GRAFIX PL PRIME<sup>◊</sup>

Lyropreserved Placental Membrane

Cryopreserved Placental Membrane

GRAFIX PRIME<sup>♦</sup> GRAFIX CORE<sup>♦</sup>

Cryopreserved Placental Membrane

**GRAFIX PLUS** 

Lyropreserved Placental Membrane

# Reimbursement Guide 2024 Physician Office



**Reimbursement Hotline Services** 

Phone: 866-988-3491 Fax: 866-304-6692

**Customer Support** 

Phone: 888-674-9551

#### **Reimbursement Hotline Services**

For assistance with reimbursement questions, contact Smith+Nephew Reimbursement Hotline Services Monday through Friday from 8:00 am - 7:00 pm EST at 1-866-988-3491.

Smith+Nephew Reimbursement Hotline Services staff can assist with the following:

- Patient-specific insurance verifications
- Payer policy and Medicare Local Coverage Determination (LCD) information
- Nurse Case Manager review of documentation and coding
- Prior authorization and pre-determination support

To initiate insurance verification support for your patients, please submit a complete Insurance Verification Request (IVR) Form with a signed practitioner authorization and fax to 866-304-6692. The provider is responsible for verifying individual contract or reimbursement rates with each payer. Smith+Nephew Reimbursement Hotline Services is not able to confirm contracted or reimbursable rates on your behalf.

#### Reimbursement Disclaimer

Information on reimbursement in the U.S. is provided as a courtesy. Due to the rapidly changing nature of the law and the Medicare payment policy, and reliance on information provided by outside sources, the information provided herein does not constitute a guarantee or warranty that reimbursement will be received or that the codes identified herein are or will remain applicable. This information is provided "AS IS" and without any other warranty or guarantee, expressed or implied, as to completeness or accuracy, or otherwise. This information has been compiled based on data gathered from many primary and secondary sources, including the American Medical Association, and certain Medicare contractors. Providers must confirm or clarify coding and coverage from their respective payers, as each payer may have differing formal or informal coding and coverage policies or decisions. Providers are responsible for accurate documentation of patient conditions and for reporting of products in accordance with particular payer requirements.

### **Advanced Therapy Documentation Checklist**

Prior to requesting insurance verification or prior authorization from a payer, the provider should have 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 – adequate compression therapy to control edema Blood perfusion is adequate (ABI ≥0.65 or toe pressure ≥30 mmHg, pedal pulse) Venous reflux studies for venous stasis ulcer diagnosis Patient is compliant with off-loading for DFU or compression for VLU (document type) Absence of acute wound infection or active 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 For patients with history of Charcot neuroarthropathy, include documentation that acute Charcot Foot is not present, and any history of acute Charcot Foot has been treated Weekly wound measurements taken; wound size is ≥1 cm2 when initiating therapy Smoking Status – smokers have been educated that smoking impairs wound healing, counseled 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





