



Qualified Treatment Center Access and Reimbursement Guide

The ZEVASKYN Qualified Treatment Center (QTC) Access and Reimbursement Guide is a resource designed to support providers and staff in helping patients gain access to treatment.

This guide can help identify the steps in the access process and provide the tools necessary to navigate ZEVASKYN reimbursement.

Use of the information in this guide does not guarantee approval or prevent denials, delays, or differences of opinion with payers. This guide is based on best practices, but we do not guarantee that the forms or guidance offered herein will accelerate payment processes for service providers. Abeona Therapeutics presents this information for convenience purposes only; it does not serve as legal advice or a medical practice recommendation.

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 ≥5%) are procedural pain and pruritus.

Please see additional Important Safety Information on page 15 and full [Prescribing Information](#).





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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-corrected skin cells are expanded into credit card-sized epidermal 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 ~480 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 Indication and Important Safety Information for ZEVASKYN on page 15 and full [Prescribing Information](#).


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Abeona Assist™ Patient Support Program



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

About Abeona Assist

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

Assistance for Patients and Caregivers

Call Abeona Assist to investigate coverage benefits for ZEVASKYN and the wide range of benefits and resources that may be available for eligible patients.*



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

Patient Navigators are members of the Abeona Assist team that provide valuable product information, offer onsite logistical support while at the QTC receiving treatment. Patient Navigators will:

- Guide patients through the Abeona support offerings
- Tailor support to meet patients' and caregivers' specific needs
- Identify additional resources that may be available to patients

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

*Eligibility requirements apply.



Patient Access Journey

Diagnosis and Abeona Assist™ Enrollment

ZEVASKYN QTC

- Consultation to determine if ZEVASKYN is an appropriate treatment
- Genetic testing if required by insurance

1

Abeona Assist*

- Abeona Assist enrollment
 - Enrollment can be completed online, via PDF, or on the phone, by the patient, caregiver, or HCP
 - Patients and caregivers will be guided through available resources and support, tailored to specific needs

Request Payer Approval

ZEVASKYN QTC

- Confirm the patient's insurance information
- Support clinical eligibility with medical documentation
- Establish single case agreements by negotiating individual contracts between HCPs and insurance companies to cover ZEVASKYN when it is not included in a provider's network

2

Abeona Assist

- Conduct an initial benefits investigation to verify insurance coverage, including copayments, deductibles, and PA requirements to help understand coverage prior to treatment with ZEVASKYN
- Provide copay assistance for eligible commercially insured patients

Treatment Authorization

ZEVASKYN QTC

- Insurers may require submission of a PA or LMN with the provider's rationale for treatment coverage and documentation of a patient's relevant medical history, before making a coverage decision

3

Abeona Assist

- Advise patients who must travel across state lines to access treatment with ZEVASKYN to understand coverage approval from their Medicaid plan or state agency may be required
- Provide billing and coding information to support treatment authorization

4

If Treatment with ZEVASKYN Is Approved by Insurance Provider, the Biopsy Scheduling Begins

Note: Abeona Assist cannot complete any prior authorization or letter of medical necessity documents, or fill out any forms on behalf of the HCP. Abeona Assist is not involved in the process of determining medical necessity.

HCP=healthcare providers; LMN=letter of medical necessity; PA=prior authorization; QTC=qualified treatment center.

*Patients who do not enroll in Abeona Assist will not be eligible for support and services provided through Abeona Assist.

Please see Indication and Important Safety Information for ZEVASKYN on page 15 and full [Prescribing Information](#).


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Treatment Journey

ZEVASKYN is an autologous cell sheet-based gene therapy. One sheet of ZEVASKYN covers an area of 41.25 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 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



Requesting Payer Approval

Abeona Assist cannot complete any forms (e.g., PA, LMN) or submit any claims on behalf of the provider or patient. Abeona Assist can assist with an insurance benefit investigation/verification; however, Abeona Assist cannot assist with any negotiations with the payers.

Benefit Verification

Healthcare providers or pharmacists may conduct a benefits investigation to ensure patients receive the maximum coverage available under their insurance plan. This process typically involves verifying coverage details, such as:

- PA requirements
- Copayments
- Deductibles

Multiple payers may cover benefits for patients who qualify for ZEVASKYN (e.g. commercial health plans and Medicaid/Medicare). Providers should work to determine the primary, secondary, and tertiary payers, if applicable, during the benefits investigation process. Once the order of benefits is established, it is important to adhere to each payer's instructions regarding the coordination of benefits for reimbursement or payment.

Patients who must travel across state lines to access treatment with ZEVASKYN may need coverage approval from their Medicaid plan or state agency.

