



# Billing and Coding Guide

A resource to support Qualified Treatment Centers with billing, coding, and reimbursement for ZEVASKYN

For additional information, contact Abeona Assist™ or visit [www.AbeonaAssist.com](http://www.AbeonaAssist.com).

## Indication

ZEVASKYN™ (prademagene zamikeracel) is an autologous cell sheet-based gene therapy indicated for the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB).

## Select Important Safety Information

- Severe hypersensitivity reactions, retroviral vector (RVV)-mediated insertional oncogenesis, and transmission of infectious disease or agents may occur with ZEVASKYN. The most common adverse reactions (incidence  $\geq 5\%$ ) are procedural pain and pruritus.



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The purpose of this guide is to support Qualified Treatment Centers with billing and coding information for ZEVASKYN. This resource identifies the appropriate billing codes and provides sample claim forms to help navigate the ZEVASKYN reimbursement process.



## Product Overview

ZEVASKYN is made from a patient's own skin cells and is used to treat wounds associated with recessive dystrophic epidermolysis bullosa (RDEB).

- ZEVASKYN is an autologous cell sheet-based gene therapy for the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB)
- Patients' own skin cells are genetically modified with functional COL7A1 gene for type VII collagen expression at site of ZEVASKYN application. These gene-modified skin cells are expanded into credit card-sized cellular sheets (~41.25 cm<sup>2</sup> each)
- In a single surgical application, ZEVASKYN sheets can be used individually or can be joined together to cover larger areas (up to 12 sheets, or up to a total of ~500 cm<sup>2</sup>, will be provided)

## Important Safety Information

- Severe hypersensitivity reactions to vancomycin, amikacin, or product excipients may occur with ZEVASKYN application. Monitor for signs and symptoms of hypersensitivity reactions such as itching, swelling, hives, difficulty breathing, runny nose, watery eyes, nausea, and in severe cases, anaphylaxis and treat according to standard clinical practice.

Please see additional Important Safety Information for ZEVASKYN on page 18 and full [Prescribing Information](#).

  
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# Treatment Journey

ZEVASKYN is an autologous cell sheet-based gene therapy. One sheet of ZEVASKYN covers an area of 41.25 cm<sup>2</sup>. Up to twelve ZEVASKYN sheets may be manufactured from a patient's biopsies.

1



## Biopsy Cell Collection<sup>1</sup>

8 mm skin biopsies are taken at a clinic or in a hospital outpatient setting and sent to Abeona to manufacture ZEVASKYN cellular sheets

2



## Keratinocytes Are Isolated and Transduced<sup>1</sup>

Transduction occurs with a functional COL7A1 transgene

2A



### COL7A1 Gene Transduction<sup>1</sup>

Transduction using a replication-incompetent retrovirus vector (LZRSE-COL7A1) results in expression and secretion of functional collagen 7 protein

3



## Cell Expansion<sup>1</sup>

Transduced cells are expanded

4



## Seeding<sup>1</sup>

Gene-modified cells are grown into cellular sheets (5.5 x 7.5 cm); up to 12 sheets may be produced per manufacturing run

5



## Product Delivery<sup>1</sup>

ZEVASKYN sheets are hand-delivered to the hospital by an Abeona Transport Specialist approximately 25 days after biopsy

6



## Surgical Application<sup>1</sup>

ZEVASKYN sheets are surgically applied onto wounds under general or other appropriate anesthesia

6A



Following surgical application of ZEVASKYN, patients stay in the hospital for 5 to 10 days to immobilize wounds



# Biopsy Cell Collection

1



## Biopsy Cell Collection<sup>1</sup>

8 mm skin biopsies are taken at a clinic or in a hospital outpatient setting and sent to Abeona to manufacture ZEVASKYN cellular sheets

## Relevant codes for biopsy cell collection in an outpatient setting may include:

### ICD-10-CM Codes

ICD-10-CM codes are managed by the CDC's National Center for Health Statistics and are used to identify and categorize medical diagnoses and conditions.

