HIGHMARK WHOLECARE

Updated: 08/2025
PARP Approved: 01/2026

Prior Authorization Criteria

Vyjuvek (beremagene geperpavec)

All requests for Epidermolysis bullosa (EB) Products require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Epidermolysis bullosa (EB) products include Filsuvez (birch triterpenes), Vyjuvek (beremagene geperpavec), and Zevaskyn (pradamagene zamikeracel). New products with this classification will require the same documentation.

For all requests for EB Products, all of the following criteria must be met in addition to the product-specific criteria below:

- Must be prescribed by or in consultation with a dermatologist
- Must have an open wound with no evidence or history of squamous-cell carcinoma or active infection
- Must not be used in combination with another EB Product on the same wound
- Must be age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines

For Filsuvez (birch triterpenes):

- Must have a diagnosis of Dystrophic Epidermolysis Bullosa (DEB) or Junctional Epidermolysis Bullosa (JEB) confirmed by genetic testing.
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
  - Must meet all initial criteria and provide documentation of improvement in wound healing (e.g. decrease in wound size for ongoing treatment, wound closure of separate and previously-treated wounds)
- **Reauthorization Duration of Approval:** 12 months

For Vyjuvek (beremagene geperpavec):

- Must have a diagnosis of Dystrophic Epidermolysis Bullosa (DEB)
- Must have a mutation in the *collagen type VII alpha 1 chain* (COL7A1) gene confirmed by genetic testing
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
  - Must meet all initial criteria and provide documentation of improvement in wound healing (e.g. decrease in wound size for ongoing treatment, wound closure of separate and previously-treated wounds)
- **Reauthorization Duration of Approval:** 12 months

For Zevaskyn (prademagene zamikeracel) gene-modified cellular sheets:

- Must have a diagnosis of Recessive Dystrophic Epidermolysis Bullosa (BDEB)
- Must have a biallelic mutation in the *collagen type VII alpha 1 chain* (COL7A1) gene confirmed by genetic testing
- Must have positive expression of the non-collagenous region 1 of the type 7 collagen protein (NC1+) in the skin
- Must have a chronic open wound (open for at least 6 months) that has NOT previously been treated with this or another EB therapy (e.g. Filsuvez, Vyjuvek)
- **Duration of approval:** 1 treatment course (per lifetime)

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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EPIDERMOLYSIS BULLOSA (EB) PRODUCTS PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Wholecare Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (800) 392-1147 Mon – Fri 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	Provider NPI:
Provider Specialty:	Office Contact:
State license #:	Office NPI:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:	ICD Code:

Is there an open wound with no evidence or history of squamous-cell carcinoma or active infection? ☐ Yes ☐ No
Will this be used in combination with any other EB-specific treatment on the same wound? ☐ Yes ☐ No

For Vyjuvek and Zevaskyn: Has the mutation in the *collagen type VII alpha 1 chain* (COL7A1) gene confirmed by genetic testing? ☐ Yes ☐ No

For Zevaskyn:
Is there positive expression of the non-collagenous region 1 of the type 7 collagen protein (NC1+) in the skin? ☐ Yes ☐ No
Has the wound to be treated been open for at least 6 months? ☐ Yes ☐ No
Has the wound(s) to be treated been previously treated with another EB-specific therapy (e.g. Filsuvez, Vyjuvek)? ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Has the member experienced an improvement in wound healing? ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date