NOW FDA-APPROVED — FOR FULL-THICKNESS SKIN DEFECTS



# 2023 RECELL® SYSTEM REIMBURSEMENT GUIDE

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The RECELL Autologous Cell Harvesting Device is indicated for the treatment of thermal burn wounds and full-thickness skin defects. The RECELL Device is used by an appropriately licensed healthcare professional at the patient's point of care to prepare autologous Spray-On Skin Cells for direct application to acute partial-thickness thermal burn wounds in patients 18 years of age and older, or application in combination with meshed autografting for acute full-thickness thermal burn wounds, in pediatric and adult patients and full-thickness skin defects after traumatic avulsion (e.g., degloving) or surgical excision (e.g., necrotizing soft tissue infection) or resection (e.g., skin cancer), in patients 15 years of age and older.



# BURN AND FULL-THICKNESS SKIN DEFECTS (FTSD): PHYSICIAN SERVICES

The information contained in this guide is designed to assist providers in accurately obtaining reimbursement for healthcare services. It is not intended to increase or maximize reimbursement by any payer. We strongly suggest that you consult your payer organization with regard to local reimbursement policies.

#### **CPT® CODES**

The American Burn Association recommends the following CPT codes for the application of cell suspension autografts, eg, RECELL.<sup>1</sup>

CPT <sup>2</sup>	Description	Global	Facility Relative Value Units (RVUs)	2023 Medicare National Payment (Facility) <sup>3</sup>
	Epiderm	al Autog	rafts	
15110	Epidermal autograft, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children	090	21.29	\$721.46
+15111	Each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof	ZZZ	3.03	\$102.68
15115	Epidermal autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children	090	20.54	\$696.04
+15116	Each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof	ZZZ	4.14	\$140.29

#### **Global Surgery Indicators**

**090** = Major surgery with a 1-day preoperative period and 90-day postoperative period included in the fee schedule amount.

**ZZZ** = The code is related to another service and is always included in the global period of the other service.

#### **Notes:**

- + Add-on code. (List separately in addition to code for primary procedure).<sup>2</sup> Add-on codes are always performed in addition to the primary service or procedure and must never be reported as a stand-alone code. All add-on codes are exempt from multiple procedure payment reduction for physician payment.
- National Medicare reimbursement rates are shown for clinician services without adjustment for geographic factors.

### SAMPLE CMS 1500: PHYSICIAN SERVICES



## RECELL WITH SPLIT-THICKNESS SKIN GRAFT ON 3% TBSA FULL-THICKNESS DEGLOVING INJURY

**Clinical Scenario:** An 85-year-old female presented to the emergency room following an auto accident collision with another vehicle where she sustained an acute full-thickness degloving injury on her right thigh totaling 3% TBSA (600 sq cm). The patient is admitted into the hospital. After the patient is hemodynamically stable, she is taken to the operating room for debridement and excision of her wounds and later autografting with a meshed 3:1 split-thickness skin graft in combination with cell suspension autograft for definitive wound closure.

DATE OF SERVICE (Field 24A), PLACE
OF SERVICE (Field 24B) and CPT/HCPCS
CODES (Field 24D): Include the date of
service, place of service and the relevant
CPT codes to report the debridement and
excision of the patient's full-thickness
burns and immediate autografting
for permanent wound coverage For example:

CPT 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

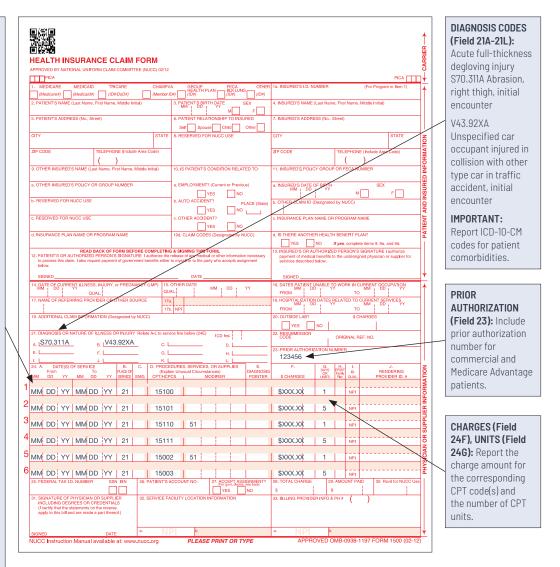
CPT 15003 – Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, legs; each additional 100 sq cm, or part thereof, or each additional 1% of body area of infants and children (List separately in addition to code for primary procedure)

**CPT 15110** – Epidermal autograft, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children

CPT 15111 – Epidermal autograft, trunk, arms, legs; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)

**CPT 15100 –** Split-thickness autograft, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children (except 15050)

CPT 15101 – Split-thickness autograft, trunk, arms, legs; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)



## SAMPLE CMS 1500: PHYSICIAN SERVICES



## RECELL WITH SPLIT-THICKNESS SKIN GRAFT ON 18% TBSA FULL-THICKNESS BURN

**Clinical Scenario:** A 28-year-old male presented to the emergency room after he sustained an acute full-thickness thermal burn on his back totaling 18% TBSA (3,600 sq cm). The patient is admitted into the hospital. After the patient is hemodynamically stable, he is taken to the operating room for debridement and excision of his full-thickness burns and later autografting with a meshed 3:1 split-thickness skin graft in combination with cell suspension autograft for definitive wound closure.