ICD-10-CM <sup>2</sup>	Description
Q81.2	Epidermolysis bullosa dystrophica

### CPT® Codes

When procedures are performed in an outpatient setting, providers report CPT codes to identify the service. CPT codes are level II HCPCS codes developed by the AMA to describe medical procedures and services performed by healthcare professionals.

CPT <sup>3</sup>	Description
11104	Punch biopsy of skin (including simple closure, when performed); single lesion
11105	Each separate/additional lesion (List separately in addition to code for primary procedure)
15040	Harvest of skin for tissue cultured skin autograft, 100 sq cm or less

**Note:** Providers may potentially report an evaluation and management code in addition to the biopsy CPT code when applicable (e.g., **99203 - Office or other outpatient visit for the evaluation and management of a new patient**, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.)

**Billing and coding requirements often vary and are specific to each individual case. Providers are responsible for accurate coding and are encouraged to contact payers for specific details regarding their policies and independently verify billing, coding, and reimbursement requirements when submitting claims.**

CPT® - Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association.

AMA, American Medical Association; CDC, Centers for Disease Control and Prevention; CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases 10th Revision, Clinical Modification.

Please see Indication and Important Safety Information for ZEVASKYN on page 18 and full [Prescribing Information](#).

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# Surgical Application

6



## Surgical Application<sup>1</sup>

ZEVASKYN sheets are surgically applied onto wounds under general or other appropriate anesthesia

## Relevant codes for surgical application of ZEVASKYN may include:

### ICD-10-CM Codes

ICD-10-CM codes are managed by the CDC's National Center for Health Statistics and are used to identify and categorize medical diagnoses and conditions.

ICD-10-CM <sup>2</sup>	Description
Q81.2	Epidermolysis bullosa dystrophica

### ICD-10-PCS Codes

ICD-10-PCS are codes maintained by CMS and used to classify procedures performed in hospital inpatient settings. Effective October 1, 2024, CMS created new ICD-10-PCS codes to specifically identify the surgical application of ZEVASKYN in hospital inpatient settings.

ICD-10-PCS <sup>4</sup>	Description
XHR0XGA	Replacement of Head and Neck Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10
XHR1XGA	Replacement of Chest Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10
XHR2XGA	Replacement of Abdomen Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10
XHR3XGA	Replacement of Back Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10
XHR4XGA	Replacement of Right Upper Extremity Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10
XHR5XGA	Replacement of Left Upper Extremity Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10
XHR6XGA	Replacement of Right Lower Extremity Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10
XHR7XGA	Replacement of Left Lower Extremity Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10

**Billing and coding requirements often vary and are specific to each individual case. Providers are responsible for accurate coding and are encouraged to contact payers for specific details regarding their policies and independently verify billing, coding, and reimbursement requirements when submitting claims.**

CDC, Centers for Disease Control and Prevention; CMS, Centers for Medicare and Medicaid Services; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases 10th Revision, Clinical Modification; ICD-10-PCS, International Classification of Diseases 10th Revision, Procedure Coding System.

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# Surgical Application (cont'd)

6



## Surgical Application<sup>1</sup>

ZEVASKYN sheets are surgically applied onto wounds under general or other appropriate anesthesia

## Relevant codes for surgical application of ZEVASKYN may include:

### HCPCS Codes

HCPCS codes are used to bill medical services and supplies.

HCPCS <sup>5</sup>	Description
J3490	Unclassified drugs
J3590	Unclassified biologic

### NDC Code

Hospitals may be required by the payer to list the NDC for ZEVASKYN on the inpatient hospital claim.

NDC <sup>1</sup>		Description
10-digit format	11-digit format	
84103-007-01	84103-0007-01	Prademagene zamikeracel, gene-modified cellular sheets

Billing and coding requirements often vary and are specific to each individual case. Providers are responsible for accurate coding and are encouraged to contact payers for specific details regarding their policies and independently verify billing, coding, and reimbursement requirements when submitting claims.

HCPCS, Healthcare Common Procedure Coding System; NDC, National Drug Code.

