



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.



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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

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.



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

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


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gene-modified cellular sheets



Biopsy Cell Collection

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

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](#).

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Surgical Application

6



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
XHROXGA	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 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 zamikericel, 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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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

PICA										CARRIER							
1. MEDICARE (Medicare#)		MEDICAID (Medicaid#)		TRICARE (DoD#)		CHAMPVA (Member ID#)		GROUP HEALTH PLAN (ID#)		FECA BLKLNG (ID#)	OTHER (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)	
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)			
CITY				STATE				8. RESERVED FOR NUCC USE		CITY		STATE					
ZIP CODE		TELEPHONE (Include Area Code) ()		ZIP CODE		TELEPHONE (Include Area Code) ()											
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)												10. IS PATIENT'S CONDITION RELATED TO: a. EMPLOYMENT? (Current or Previous) <input type="checkbox"/> YES <input type="checkbox"/> NO		11. INSURED'S POLICY GROUP OR FECA NUMBER a. INSURED'S DATE OF BIRTH MM DD YY			
b. RESERVED FOR NUCC USE												b. AUTO ACCIDENT? <input type="checkbox"/> YES <input type="checkbox"/> NO		b. SEX M <input type="checkbox"/> F <input type="checkbox"/>			
c. RESERVED FOR NUCC USE												c. OTHER ACCIDENT? <input type="checkbox"/> YES <input type="checkbox"/> NO		c. OTHER CLAIM ID (Designated by NUCC)			
d. INSURANCE PLAN NAME OR PROGRAM NAME												d. INSURANCE PLAN NAME OR PROGRAM NAME		d. INSURANCE PLAN NAME OR PROGRAM NAME			
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.												10d. CLAIM CODES (Designated by NUCC)		d. IS THERE ANOTHER HEALTH BENEFIT PLAN? <input type="checkbox"/> YES <input type="checkbox"/> NO			
SIGNED _____ DATE _____														If yes, complete items 9, 9a, and 9d.			
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL: _____				15. OTHER DATE 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 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? \$ CHARGES <input type="checkbox"/> YES <input type="checkbox"/> NO					
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E)												22. RESUBMISSION CODE ORIGINAL REF. NO.					
A. <u>Q81.2</u>		B. _____		C. _____		D. <u> </u>		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)

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. _____								
24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY B. PLACE OF SERVICE C. EMG D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS E. MODIFIER F. DIAGNOSIS POINTER												F. \$ CHARGES	G. DAYS OR UNITS	H. EPDS/ Pmt	I. ID, QAL.	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	24A			24B			24D			24E			24G						
4																			
5																			
6																			
25. FEDERAL TAX I.D. NUMBER				SSN EIN		26. PATIENT'S ACCOUNT NO.			27. ACCEPT ASSIGNMENT? (For govt. claims, see back)		28. TOTAL CHARGE		29. AMOUNT PAID		30. Rsvd for NUCC Use				
									<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.			a. NPI		b.					
NUCC Instruction Manual available at: www.nucc.org																			
PLEASE PRINT OR TYPE																			
APPROVED OMB-0938-1197 FORM 1500 (02-12)																			

PHYSICIAN OR SUPPLIER INFORMATION

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)

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

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

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.