DATE OF SERVICE (Field 24A), PLACE
OF SERVICE (Field 24B) and CPT/HCPCS
CODES (Field 24D): Include the date of
service, place of service and the relevant
CPT codes to report the debridement and
excision of the patient's full-thickness
burns and immediate autografting
for permanent wound coverage - For
example:

CPT 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

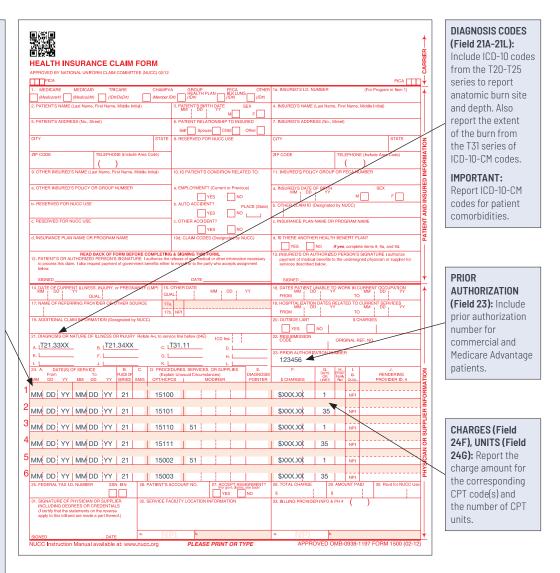
CPT 15003 – Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, legs; each additional 100 sq cm, or part thereof, or each additional 1% of body area of infants and children (List separately in addition to code for primary procedure)

**CPT 15110** – Epidermal autograft, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children

CPT 15111 – Epidermal autograft, trunk, arms, legs; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)

**CPT 15100** – Split-thickness autograft, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children (except 15050)

CPT 15101 – Split-thickness autograft, trunk, arms, legs; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)



### INPATIENT FACILITY

#### FY 2023 ICD-10-PCS PROCEDURE CODES (EFFECTIVE OCTOBER 1, 2022)<sup>4</sup>

At least two ICD-10-PCS codes are required when reporting the use of RECELL System:

- 1. Harvest of skin sample
- 2. Application of cell suspension autograft (RECELL)

#### 1. HARVEST OF SKIN SAMPLE<sup>5,6,7</sup>

Code	Description
OHB_XZZ	Excision of skin and breast, skin

#### **Notes:**

- In the fourth character, specify the body part from which the skin sample is taken, eg, 7-Skin, Abdomen; 8-Skin, Buttock; 8-J-Skin; 9-Left Upper Leg.
- For sixth and seventh characters, use qualifier Z-No Qualifier.
- Although the term "biopsy" is sometimes used in the operative report for taking the skin sample from the donor site, this is not a diagnostic biopsy. The harvest of skin tissue for grafting is therapeutic.

#### OHB ICD-10-PCS Table Excerpt

Body System	<ul><li>0 Medical and Surgical</li><li>H Skin and Breast</li><li>B Excision: Cutting out or off, with</li></ul>	nout replacement	t, a portion of a body	part
Body Part		Approach	Device	Qualifier
O Skin, Scalp Skin, Face Skin, Right Ear Skin, Left Ear Skin, Neck Skin, Chest Skin, Back Skin, Abdomen Skin, Buttock Skin, Perineum	A Skin, Inguinal B Skin, Right Upper Arm C Skin, Left Upper Arm D Skin, Right Lower Arm E Skin, Left Lower Arm F Skin, Right Hand G Skin, Left Hand H Skin, Right Upper Leg J Skin, Left Upper Leg K Skin, Right Lower Leg K Skin, Right Lower Leg M Skin, Left Lower Leg M Skin, Right Foot N Skin, Left Foot O Finger Nail R Toe Nail	<b>X</b> External	<b>Z</b> No Device	X Diagnostic Z No Qualifier

#### **Code Examples**

Code	Description	
OHB7XZZ	Excision of the skin on the abdomen	
OHBLXZZ Excision of the skin on the left lower leg		

#### 2. APPLICATION OF CELL SUSPENSION AUTOGRAFT<sup>5,7</sup>

Code	Description		
0HR_X72	Skin replacement on theusing Cell Suspension Technique	, autologous tissue substitute,	

The ICD-10-PCS code for use of RECELL is constructed from code table 0HR. RECELL is uniquely identified by assignment of qualifier value 2.