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# Coding Summary

Code Type <sup>2-5</sup>	Code	Description
ICD-10-CM	Q81.2	Epidermolysis bullosa dystrophica
CPT®	11104	Punch biopsy of skin (including simple closure, when performed); single lesion
	11105	Each separate/additional lesion (List separately in addition to code for primary procedure)
	15040	Harvest of skin for tissue cultured skin autograft, 100 sq cm or less
ICD-10-PCS	XHR0XGA	Replacement of Head and Neck Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10
	XHR1XGA	Replacement of Chest Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10
	XHR2XGA	Replacement of Abdomen Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10
	XHR3XGA	Replacement of Back Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10
	XHR4XGA	Replacement of Right Upper Extremity Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10
	XHR5XGA	Replacement of Left Upper Extremity Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10
	XHR6XGA	Replacement of Right Lower Extremity Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10
	XHR7XGA	Replacement of Left Lower Extremity Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10
HCPCS	J3490	Unclassified drugs
	J3590	Unclassified biologic
NDC	84103-007-01	Prademagene zamikeracel, gene-modified cellular sheets (10-digit)
	84103-0007-01	Prademagene zamikeracel, gene-modified cellular sheets (11-digit)

CPT codes are typically used for reporting outpatient procedures, while ICD-10-PCS codes are used for reporting procedures performed in a hospital inpatient setting.

Billing and coding requirements often vary and are specific to each individual case. Providers are responsible for accurate coding and are encouraged to contact payers for specific details regarding their policies and independently verify billing, coding, and reimbursement requirements when submitting claims.

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CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; ICD-10-PCS, International Classification of Diseases 10th Revision, Procedure Coding System; NDC, National Drug Code.

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# Coding Summary (cont'd)

The following are list of revenue codes that may be associated with ZEVASKYN®

Revenue Code <sup>6</sup>	Description
0250	Pharmacy: general
0500	Outpatient Services: general
0636	Drugs requiring detailed coding
0870	Cell/Gene Therapy - general
0871	Cell/Gene Therapy - cell collection
0892	Special processed drugs - FDA approved gene therapy (Effective 4/1/20)

MS-DRG assignment and payments are based on the patient's diagnoses and procedures performed.

Payment Group <sup>7</sup>	Payment Group #	Description
MS-DRG	018	Chimeric antigen receptor (CAR) T-Cell and other immunotherapies

CPT codes are typically used for reporting outpatient procedures, while ICD-10-PCS codes are used for reporting procedures performed in a hospital inpatient setting.

Billing and coding requirements often vary and are specific to each individual case. Providers are responsible for accurate coding and are encouraged to contact payers for specific details regarding their policies and independently verify billing, coding, and reimbursement requirements when submitting claims.

MS-DRG, Medicare severity diagnosis-related group.

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Product  
Information

Treatment  
Journey

Biopsy Cell  
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Abeona Assist™  
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# Sample Claim Forms

## Example Billing and Coding Case



A 14-year-old patient receives a diagnosis of recessive dystrophic epidermolysis bullosa (RDEB) confirmed by biopsy and genetic testing. Patient has wounds on upper back and upper left arm.



There may be 2 billable steps for ZEVASKYN

- Biopsy Cell Collection
- Surgical Application



### Biopsy Claims

For procedures performed in an **outpatient clinic**, Qualified Treatment Centers will use the CMS 1500 form.

For procedures performed in a **hospital outpatient setting**, Qualified Treatment Centers will use the CMS 1450 form.



### Surgical Application Claims

Since the surgical application of ZEVASKYN is an **inpatient** procedure, Qualified Treatment Centers will use the CMS 1450 form.