1. Type of Insurance Verification Requested: Prior Authorization sup	pport will be initiated if required by	Payer, include clinical documenta	tion to support PA					
☐ New Wound ☐ Subsequent Applications ☐ Re-Verification	New Insurance IVR Lite	I opt out of Prior Authorization su	pport services					
☐ Single Wound ☐ Multiple Wounds Procedure Date:								
2. Patient Information: Please list the patient's name on this form when attaching a face sheet								
First Name:	Last Name:		M.I.:					
Address:	Apt./Suite#: City:	State:	Zip:					
Date of Birth:	Phone #:	Gender: ☐ Female ☐	Male					
3. Insurance Information: Please attach a copy (front & back) of patie	ent's insurance card(s)							
Cardholder Name:	DOB:	Relationship to patient	Relationship to patient:					
Primary Payer:	SSN:	Plan Type:						
Policy #:	Group #:	Card Phone #:						
Secondary Payer:		Plan Type:	Plan Type:					
Policy #:	Group #:	Card Phone #:						
4. Healthcare Provider (HCP) & Facility/Agency Information: Pleαse note, ν	'	ider must confirm Place of Service (POS	S). Select only ONE POS.					
Place of Service: ☐ Physician Office (POS11) ☐ Hospital Outpatier ☐ Home Visit (POS12) ☐ Assisted Living Facility ( Skilled Nursing Facility: Provider is responsible for confirming skilled/unsl HCP First Name:	POS13) Unskilled Nursing Bed (	(POS32) Other POS:	service? Yes No					
HCP NPI:	HCP Tax ID#:							
Specialty: MD DO DPM PA NP/FNP Other:	10. 10. 10.							
Contact Name:	Phone #:							
Facility Name:	Thoric II.	Facility NPI:						
Facility Address:	Facility Tax ID:	Tacility IVI I.						
	Phone #:	Fax #:						
City, State, Zip:		rax #:						
5. Treatment Information: If needed, select up to 3 products in order								
GRAFIX° PL PRIME Membrane (Q4133) GRAFIX° PRIME Memb	, ,	,	US Membrane (Q4304)					
OASIS® Wound Matrix (Q4102) OASIS® Burn Matrix (	Q4103) OASIS® ULTRA	Tri-Layer Matrix (Q4124)						
<b>CPT:</b> Legs/Arms/Trunk < <b>100</b> sq cm: 15271/15272-C5271/C Feet/Hands/Head < <b>100</b> sq cm: 15275/15276-C5275/C		<b>100 sq cm</b> : 15273/15274-C5 <b>100 sq cm</b> : 15277/15278-C5						
NOTE: Prior use of skin substitutes or glob								
<ol> <li>Wound Information &amp; Diagnosis Code(s): Please include ICD-10 c numeric ICD-10 Code. Ex: E11.621; L97.512; If treating more tha</li> </ol>		• • •						
ICD-10 Codes: #1 Wound (Required)	ICD-10 Codes: #2 Wound							
Primary (Etiology):	Primary (Etiology):							
Secondary (Ulcer/Location):	Secondary (Ulcer/Location):							
Tertiary (Optional):	Tertiary (Optional):							
	Wound Dimensions: LDD							
7. Prior Authorization: For PA support please attach all clinical notes # of Anticipated Applications/Visits Anticipated Units		isode						
8. Authorized Signature: Please include all required information and a By signing below, I certify that I have obtained a valid authorization from		ormitting mo to release the nationt	's protected bealth					
information (PHI) to the Smith+Nephew Reimbursement Hotline Serv as necessary to research insurance coverage and payment information behalf of the patient. I further understand that completing this for patient. I certify that the information provided on this form is current, If prior authorization is required, I authorize Smith and Nephew to init	ices, Smith & Nephew, Inc., its continuous of the determine benefits related to 0 m does not guarantee that insurance complete, and accurate to the best tiate the authorization.	ractors, and the patient's health insi GRAFIX PL°/GRAFIX° and/or OASIS° te coverage or reimbursement will b tof my knowledge.	urance company Matrix products be provided to the					
Authorized Signature:		Date:						
Disclaimer: The Smith+Nephew Reimbursement Hotline is an informa Results of this research are not a guarantee of coverage or reimburse claims, benefits or costs.	tion service only. Benefits informati	on is provided by the insurer or third	d-party payer.					

Smith+Nephew group company.

MSFE15-41896-0524

### **CPT Procedure Codes and Medicare Payments**

Medicare has designated specific CPT codes (15271-15278) for qualified healthcare providers to report the application of skin substitute graft procedures when applying CTPs/skin substitute products. The selection of the code is based upon the location and size of the defect. Ensure the medical record reflects these elements and a procedure description including the fixation method.

Physicians applying Cellular and/or Tissue-Based Products (CTPs) in the office setting should report both the Current Procedural Terminology (CPT) application code(s) and the applicable GRAFIX° Membrane product Healthcare Common Procedural Coding System (HCPCS) codes when submitting claims—Q4133 for GRAFIX PRIME° and GRAFIX PL°, Q4132 for GRAFIX CORE° and Q4304 for GRAFIX PLUS°

	Coding	Non-Facility* (Physician Office) Rate	Facility (HOPD) Rate
CPT codes	Code description	2024 Medicare national avg. payment	2024 Medicare national avg. payment
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	\$154.12	\$83.22
+15272	Each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)	\$24.63	\$16.64
15273	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infant and children		\$193.07
+15274	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)	<b>\$80.89</b>	\$43.94
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	<b>\$158.78</b>	\$92.21
+15276	Each additional 25 sq cm wound surface area, or part thereof (lis separately in addition to code for primary procedure)	t <b>\$32.29</b>	\$24.63
15277	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children	\$340.20	\$220.03
+15278	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)	<b>\$94.54</b>	\$54.92

Important Notes: The Medicare payment amounts listed do not reflect adjustments for deductible, copayments, coinsurance, sequestration or any other reductions. All payment amounts listed are based on national averages and will vary by geographical locations.

