

For people aged 6 months and older with dystrophic epidermolysis bullosa (DEB)

# Big or small, each wound healed is a **victory**

**VYJUVEK** is the **FIRST** and **ONLY** treatment that addresses the **genetic cause** of DEB to provide **powerful wound healing** in a topical gel.

See VYJUVEK study results within.

## INDICATION AND USAGE

VYJUVEK is a topical gel used to treat wounds in patients 6 months and older with dystrophic epidermolysis bullosa (DEB).

## IMPORTANT SAFETY INFORMATION

VYJUVEK gel must be applied by a healthcare provider.

After treatment, patients and caregivers should be careful not to touch treated wounds and dressings for 24 hours. If accidentally exposed to the VYJUVEK gel, clean the affected area.

Please see Important Safety Information throughout and click here for full [Prescribing Information](#).

**Vyjuvek**<sup>®</sup>  
beremagene geperpavec-svdt  
5x10<sup>9</sup> PFU/mL single-use vial

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Emily,  
Living with DEB

## Dystrophic epidermolysis bullosa (DEB) is a type of epidermolysis bullosa (EB), a group of serious genetic blistering disorders

The most common symptom of DEB is fragile skin. This can lead to blisters, wounds, skin infections, and scarring.

- ▶ There are 2 types of DEB: dominant and recessive
- ▶ Whether you have dominant DEB (DDEB) or recessive DEB (RDEB), wounds can be large or small, take a long time to heal or not heal at all, and reopen after healing
- ▶ Beyond symptoms you can see on the skin, DEB can affect other organs and body systems, including the eyes, mouth, gastrointestinal tract, and urinary tract
- ▶ In addition to physical symptoms, people with DEB and those who care for them can face significant emotional, mental, and financial burdens

All DEB wounds should be taken seriously. It's possible for any DEB wound to develop complications, such as infections or a certain type of aggressive skin cancer called squamous cell cancer (SCC).

[The Genetic Cause of DEB >>](#)

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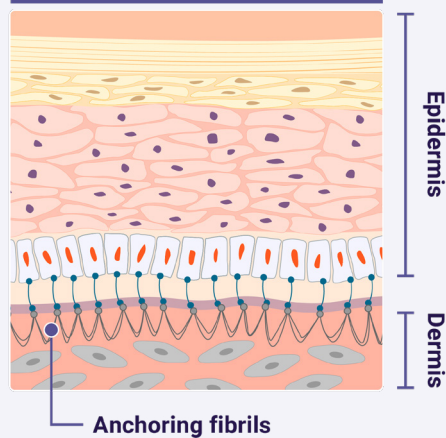
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# DEB is a genetic condition caused by variants in a gene called *COL7A1*

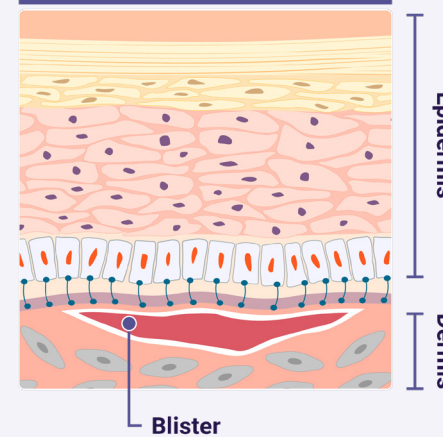
Genes carry instructions that tell the body how to build specific proteins. Changes in the instructions are called gene mutations or variants.

## Skin Not Affected by DEB



- ▶ The *COL7A1* gene carries instructions to make a protein called **type VII collagen (type 7 collagen)**
- ▶ Type VII collagen protein is the main component of **anchoring fibrils**. Anchoring fibrils help bind the inner skin layer (dermis) and outer skin layer (epidermis) together

## DEB-Affected Skin



- ▶ In people with DEB, the variant in the *COL7A1* gene means the body cannot create enough working **type VII collagen** protein
- ▶ This leads to a lack of or a reduced number of working **anchoring fibrils**. Without anchoring fibrils, the skin layers can easily separate due to friction

Adapted from De Rosa L, Latella MC, Secone Seconetti A, et al. *Cold Spring Harb Perspect Biol.* 2020.