Preparing the Patient's Insurance Information



During your patient's first visit, be sure to gather the following information:

- ✓ Primary and secondary insurance information
- ✓ Copy of patient's/policyholder's medical and pharmacy insurance benefit cards, front and back
- ✓ Contact information for patient and their caregiver(s), including phone numbers and email addresses

Establishing Single Case Agreements

Establishing a single case agreement requires negotiating an individual contract between the QTC and the insurer to cover ZEVASKYN when it is not included in the payer's network. Providers should submit a request detailing the patient's needs and treatment plan to the insurer, who will then evaluate and establish terms for reimbursement.



Requesting Payer Approval (cont'd)

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Confirming Clinical Eligibility

Review the patient's medical history to ensure there is documentation of RDEB pathology. Insurance companies may require documentation of the patient's medical history, genetic testing, and/or diagnostic and baseline assessments. Relevant test results may include, but are not limited to 2 confirmed RDEB C7 mutations with recessive inheritance patterns.

Completing and Submitting Relevant Forms

Insurance companies may ask for a PA or LMN before deciding on coverage. When submitting a PA or LMN, supplementary materials such as additional relevant medical documentation, care coordination information, and your personal history managing the patient's RDEB can be included for additional context.

Letter of Medical Necessity*

SAMPLE LETTER OF MEDICAL NECESSITY

[Patient Contact]
[Patient Name]
[Patient Address]
[Patient City, State Zip]
[Patient DOB]

[Patient Insurance ID#]
[Patient Group#]
[Reference Number if Available]

Dear [Insurance Company Contact],

I am writing on behalf of my patient, [Patient Name, Date of Birth] to demonstrate medical necessity for the coverage of ZEVRASKYN® (prademagene zamikeracel, pz-cel). This letter of medical necessity includes the patient's relevant past medical history, overview of prior care delivered, treatment rationale and supporting medical necessity data.

ZEVRASKYN was approved by the U.S. Food and Drug Administration on XX, 2025. *Insert Indication.* This request is supported by the following information:

Summary of Patient's History

- [Patient's age, diagnosis, date of diagnosis]
- [Laboratory results and date if applicable]
- [Brief description of patient's current medical condition]
- [Patient's previous and current treatments/therapies]

Treatment Rationale

- [Patient's response to treatments/therapies]
- [If the patient has discontinued, include information on lack of response or tolerability]
- [Anticipated prognosis]
- [Rationale for ZEVRASKYN]
- [Supporting Data, if applicable]

It is my professional opinion that treatment of [Patient Name] with ZEVRASKYN is medically necessary based on the evidence summarized above. If you need additional information for a timely approval, please do not hesitate to contact my office at [Phone Number].

Sincerely,

[Physician's Signature]
[Physician's Name]
[Name of QTC/Hospital]
[Phone Number]

Enclosures: attach as appropriate [ZEVRASKYN Prescribing Information]

Letter of Medical Necessity

Criteria for assessing medical necessity may differ depending on the payer. Providers should draft this letter on official letterhead. It should include relevant information that payers may require when establishing medical necessity, including:

- Patient's medical history (e.g., diagnosis, current condition, prior treatments)
- A summary of the clinical assessment and the rationale for requesting coverage

*The information on this form/letter is for informational purposes only and serves as a convenient reference for healthcare providers. It is not intended as medical or legal advice, is not a substitute for a provider's independent professional judgment, and does not guarantee coverage or payment. Healthcare providers should verify coverage for individual patients directly with their insurance providers.

Please see Indication and Important Safety Information for ZEVRASKYN on page 15 and full [Prescribing Information](#).


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Requesting Payer Approval (cont'd)

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Prior Authorization Checklist

Obtaining a PA is necessary when a patient with RDEB faces restricted access to treatment with ZEVASKYN. Healthcare providers may seek a PA from an insurer to obtain approval for treatment with ZEVASKYN. Prior authorization requirements and the treatments necessitating PA can differ among insurers, so it is helpful to contact the plan's customer service for specific details such as required forms and contact information. Abeona Assist™ can help you navigate the PA form submission process.



This checklist serves as a reference for the information typically needed for PA submissions. Insurance companies have their own preferred PA forms, which can typically be found on the insurer's website. It is important to review payer policies for the most up-to-date requirements, as the checklist merely outlines the general scope of required information and does not constitute medical advice or ensure approval or payment/reimbursement.

Help patients start treatment without delay.