**Reference:** The Centers for Medicare and Medicaid Services, CY 2024 Physician Fee Schedule, Addendum B, Retrieved from https://www.cms.gov/medicare/medicare-fee-service-payment/physicianfeesched/pfs-federal-regulation-notices/cms-1784-f (3/14/2024)

\*Commercial Payer Payment Rates It is commonly understood that the payment rates of a commercial payer for the application of skin substitutes (CPTs 15271-15278) and Cellular Tissue Product (CTP) used in the procedure (HCPCS code) are confidentially negotiated between the commercial payer and providers. During such negotiations, the commercial payer may use different methodologies to establish payment rates, such as Medicare Physician Fee Schedule (MPFS), payment based on a set percentage of charges, or bundled payment, where the CPT fee includes the Cellular Tissue Product. Providers participating in Value-Based Pricing agreements may also be paid on a per member per month basis. Additionally, those different rate-determining methodologies vary greatly among commercial payers. Therefore, to confirm payment rates, please consult your office practice manager or billing manager. If you are unable to identify your practice's contracted rates, please reach out to the specific payer's Provider Relations Representative.

### **Product HCPCS Codes and Modifiers**

#### GRAFIX° HCPCS Codes, UPC Codes and Billing Units:

All GRAFIX Membranes are billed per square centimeter. One billable unit is 1 cm<sup>2</sup>. To calculate the number of billable units multiply the length by the width of the wound cover that was applied. The below chart lists the assigned HCPCS codes for GRAFIX Membranes and the billable units per product size.

In general, skin substitutes are reimbursed by Medicare based on the Average Sales Price (ASP) published quarterly by CMS on the cms.gov website under the ASP Drug Pricing File.

The ASP rate is per square centimeter. In the absence of a published ASP by CMS, a product will be reimbursed based off Invoice or List Price (see Important Notes below). Please ask your GRAFIX Sales Representative or FRM for the currently effective ASP or List Price. Providers must check contracted payment rates for private insurers.

Preservation and storage	Product description	Part number	UPC code	Billing units (per sq cm)	HCPCS Q-code
Lyopreserved	GRAFIX PL PRIME <sup>♦</sup> 16 mm Disc (2 cm <sup>2</sup> )	PS13016	859857003395	(per sq cm)         Q-code           59857003395         2         Q4133           59857003388         3         Q4133           59857003371         6         Q4133           59857003449         9         Q4133           59857003364         12         Q4133           59857003357         25         Q4133           59857003555         12         Q4304           59857003340         2         Q4133           59857003081         3         Q4133           59857003067         6         Q4133           59857003074         12         Q4133           59857003104         3         Q4132           59857003050         6         Q4132	Q4133
and storage Lyopreserved and stored at room temperature  Cryopreserved and stored at -75°C to -85°C	GRAFIX PL PRIME 1.5 x 2 cm (3 cm <sup>2</sup> )	PS13015	859857003388	3	Q4133
	GRAFIX PL PRIME 2 x 3 cm (6 cm <sup>2</sup> )	PS13023	859857003371	6	Q4133
	GRAFIX PL PRIME 3 x 3 cm (9 cm <sup>2</sup> )	PS13033	859857003449	9	Q4133
	GRAFIX PL PRIME 3 x 4 cm (12 cm <sup>2</sup> )	PS13034	859857003364	12	Q4133
	GRAFIX PL PRIME 5 x 5 cm (25 cm <sup>2</sup> )	PS13055	859857003357	25	Q4133
	GRAFIX PLUS 2 x 3 cm (6 cm <sup>2</sup> )	PS16023	859857003562	6	Q4304
	GRAFIX PLUS 3 x 4 cm (12 cm²)	PS16034	859857003555	12	Q4304
, ,	GRAFIX PRIME <sup>0</sup> 16 mm Disc (2 cm²)	PS60013	859857003340	2	Q4133
and storage Lyopreserved and stored at room temperature  Cryopreserved and stored at	GRAFIX PRIME 1.5 x 2 cm (3 cm <sup>2</sup> )	PS11015	859857003081	3	Q4133
	GRAFIX PRIME 2 x 3 cm (6 cm²)	PS11023	859857003067	6	Q4133
	GRAFIX PRIME 3 x 4 cm (12 cm²)	PS11034	859857003074	12	Q4133
	GRAFIX PRIME 5 x 5 cm (25 cm²)	PS11055	859857003098	25	Q4133
	GRAFIX CORE <sup>◊</sup> 1.5 x 2 cm (3 cm²)	PS12015	859857003104	3	Q4132
	GRAFIX CORE 2 x 3 cm (6 cm²)	PS12023	859857003050	6	Q4132
	GRAFIX CORE 3 x 4 cm (12 cm²)	PS12034	859857003111	12	Q4132
	GRAFIX CORE 5 x 5 cm (25 cm²)	PS12055	859857003128	25	Q4132