[Learn About a Treatment Option That Addresses the Genetic Cause of DEB >](#)

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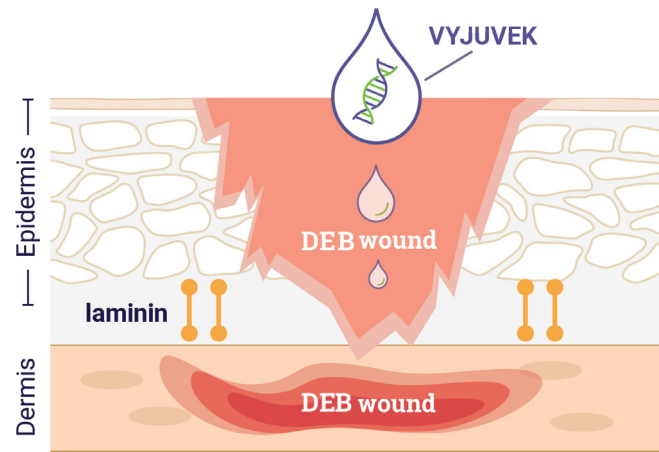
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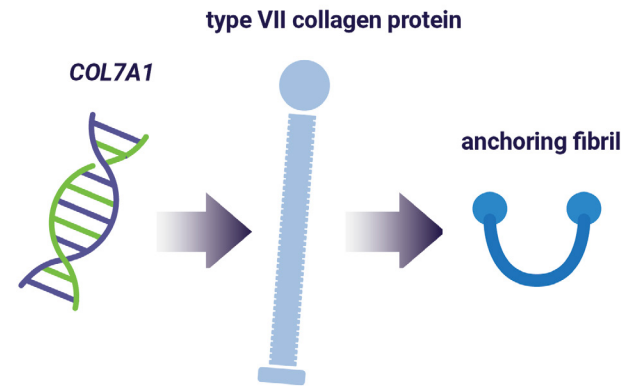
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## VYJUVEK is a topical therapy that delivers new *COL7A1* genes directly to DEB skin wounds to promote wound healing



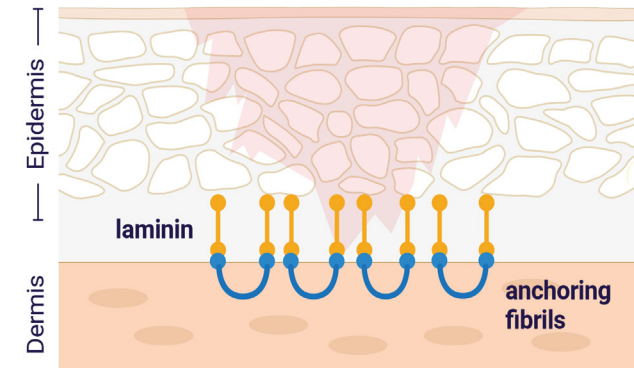
Open wound on skin affected by DEB

VYJUVEK delivers new *COL7A1* genes directly to skin cells in DEB wounds.



New genes form anchoring fibrils

These *COL7A1* genes restore the ability of those cells to make functional **type VII collagen** protein and form **anchoring fibrils**.



Skin treated with VYJUVEK

**Anchoring fibrils** bind the inner skin layer (dermis) and outer skin layer (epidermis) together and promote wound healing.

[How VYJUVEK Was Studied >](#)

### IMPORTANT SAFETY INFORMATION (cont'd)

Wash hands and wear protective gloves when changing wound dressings. Disinfect bandages from the first dressing change with a virucidal agent, and dispose of the disinfected bandages in a separate sealed plastic bag in household waste. Dispose of the subsequent used dressings in a sealed plastic bag in household waste.