#### OHR ICD-10-PCS Table Excerpt

Section Body System Operation R Replacement: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part					
Body Part			Approach	Device	Qualifier
O Skin, Scalp Skin, Face Skin, Right Ear Skin, Left Ear Skin, Neck Skin, Chest Skin, Back Skin, Abdomen Skin, Buttock Skin, Perineum		A Skin, Inguinal B Skin, Right Upper Arm C Skin, Left Upper Arm D Skin, Right Lower Arm E Skin, Left Lower Arm F Skin, Right Hand G Skin, Left Hand H Skin, Right Upper Leg J Skin, Left Upper Leg K Skin, Right Lower Leg L Skin, Right Foot N Skin, Left Foot	<b>X</b> External	<b>7</b> Autologous Tissue Substitute	2 Cell Suspension Technique 3 Full Thickness 4 Partial Thickness

#### **Code Examples**

Code	Description
OHR7X72	Skin replacement on the abdomen, autologous tissue substitute, using Cell Suspension Technique
OHRHX72	Skin replacement on the right upper leg, autologous tissue substitute, using Cell Suspension Technique

#### MS-DRG ASSIGNMENTS<sup>4</sup>

Medicare reimburses hospitals for inpatient services using MS-DRGs (Medicare Severity Diagnosis-Related Groups). Common MS-DRGs for patients admitted with trauma or burn treatment with RECELL are included in the following table. Potential MS-DRGs are not limited to this list nor is the list exhaustive. The applicable MS-DRG depends upon the patient's diagnoses and the procedures performed during the inpatient stay.

MS-DRG	Description	FY 2023 Medicare National Payment <sup>4,9</sup>			
	Trauma Treatment				
904	Skin grafts for injuries with cc/mcc	\$24,364.26			
905	Skin grafts for injuries without cc/mcc	\$10,700.13			
957	Other O.R. procedures for multiple significant trauma with MCC	\$50,832.32			
958	Other O.R. procedures for multiple significant trauma with CC	\$42,469.41			
959	Other O.R. procedures for multiple significant trauma without cc/mcc	\$20,158.79			
	Burn Treatment				
927	Extensive burns or full-thickness burns with mechanical ventilation 96+ hours with skin graft	\$130,208.97			
928	Full-thickness burn with skin graft or inhalation injury with CC/MCC	\$42,469.41			
929	Full-thickness burn with skin graft or inhalation injury without CC/MCC	\$20,158.79			

#### **Notes:**

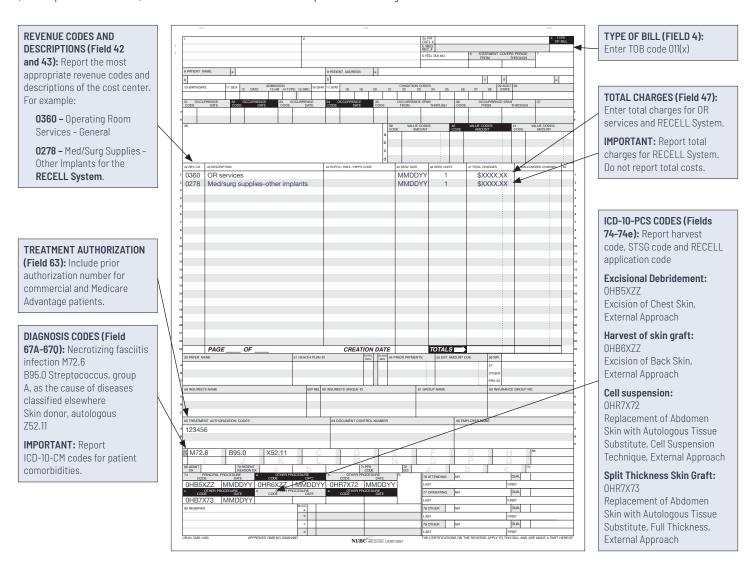
- CC = Complication or Comorbidity; MCC = Major Complication or Comorbidity
- The listed MS-DRGs are located in Major Diagnostic Category (MDC) 22 Burns.
- Medicare National base MS-DRG payment amounts (for urban areas) as of October 1, 2022, based on most common
  diagnoses for burns and assumes that the hospital has submitted quality data and is a Meaningful EHR user (3.8%
  update). Academic teaching and disproportionate share hospitals may qualify for additional payment amounts in
  addition to the base MS-DRG.

### SAMPLE UB-04/CMS 1450: HOSPITAL INPATIENT DEPARTMENT



## RECELL WITH SPLIT-THICKNESS SKIN GRAFT ON 9% TBSA NECROTIZING FASCIITIS WOUND

**Clinical Scenario:** A 23-year-old male was admitted with a necrotizing fasciitis infection from Group A strep of the upper torso. Following treatment of the infection and excisional debridement of necrotic tissue, the patient had a full-thickness open wound of the chest portion of the torso totaling 9% TBSA (1,800 sq cm). He is taken to the operating room for surgical preparation of his wounds and autografting with a meshed 3:1 split-thickness skin graft (from patient's back) in combination with cell suspension autograft for definitive wound closure.

