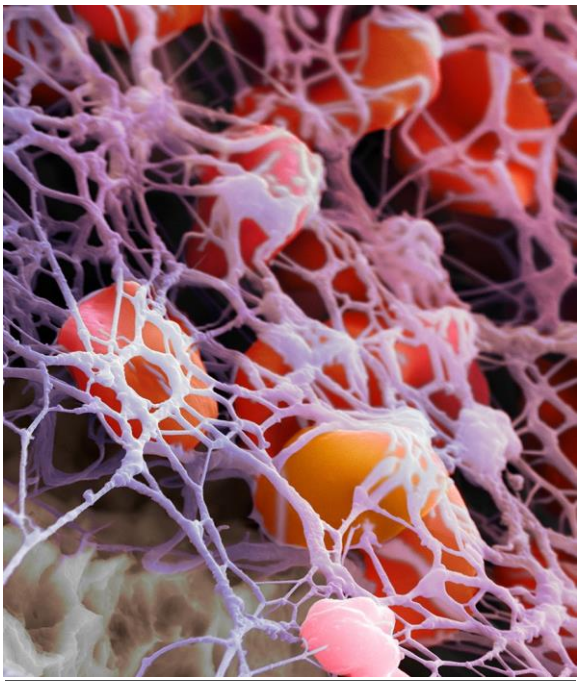
2020 ActiGraft Reimbursement Guide
Wound Care

PRODUCT DESCRIPTION

ActiGraft, which is based on RedDress' proprietary patented technology, is the first wound care product which enables health care providers to produce in real time, in vitro whole blood clots, for use as a chronic wound care product.



MICROSCOPIC VIEW OF A WHOLE BLOOD CLOT

INDICATION FOR USE

Please Refer to Product Label for Full Instruction for Use

The ActiGraft System is intended to be used at point-of-care for the safe and rapid preparation of Whole Blood Clot gel from a small sample of a patient's own peripheral blood. Under supervision of a healthcare professional, the whole blood clot gel produced by the ActiGraft System is topically applied for the management of exuding cutaneous wounds, such as leg ulcers, pressure ulcers, diabetic ulcers, and mechanically or surgically-debrided wounds.

REDDRESS REIMBURSEMENT HOTLINE

Hotline: +1.844.339.8131
Monday - Friday, 8:00am - 5:00pm CST

RedDressReimbursement@argentaadvisors.com

RedDress is committed to surgeons and facilities using ActiGraft Autologous Whole Blood Matrix to benefit their patients. Our hotline team of specialists is ready to assist you with all coding, billing, and reimbursement questions. Additionally, our hotline team is available to help you and your patients navigate the insurance coverage process.

PHYSICIAN OR QUALIFIED PRACTIONER (PART B) BILLING - SKIN SUBSTITUTE APPLICATION

The following physician services may be appropriate for the application of ActiGraft Autologous Whole Blood Matrix.

CPT® Code[1]	CPT® Description[1]	MPFS Status Code	Relative Value Unit (Facility)[2]	Medicare Payment (Facility)[2]	Relative Value Unit (Office)[2]	Medicare Payment (Office)[2]
Skin Replacement Procedures – Skin Substitute Application						
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	2.45	$88.42	4.29	$154.82
+15272	Each additional 25 sq. cm wound surface area, or part thereof (List separately in addition to code for primary procedure)	A	0.51	$18.41	0.75	$27.07
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	5.82	$210.04	8.93	$322.28
+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	1.32	$47.64	2.26	$81.56
15275	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple dig- its, total wound surface area up to 100 sq. cm; first 25 sq. cm or less wound surface area	A	2.75	$99.25	4.48	$161.68
+15276	Each additional 25 sq. cm wound surface area, or part thereof (List separately in addition to code for primary procedure)	A	0.75	$27.07	0.98	$35.37
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	6.60	$238.19	9.79	$353.32
+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)	A	1.67	$60.27	2.67	$96.36

A: Status for active CPT code

These codes are not intended to be reported for simple graft application alone or application stabilized with dressings (e.g., by simple gauze wrap). Removal of current graft and/or simple cleansing (debridement) of the wound is included, when performed. The ActiGraft Autologous Whole Blood Matrix is anchored using the surgeon's choice of fixation. When services are performed in the office, the ActiGraft Autologous Whole Blood Matrix product should be reported separately. Routine dressing supplies are not reported separately.