# Sample Claim Forms (cont'd)

## Example Billing and Coding Case (cont'd)

### Sample CMS 1500 Claim Form for Biopsy Cell Collection When Performed in an Outpatient Clinic



#### HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

<input type="checkbox"/> PICA		<input type="checkbox"/> PICA	
1. MEDICARE <input type="checkbox"/> (Medicare#) MEDICAID <input type="checkbox"/> (Medicaid#) TRICARE <input type="checkbox"/> (ID#/DoD#) CHAMPVA <input type="checkbox"/> (Member ID#) GROUP HEALTH PLAN <input type="checkbox"/> (ID#) FECA BLK LUNG <input type="checkbox"/> (ID#) OTHER <input type="checkbox"/> (ID#)		1a. INSURED'S I.D. NUMBER (For Program in Item 1)	
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)		3. PATIENT'S BIRTH DATE MM DD YY SEX M <input type="checkbox"/> F <input type="checkbox"/>	
5. PATIENT'S ADDRESS (No., Street)		6. PATIENT RELATIONSHIP TO INSURED Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>	
CITY STATE		7. INSURED'S ADDRESS (No., Street)	
ZIP CODE TELEPHONE (Include Area Code) ( )		CITY STATE	
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)		10. IS PATIENT'S CONDITION RELATED TO:	
a. OTHER INSURED'S POLICY OR GROUP NUMBER		a. EMPLOYMENT? (Current or Previous) YES <input type="checkbox"/> NO <input type="checkbox"/>	
b. RESERVED FOR NUCC USE		b. AUTO ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/> PLACE (State)	
c. RESERVED FOR NUCC USE		c. OTHER ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/>	
d. INSURANCE PLAN NAME OR PROGRAM NAME		10d. CLAIM CODES (Designated by NUCC)	
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.		11. INSURED'S POLICY GROUP OR FECA NUMBER	
SIGNED DATE		a. INSURED'S DATE OF BIRTH MM DD YY SEX M <input type="checkbox"/> F <input type="checkbox"/>	
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.		b. OTHER CLAIM ID (Designated by NUCC)	
15. OTHER DATE MM DD YY QUAL.		c. INSURANCE PLAN NAME OR PROGRAM NAME	
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE		d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES <input type="checkbox"/> NO <input type="checkbox"/> If yes, complete items 9, 9a, and 9d.	
17a. NPI		13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.	
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)		SIGNED	
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.		16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY	
A. Q81.2 B. C. D.		18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY	
E. F. G. H.		20. OUTSIDE LAB? YES <input type="checkbox"/> NO <input type="checkbox"/> \$ CHARGES	
I. J. K. L.		22. RESUBMISSION CODE ORIGINAL REF. NO.	
21		23. PRIOR AUTHORIZATION NUMBER [xxxxxx] 23	

#### 21 Diagnosis or Nature of Illness or Injury

Enter all appropriate diagnosis codes.

There is currently no unique ICD-10-CM code for RDEB.

Q81.2 epidermolysis bullosa dystrophica may be used in this scenario.

#### 23 Prior Authorization Number

Enter the prior authorization number.

List the prior authorization number provided by payer.

RDEB, recessive dystrophic epidermolysis bullosa.

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# Sample Claim Forms (cont'd)

## Example Billing and Coding Case (cont'd)

### Sample CMS 1500 Claim Form for Biopsy Cell Collection When Performed in an Outpatient Clinic

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E)										ICD Ind.		22. RESUBMISSION CODE		ORIGINAL REF. NO.							
A. _____ B. _____ C. _____ D. _____																					
E. _____ F. _____ G. _____ H. _____																					
I. _____ J. _____ K. _____ L. _____																					
23. PRIOR AUTHORIZATION NUMBER																					
24. A. DATE(S) OF SERVICE		B. PLACE OF SERVICE		C. EMG		D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances)				E. DIAGNOSIS POINTER		F. \$ CHARGES		G. DAYS OR UNITS		H. EPSON Family Plan		I. ID. QUAL.		J. RENDERING PROVIDER ID. #	
MM	DD	YY	MM	DD	YY		CPT/HCPCS MODIFIER														
1	XX	XX	XX	XX	XX	11	11104				A			[XX]							
2	XX	XX	XX	XX	XX	11	11105				A			[XX]							
3																					
4																					
5																					
6																					
25. FEDERAL TAX I.D. NUMBER						SSN EIN		26. PATIENT'S ACCOUNT NO.				27. ACCEPT ASSIGNMENT? (For gov't claims, see back)		28. TOTAL CHARGE		29. AMOUNT PAID		30. Rsvd for NUCC Use			
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)						32. SERVICE FACILITY LOCATION INFORMATION						33. BILLING PROVIDER INFO & PH # ( )									
SIGNED						DATE						a. NPI		b. NPI		a. NPI		b. NPI			

NUCC Instruction Manual available at: [www.nucc.org](http://www.nucc.org) PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

24A

#### Date(s) of Service

Enter the date of administration and/or procedure.