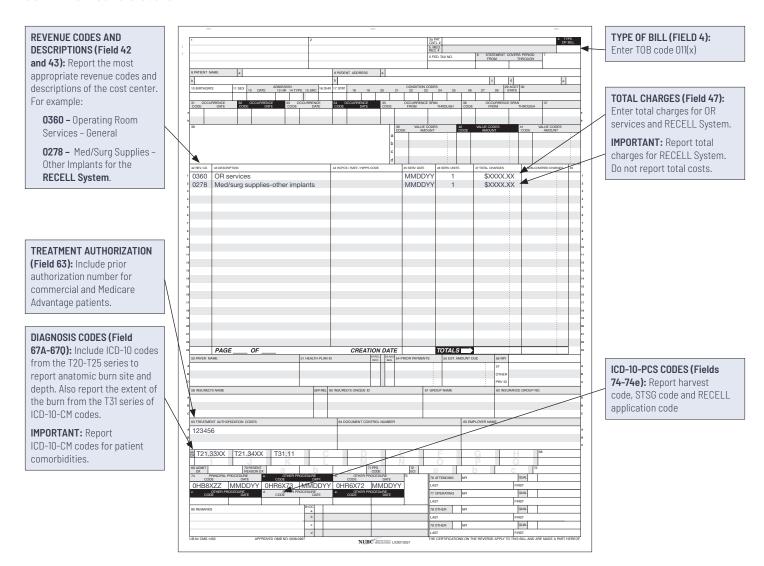


### SAMPLE UB-04/CMS 1450: HOSPITAL INPATIENT DEPARTMENT



## RECELL WITH SPLIT-THICKNESS SKIN GRAFT ON 18% TBSA FULL-THICKNESS BURN

**Clinical Scenario:** A 28-year-old male presented to the emergency room after he sustained an acute full-thickness thermal burn on his back totaling 18% TBSA (3,600 sq cm). He is admitted into the hospital. After the patient is hemodynamically stable, he is taken to the operating room for debridement and excision of his full-thickness burns and later autografting with a meshed 3:1 split-thickness skin graft in combination with cell suspension autograft for definitive wound closure.



### **OUTPATIENT FACILITY**

## CY 2023 HOSPITAL OUTPATIENT DEPARTMENT AND AMBULATORY SURGICAL CENTER (ASC) CODING AND PAYMENT FOR RECELL SYSTEM PROCEDURES

For autograft procedures involving the RECELL System, hospital outpatient departments and ASCs should report:

- 1. Procedure: Appropriate CPT® code(s)
- 2. Device: New device pass-through C-code for RECELL System

#### 1. APPLICATION OF CELL SUSPENSION AUTOGRAFT

The American Burn Association recommends the following CPT codes for the application of cell suspension autografts, eq. RECELL.<sup>1</sup>

		Hos	oital Outpat	ient <sup>®</sup>	ASC <sup>8</sup>	
CPT <sup>2</sup>	Description	2023 Payment	Status Indicator	Device Offset	2023 Payment	Payment Indicator
15110	Epidermal autograft, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children	\$1,725.86	Т	\$0.00	\$898.54	A2
+15111	Each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)	Packaged	N	-	Packaged	N1
15115	Epidermal autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children	\$1,725.86	Т	\$0.00	\$898.54	A2
+15116	Each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)	Packaged	N	-	Packaged	N1

#### 2. RECELL SYSTEM

Effective January 1, 2022, the Centers for Medicare & Medicaid Services (CMS) established a new transitional pass-through (TPT) category with new HCPCS C-code (C1832) for the RECELL System.<sup>9</sup>

Code	Description	Hospital Outpatient Status Indicator	ASC Payment Indicator
C1832	Autograft suspension, including cell processing and application, and all system components	Н	J7

Hospital outpatient departments and ASCs must report HCPCS code C1832 when the RECELL System is used. Since the RECELL System has TPT status, hospital outpatient departments and ASCs are eligible to obtain additional separate payment for the RECELL System in addition to payment(s) for the epidermal autograft procedure(s). TPT status remains in effect for 3 years through December 31, 2024.8

#### **Hospital Outpatient Status Indicators**

- **H =** Separate cost-based pass-through payment; not subject to copayment.
- **N** = Paid under OPPS; payment is packaged into payment for other services. Therefore, there is no separate APC payment.
- T = Paid under OPPS; separate APC payment.

#### **ASC Payment Indicators**

- A2 = Surgical procedure on ASC list in CY 2007; payment based on OPPS relative payment weight.
- **J7** = OPPS pass-through device paid separately when provided integral to a surgical procedure on ASC list; payment contractor-priced.
- N1 = Packaged service/item; no separate payment made.

#### **Notes:**

- ASCs are required to separately report C-codes that have pass-through payment status.<sup>10</sup>
- Medicare bases the hospital outpatient C-code payment on the hospital's charges reduced to cost.
- The Medicare Administrative Contractor (MAC) sets the C-code payment rate (known as Contractor pricing) for ASCs.

