# Smith-Nephew

GRAFIX PL PRIME<sup>◊</sup>

Lyropreserved Placental Membrane

# GRAFIX PRIME

Cryopreserved Placental Membrane

## GRAFIX CORE<sup>◊</sup>

Cryopreserved Placental Membrane

# Reimbursement Guide **2022** 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 eachpayer. Smith+Nephew Reimbursement Hotline Services is not able to confirm contracted or reimbursable rateson 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>(i.e. Type II Diabetes)</i>
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 <i>(document type)</i>
Absence of acute wound infection or active osteomyelitis – must state in the record
<i>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</i>
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



#### Smith-Nephew

#### **Smith+Nephew Reimbursement Hotline Services** Insurance Verification Request (IVR) Form Phone: 866-988-3491 Fax: 866-304-6692

1.Type of Insurance Verification Requested							
New Wound Additional Applications Re-Verification New Insurance Check Out-Of-Pocket Maximum							
If prior authorization is required, I authorize Smith and Nephew to initiate the authorization. Single Wound Application Date:							
Please select one: Yes No							
If yes, please attach all clinical notes related to the wound treatment episode.  Imultiple wounds							
First Name:	Last Name:	n attacinity	a lace sil	leel	M.I.:		
Address:	Apt./Suite#:	City:		State:	Zip:		
	Gender:  Female  Male	Phone #:		State.	2101		
			aca card(c	١			
3. Insurance Information: Please attach a co Cardholder Name/Relationship:	ру (попс & раск) ог рацег	nt s insurar	ice caru(s	Date of B	irth:		
Primary Payer:			Plan Type:				
Policy #:	Group #:		Card Phone				
Secondary Payer:			Plan Type:	-			
	Crown #1						
Policy #:	Group #:		Card Phone				
Tertiary Payer:			Plan Type:				
Policy #:	Group #:		Card Phone	e #:			
4. Healthcare Provider (HCP) & Facility Inf							
Place of Service: Physician Office (POS11)	Hospital Outpatient Depart	ment (POS1	.9/22)	Ambulatory Surge	ery Center (POS24)		
Home Visit (POS12) Assisted Living Fa	acility (POS13) 🗌 Uns	killed Nursi	ng Bed (PC	DS32) 🗌 0	ther POS:		
NOTE: Select only ONE POS. It is the p	rovider's responsibility t	o confirm l	POS and s	killed vs. unskill	ed status		
HCP First Name:	HCP Last Name:				M.I.:		
HCP NPI: H	ICP Tax ID#:			Specialty: MD	□do □dpm □pa		
Contact Name:	Phone #:			□ NP/	FNP 🔲 Other:		
Facility Name: Facility NPI:							
Facility Address: Facility Tax ID:							
City, State, Zip:	Phone #:			Fax #:			
5. Treatment Information: May select up to	FOUR products with corres	sponding Ci	PT applica	tion code groups			
☐ GRAFIX PL PRIME <sup>◆</sup> (Q4133) ☐ G	GRAFIX PRIME <sup>(Q4133)</sup>	C	GRAFIX	( CORE <sup>¢</sup> (Q4132)	1		
OASIS <sup>®</sup> Wound Matrix (Q4102)	ASIS® Burn Matrix (Q41	03) [		<sup>®</sup> ULTRA Tri-Laye	r Matrix (Q4124)		
CPT: Legs/Arms/Trunk ≤ 100 sq cm:152	71/15272-C5271/C5272 Le	egs/Arms/1	Frunk <u>&gt;</u> 10	<b>)0 sq cm:</b> 15273	/15274-C5273/C5274		
<b>Feet/Hands/Head</b> $\leq$ <b>100 sq cm</b> : 1523	75/15276-C5275/C5276 <b>F</b> e	et/Hands/	Head <u>&gt;</u> 10	<b>00 sq cm:</b> 15277	/15278-C5277/C5278		
NOTE: Prior use of skin substitutes or	global periods related to	the the sa	me woun	d may impact re	imbursement		
6. Wound Information & Diagnosis Code(s	): Please include codes that	at indicate	etiology, ι	lcer type, AND lo	cation		
ICD-10 Codes: #1 Wound (Required)	ICD-10 Codes: #2 Wound	d (*Require	ed) IC	D-10 Codes: #3	Wound (*Required)		
Primary (Etiology):	Primary (Etiology):			Primary (Etic	logy):		
Secondary (Ulcer/Location): S	Secondary (Ulcer/Location):				ation):		
Tertiary (Optional):	Tertiary (Optional):				tional):		
Wound #1 Size: L W D V	<b>Vound #2 Size:</b> ∟ W	D	Wo	ound #3 Size: ∟ _	W D		
*If intending to treat more than	one wound, please prov	ide diagno	sis codes	for each additio	nal wound		
7. Healthcare Provider Signature: Please inc	clude all required informat	ion and sig	n below				
By signing below, I certify that I have obtained a valid authorization from the patient listed on this form permitting me to release the patient's protected health information (PHI) to the Smith+Nephew Reimbursement Hotline Services, Smith & Nephew, Inc., its contractors, and the patient's health insurance company as necessary to research insurance coverage and payment information to determine benefits related to GRAFIX PL_\GRAFIX and/or OASIS® Matrix products on behalf of the patient. I further understand that completing this form does not guarantee that insurance coverage or reimbursement will be provided to the patient. I certify that the information provided on this form is current, complete, and accurate to the best of my knowledge.							
HCP Signature:	in on information or start i	Den of the too		Date:	way an third an the second		
Disclaimer: The Smith+Nephew Reimbursement Hotline Results of this research are not a guarantee of coverage claims, benefits or costs.							