#### **Important Notes:**

CMS instructions indicate that payment for drugs and biologicals that are not included in the ASP
File are based on the published wholesale acquisition cost (WAC) or invoice price. The payment
limit is typically 103 to 106 percent of the lesser of the lowest priced brand or median generic
WAC. Physician offices should verify if the Medicare Administrative Contractor (MAC) that
processes their claims, covers the product and whether the MAC pays for it based on WAC or
invoice price.

a. If the MAC pays for the product based on WAC, the following information should be included in field 19 of a paper claim or in the narrative field of an electronic claim:

- Product name
- NDC code
- WAC of product
- WAC per sq. cm.
- Source of the WAC (e.g., Red Book)

b. If the MAC pays for the product based on invoice price, the following information should be included in field 19 of a paper claim or in the narrative field of an electronic claim:

- Product name
- Product size (in sq. cm.)
- Product number
- Invoice price per piece
- Shipping cost
- 2. The Medically Unlikely Edit (MUE) is the maximum units of a product reimbursed in one application per day. The MUE for GRAFIX Membrane products areas follows: a. MUE for GRAFIX CORE° (Q4132) = 50 units. b. MUE for GRAFIX PL PRIME° and GRAFIX PRIME° (Q4133) = 113 units. Note: MUE data as of 2019.
- 3. Payers including some MACs will require use of certain modifiers. Please check with the patient's insurance plan or MAC to identify whether modifiers are required with Q4132 or Q4133.
  - a. Common Modifiers:
    - i. JC skin substitute used as a graft
    - ii. JD skin substitute not used as a graft
    - iii. JW discarded skin substitute, not used (wastage)
    - iv. JZ zero discarded skin substitute, no wastage

### ICD-10 Diagnosis Code Guidelines for Wound Care

GRAFIX PL<sup>o</sup> and GRAFIX<sup>o</sup> Membrane coverage is based on medical necessity and subject to payer coverage guidelines. For most payers, GRAFIX PL and GRAFIX Membrane are considered medically necessary as an adjunct in the treatment of chronic ulcers that fail to progress toward healing after a period of standard wound care. Providers should always follow payer coverage guidelines for covered indications.

#### Examples of common lower-extremity chronic wounds include:

- Diabetic foot ulcers (DFU) / diabetic ulcers of the lower extremities (ankle)
- Venous stasis ulcers (VSU) / venous leg ulcers (VLU)
- Pressure ulcers
- Chronic non-healing surgical or trauma wounds of the lower extremity with co-morbidities

It is recommended that providers select the most specific primary and secondary diagnosis codes to accurately describe the reason the wound is not healing properly, and codes that indicate the wound is chronic and describe the location, severity, and laterality.