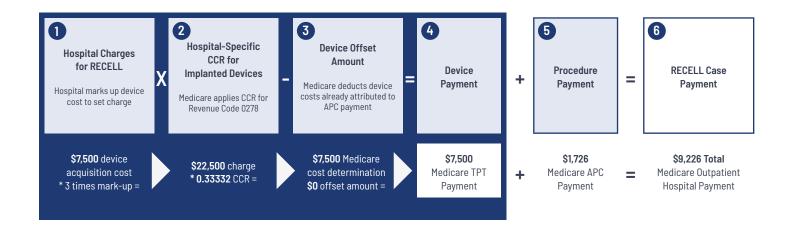
#### TPT PAYMENT METHODOLOGY

Medicare payment for medical devices with TPT status is based on the hospital's device charges on the claim form adjusted to cost (the device cost) multipled by the cost-to-charge ratio (CCR), less the device-related portion of the procedure (also called the device offset) that is already included in the Medicare outpatient department fee schedule amount (APC payment) for that procedure. The total facility payment will include the TPT payment plus the APC payment(s).

#### **TPT PAYMENT EXAMPLE**

Medicare will establish each hospital's TPT payment amount for the RECELL System and all accessories and components using the following formula:

- 1 **Hospital establishes a charge for the RECELL System.** The hospital should consider the CCR for Revenue Code 0278 along with the cost of the device to ensure that an appropriate charge is established.
- 2 Medicare calculates the device cost. Medicare then applies the CCR for Revenue Code 0278 for that specific hospital to the hospital's device charge to determine the actual cost of the RECELL System.
- Medicare deducts the device offset amount. Medicare applies the device-related portion of the associated HCPCS code. In CY 2023, the device offset amount is \$0.00 for both CPT 15110 and CPT 15115.
- 4 Medicare determines the TPT device payment. The device offset is subtracted from the adjusted charge to calculate the TPT payment.
- 5 Include the relevant APC payment(s). The procedure is paid as usual (e.g., the APC payment for CPT 15110 is \$1,725.86).
- **Medicare calculates the total procedure payment.** The TPT payment amount is added to the APC payment for the related CPT to calculate the total payment for the patient case.



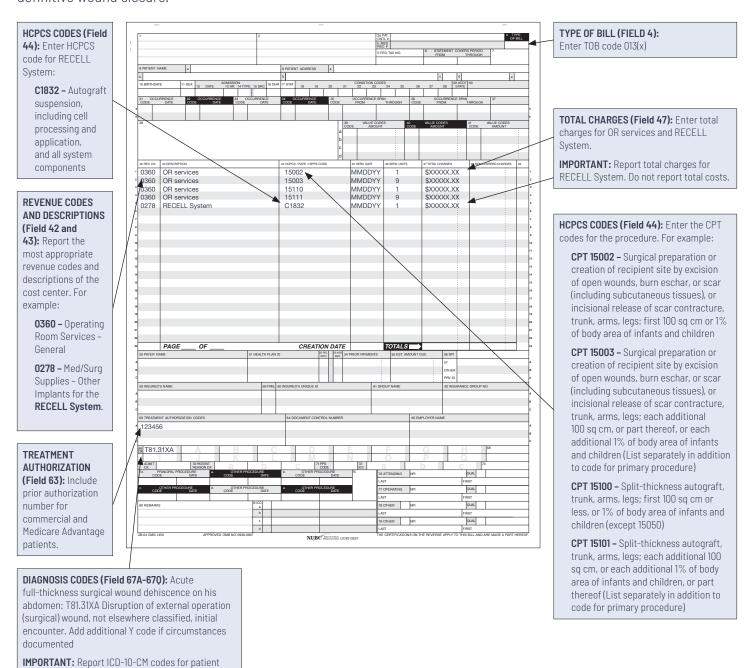
comorbidities.

## SAMPLE UB-04/CMS 1450: HOSPITAL OUTPATIENT DEPARTMENT



## RECELL WITH SPLIT-THICKNESS SKIN GRAFT ON 5% TBSA FULL-THICKNESS SURGICAL WOUND

**Clinical Scenario:** A 58-year-old female sustained an acute full-thickness surgical wound dehiscence on his abdomen totaling 5% TBSA (1,000 sq cm). The patient is taken to the operating room for debridement and excision of her wounds and autografting with a meshed 3:1 split-thickness skin graft in combination with cell suspension autograft for definitive wound closure.