HOSPITAL OUTPATIENT AND AMBULATORY SURGICAL CENTER (ASC)

Procedure Coding and Payment

The following procedures may be appropriate to report in an outpatient hospital setting or ambulatory surgery center (ASC) for application of a skin substitute. 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.

HCPCS[3] Code	HCPCS Description[3]	ASC Status Indicator[4]	ASC Payment[4]	OPPS Status Indicator[5]	OPPS APC[5]	OPPS Payment[5]
Trunk, Arms, Legs						
C5271	Application of low cost 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	G2	$251.14	T	5053	$497.02
+C5272	Each additional 25 sq. cm wound surface area, or part thereof (list separately in addition to code for primary procedure)	N1	Packaged	N	Packaged	Packaged
C5273	Application of low cost 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	G2	$819.95	T	5054	$1,622.74
+C5274	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)	N1	Packaged	N	Packaged	Packaged
Face, Scalp, Eyelids, Mouth, Neck, Ears, Orbits, Genitalia, Hands, Feet and/or Multiple Digits						
C5275	Application of low cost 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	G2	$251.14	T	5053	$497.02
+C5276	Each additional 25 sq. cm wound surface area, or part thereof (list separately in addition to code for primary procedure)	N1	Packaged	N	Packaged	Packaged
C5277	Application of low cost 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	G2	$251.14	T	5053	$497.02
+C5278	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	N1	Packaged	N	Packaged	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

DEVICE CODING

The following HCPCS code may be appropriate to report the ActiGraft Autologous Whole Blood Matrix when used in skin substitute application procedures.

HCPCS Code	HCPCS Description[4]	ASC Status Indicator[4]	ASC Payment[4]	OPPS Status Indicator[5]	OPPS APC[5]	OPPS Payment[5]
Q4100	Skin substitute, not otherwise classified	N1	Packaged	N	Packaged	Packaged

BILLING REMINDERS

Units Billed

ActiGraft should be billed per kit where 1 unit is equal to 1 kit used. Each kit creates a 28.3 sq.cm whole blood clot. If for example, an additional kit is required due to the size of the wound, Q4100 should be reported with the total number of kits used (i.e., 2 units).

Wastage

Each ActiGraft kit is considered 1 unit. The guidelines for reporting wastage state that if the product used is less than the billing unit, wastage does not apply.

Wound Size

Determining the wound location and surface area is essential in order to select the appropriate CPT code. Please reference the CPT® Descriptions and AMA Coding Guidance for the application of skin substitutes. Wound characteristics such as size and location should also be clearly documented in the medical records.

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 payer on payer-specific guidance.