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

1		2		3a. PAY CONT'D		4. TYPE OF BILL																			
				b. MED REC #		013X Hospital Outpatient																			
				5. FED. TAX NO.		6. STATEMENT COVERS PERIOD FROM _____ THROUGH _____																			
						7.																			
8. PATIENT NAME		a. PATIENT ADDRESS		b.		c.																			
b.		b.		c.		d.																			
10. BIRTH DATE		11. SEX		12. DATE		13. ADMISSION HR		14. TYPE		15. SRC		16. DHR		17. STAT		18. 19. 20. 21.		22. CONDITION CODES 23. 24. 25. 26.		27. 28.		29. ACCT#		30. STATE	
31. OCCURRENCE CODE		32. OCCURRENCE CODE		33. OCCURRENCE CODE		34. OCCURRENCE CODE		35. CODE		36. CODE		37. CODE		38.		39. CODE		40. CODE		41. CODE		42. CODE			
DATE		DATE		DATE		DATE		CODE		CODE		CODE		OCCURRENCE SPAN FROM _____ THROUGH _____		CODE		CODE		CODE		OCCURRENCE SPAN FROM _____ THROUGH _____		CODE	
a.		b.		c.		d.		a.		b.		c.		d.		a.		b.		c.		d.		a.	
42. REV. CD.		43. DESCRIPTION		44. HCPCS / RATE / HIPPS CODE		45. SERV. DATE		46. SERV. UNITS		47. TOTAL CHARGES		48. NON-COVERED CHARGES		49.											
0500		General		11104- Punch biopsy of skin (including simple closure, when performed); single lesion				1																	
0500		General		11105- Each separate/additional lesion (List separately in addition to code for primary procedure)				1																	
42		43		44		45		46		47		48		49											

42

Revenue Codes

Enter revenue codes.

Revenue codes describe settings, services, and procedures.

43

Description

Enter description.

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

44

HCPCS/Rate/HIPPS Code

Enter the appropriate HCPCS and CPT® codes.

If the biopsy will be performed in a hospital 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)

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

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. Be sure to accurately enter the total amount for each line item.

For ZEVASKYN, 1 will always be entered.



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gene-modified cellular sheets



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

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 #	011X				
		5 FED. TAX NO.	6 STATEMENT COVERS PERIOD FROM _____ THROUGH _____				
			7				
8 PATIENT NAME	a	9 PATIENT ADDRESS	a				
b	b	c	d				
10 BIRTHDATE	11 SEX	12 DATE ADMISSION 13 HR 14 TYPE 15 SRC 16 DHR 17 STAT	18 19 20 21 CONDITION CODES 22 23 24 25 26 27 28 29 ACDT 30 STATE				
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 CODE VALUE CODES AMOUNT	40 CODE VALUE CODES AMOUNT	41 CODE VALUE CODES AMOUNT				
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		
42	43	44		46	47		

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.



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.		57 OTHER PRV ID	
63 TREATMENT AUTHORIZATION CODES				64 DOCUMENT CONTROL NUMBER			65 EMPLOYER NAME			
[xxxxxx]				63						
66 DX	67A- 67Q	Q81.2	B	C	D	E	F	G	H	68
69 ADMIT DX		J	K	L	M	N	O	P	Q	73
70 PATIENT REASON DX		a	b	c	d	e	f	g	h	
74 PRINCIPAL PROCEDURE CODE		a.	OTHER PROCEDURE CODE	b.	OTHER PROCEDURE CODE	c.	71 PPS CODE	d.	e.	75
XHR3XGA	XXXX XX	XHR5XGA	XXXX XX				72 ECI			
c. OTHER PROCEDURE CODE	OTHER PROCEDURE DATE	74	OTHER PROCEDURE CODE	OTHER PROCEDURE DATE	e. OTHER PROCEDURE CODE	OTHER PROCEDURE DATE				
80 REMARKS		81CC a						76 ATTENDING LAST	NPI	QUAL
[NAME]; [DOSAGE]; NDC		b						77 OPERATING LAST	NPI	QUAL
		c						78 OTHER LAST	NPI	QUAL
		d						79 OTHER LAST	NPI	QUAL
										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

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).

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®
(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.

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





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
Information

Treatment
Journey

Biopsy Cell
Collection

Surgical
Application

Coding
Summary

Sample
Claim Forms

Abeona Assist™
Patient Support
Program

Important
Safety
Information

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 **5.** American Academy of Professional Coders (AAPC). CPT® Codes Lookup. Accessed February 27, 2025. <https://www.aapc.com/codes> **6.** Nорidian Healthcare Services. Revenue Codes. Accessed January 23, 2025. <https://med.noridianmedicare.com/web/jea/topics/claimsSubmission/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-ipps-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 for more information.

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



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