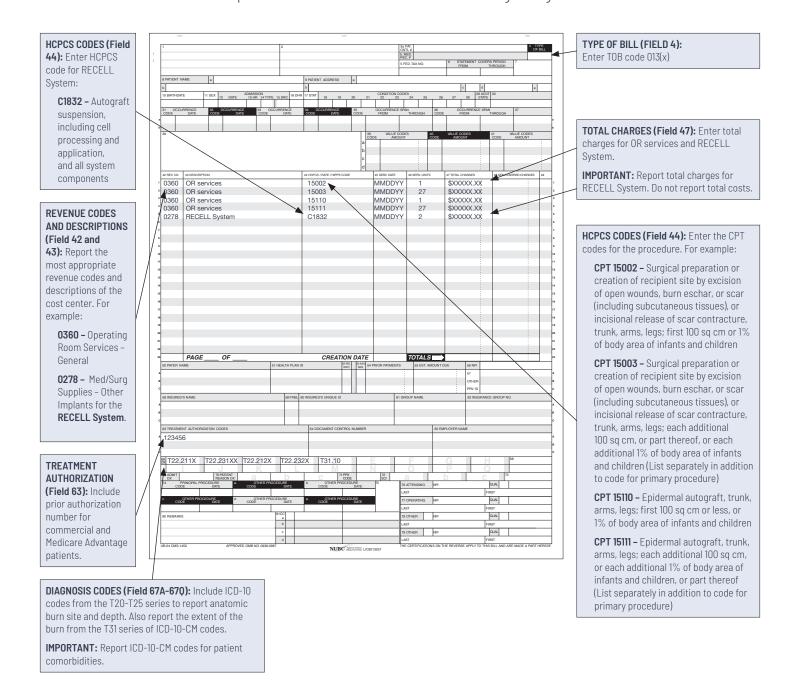


## SAMPLE UB-04/CMS 1450: HOSPITAL OUTPATIENT DEPARTMENT



#### RECELL ALONE ON 14% TBSA DEEP PARTIAL-THICKNESS BURNS

**Clinical Scenario:** A 42-year-old male received flash burns on his arms (upper and lower) while lighting a gas grill. He is transported to the nearby emergency room where he is assessed to have deep partial-thickness burns on his arms covering 14% TBSA (2,800 sq cm). After the patient is hemodynamically stable, he is taken to the operating room for debridement and excision of his partial-thickness burns and immediate autografting for definitive wound closure.

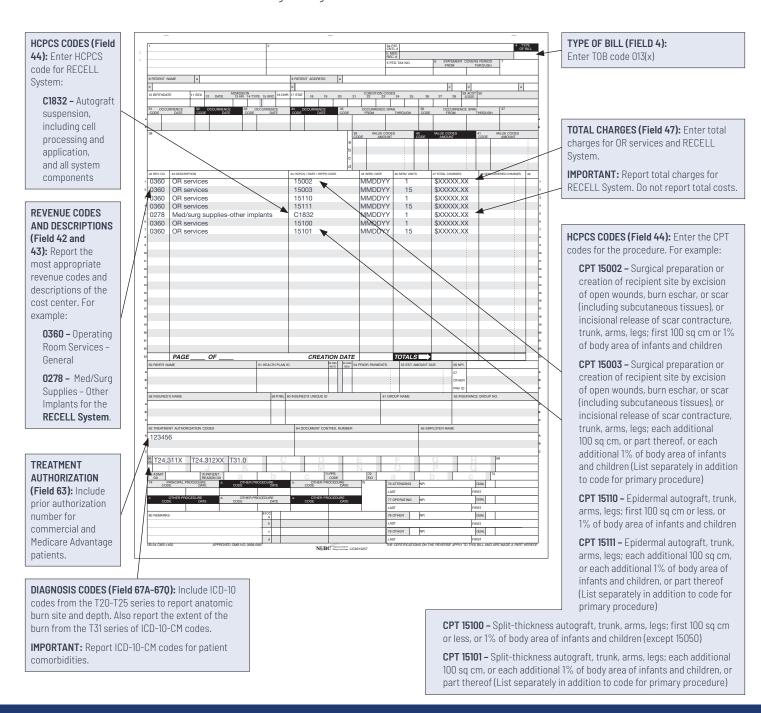


## SAMPLE UB-04/CMS 1450: HOSPITAL OUTPATIENT DEPARTMENT



## RECELL PLUS SPLIT-THICKNESS SKIN GRAFT ON 8% TBSA FULL-THICKNESS/MIXED DEPTH BURNS

**Clinical Scenario:** A 74-year-old female was burned on her upper thighs when boiling water spilled while moving a large pot from the stove to the sink in her home. She is transported to the nearby emergency room, where she is assessed to have full-thickness/mixed depth burns on her thighs covering 8% TBSA (1,600 sq cm). After determining that the patient is hemodynamically stable, she is taken to the operating room for debridement and excision of her burns and immediate autografting for definitive wound closure.



## SAMPLE CMS 1500: AMBULATORY SURGICAL CENTER (ASC)



## RECELL WITH SPLIT-THICKNESS SKIN GRAFT ON 3% TBSA FULL-THICKNESS ROAD RASH/FRICTION BURN INJURY

**Clinical Scenario:** A A 32-year-old male presented to the emergency room following a motorcycle accident where he sustained an acute full-thickness road rash/friction burn injury on his left upper arm and shoulder totaling 2% TBSA (400 sq cm). Following initial debridement and excision of his wound, the patient is scheduled for grafting at an ASC at a later date. At the ASC, the patient is taken to the operating room for surgical preparation of his wounds and autografting with a meshed 3:1 split-thickness skin graft in combination with cell suspension autograft for definitive wound closure.

#### ADDITIONAL CLAIM INFORMATION:

For Medicare claims, ASCs must report the total cost of the RECELL System as noted on the invoice in a currency format using a decimal point. Verify appropriate billing with commercial payers who may have different requirements.

