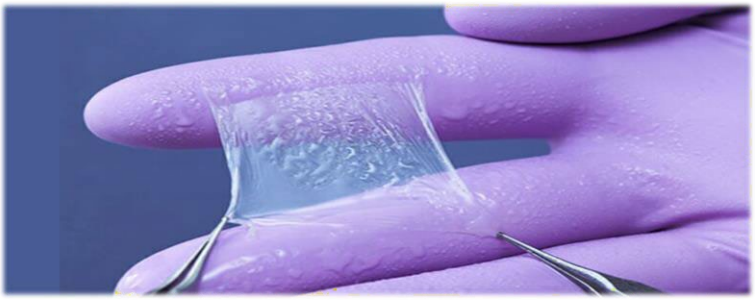
surgiGRAFT™

Coding & Reimbursement Guide



For assistance or additional information, please contact Customer Support: (850) 328-0340

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Product Overview:

surgiGRAFT™ suite of products are amniotic tissue derived allografts intended for reconstruction, repair, or replacement of a donor recipients' tissue. surgiGRAFT™ products serve to act as a tissue barrier/covering.

surgiGRAFT™ is regulated as human cells, tissue, or a cellular or tissue-based product (HCT/P) under 21 CFR part 1271 and section 361 of the Public Health Service (PHS) Act. Synergy Biologics, LLC is registered with the FDA as a tissue establishment.

Product Description:

Amniotic tissue acts as an immune-privileged protective barrier during fetal development. Applied as an anatomical barrier, surgiGRAFT™ and surgiGRAFT™ DUAL offers mechanical protection while providing a regenerative tissue matrix with specific anti-inflammatory, anti-scarring, and anti-microbial properties.

surgiGRAFT™ and surgiGRAFT™ DUAL is an alternative to autologous skin grafting that eliminates the pain, co-morbidities, and procedure time associated with obtaining autologous grafts as well as an alternative to cost-prohibitive decellularized cadaveric skin or xenographic products.

Product Code	Description	Dimensions
SGD - 202	surgiGRAFT™ - Dry Graft	2 x 2 cm
SGD - 204	surgiGRAFT™ - Dry Graft	2 x 4 cm
SGD - 208	surgiGRAFT™ - Dry Graft	2 x 8 cm
SGD - 404	surgiGRAFT™ - Dry Graft	4 x 4 cm
SGD - 408	surgiGRAFT™ - Dry Graft	4 x 8 cm
SGD - 316	surgiGRAFT™ - Dry Graft	3 x 16 cm
SGD - 810	surgiGRAFT™ - Dry Graft	8 x 10 cm
SGD - 820	surgiGRAFT™ - Dry Graft	8 x 20 cm
SGD - 1016	surgiGRAFT™ - Dry Graft	10 x 16 cm

Product Code	Description	Dimensions
SGDL - 202	surgiGRAFT™ DUAL - Dry Graft	2 x 2 cm
SGDL - 203	surgiGRAFT™ DUAL - Dry Graft	2 x 3 cm
SGDL - 204	surgiGRAFT™ DUAL - Dry Graft	2 x 4 cm
SGDL - 208	surgiGRAFT™ DUAL - Dry Graft	2 x 8 cm
SGDL - 404	surgiGRAFT™ DUAL - Dry Graft	4 x 4 cm

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SGDL - 505	surgiGRAFT™ DUAL - Dry Graft	5 x 5 cm
SGDL - 408	surgiGRAFT™ DUAL - Dry Graft	4 x 8 cm
SGDL - 707	surgiGRAFT™ DUAL - Dry Graft	7 x 7 cm

HCPCS Codes

The following HCPCS Codes was issued effective Jan. 1, 2019, to describe surgiGRAFT™ and surgiGRAFT™ DUAL. surgiGRAFT™ and surgiGRAFT™ DUAL was determined by CMS to be high cost for hospital outpatient and ASC effective April 1, 2019.