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## Wound healing with VYJUVEK was assessed in a clinical study (GEM-3 study) of patients with DEB

**The goal of the study was to evaluate complete wound healing (100% closure).**

- ▶ This study included 31 people, ranging in age from 1 to 44 years old, with dominant DEB or recessive DEB
- ▶ For each person, 2 similar wounds were chosen. One was treated with VYJUVEK and the other received placebo
  - Placebo is a treatment containing no medication that was given to participants the same way as VYJUVEK
- ▶ The main measure of the study was complete wound healing at **6 months**
- ▶ Treatments were applied weekly until wounds were completely healed. Treatment resumed if wound reopened
- ▶ After completion of the GEM-3 study, patients were allowed to enroll in the Open Label Extension study\*



\*The Open Label Extension study was designed to assess long-term safety.

[Complete Wound Healing Results >>](#)

### IMPORTANT SAFETY INFORMATION (cont'd)

Patients should avoid touching or scratching wound sites or wound dressings.

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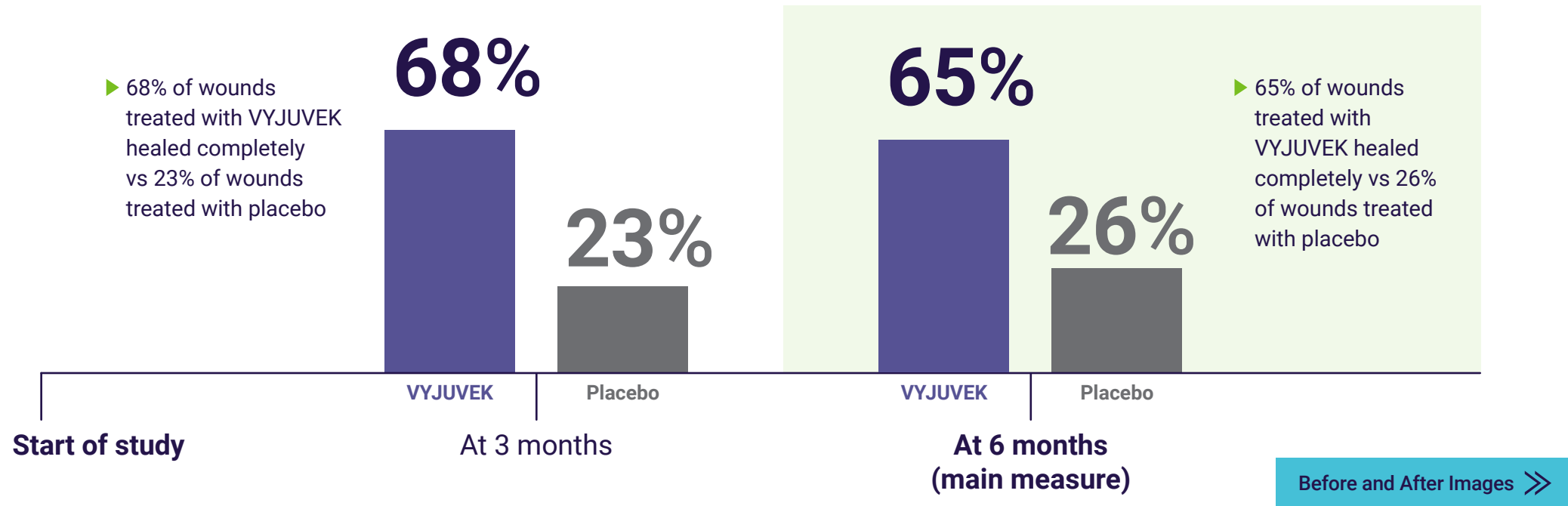
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## VYJUVEK achieved significantly greater complete wound healing (100% closure) compared with placebo

Complete wound healing in 31 patients at 3 and 6 months.