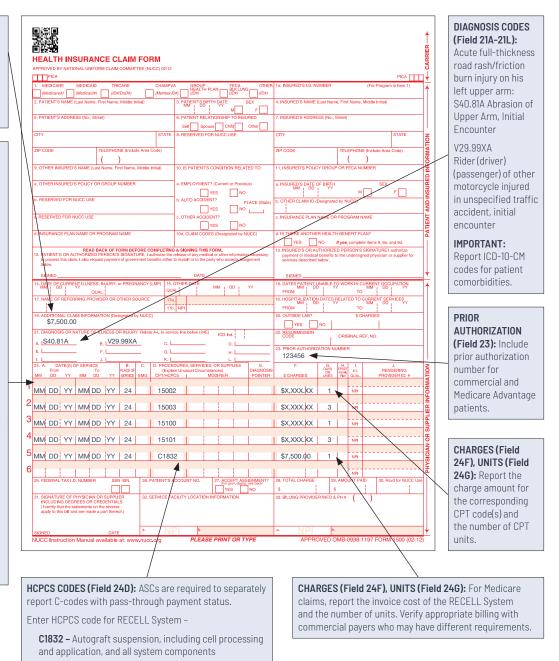
DATE OF SERVICE (Field 24A), PLACE OF SERVICE (Field 24B) and CPT/HCPCS CODES (Field 24D): Include the date of service, place of service and the relevant CPT codes - For example:

CPT 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

CPT 15003 – 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; 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)

**CPT 15100 –** Split-thickness autograft, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children (except 15050)

CPT 15101 – Split-thickness autograft, trunk, arms, legs; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)



## SAMPLE CMS 1500: AMBULATORY SURGICAL CENTER (ASC)



#### RECELL ON 4% TBSA DEEP-PARTIAL THICKNESS BURN

**Clinical Scenario:** A 35-year-old male received a burn on his right forearm from escaping radiator steam. He is transported to the nearby ASC where he is assessed to have a deep partial-thickness burn on his right forearm covering 4% TBSA (800 sq cm). After the patient is hemodynamically stable, he is taken to the surgical suite for debridement and excision of his partial-thickness burn and immediate autografting for definitive wound closure.

#### ADDITIONAL CLAIM INFORMATION:

For Medicare claims, ASCs must report the total cost of the RECELL System as noted on the invoice in a currency format using a decimal point. Verify appropriate billing with commercial payers who may have different requirements.

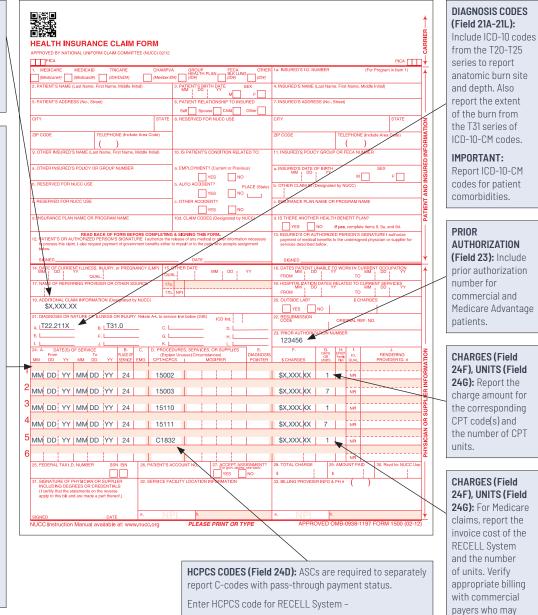
DATE OF SERVICE (Field 24A), PLACE
OF SERVICE (Field 24B) and CPT/HCPCS
CODES (Field 24D): Include the date of
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CPT codes to report the debridement and
excision of the patient's full-thickness
burns and immediate autografting
for permanent wound coverage - For
example:

CPT 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

CPT 15003 – 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; 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)

**CPT 15110** – Epidermal autograft, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children

CPT 15111 – Epidermal autograft, trunk, arms, legs; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)



have different

requirements.

