some Medicare Administrative Contractors (MAC) also list their own ASP amounts. Please check with your MAC and/or the Osiris Reimbursement Hotlines for detailed information.

***IMPORTANT***

**Billing Instructions Box 19 and UPC codes:** Box 19 on the CMS-1500 claim form allows the provider to include the invoice cost, UPC, and product details including product name and size used. Payment based on invoice cost does not delay the electronic processing of claims.

**Copayments/Deductibles:** As with all products and services, Medicare reimburses 80 percent of this allowable amount and the patient, or secondary/supplemental plan, is responsible for the remaining 20 percent copayment amount. The appropriate 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 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 copayment amount.

**Wage Index:** The referenced amounts below are based on the National average payment amounts listed by CMS. 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 CMS 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.

**MEDICARE - 2017 National Average Physician Service Payments**
Detailed below are the national average payment amounts per CPT for the facility (when the physician treats in the hospital/ASC) or non-facility (when the physician treats in his office).

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
<th>National Average Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Facility (Hospital/ASC)</td>
</tr>
<tr>
<td>15271</td>
<td>Skin sub graft trunk/arm/leg</td>
<td>$ 87.38</td>
</tr>
<tr>
<td>15272</td>
<td>Skin sub graft trunk/arm/leg add-on</td>
<td>$ 17.90</td>
</tr>
<tr>
<td>15273</td>
<td>Skin sub graft trunk/arm/leg child</td>
<td>$ 209.10</td>
</tr>
<tr>
<td>15274</td>
<td>Skin sub graft trunk/arm/leg child add-on</td>
<td>$ 47.62</td>
</tr>
<tr>
<td>15275</td>
<td>Skin sub graft face, scalp, hands, feet, and/or multiple digits</td>
<td>$ 98.46</td>
</tr>
<tr>
<td>15276</td>
<td>Skin sub graft face, scalp, hands, feet, and/or multiple digits add-on</td>
<td>$ 25.78</td>
</tr>
<tr>
<td>15277</td>
<td>Skin sub graft face, scalp, hands, feet infants and children</td>
<td>$ 232.37</td>
</tr>
<tr>
<td>15278</td>
<td>Skin sub graft face, scalp, hands, feet infants and children add-on</td>
<td>$ 59.08</td>
</tr>
</tbody>
</table>
The foregoing information on page 6 regarding reimbursement averages is provided for your reference. 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.

**Commercial Payers**

***IMPORTANT***

Check your facility’s specific payer contracts prior to applying Grafix. Many insurers consider contracted rates to be proprietary information and they do not release this information upon verifying benefits. However, some insurers may release a general fee schedule allowable. **Please verify your individual contracted rates by either accessing your contract or contacting your provider relations representative.**

Commercial payers reimburse physicians and facilities based on contracted rates, fee-for-service rates, and/or fee schedules. Some commercial payers may also require prior authorization/pre-certification or pre-determination for Grafix. A contracted rate is a set rate agreed to in a contract between the provider and the payer. Commercial payer contracts contain requirements regarding timely processing of claims and reimbursement. The payer contract explains how reimbursement payment determinations are made and what method will be utilized to calculate payment for covered services. This information is often considered proprietary by the insurer; however, the Osiris Reimbursement Hotline can assist in understanding your payer contract and if necessary assist you with contract negotiation.

A fee-for-service reimbursement method provides payment for physician services based on an established fee schedule for each service. In contrast, a fee schedule is a listing of established allowed amounts for specific medical services and procedures.

Osiris Reimbursement Hotline staff can provide detailed patient specific coding, coverage, reimbursement and **prior authorization/pre-certification or pre-determination** requirements for your commercially-insured beneficiaries. **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.

**Medicaid**

Medicaid is a joint federal-state program that provides health coverage or nursing home coverage to certain categories of low-asset people, including children, pregnant women, parents of eligible children, people with disabilities and elderly needing nursing home care. Medicaid was created to help low-asset people who fall into one of these eligibility categories and to pay for some or all of their medical bills.

Medicaid reimbursement varies by state. Each state establishes and administers its own programs and determines the type, amount, and scope of services it provides. States are required to cover certain mandatory benefits, however they can choose to provide other optional benefits to their covered recipients. The Osiris Reimbursement Hotline can provide detailed patient specific coding, coverage, and reimbursement information for Medicaid beneficiaries. **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.
Osiris Reimbursement Hotline staff is available to assist with coding, coverage, and reimbursement questions.
Phone: 1-866-988-3491   Fax: 1-866-304-6692

Units Billed:
Check units billed. 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 Q4133 (5x5 cm) is billed as 25 units.