Use the MM/DD/YY format.

24B

#### Place of Service (POS)

Enter the relevant POS codes.

POS codes represent the setting of service and are shown with 2 digits.

For the physician office, report POS code 11.

24D

#### Procedures, Services, or Supplies

Enter the appropriate HCPCS and CPT® codes.

If the biopsy will be performed in an outpatient setting, it may be appropriate to use CPT codes.

- 11104 - Punch biopsy of skin (including simple closure, when performed); single lesion
- 11105 - Each separate/additional lesion (List separately in addition to code for primary procedure)

24E

#### Diagnosis Pointer

Enter the appropriate diagnosis pointer.

The diagnosis pointer aligns to Box 21 (diagnosis).

24G

#### Days or Units

Enter the appropriate days or units.

Enter the number of units associated with the CPT code reported in Box 24D.

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## Sample Claim Forms (cont'd)

## Example Billing and Coding Case (cont'd)

## Sample UB-04 (CMS 1450) Claim Form for Biopsy Cell Collection Performed in a Hospital Outpatient Setting

[illegible]

## 63 Treatment Authorization Codes

**Enter the authorization number.**

If required by the payer, this field is used for the Prior Authorization (PA) number.

## 67A-67Q Diagnosis

Enter ICD-10-CM diagnosis codes.

There is currently no unique ICD-10-CM code RDEB.

Q81.2-epidermolysis bullosa dystrophica may be used in this scenario.

## 80 Remarks

Enter additional information.

Enter any additional information required by the payer, such as drug name, dose, route of administration, 11-digit NDC number, etc (if applicable).

RDEB, recessive dystrophic epidermolysis bullosa.

**This is a sample form. Appropriate codes can vary by setting of care, patient, and payer. It is the responsibility of the provider to code accurately for product and service. Please review and confirm all appropriate codes with each individual payer.**

Please see Indication and Important Safety Information for ZEVASKYN on page 18 and full [Prescribing Information](#).



# Sample Claim Forms (cont'd)

## Example Billing and Coding Case (cont'd)

### Sample UB-04 (CMS 1450) Claim Form for the Surgical Application of ZEVASKYN Performed in Inpatient Hospital Facilities

1		2		3a PAT. CNTL. #		4 TYPE OF BILL 01X	
				b. MED. REC. #			
				5 FED. TAX NO.		6 STATEMENT COVERS PERIOD FROM THROUGH	
8 PATIENT NAME		9 PATIENT ADDRESS					
b		c		d		e	
10 BIRTHDATE	11 SEX	12 DATE	ADMISSION 13 HR 14 TYPE 15 SRC 16 DHR	17 STAT	18	19	20
31 OCCURRENCE DATE		32 OCCURRENCE DATE		33 OCCURRENCE DATE		34 OCCURRENCE DATE	
35 OCCURRENCE SPAN FROM THROUGH		36 OCCURRENCE SPAN FROM THROUGH		37			
38		39 VALUE CODES AMOUNT		40 VALUE CODES AMOUNT		41 VALUE CODES AMOUNT	
		a 87 \$XXXXX XX		b		c	
		d		39-41			
42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
0892	Special Processed Drugs - FDA Approved Gene Therapy (Effective 4/1/20)	J3490		1	XXXXXX		

4

#### Type of Bill

Enter the appropriate type of bill code.

Type of bill codes describe the facility and care type. For example, 011X for inpatient hospital.

39-41

#### Value Codes<sup>8</sup>

Enter the appropriate value codes.

Some payers may require adding a value code to show the acquisition cost of ZEVASKYN.

For example, value code 87 may be used with revenue code 0892.

Value code 87: Invoice/acquisition cost of modified biologics.

42

#### Revenue Codes

Enter revenue codes.

For example, revenue code 0892 may be used for FDA-approved gene therapy.

43

#### Description

Enter description.

Enter revenue code descriptions and any associated procedures, supplies, and drugs.

44

#### HCPCS/Rate/HIPPS Code

Enter the appropriate CPT/HCPCS code.