### IMPORTANT SAFETY INFORMATION (cont'd)

The most common adverse reactions (>5%) were itching, chills, redness, rash, cough, and runny nose. These are not all the possible side effects with VYJUVEK. **Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or to the Sponsor at 1-844-557-9782.**

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## Before and after treatment with VYJUVEK— in small, medium, and large wounds

<p>Patient A <b>Small Wound</b> Lower Abdomen Pediatric Female</p>	 <p>Baseline</p>	 <p>6 months</p>	<p>Patient B <b>Medium Wound</b> Knee Pediatric Male</p>	 <p>Baseline</p>	 <p>6 months</p>	
<p>Patient C <b>Medium Wound</b> Shoulder Blade Adult Female</p>	 <p>Baseline</p>	 <p>6 months</p>	<p>Patient D <b>Large Wound</b> Back Adult Male Complete wound closure was achieved 2 months into the Open Label Extension trial following completion of the GEM-3 study.*</p> <p>*The Open Label Extension study was designed to assess long-term safety.</p>	 <p>Baseline</p>	 <p>6 months</p>	 <p>8 months</p>

Across small, medium, and large wounds, VYJUVEK achieved complete wound closure.

[More Wound Healing Data >>](#)

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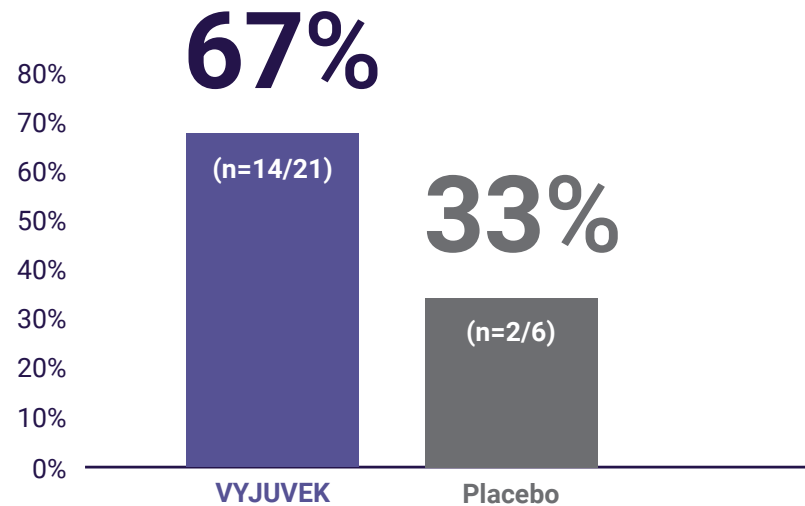
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Of the wounds treated with VYJUVEK that were healed at 3 months, 67% (14/21) were also healed at 6 months\*

Wounds healed at 3 months also healed at 6 months.



\*Data on file.

- ▶ In an analysis done after the study was completed, wounds that were completely healed at 3 months were then reevaluated at 6 months to see what percentage were completely healed
- ▶ These analyses were conducted after the study was completed in an unplanned exploratory analysis of both VYJUVEK-treated and placebo-treated wounds. These findings are based on a limited sample size and should be interpreted carefully

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#### IMPORTANT SAFETY INFORMATION (cont'd)

Wash hands and wear protective gloves when changing wound dressings. Disinfect bandages from the first dressing change with a virucidal agent, and dispose of the disinfected bandages in a separate sealed plastic bag in household waste. Dispose of the subsequent used dressings in a sealed plastic bag in household waste.

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## VYJUVEK was well tolerated by study participants

Most common side effects in 31 people treated with VYJUVEK	
Side effects	Number of people (%)
Itching	3 (10)
Chills	3 (10)
Redness	2 (6)
Rash	2 (6)
Cough	2 (6)
Runny nose	2 (6)

No study participants stopped treatment with VYJUVEK due to side effects.

Treatment with VYJUVEK >

### IMPORTANT SAFETY INFORMATION (cont'd)

Patients should avoid touching or scratching wound sites or wound dressings.