HCPCS Code	HCPCS Description	2023 Cost Category[5]
Q4183	surgiGRAFT™ per square cm	High
Q4219	surgiGRAFT™ DUAL per square cm	High

Skin Replacement Procedures:

For the surgical preparation of wounds, CPT® Codes 15002-15005 may be reported.

CPT® Code	CPT® Description
15002	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, legs; first 100 sq. cm or 1% of body area of infants and children
+15003	each additional 100 sq. cm, or part thereof, or each additional 1% of body area of infants and children (List separately in addition to code for primary procedure)
15004	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet and/or multiple digits; first 100 sq cm or 1% of body area of infants and children
+15005	each additional 100 sq. cm, or part thereof, or each additional 1% of body area of infants and children (List separately in addition to code for primary procedure)

These codes are not intended to be reported for simple graft application alone or non-surgical application of a skin substitute stabilized with dressings (e.g., by simple gauze wrap). CMS Local Coverage Determinations for 15002/15005 may require that procedures are only appropriate in place of service (POS) inpatient hospital, outpatient hospital or ambulatory surgical center with regional or general anesthesia to resurface the area damaged by burns, traumatic injury, or surgery.

Physician Services:

When used as a Bioengineered Skin Substitute, treatments using surgiGRAFT™ are reported under CPT® Code range 15271-15278 for topical application to a wound surface in a physician office setting. Physicians may also report application of a skin substitute in a facility (i.e., Hospital and/or ASC) using CPT code range 15271-15278.

CPT® Code	CPT® Description	MPFS Status Code[1]	Relative Value Unit (Facility)[2]	Medicare Payment (Facility)[2]	Relative Value Unit (Office)[3]	Medicare Payment (Office)[3]
Trunk, Arms, Legs						
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	A	2.47	$83.70	4.6	$155.88
+15272	Each additional 25 sq. cm wound surface area, or part thereof (List separately in addition to code for primary procedure)	A	0.49	$16.61	0.72	$24.40
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	A	5.8	$196.55	9.32	$315.83
+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)	A	1.33	$45.07	2.48	$84.04
Face, Scalp, Eyelids, Mouth, Neck, Ears, Orbits, Genitalia, Hands, Feet and /or Multiple Digits						
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	A	2.75	$93.19	4.74	$160.63
+15276	Each additional 25 sq. cm wound surface area, or part thereof (List separately in addition to code for primary procedure)	A	0.74	$25.08	0.97	$32.87
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	A	6.65	$225.35	10.34	$350.39
+15278	Each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children	A	1.65	$55.91	2.86	$96.92

surgiGRAFT™ is not included on the Part B Average Sales Price (ASP) list published by the CMS at this time. Therefore, surgiGRAFT™ is instead paid at Invoice Cost + 3% or WAC + 3%, if available.[4]

Hospital Outpatient and Ambulatory Surgical Center (ASC)

Procedure Coding and Payment

Skin substitutes for which no cost data has been established with CMS are reported under HCPCS codes C5271 – C5278 in the hospital outpatient and ASC settings.

CPT® Code	CPT® Description	OPPS APC[5]	OPPS Status Indicator[3]	OPPS Payment[5]	ASC Status Indicator[4]	ASC Payment[6]
Trunk, Arms, Legs						
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	5054	T	$1,725.86	G2	$898.54
+15272	Each additional 25 sq. cm wound surface area, or part thereof (List separately in addition to code for primary procedure)	-	N	Packaged	N1	Packaged
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	5055	T	$3,253.04	G2	$1,693.63
+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)	-	N	Packaged	N1	Packaged
Face, Scalp, Eyelids, Mouth, Neck, Ears, Orbits, Genitalia, Hands, Feet and/or Multiple Digit s						
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	5054	T	$1,749.26	P3	$92.17
+15276	Each additional 25 sq. cm wound surface area, or part thereof (List separately in addition to code for primary procedure)	-	N	Packaged	N1	Packaged
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	5054	T	$1,749.26	G2	$887.09
+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)	-	N	Packaged	N1	Packaged

T: Significant procedure, multiple reduction applies
N: Items and services are packaged into payment for other services
G2 Non-office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight N1
Packaged service/item; no separate payment made

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Billing Reminders:

Units Billed

Verify units billed – due to cross contaminations issues, payers generally reimburse for the entire graft centimeter piece, as it is often reasonable and necessary to discard a portion of the product.

