



# 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.



Treatment  
Journey

Biopsy Cell  
Collection

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Application

Coding  
Summary

Sample  
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Abeona Assist™  
Patient Support  
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Important  
Safety  
Information

## 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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gene-modified cellular sheets



# 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
J3389	Topical administration, ZEVASKYN, prademagene zamikerice, per treatment

### 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 zamikerace, 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	J3389	Topical administration, ZEVASKYN, prademagene zamikeracel, per treatment
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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# 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)	
READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.		11. INSURED'S POLICY GROUP OR FECA NUMBER	
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.		13. INSURED'S DATE OF BIRTH MM DD YY SEX M <input type="checkbox"/> F <input type="checkbox"/>	
SIGNED DATE		b. OTHER CLAIM ID (Designated by NUCC)	
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.		c. INSURANCE PLAN NAME OR PROGRAM NAME	
15. OTHER DATE MM DD YY QUAL.		d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES <input type="checkbox"/> NO <input type="checkbox"/> If yes, complete items 9, 9a, and 9d.	
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE		16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY	
17a. 17b. NPI		18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY	
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)		20. OUTSIDE LAB? YES <input type="checkbox"/> NO <input type="checkbox"/> \$ CHARGES	
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. Q81.2 B. C. D.		23. PRIOR AUTHORIZATION NUMBER [xxxxxx]	
E. F. G. H.			
I. J. K. L.			

#### 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 XX				11				11104				A				[XX]				NPI			
2 XX XX XX XX XX XX				11				11105				A				[XX]				NPI			
3				24A		24B		24D				24E				24G				NPI			
4																				NPI			
5																				NPI			
6																				NPI			
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. _____								a. NPI b. _____							

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)



# 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

PAGE ____ OF ____		CREATION DATE		TOTALS	
50 PAYER NAME		51 HEALTH PLAN ID		52 REL INFO	53 ASG BEN
				54 PRIOR PAYMENTS	55 EST. AMOUNT DUE
					56 NPI
					57 OTHER
					PRV ID
58 INSURED'S NAME		59 P REL	60 INSURED'S UNIQUE ID		61 GROUP NAME
					62 INSURANCE GROUP NO.
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	I	J
69 ADMIT DX	70 PATIENT REASON DX	a. OTHER PROCEDURE CODE	b. OTHER PROCEDURE CODE	71 PPS CODE	72 ECI
74 PRINCIPAL PROCEDURE CODE	75	c. OTHER PROCEDURE CODE	d. OTHER PROCEDURE CODE	e. OTHER PROCEDURE CODE	76 ATTENDING NPI
					QUAL
					LAST
					FIRST
					77 OPERATING NPI
					QUAL
					LAST
					FIRST
					78 OTHER NPI
					QUAL
					LAST
					FIRST
					79 OTHER NPI
					QUAL
					LAST
					FIRST
80 REMARKS		81CC a	b	c	d

#### 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.

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](#).

#### 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).



# 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. CNTRL. #		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
				CONDITION CODES			
21	22	23	24	25	26	27	28
				29 ACDT STATE 30			
31 OCCURRENCE DATE	32 CODE	33 OCCURRENCE DATE	34 CODE	35 OCCURRENCE DATE	36 CODE	37 OCCURRENCE DATE	38 CODE
				39 VALUE CODES AMOUNT			
				40 CODE			
				41 CODE			
				42			
				43			
				44			
				45			
				46			
				47			
				48			
				49			

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

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

#### 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.

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

**zevaskyn**<sup>®</sup>  
(prademagene zamikeracel)  
gene-modified cellular sheets





# 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.

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# Indication and Important Safety Information

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## 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](#).

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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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