For example, J3490 may be used for unclassified drugs.

J3590: Unclassified biologics may also be an option.

Payer requirements vary. Check with specific payers for appropriate codes to use.

46

#### Service Units

Provide total amount for each line item.

Enter the total number of units associated with the service, supplies, or drugs provided during the encounter. For example, 1 unit is reported here.

47

#### Total Charges

Enter total charges.

Enter the charges for each line of service.



# Sample Claim Forms (cont'd)

## Example Billing and Coding Case (cont'd)

### Sample UB-04 (CMS 1450) Claim Form for the Surgical Application of ZEVASKYN Performed in Inpatient Hospital Facilities

58 INSURED'S NAME					59 P REL	60 INSURED'S UNIQUE ID					61 GROUP NAME					62 INSURANCE GROUP NO.													
[XXXXXX]																													
63 TREATMENT AUTHORIZATION CODES										64 DOCUMENT CONTROL NUMBER										65 EMPLOYER NAME									
[XXXXXX]																													
66 DX		67A-67Q		Q81.2		B		C		D		E		F		G		H		68									
69 ADMIT DX		70 PATIENT REASON DX		71 PPS CODE		72 ECI		73		74		75		76 ATTENDING NPI		QUAL		77		78									
XHR3XGA		XX XX XX		XHR5XGA		XX XX XX		OTHER PROCEDURE CODE		OTHER PROCEDURE DATE		OTHER PROCEDURE CODE		OTHER PROCEDURE DATE		LAST		FIRST		QUAL									
c.		OTHER PROCEDURE CODE		OTHER PROCEDURE DATE		e.		OTHER PROCEDURE CODE		OTHER PROCEDURE DATE		LAST		FIRST		QUAL		79		80									
80 REMARKS		[NAME]; [DOSAGE]; NDC		81CC a		b		c		d		76 OTHER NPI		QUAL		LAST		FIRST		QUAL									
												77 OTHER NPI		QUAL		LAST		FIRST		QUAL									
												78 OTHER NPI		QUAL		LAST		FIRST		QUAL									
												79 OTHER NPI		QUAL		LAST		FIRST		QUAL									

#### 63 Treatment Authorization Codes

Enter the authorization number.

If required by the payer, this field is used for the Prior Authorization (PA) number.

#### 67A-67Q Diagnosis

Enter ICD-10-CM diagnosis codes.

There is currently no unique ICD-10-CM code for recessive dystrophic epidermolysis bullosa.

Q81.2 epidermolysis bullosa dystrophica may be used in this example.

#### 74 Principal Procedure Code and Date

Enter ICD-10-PCS codes and dates.

In an inpatient setting, the following ICD-10-PCS codes may be used.

- XHR3XGA - Replacement of Back Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10
- XHR5XGA - Replacement of Left Upper Extremity Skin with Prademagene Zamikeracel, Genetically Engineered Autologous Cell Therapy, External Approach, New Technology Group 10

#### Remarks

Enter additional information.

- 80 Enter any additional information required by the payer, such as drug name, dose, route of administration, 11-digit NDC number, etc (if applicable).

This is a sample form. Appropriate codes can vary by setting of care, patient, and payer. It is the responsibility of the provider to code accurately for product and service. Please review and confirm all appropriate codes with each individual payer.

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# Abeona Assist™ Patient Support Program



**Abeona Assist offers enrolled patients and their caregivers personalized support navigating the entire treatment journey with ZEVASKYN**

## About Abeona Assist

Abeona Assist is a team of dedicated Patient Navigators\* who can discuss the ZEVASKYN treatment pathway and review insurance coverage, financial assistance, and travel and logistical support.

## Assistance for Patients and Caregivers

Call Abeona Assist to investigate coverage benefits for ZEVASKYN and the wide range of benefits and resources that may be available for eligible patients, including†:

- Insurance Benefit Verification
- Financial and Copay Assistance
- Travel and Logistical Support



**Abeona Assist is here to help with patient access to ZEVASKYN by providing support and resources needed throughout the treatment pathway.**

**When you see this sticker, it means Abeona Assist is here to help!**

## Personalized Patient Navigators

Once your patients are enrolled in Abeona Assist, a personalized Patient Navigator will be matched to the patient and the patient's geographic region. The Patient Navigator will help identify available resources and guide the patient through the support offerings provided by Abeona Assist.