Gather Important Information:

- ✓ Investigate the PA requirements for the patient's insurance plan
- ✓ Provide relevant patient medical history, including:
 - Diagnosis and the appropriate ICD-10-CM code(s)
 - Patient symptoms and test results

Provide Relevant Information to the Payer:

- ✓ Patient name, address, date of birth, gender, and insurance policy number
- ✓ Provider name, specialty, address, National Provider Identifier, and office/fax numbers



Managing Denials and Appeals

Abeona Assist cannot complete any forms (e.g., PA, LMN) or submit any claims on behalf of the provider or patient. Abeona Assist can assist with an insurance benefit investigation/verification; however, Abeona Assist cannot assist with any negotiations with the payers.

Denied ZEVASKYN Coverage

Healthcare denials occur when a payer rejects an HCP's reimbursement claim for a medical service or treatment due to eligibility, coverage, or documentation issues, resulting in nonpayment. Denial of coverage can significantly impact patients' access to necessary treatments and healthcare services. By law, insurance companies are required to provide patients and their healthcare providers with a written rationale for claim denials. Common causes for denials include, but are not limited to:

- Perceived lack of medical necessity
- Inaccurate or incomplete patient information
- Billing or coding errors
- Non-covered services or treatments
- Out-of-network provider or facility

Many specialty drugs are denied coverage after an initial PA request. Gaining approval following a denial requires additional effort by the healthcare provider, as an appeal will need to be submitted.

Overview of Appeals

A coverage denial appeal is a formal request by a healthcare provider for the insurance company to reconsider a denied claim, typically requiring additional evidence to validate the claim and seek coverage for the service or treatment.

Letter of Appeal*

SAMPLE LETTER OF APPEAL

The following sample letter of appeal is provided for illustrative purposes only. It is intended for use by Qualified Treatment Centers (QTCs) in drafting a letter of appeal following a denial of coverage for ZEVASKYN[®] (prademagene zamikeracel). This example offers a framework for a clinical rationale and demonstrating the medical necessity of ZEVASKYN for the patient. It also identifies key documentation to support the treatment decision. Colored text is for you to customize.

(INSERT ON QTC/PHYSICIAN LETTERHEAD)

Re: Appeal of denied coverage for ZEVASKYN[®] (prademagene zamikeracel)

(Date)

(Insurance Company Contact) (Insurance Company Name) (Insurance Company Address) (Insurance Company City, State Zip)	(Insured Name) (DOB) (Patient Name) (Patient Insurance ID#) (Patient Insurance Group#) (Policy Number if Available)
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Dear (Insurance Company Contact Name):

I am writing to appeal your denial of coverage for ZEVASKYN for my patient, (Patient Name), a (age)-year-old (male/female) diagnosed with recessive dystrophic epidermolysis bullosa (RDEB), ICD-10-CM Q81.2, on (date). Please note that there is no ICD-10-CM code specifically for RDEB.

According to your denial letter dated (insert date), coverage was denied due to: (reason stated in the denial letter). I urge you to reconsider based on the following medical rationale.

ZEVASKYN received FDA approval on (Month XX, 2025) as the only autologous cell sheet-based gene therapy indicated for the treatment of wounds in both adult and pediatric patients with RDEB.

(Patient Name) has a confirmed diagnosis of RDEB, a debilitating condition characterized by chronic, painful, blistering wounds and an increased risk of life-threatening complications. A summary of (his/her) clinical background is as follows:

- (Laboratory results and date if applicable (eg, genetic testing for COL7A1 mutation))
- (Brief description of patient's current medical condition)

Letter of Appeal

Policies for appealing coverage denial can vary among payers. Providers should draft their letter on official letterhead and refer to the PA denial letter to determine what documentation the payer requires for coverage or authorization reconsideration. The letter should include relevant information that payers may require when appealing a denial of coverage, including:

- Patient's diagnosis
- Information about the denied treatment
- Patient's medical history, including prior treatments
- A summary of the clinical assessment and the rationale for requesting coverage

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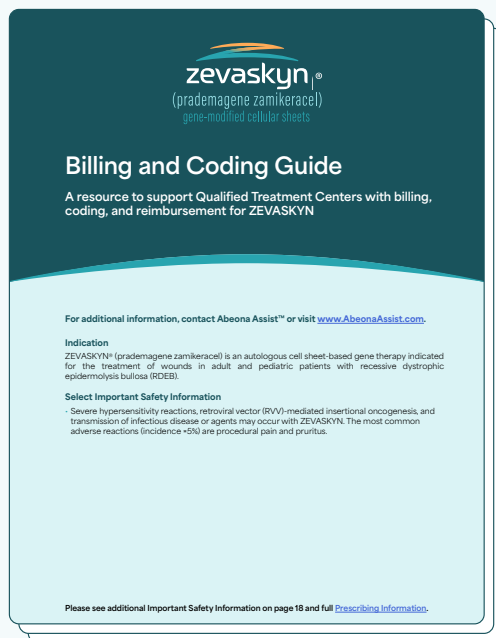
Please see Indication and Important Safety Information for ZEVASKYN on page 15 and full [Prescribing Information](#).

