



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.

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.

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



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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 Information

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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 cm² 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 cm², 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](#).


zevaskyn®
(prademagene zamikeracel)
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 cm². Up to twelve ZEVASKYN sheets may be manufactured from a patient's biopsies.

1



Biopsy Cell Collection¹

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 Transduced¹

Transduction occurs with a functional COL7A1 transgene

2A



COL7A1 Gene Transduction¹

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

3



Cell Expansion¹

Transduced cells are expanded

4



Seeding¹

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 Delivery¹

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

6



Surgical Application¹

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



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Biopsy Cell Collection

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Biopsy Cell Collection¹

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 ²	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 ³	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](#).





Surgical Application

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Surgical Application¹

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 ²	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 ⁴	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.

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





Surgical Application (cont'd)

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Surgical Application¹

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 ⁵	Description
J3389	Topical administration, ZEVASKYN, prademagene zamikericel, per treatment

NDC Code

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

NDC ¹		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 ²⁻⁵	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 ⁶	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 ⁷	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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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)

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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

PICA <input type="checkbox"/> <input type="checkbox"/>		PICA <input type="checkbox"/> <input type="checkbox"/>	
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"/>	
4. INSURED'S NAME (Last Name, First Name, Middle Initial)		4. INSURED'S NAME (Last Name, First Name, Middle Initial)	
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"/>	
7. INSURED'S ADDRESS (No., Street)		7. INSURED'S ADDRESS (No., Street)	
CITY STATE		CITY STATE	
8. RESERVED FOR NUCC USE		8. RESERVED FOR NUCC USE	
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)		10. IS PATIENT'S CONDITION RELATED TO:	
11. INSURED'S POLICY GROUP OR FECA NUMBER		11. INSURED'S POLICY GROUP OR FECA NUMBER	
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.		13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.	
SIGNED _____ DATE _____		SIGNED _____	
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL. _____		15. OTHER DATE MM DD YY QUAL. _____	
16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY		17. NAME OF REFERRING PROVIDER OR OTHER SOURCE	
18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY		17a. _____ 17b. NPI _____	
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. <u>Q81.2</u> B. _____ C. _____ D. _____		23. PRIOR AUTHORIZATION NUMBER [xxxxxx] 23	
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.

Please see Indication and Important Safety Information for ZEVASKYN on page 18 and full Prescribing Information.





Sample Claim Forms (cont'd)

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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) CPT/HCPCS MODIFIER			E. DIAGNOSIS POINTER	F. \$ CHARGES		G. DAYS OR UNITS	H. EPSON Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
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															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			
		<input type="checkbox"/> <input type="checkbox"/>				<input type="checkbox"/> YES <input type="checkbox"/> NO		\$		\$					
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 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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Please see Indication and Important Safety Information for ZEVASKYN on page 18 and full Prescribing Information.





Sample Claim Forms (cont'd)

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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 ASSG 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	67 67A-67Q	Q81.2	B	C	D	E	F	G	H	68
69 ADMIT DX	70 PATIENT REASON DX	a. OTHER PROCEDURE CODE	b. OTHER PROCEDURE DATE	c. OTHER PROCEDURE CODE	d. OTHER PROCEDURE DATE	71 PPS CODE	72 ECI	73		
74 PRINCIPAL PROCEDURE CODE	75	76 ATTENDING NPI		77 OPERATING NPI		78 OTHER NPI		79 OTHER NPI		
80 REMARKS		81CC a	b	c	d	LAST		FIRST		
						LAST		FIRST		
						LAST		FIRST		
						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 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. CNTL. #		4 TYPE OF BILL	
				b. MED. REC. #		01X	
				5 FED. TAX NO.		6 STATEMENT COVERS PERIOD FROM THROUGH	
8 PATIENT NAME		9 PATIENT ADDRESS					
10 BIRTHDATE		11 SEX		12 DATE		13 HR	
14 TYPE		15 SRC		16 DHR		17 STAT	
18		19		20		21	
22		23		24		25	
26		27		28		29 ACDT STATE	
30		31 OCCURRENCE DATE		32 OCCURRENCE DATE		33 OCCURRENCE DATE	
34 OCCURRENCE DATE		35 OCCURRENCE DATE		36 OCCURRENCE DATE		37 OCCURRENCE DATE	
38		39 CODE		40 CODE		41 CODE	
		a 87		b XXXXXX XX		c	
		d		39-41			
42 REV. CD.		43 DESCRIPTION		44 HCPCS / RATE / HIPPS CODE		45 SERV. DATE	
0892		Special Processed Drugs - FDA Approved Gene Therapy (Effective 4/1/20)		J3490		46 SERV. UNITS	
42		43		44		46	
						47 TOTAL CHARGES	
						XXXXXX	
						48 NON-COVERED CHARGES	
						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 Codes⁸
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.

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

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





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](#).



Product Information

Treatment Journey

Biopsy Cell Collection

Surgical Application

Coding Summary

Sample Claim Forms

Abeona Assist[®] Patient Support Program

Important Safety Information



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 for more information.

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



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