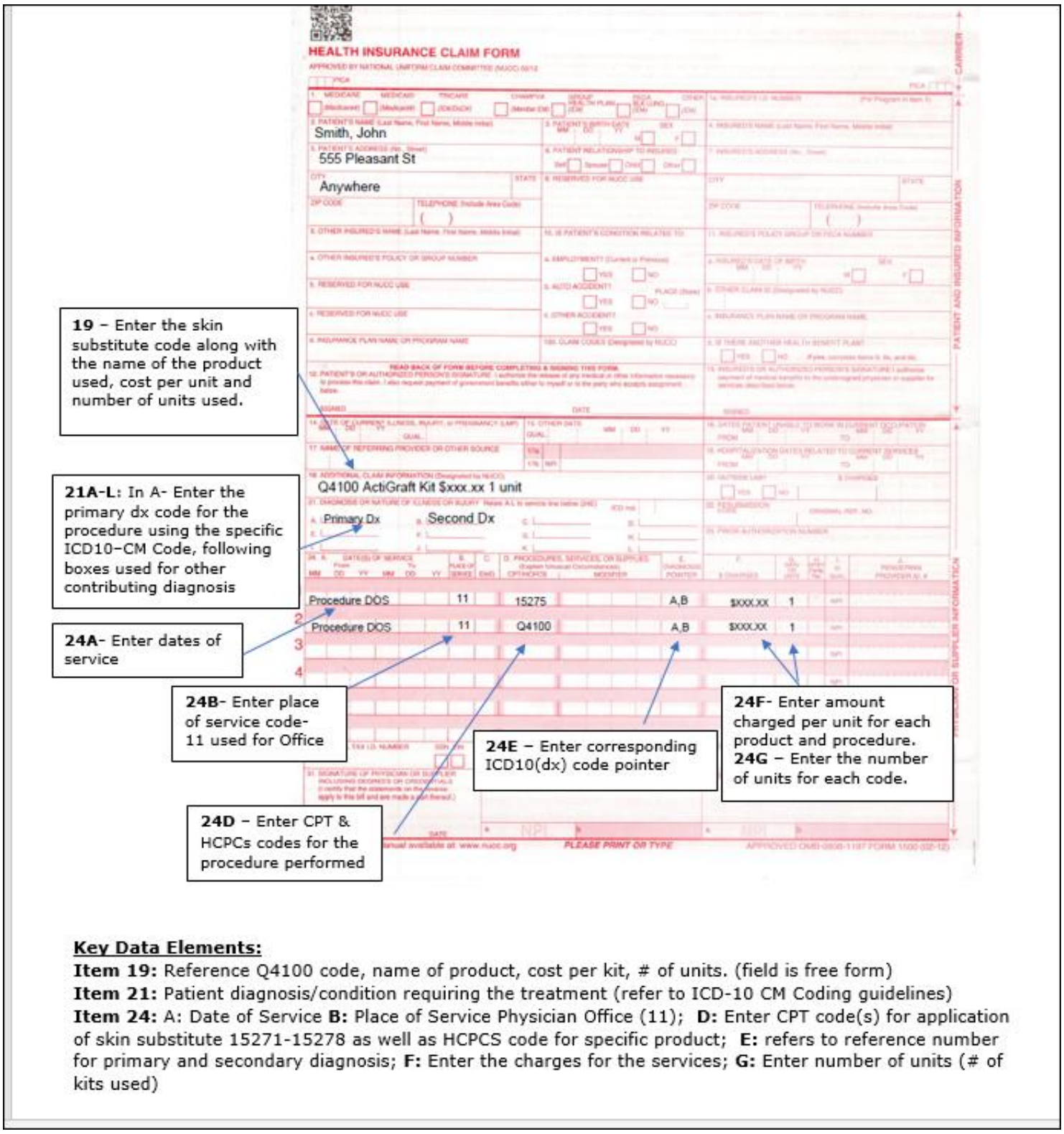
Reporting Invoice/ Cost – Payer Specific Requirements

Invoice cost and product details, including name, must be reported in box 19 for each claim (CMS-1500 claim form). For example, include Q4100, ActiGraft Kit, invoice price per kit x number of units (kits). Billing requirements and payment allowances may vary by local Medicare Administrative Contractor (MAC) and or third-party payer.

Check with the payer to determine specific billing requirements.