3

## **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°.

	Coding	Non-Facility (Physician Office) Rate	Facility (HOPD) Rate
CPT Codes	Code Description	2022 Medicare National Avg. Payment	2022 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	\$159.88	\$85.13
+15272	Each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)	\$25.95	\$18.00
15273	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children	\$327.72	\$201.41
+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)	\$86.86	\$46.37
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	\$164.38	\$94.82
+15276	Each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)	\$33.57	\$25.95
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	\$359.56	\$229.44
+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)	\$100.36	\$57.79

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.

## **Product HCPCS Codes and Modifiers**

GRAFIX<sup>°</sup> 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>o</sup> 16 mm Disc (2 cm <sup>2</sup> )	PS13016	859857003395	2	Q4133
and stored at room	GRAFIX PL PRIME 1.5 X 2 Cm (3 Cm <sup>2</sup> ) PS1.	PS13015	859857003388	3	Q4133
temperature	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
Cryopreserved	GRAFIX PRIME <sup>o</sup> 16 mm Disc (2 cm <sup>2</sup> )	PS60013	859857003340	2	Q4133
and stored at	GRAFIX PRIME 1.5 x 2 cm (3 cm <sup>2</sup> )	PS11015	859857003081	3	Q4133
-75°C to -85°C	GRAFIX PRIME 2 x 3 cm (6 cm <sup>2</sup> )	PS11023	859857003067	6	Q4133
	GRAFIX PRIME 3 x 4 cm (12 cm <sup>2</sup> )	PS11034	859857003074	12	Q4133
	GRAFIX PRIME 5 x 5 cm (25 cm <sup>2</sup> )	PS11055	859857003098	25	Q4133
	GRAFIX CORE <sup>0</sup> 1.5 x 2 cm (3 cm <sup>2</sup> )	PS12015	859857003104	3	Q4132
	GRAFIX CORE 2 x 3 cm (6 cm <sup>2</sup> )	PS12023	859857003050	6	Q4132
	GRAFIX CORE 3 x 4 cm (12 cm <sup>2</sup> )	PS12034	859857003111	12	Q4132
	GRAFIX CORE 5 x 5 cm (25 cm <sup>2</sup> )	PS12055	859857003128	25	Q4132

Important Notes:

1. 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:

o Product name o NDC code o WAC of product o WAC per sq. cm. o 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:

o Product name o Product size (in sq. cm.) o Product number o Invoice price per piece o 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)

# 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 lowerextremity 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 comorbidities

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 (idiopathic) 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.

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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 <b>foot ulcer</b>			
E10.622	Type 1 diabetes mellitus with other skin ulcer			
E11.621	Type 2 diabetes mellitus with <b>foot ulcer</b>			
E11.622	Type 2 diabetes mellitus with other <b>skin ulcer</b>			
E13.621	Other specified diabetes mellitus with foot ulcer			
	Venous Ulcer Codes (not meant to be an exhaustive list)			
183.012	Varicose veins of <b>right</b> lower extremity with ulcer of <b>calf</b>			
183.013	Varicose veins of <b>right</b> lower extremity with ulcer of <b>ankle</b>			
183.014	Varicose veins of <b>right</b> lower extremity with ulcer of <b>heel &amp; midfoot</b>			
183.015	Varicose veins of <b>right</b> lower extremity with ulcer of <b>other part of foot</b>			
183.018	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 <b>left</b> 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 <b>right</b> 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