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Billing and Coding

Billing & Coding Guide



The Billing and Coding Guide provides Qualified Treatment Centers with billing and coding information related to ZEVASKYN. This resource identifies possible billing codes and provides sample claim forms to help navigate the ZEVASKYN reimbursement process.

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.

Access Billing & Coding Guide ►

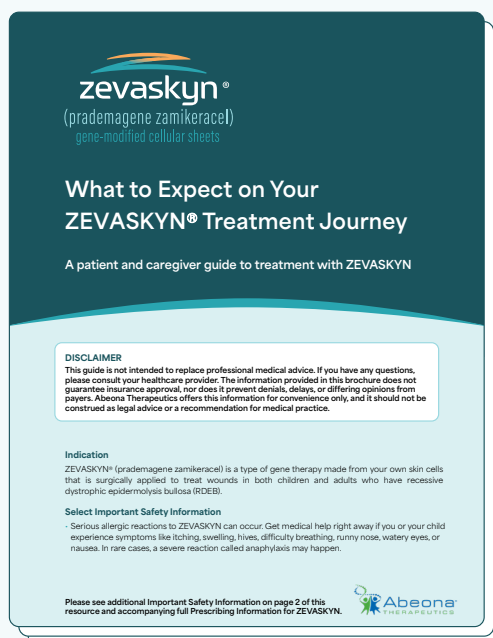
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Patient Resources

What to Expect on Your ZEVASKYN® Treatment Journey



Patients enrolled in Abeona Assist will receive What to Expect on Your ZEVASKYN Treatment Journey, a resource that reviews the patient journey and provides detailed information for patients and caregivers on what to expect at every step of treatment with ZEVASKYN.

Patient Brochure



The Patient Brochure is an educational resource for patients and caregivers to learn more about treatment with ZEVASKYN. It provides an overview of the ZEVASKYN manufacturing process, clinical trial outcomes, and Important Safety Information. Patients can also find resources in the brochure, such as Abeona Assist and helpful questions to ask their care team.

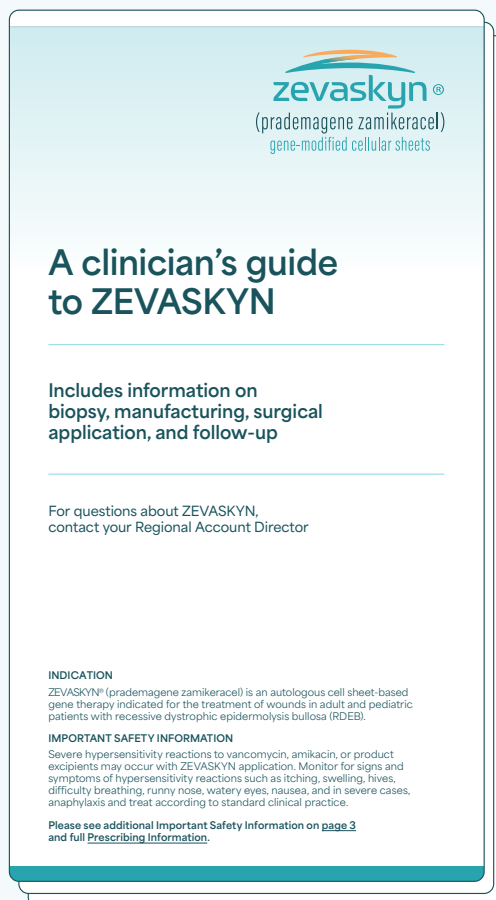
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Provider Resources

A Clinician's Guide to ZEVASKYN



The clinician's guide includes an overview of treatment with ZEVASKYN and more detailed information on the biopsy procedure, manufacturing of ZEVASKYN, surgical application of ZEVASKYN, and follow-up care.

INDICATION

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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 on [page 3](#) and full [Prescribing Information](#).



Important Safety Information

Indication

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Important Safety Information

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- 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.

Introduction

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References: 1. ZEVASKYN. Prescribing information. Abeona Therapeutics; 2024.

Please visit www.AbeonaAssist.com for more information.

Please see Indication and Important Safety Information for ZEVASKYN on page 15 and full [Prescribing Information](#).



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