SAMPLE CMS-1500 CLAIM FORM (PHYSICIAN OFFICE)

For illustration purposes only



Key Data Elements:

Item 19: Reference Q4100 code, name of product, cost per kit, # of units. (field is free form)
Item 21: Patient diagnosis/condition requiring the treatment (refer to ICD-10 CM Coding guidelines)
Item 24: A: Date of Service **B:** Place of Service Physician Office (11); **D:** Enter CPT code(s) for application of skin substitute 15271-15278 as well as HCPCS code for specific product; **E:** refers to reference number for primary and secondary diagnosis; **F:** Enter the charges for the services; **G:** Enter number of units (# of kits used)

MEDICAL NECESSITY / DOCUMENTATION

How do I determine if ActiGraft Autologous Whole Blood Matrix is considered reasonable and necessary for my patient's condition?

It is recommended that the provider review the clinical evidence requirements for ActiGraft Autologous Whole Blood Matrix with respect to appropriate diagnoses, application, frequency, etc. If there is an applicable LCD or medical policy for ActiGraft Autologous Whole Blood Matrix, all coverage requirements and guidelines must be met for the patient to be covered.

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 and size (length and width or circumference and depth)
- Baseline measurements immediately prior to initial treatment and all subsequent treatments
- Number of previous application(s) and improvement since last treatment
- Wound is free of active infection and active osteomyelitis
- Adequate treatment of the underlying disease contributing to the wound
- Adequate blood flow
- Amount of ActiGraft Autologous Whole Blood Matrix used and amount discarded (wastage)
- Type of fixation
- Appropriate wound dressing changes, patient compliance, and off-loading (if applicable)

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 wound 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, if applicable

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

Is a Pre-Service Review Required?

Medicare does not require, nor allow for a pre-service/prior authorization review. However, the majority of payers will require or allow for a healthcare provider to submit a Letter of Medical Necessity to obtain prior authorization or pre-determination in advance of treatment. Included in the letter should be detailed information that supports the provider's decision to use the Actigraft Autologous Whole Blood Matrix for the patient. Such information should include: the severity and duration of the wound, impact upon the patient's quality of life, previous treatments tried and failed, the number and frequency of anticipated applications as course of treatment, and if applicable, any progress notes post applications.

For more information about pre-service review and/or the Letter of Medical Necessity, please contact our hotline.

Sources

[1]Current Procedural Terminology (CPT) Copyright 2019 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

[2]Centers for Medicare & Medicaid Services CY2020 Physician Fee Schedule Final Rule: Addendum A; National Average Medicare payment rates calculated using a conversion factor of $36.0896 Based on CY2020 Relative Value Units (RVU) information available as of 11.15.19.

[3]2020 HCPCS Level II information obtained from https://www.findacode.com/code.php?set=HCPCS&c=Q4100

[4] Centers for Medicare & Medicaid Services CY2020 ASC Final Rule: Addendum AA.

[5] Centers for Medicare & Medicaid Services CY2020 Hospital OPPS Final Rule: Addendum B.

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DISCLAIMER

The information presented in this coding guide is informational only and should not be construed to be advice, legal advice or a recommendation of any kind. The coding, payment and coverage information in this reimbursement guide was obtained from third party sources and is subject to change without notice, including as a result in changes in reimbursement laws, regulations, rules, and policies. All medical services must be reasonable and necessary for the care of the patient to support reimbursement. Providers should report the procedure and related codes that most accurately describe the patient's medical condition, procedures performed, and the products used. The information presented in this reimbursement guide represents no promise or guarantee of coverage or payment for products or procedures by Medicare or other payers. Providers should review Medicare bulletins, manuals, program memoranda, and guidelines to ensure compliance with Medicare billing and documentation requirements. Inquiries can be directed to the provider's appropriate Medicare Part A/Part B Administrative Contractor (MAC), Durable Medical Equipment Medicare Administrative Contractor (DMEMAC), or to the appropriate payer. RedDress specifically refuses liability or responsibility for the results or consequences of any actions taken through reliance on information presented in this reimbursement guide. Additionally, the information provided in this reimbursement guide should not be construed to be advertising or promotion. RedDress neither promotes nor advocates off-label use of any product. Please consult the product literature supplied with the product to determine intended use.