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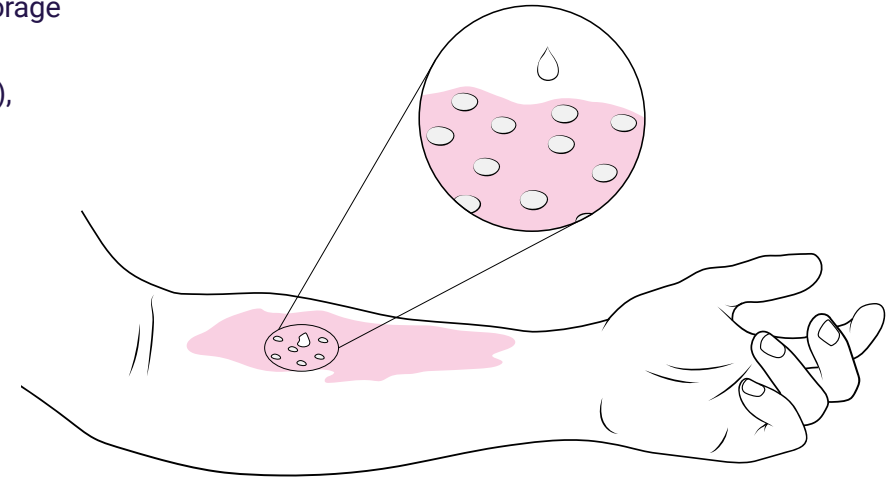
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## Treatment with VYJUVEK

**VYJUVEK gel is applied topically once weekly to promote wound healing.**

### Administration

- ▶ Only a healthcare professional can prescribe and apply VYJUVEK gel. There are special storage and preparation requirements with VYJUVEK
- ▶ VYJUVEK can be administered at a healthcare professional setting (for example, a clinic), or home setting, depending on your doctor's instructions, your insurance plan coverage, and your preference
- ▶ VYJUVEK can be administered in the course of routine bandage changes at home
- ▶ To begin administration, the wound must be unwrapped
- ▶ VYJUVEK gel is then applied in small droplets that are evenly spaced (1 cm by 1 cm apart) on the selected wound to form a thin film after a water-resistant dressing is applied. Other wounds are then treated until the maximum weekly dose is reached. Wounds are covered by a water-resistant dressing. Standard dressings are then applied on top
- ▶ Routine dressing changes can resume after approximately 24 hours
  - Avoid touching treated wounds and dressings for the first 24 hours after application. In case accidental contact happens, flush the affected area with clean water for at least 15 minutes
  - Wash hands and wear protective gloves when changing wound dressings. Disinfect bandages from first dressing change and dispose of disinfected bandages in a separate sealed plastic bag in household waste. Dispose of subsequent used dressings in a sealed plastic bag in household waste



Treatment with VYJUVEK (cont'd) >>>

### IMPORTANT SAFETY INFORMATION (cont'd)

The most common adverse reactions (>5%) were itching, chills, redness, rash, cough, and runny nose. These are not all the possible side effects with VYJUVEK. **Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or to the Sponsor at 1-844-557-9782.**

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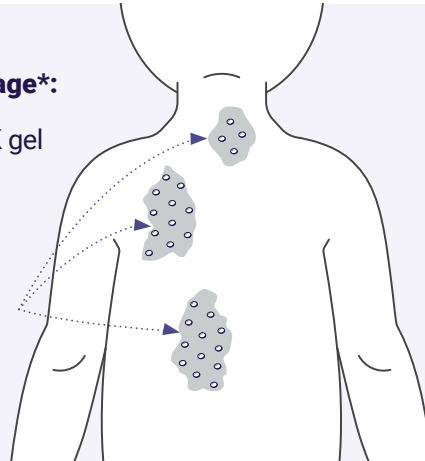
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## Treatment with VYJUVEK (cont'd)

VYJUVEK has a maximum weekly dose dependent on patient age.