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.
- Date, time, and location of ulcer treated
- Approximate amount of product unit used
- Approximate amount of product unit discarded
- Reason for the wastage
- Manufacturer’s serial/lot/batch or other unit identification number of graft material

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

Wound Size:
Determining the wound location and surface area is important in order to select the appropriate CPT code. Please reference the CPT descriptions.

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.

Diagnosis Code(s) Order:
Check with the insurer to ensure diagnoses are in the proper primary and secondary order on claims forms.

Commercial Insurers/Contracted Rates:
Check your facility’s specific payer contracts prior to applying Grafix. Many insurers consider contracted rates to be proprietary information and they do not release this information upon verifying benefits. However, insurers may release a general fee schedule rate. Be aware that your practice or facility’s contract may not necessarily reimburse at that rate. Some insurers also require prior authorization and predeterminations before authorizing treatment for a patient. Please verify your contracted rates by either accessing your contract or contacting your provider relations representative directly. Osiris Reimbursement Hotline staff may also be able assist you in obtaining the appropriate contact information for your contract as well as prior authorization and predetermination requirements. The Osiris Reimbursement Hotline staff is not able to and will not, however, confirm the contracted or reimbursable rates on your behalf. The provider is responsible for verifying individual contract or reimbursement rates with each payer.
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 requirement and guidelines must be met in order for the patient to be covered.

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 wound
• Prior conservative treatments that have failed to induce significant healing
• Exact location of wound
• Baseline measurements immediately prior to initiation of treatment
• Wound is free of infection and osteomyelitis
• Adequate treatment of the underlying disease contributing to the wound
• Adequate blood flow
• 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
• Appropriate wound dressing changes, patient compliance, and off-loading (if applicable)

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Sample Letter of Medical Necessity

(Please Type on Physician’s 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./Mrs./Ms. <Patient’s Name>, DOB with Grafix (PRIME or CORE) Q_______ and CPT __________. I have had clinical success using Grafix to treat other patients with hard to treat, chronic wounds that have not responded to good standard wound care and other advanced therapies. I feel this request is medically urgent and necessary.

Mr./Mrs./Ms. <Patient Name>, is a <age> year-old man/woman who was referred to <Facility/Office Name> for treatment of <Wound type>. ICD 10 code: __________. His/Her wound measurements were (LxWxD) on (mo/day/year) when Mr./Mrs./Ms.< (Last Name) first presented to the <Facility/Office Name>. Since that time, my patient has not responded to conservative care and has not responded to more advanced therapy including <procedures, product name(s) tried and failed>. It is my medical expert opinion that more aggressive treatment is medically necessary at this point of my patients care to prevent further damage and <list risk(s) of non-closure, comorbidities if applicable>. I believe my patient will benefit from Grafix treatment to not only expedite his/her wound healing, but reduce any extra incurred healthcare costs associated with possible adverse complications should this wound remain unhealed.

Grafix is a biological skin substitute used in the treatment of acute and chronic wounds. To assist with your review of my recommendation, I have included the following information concerning Grafix.

Manufacturer and Product Description

Grafix is an allograft tissue matrix manufactured by Osiris Therapeutics, Inc. and regulated 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 may decrease pain, comorbidities, and procedure time associated with obtaining autologous grafts.

There is published clinical data to support the use of Grafix for patients with chronic non-healing wounds. Studies have shown faster and higher healing rates with Grafix than other tissue grafts.
Grafix Publication References:


It is my hope that upon complete and thorough review of this request and the information provided you will agree with my medical expert opinion to allow for treatment with Grafix.

I welcome an opportunity to discuss this with you over the phone if necessary. Please feel free to contact me if additional information is required.

Thank you for your valuable time. I look forward to hearing from you.

Sincerely,

[Physician Name]
[Contact Information]
SAMPLE CLAIM EXAMPLES

HOPD or Hospital-Affiliated ASC:
This example represents the application of Grafix CORE, 3x4 cm (12 cm²), to an area on the foot, conducted in the hospital or hospital-affiliated ASC and the hospital/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>41 HOPS / DATE / APP. CODE</th>
<th>45 SITE/DATE</th>
<th>46 SUP. UNITS</th>
<th>47 TOTAL CHARGES</th>
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<td>15275</td>
<td>12</td>
<td>XXX</td>
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<tr>
<td>Grafix Core</td>
<td>Application</td>
<td></td>
<td>XXX</td>
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</tr>
</tbody>
</table>

Note: Use site of service 19 (off-campus) or 22 (on-campus) for HOPD or 24 for ASC.
**Physician Services in HOPD:**
Example of a physician service submission 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.

| 1. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate Items 1, 2 or 4 to Item 24C by Line) |
|----------------------------------|----------------------------------|
| 1. 197 | 523 |
| 2. E11 | 40 |

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<tr>
<th>22. MEDICAID RESUBMISSION CODE</th>
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<table>
<thead>
<tr>
<th>23. PRIOR AUTHORIZATION NUMBER</th>
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</table>

**Physician Services in a Physician Office:**
Example of a physician submission for reimbursement when procedures are performed within a physician's office. Physician services are billed on the CMS-1500 claim form.