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

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#### Smith-Nephew



## Sample Claim Form

#### HEALTH INSURANCE CLAIM FORM

EALTH INSURA	NCE CLAIM FORM						
PROVED BY NATIONAL UNIF	ORM CLAIM COMMITTEE (NUCC)	02/12					
MEDICARE MEDICAID		IAMPVA GROUP	PLAN BLK LUNG	THER 1a. INSURED'S I.D. 1	NUMBER	(For Program in Item 1)	
(Medicare#) (Medicaid# PATIENT'S NAME (Last Name		ember ID#) (ID#) 3. PATIENT'S BIF MM   DD		4. INSURED'S NAME	E (Last Name, First Name	. Middle Initial)	
20			M F				
ATIENT'S ADDRESS (No., S	treet)	6. PATIENT RELA	NTIONSHIP TO INSURED	7. INSURED'S ADDR	ESS (No., Street)		
Y	8	TATE 8. RESERVED FO				STATE	
		<u> </u>					
CODE	TELEPHONE (Include Area Code	2		ZIP CODE	TELEPHON	NE (Indude Area Code)	
THER INSURED'S NAME (L	X / ast Name, First Name, Middle Initia	) 10. IS PATIENT'S	CONDITION RELATED TO	11. INSURED'S POL	ICY GROUP OR FECA N	UMBER	
THER INSURED'S POLICY (	JR GROUP NUMBER	a. EMPLOYMENT	? (Current or Previous) YES NO	a. INSURED'S DATE MM   DD		SEX	
ESERVED FOR NUCC USE		b. AUTO ACCIDE		Btate) b. OTHER CLAIM ID	I (Designated by NUCC)		
ESERVED FOR NUCC USE						NIANAT	
LIGENVED FOR NOUCOSE				U. INSURANCE PLAP	N NAME OR PROGRAM	IN ANVIE	
ISURANCE PLAN NAME OR	PROGRAM NAME	10d. CLAIM CODE	ES (Designated by NUCC)	d. IS THERE ANOTH	IER HEALTH BENEFIT P	LAN?	
BEAD	BACK OF FORM BEFORE COMP	ETING & SIGNING THIS	FORM		YES NO <i>If yes</i> , complete items 9, 9a, and 9d. 13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize		
PATIENT'S OR AUTHORIZED o process this claim. I also req	PERSON'S SIGNATURE I autho pest payment of government benefit	ize the release of any medic	al or other information neces		al benefits to the undersi	gned physician or supplier for	
elow.							
	, or PREGNANCY (LMP	DATE					
Service Descript	tion	QUAL.	MM DD YY	FROM	T		
	OTHER SOURCE	17a.			N DATES RELATED TO		
ADDITIONAL CLAIM INFORM	MATION (Designated by NUCC)	17b NPI		20. OUTSIDE LAB?	T) \$(	D	
GRAFIX PL PRIME (5	x 5) per sq cm			YES	NO		
DIAGNOSIS OR NATURE OF	Dr	imary and Seco		22. RESUBMISSION	ORIGINALI	REF. NO.	
E11.621	B. L97.522	ICD-10 Code	s L	Product &	MBER		
	J	к. L		Procedure Cha			
	TO PLACE OF	PROCEDURES, SERVICES (Explain Unusual Circums	tances) DIAG		G. H. I. DAYS EPSDT OR Family ID. UNITS Plan QUAL	J. RENDERING	
DD YY MM E	<u>DD YY SERVICE EMG 0</u>			ITER \$ CHARGES	UNITS Plan' QUAL	PROVIDER ID. #	
01 19 01	01 19 11	15275 CPT	Code A	В	1	ling Units	
. 01 19 01	01 19 11	04133 HCP0	S Code A	в	25 NPT		
		1100					
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Date of Service					NPI		
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				1	NPI		
FEDERAL TAX I.D. NUMBER	SSN EIN 26. PATI	ENT'S ACCOUNT NO.	27. ACCEPT ASSIGNME (For govt claims, see bad		29. AMOUNT P	AID 30. Rsvd.for NUCC U	
BIGNATURE OF PHYSICIAN	I OR SUPPLIER 32. SERV	ICE FACILITY LOCATION		\$ 33. BILLING PROVID	SER INFO & PH# (		
NCLUDING DEGREES OR ( () certify that the statements o apply to this bill and are made	CREDENTIALS in the reverse				1	2	
NED	DATE	NPI b.		a. NPI	h		