#### Example of specific DFU codes:

Primary diagnosis:
 E11.621, type 2 diabetes mellitus with a foot ulcer

Secondary diagnosis: L97.522, non-pressure chronic ulcer of other part of left foot with fat

layer exposed

#### Example of specific VLU codes:

Primary diagnosis: 187.312, chronic venous hypertension (idiopαthic) with ulcer of left lower

extremity

Secondary diagnosis: L97.222, non-pressure chronic ulcer of left calf with fat layer exposed

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.

The ICD-10 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. Codes were selected from internal benefit investigation data and represent the most common codes submitted to the S+N Reimbursement Hotline.

Common ICD-	10 Codes Associated with Chronic Lower Extremity Ulcers
Code	Decription
	Diabetic Ulcer Codes (not meant to be an exhaustive list)
E10.621	Type 1 diabetes mellitus with foot ulcer
E10.622	Type 1 diabetes mellitus with other skin ulcer
E11.621	Type 2 diabetes mellitus with foot ulcer
E11.622	Type 2 diabetes mellitus with other skin ulcer
E13.621	Other specified diabetes mellitus with foot ulcer
	Venous Ulcer Codes (not meant to be an exhaustive list)
I83.012	Varicose veins of right lower extremity with ulcer of calf
I83.013	Varicose veins of right lower extremity with ulcer of ankle
I83.014	Varicose veins of right lower extremity with ulcer of heel & midfoot
I83.015	Varicose veins of right lower extremity with ulcer of other part of foot
I83.018	Varicose veins of right lower extremity with ulcer of other part of lower leg
	Non-Pressure Chronic Ulcer of Lower Limb
L97.211	Non-Pressure Chronic Ulcer of right calf limited to breakdown of skin
L97.212	Non-Pressure Chronic Ulcer of right calf with fat layer exposed
L97.221	Non-Pressure Chronic Ulcer of left calf limited to breakdown of skin
L97.222	Non-Pressure Chronic Ulcer of left calf with fat layer exposed
L97.311	Non-Pressure Chronic Ulcer of right ankle limited to breakdown of skin

Please see the product's Instructions for Use (IFU) for indications, contraindications, warnings, precautions and other important information.

Advanced Wound Management

Smith+Nephew, Inc. Fort Worth, TX 76109 USA

♦ GRAFIX, GRAFIX CORE, and GRAFIX PRIME are trademarks of Osiris Therapeutics, Inc., a wholly owned direct subsidiary of Smith & Nephew Consolidated, Inc.

Oasis is manufactured by: Cook Biotech, Inc. 1425 Innovation Place West Lafayette, IN 47906

Oasis is distributed by: Advanced Wound Management Smith & Nephew Inc. Fort Worth, TX 76109 Customer Care Center: T 888-674-9551 F 443-283-4419 **Smith**Nephew

www.smith-nephew.com www.grafixpl.com

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### HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIF	ORM CLAIM COMMIT	ITEE (NUCC) 02	2/12							
PICA									PICA	
1. MEDICARE MEDICAL			MPVA GF		KLUNG	1a. INSURED'S I.D. NU	JMBER	(Fo	r Program in Item 1)	
(Medicare#) (Medicaid#	· <u> </u>		berID#) [ (ID	)#) (ID	<u>′ ⊔' ′</u>					
2. PATIENT'S NAME (Last Name	, First Name, Middle I	nitial)	3. PATIEN MM	IT'S BIRTH DATE DD   YY	SEX	4. INSURED'S NAME (	Last Name, F	irst Name, Middle	e Initial)	
				М	F _					
5. PATIENT'S ADDRESS (No., S	reet)			IT RELATIONSHIP TO		7. INSURED'S ADDRE	SS (No., Stre	et)		
			Self	Spouse Child	Other					
CITY		STA	NTE   8. RESER	VED FOR NUCC US		CITY			STATE	
ZIP CODE	TELEPHONE (Indu	de Area Code)				ZIP CODE	Т	ELEPHONE (Ind	ude Area Code)	
	( )							( )		
9. OTHER INSURED'S NAME (L	ast Name, First Name	, Middle Initial)	10. IS PAT	TIENT'S CONDITION	RELATED TO:	11. INSURED'S POLIC	Y GROUP OI	R FECA NUMBER	4	
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