C1832 - Autograft suspension, including cell processing

and application, and all system components

NOTES			

### REFERENCES

- **1.** American Burn Association. Burn News: Cell Suspension Autograft CPT Coding Recommendation. http://ameriburn.org/cell-suspension-autograft-cpt-coding-recommendation/. Accessed December 13, 2022.
- **2.** American Medical Association. 2023 Current Procedural Terminology (CPT®), Professional Edition. CPT Copyright 2023 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association.
- **3.** Centers for Medicare & Medicaid Services. Payment Policies Under the Physician Fee Schedule for CY 2023 (Final rule). 87 Fed. Reg. 222, November 18, 2022; PPRRVU January 2022 Update 12.15.22. All MPFS Fee Schedules calculated using conversion factor of \$33.8872 effective January 2023.
- **4.** Centers for Medicare & Medicaid Services. Hospital Inpatient Prospective Payment System for FY 2023 (Final Rule and Correcting Amendments). 87 Fed. Reg. 153, August 10, 2022; and 87 Fed. Reg. 213, November 4, 2022. Payment rates calculated using standardized amounts in Tables 1A-1E that were updated in the Correcting Amendment.
- **5.** Centers for Medicare & Medicaid Services. ICD-10-PCS Reference Manual. https://www.cms.gov/Medicare/Coding/ICD10/downloads/pcs\_refman.pdf. Accessed December 14, 2022.
- **6.** Centers for Medicare & Medicaid Services. ICD-10 Coordination and Maintenance Committee Meeting Agenda. September 11, 2018. https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/Downloads/2018-09-11-Agenda.pdf. Accessed December 14, 2022.
- **7.** Centers for Medicare & Medicaid Services. 2023 ICD-10-PCS Code Tables and Index. https://www.cms.gov/medicare/icd-10/2023-icd-10-pcs. Accessed December 15, 2022.
- **8.** Centers for Medicare & Medicaid Services. Hospital Outpatient Prospective Payment System for CY 2023 (Final Rule). 87 Fed. Reg. 225, November 23, 2022 and https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatie ntppshospital-outpatient-regulations-and-notices/cms-1772-fc. Accessed January 3, 2022.
- **9.** Centers for Medicare & Medicaid Services. Hospital Outpatient Prospective Payment System for CY 2022 (Final Rule). 86 Fed. Reg. 218, November 16, 2021 and https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientpps/cms-1753-fc. Accessed December 15, 2022.
- **10.** Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual, Chapter 14 Ambulatory Surgical Centers, page 19. Rev. 3939, 12-22-17. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c14.pdf. Accessed December 15, 2022.
- **11.** Centers for Disease Control and Prevention, National Center for Health Statistics. International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM).

#### **OUESTIONS? PLEASE CONTACT RECELL ACCESS PROGRAM AT**

833-674-1688

OR

#### SUPPORT@RECELLACCESSPROGRAM.COM

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#### IMPORTANT SAFETY INFORMATION

**INDICATIONS FOR USE:** The RECELL Autologous Cell Harvesting Device is indicated for the treatment of thermal burn wounds and full-thickness skin defects. The RECELL Device is used by an appropriately licensed healthcare professional at the patient's point of care to prepare autologous Spray-On Skin Cells for direct application to acute partial-thickness thermal burn wounds in patients 18 years of age and older, or application in combination with meshed autografting for acute full-thickness thermal burn wounds, in pediatric and adult patients and full-thickness skin defects after traumatic avulsion (e.g., degloving) or surgical excision (e.g., necrotizing soft tissue infection) or resection (e.g., skin cancer), in patients 15 years of age and older.

**CONTRAINDICATIONS:** RECELL is contraindicated for the treatment of wounds clinically diagnosed as infected or with necrotic tissue present in the wound bed. RECELL is contraindicated for: the treatment of patients with a known hypersensitivity to trypsin or compound sodium lactate (Hartmann's) solution, patients having a known hypersensitivity to anesthetics, adrenaline/epinephrine, povidone-iodine, or chlorhexidine solutions.

**WARNINGS:** Autologous use only. Control infections on wounds prior to application of the cell suspension. Excise the necrotic tissues on wound bed prior to application of the cell suspension. Wound beds treated with a cytotoxic agent (e.g., silver sulfadiazine) should be rinsed prior to application of the cell suspension. RECELL is provided sterile and is intended for singleuse. Do not use if packaging is damaged or expired. Choose a donor site with no evidence of cellulitis or infection and process skin immediately. A skin sample should require between 15 and 30 minutes contact with Enzyme. Contact in excess of 60 minutes is not recommended. RECELL Enzyme is animal derived and freedom from infectious agents cannot be guaranteed.

**PRECAUTIONS:** RECELL is not intended for use without meshed autograft for treatment of acute full-thickness burn wounds or full-thickness skin defects after traumatic avulsion (e.g., degloving) or surgical excision (e.g., necrotizing soft tissue infection) or resection (e.g., skin cancer). The safety and effectiveness of RECELL without meshed autograft have not been established for treatment of partial-thickness burn wounds: on the hands and articulating joints >320cm², in patients with wounds totaling >20% total body surface area (TBSA). The safety and effectiveness of RECELL with autografting have not been established for treatment of full-thickness burn wounds: on the hands and articulating joints, and in patients younger than 28 days of age (neonates). The safety and effectiveness of RECELL plus autografting have not been established for application in combination with meshed autografting on full-thickness skin defects after traumatic avulsion (e.g., degloving) or surgical excision (e.g., necrotizing soft tissue infection) or resection (e.g., skin cancer): on the hands and genitalia.

**SPECIAL PATIENT POPULATIONS:** The safety and effectiveness of RECELL have not been established for treatment of acute thermal partial-thickness burn wounds in pediatric patients younger than 18 years of age. For complete Important Safety Information, refer to Instructions for Use.

**INSTRUCTIONS FOR USE:** Consult the Instructions for Use prior to using RECELL. The Instructions for Use can be located at <a href="https://www.RECELLsystem.com">www.RECELLsystem.com</a>.