Product Wastage Documentation Requirements

Any amount of wasted material should be clearly documented in the medical record with the following information:

- 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

Wound Size

Determining the wound location and surface area is important in order to select the appropriate CPT code. Please reference the CPT® Descriptions and AMA Coding Guidance for the application of skin substitutes.

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 on 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 and Contracted Rates

Check your facility's specific payer contracts prior to applying surgiGRAFT™.

IMPORTANT: Many insurers consider contracted rates to be proprietary information and may not release this information upon verifying benefits. We recommend verifying your contracted rates by either accessing your contract or contacting your provider relations representative.

Medical Necessity/Documentation

How do I determine if surgiGRAFT™ is considered reasonable and necessary for my patient's condition?

It is recommended that the provider review clinical evidence for surgiGRAFT™ with respect to appropriate diagnoses, application, frequency, etc. If there is an applicable LCD or medical policy for surgiGRAFT™, all coverage requirements and guidelines must be met 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
- Type(s) of conservative treatment that 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 (length and width or circumference and depth)
- Application number and improvement since last treatment
- Amount of surgiGRAFT™ used and amount discarded (wastage)
- Physician's choice of fixation
- Appropriate wound dressing changes, patient compliance, and off-loading (if applicable)

The information provided above is not a guarantee of coverage or payment. Documentation should always reflect the actual services completed. Please refer to the patient's insurance plan and/or the local Medicare Administrative Contractor (MAC) LCD for additional information regarding documentation.

Sample Letter of Medical Necessity

Some payers may require a healthcare provider to provide a letter of medical necessity to obtain prior authorization or to accompany a claim to justify payment. When providing such a letter, the provider should include information in the letter of medical necessity that supports the decision to apply surgiGRAFT™ or surgiGRAFT™ to the patient. The letter should include information on the severity of the wound, previous medications and treatments tried and their outcome, impact upon the patient's quality of life, and the provider's past clinical experience with the product. Below is a sample letter of medical necessity for the application of surgiGRAFT™. This is a sample only and should be modified as necessary to be accurate and to fit each patient's specific situation.

"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 surgiGRAFT™

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 surgiGRAFT™ 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:

surgiGRAFT™ is an allograft tissue matrix 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). Synergy Biologics, LLC is registered with the FDA as a tissue establishment.

surgiGRAFT™ is a cryopreserved placental membrane retaining the extracellular matrix, growth factors, and endogenous neonatal stem cells, fibroblasts, and epithelial cells of the native tissue. surgiGRAFT™, 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.

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, as appropriate>.** This treatment is therefore medically necessary to prevent further damage and **<list risk(s) of non-closure>.** I believe my patient will benefit from this therapy. Please feel free to contact me if additional information is required to process my request for coverage.

Sincerely,

References:

1 2023 Medicare Physician Fee Schedule Relative Value File January Release.
2 Medicare Hospital Outpatient Prospective Payment System (OPPS) Status Indicators describe the payment status of procedures and devices in the hospital outpatient setting;
T = Procedures subject to multiple-procedure discounting rules,
N = No additional payment, payment included in line items with APCs for incidental service
3 Medicare Ambulatory Surgery Center (ASC) Status Indicators describe the payment status of procedures and devices in ASC setting;
G2 = Non-office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight
N1 = Packaged service/item; no separate payment made.
4 Novitas Local Coverage Determination L35041, Application of Bioengineered Skin Substitutes to Lower Extremity Chronic HonHealing Wounds
5 CY2023 Ambulatory Surgical Center Final Rule Addendum A. Effective Jan 1, 2023.
6 CY2021 OPPS Final Rule Addendum B. Effective Jan 1, 2021.

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