### Contact a Patient Navigator\* at Abeona Assist

855-ABEONA-1 (855-223-6621)

MyNavigator@AbeonaAssist.com

Monday-Friday 9:00 AM – 6:30 PM ET

Additionally, someone is available to help you 24/7

For additional questions, email Abeona Assist at MyNavigator@AbeonaAssist.com.

RDEB, recessive dystrophic epidermolysis bullosa; QTC, qualified treatment center.

\*Patient Navigators do not direct patient care or provide medical advice.

†Eligibility requirements apply.

**Please see Indication and Important Safety Information for ZEVASKYN on page 18 and full [Prescribing Information](#).**

**zevaskyn™**  
(prademagene zamikeracel)  
gene-modified cellular sheets



# Indication and Important Safety Information

## Indication

ZEVASKYN™ (prademagene zamikeracel) is an autologous cell sheet-based gene therapy indicated for the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB).

## Important Safety Information

- Severe hypersensitivity reactions to vancomycin, amikacin, or product excipients may occur with ZEVASKYN application. Monitor for signs and symptoms of hypersensitivity reactions such as itching, swelling, hives, difficulty breathing, runny nose, watery eyes, nausea, and in severe cases, anaphylaxis and treat according to standard clinical practice.
- Retroviral vector (RVV)-mediated insertional oncogenesis may potentially occur after treatment with ZEVASKYN. Monitor patients lifelong after treatment for the development of malignancies. In the event that a malignancy occurs, contact Abeona Therapeutics Inc. at 1-844-888-2236.
- Transmission of infectious disease or agents may occur with ZEVASKYN because it is manufactured using human- and bovine-derived reagents, which are tested for human and animal viruses, bacteria, fungi, and mycoplasma before use. These measures do not eliminate the risk of transmitting these or other infectious diseases or agents.
- The most common adverse reactions (incidence  $\geq 5\%$ ) were procedural pain and pruritus.

Please see full [Prescribing Information](#).

Product  
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Surgical  
Application

Coding  
Summary

Sample  
Claim Forms

Abeona Assist™  
Patient Support  
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Important  
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**References:** **1.** ZEVASKYN. Prescribing information. Abeona Therapeutics; 2024. **2.** American Medical Association. ICD-10-CM 2025 The Complete Official Codebook. Chicago, IL: AMA Press; 2025. **3.** American Medical Association. Current Procedural Terminology: CPT® 2025: Professional Edition. Chicago, IL: AMA Press; 2024. **4.** Centers for Medicare and Medicaid Services. 2025 ICD-10-PCS. 2025 ICD-10-PCS Addendum. Published July 9, 2024. Accessed December 20, 2024. [https://www.cms.gov/icd10m/fy2025-version42.0-fullcode-cms/fullcode\\_cms/P0038.html](https://www.cms.gov/icd10m/fy2025-version42.0-fullcode-cms/fullcode_cms/P0038.html) **5.** American Academy of Professional Coders (AAPC). CPT® Codes Lookup. Accessed February 27, 2025. <https://www.aapc.com/codes> **6.** Noridian Healthcare Services. Revenue Codes. Accessed January 23, 2025. <https://med.noridianmedicare.com/web/jea/topics/claimsubmission/revenue-code> **7.** Centers for Medicare and Medicaid Services. FY 2025 final rule tables. Table 5. Accessed August 26, 2024. <https://www.cms.gov/files/zip/fy-2025-ipp-final-rule-table-5.zip> **8.** National Uniform Billing Committee (NUBC). Summary of Gene and Cell Therapy Coding Changes. Accessed January 23, 2025. <https://www.nubc.org/system/files/media/file/2020/02/Cell-Gene%20Therapy%20Code%20Changes.pdf>

Please visit [www.AbeonaAssist.com](http://www.AbeonaAssist.com) for more information.

Please see Indication and Important Safety Information for ZEVASKYN on page 18 and full [Prescribing Information](#).



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