**Note:** Use site of service 11 for physician services in the Physician Office.
### PATIENT AND PAYER INFORMATION

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
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<tbody>
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<tr>
<td>Date of Birth:</td>
<td>Female</td>
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<tr>
<td>Address:</td>
<td>City:               State: Zip Code:</td>
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<tr>
<td>Phone:</td>
<td></td>
</tr>
<tr>
<td>Social Security Number:</td>
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#### Primary Insurance

- **Payer Phone #:**
- **Policy Number:**
- **Subscriber Name:**

#### Secondary Insurance

- **Payer Phone #:**
- **Policy Number:**
- **Subscriber Name:**

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### PHYSICIAN AND FACILITY INFORMATION

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<tr>
<td>Fax #:</td>
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<tr>
<td>Email Address:</td>
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</table>

#### Treatment Setting

- Hospital Based Outpatient Wound Department (HOPD)
- Ambulatory Surgery Center (ASC)
- Physician Office
- Skilled Nursing Facility (SNF)
- Other:

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### RESEARCH INFORMATION

#### ETOLOGY

- Grafix CORE®
- Grafix PRIME®
- Stravix®
- Diabetes
- Vascular
- Other

<table>
<thead>
<tr>
<th>Diagnosis Codes</th>
<th>Primary:</th>
<th>Secondary:</th>
<th>Tertiary:</th>
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</thead>
<tbody>
<tr>
<td>ICD-10</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

#### Known Comorbidities

- No Applicable Secondary or Tertiary Diagnoses to Report

#### Anticipated Treatment

- **Start Date:**
- **Frequency:**
- **Number of Applications:**

#### Authorization for Research

- Do you have a Business Associate Agreement (BAA) signed with Osiris Therapeutics? Yes | No

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### Disclaimer:

The Osiris Reimbursement Hotline is an information service only. Information gathered during requested research will be provided by the insurer or third-party payer. **Results of this research are not a guarantee of coverage or reimbursement now or in the future**, and the Osiris Reimbursement Hotline and Osiris Therapeutics disclaim liability for payment of any claims, benefits or costs.
Patient Signature (Optional):

By signing this authorization, I, the patient, authorize my healthcare provider and my health insurance company to use and/or disclose protected health information (PHI) such as my name, address, date of birth, medical information on my condition, and insurance information related to Osiris products from my health records and insurance information to Osiris Therapeutics, Inc., and its contractors as necessary to research insurance coverage. I understand that the information used or disclosed under this authorization may be shared with other people or entities and may no longer be protected by federal privacy regulations. In carrying out these activities, Osiris Therapeutics, Inc., and its contractors may relay information to health insurer(s), receive information from health insurer(s), and communicate such information to my healthcare provider. I understand that this authorization is voluntary and that I may refuse to sign this authorization. I understand that my refusal to sign does not affect payment for services, my ability to obtain treatment, or my eligibility for benefits. I understand that if I choose to cancel (revoke) this authorization, I must do so in writing to my healthcare provider. However, I cannot cancel actions that have already been taken by relying on my authorization. This authorization will expire one (1) year after the date it is signed below.

Signature of Patient or Guardian : ________________________________
Signature of Witness: _________________________________________
Date:____________________

Please fax this form along with a copy of the front and back of the patient’s insurance card to 866-304-6692.

Disclaimer: The Osiris Reimbursement Hotline is an information service only. Information gathered during requested research will be provided by the insurer or third-party payer. Results of this research are not a guarantee of coverage or reimbursement now or in the future, and the Osiris Reimbursement Hotline and Osiris Therapeutics disclaim liability for payment of any claims, benefits or costs.
The Osiris Reimbursement Hotline

Osiris Reimbursement Hotline: 1-866-988-3491
FAX: 1-866-304-6692

The Osiris Reimbursement Hotline is 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:

- General product and service questions
- 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

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 process an IVR, the practitioner must either (a) provide a completed IVR Form, with a signed practitioner authorization or signed patient consent, or (b) enter into a Business Associate Agreement with Osiris.

Before Osiris will provide any individualized claim support services, which requires access to Protected Health Information, the provider and Osiris must enter into a Business Associate Agreement. (The Osiris template Business Associate Agreement is available upon request.)

HOW TO GET STARTED WITH THE HOTLINE?

Complete the Insurance Verification Form and fax to: 1-866-304-6692

Call the Osiris Reimbursement Hotline between the hours of 8 am – 7 pm EST: 1-866-988-3491

GR17003/REV01