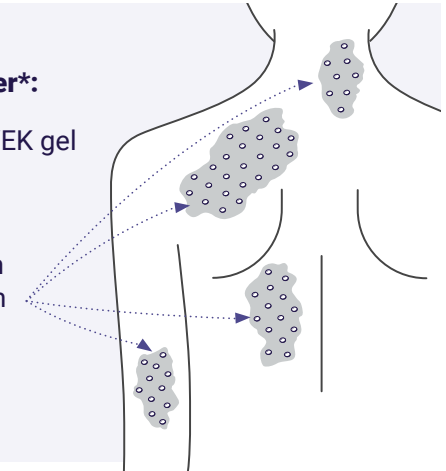
### For individuals 6 months to 3 years of age\*:

- The maximum weekly dose of VYJUVEK gel is a volume of 0.8 milliliters (mL)
- VYJUVEK gel is applied in small droplets, evenly spaced, 1 cm by 1 cm apart, on the selected wounds to form a thin film after a water-resistant dressing is applied



### For individuals 3 years of age and older\*:

- The maximum weekly dose of VYJUVEK gel is a volume of 1.6 milliliters (mL)
- VYJUVEK gel is applied in small droplets, evenly spaced, 1 cm by 1 cm apart, on the selected wounds to form a thin film after a water-resistant dressing is applied



\*For illustrative purposes only. The total surface area covered may vary. Your healthcare provider will follow the 1cm by 1cm application process based on the full Prescribing Information.

[Creating a Treatment Plan >>](#)

### IMPORTANT SAFETY INFORMATION

VYJUVEK gel must be applied by a healthcare provider.

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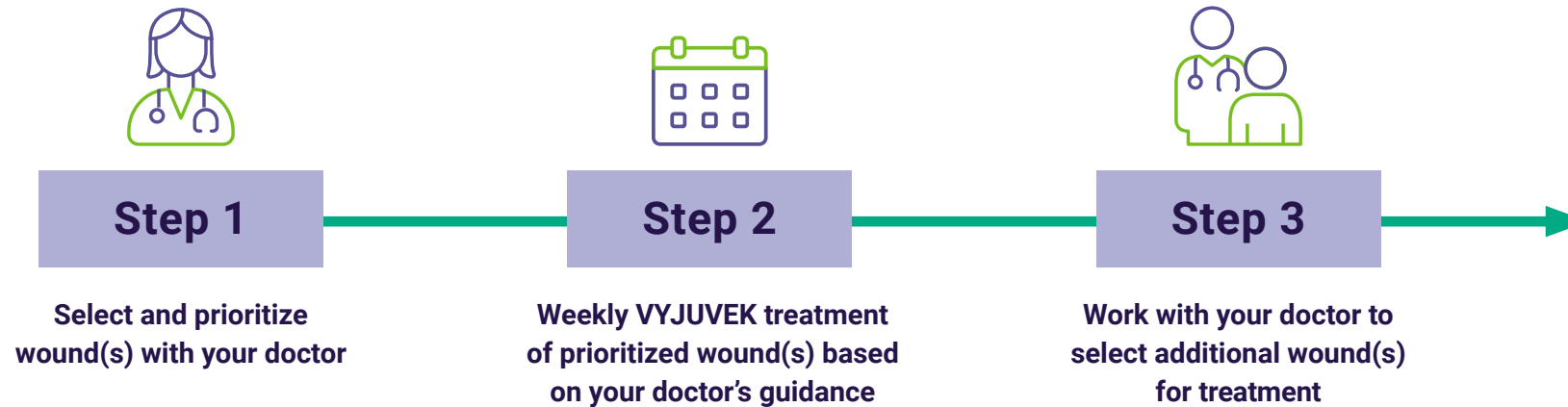
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## Creating a VYJUVEK treatment plan

Because of the maximum weekly dose, it may not be possible to apply VYJUVEK gel to all wounds during your appointment—you and your doctor can work together to create a prioritized wound treatment plan.



It is important to continue weekly treatment of each treated wound(s) until it is fully healed. Once completely healed, other wound(s) can be treated with VYJUVEK. If you miss a dose of VYJUVEK, it should be applied as soon as possible. After that, resume weekly dosing.

[Resources and Support](#) >

### IMPORTANT SAFETY INFORMATION (cont'd)

Wash hands and wear protective gloves when changing wound dressings. Disinfect bandages from the first dressing change with a virucidal agent, and dispose of the disinfected bandages in a separate sealed plastic bag in household waste. Dispose of the subsequent used dressings in a sealed plastic bag in household waste.

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## Krystal Connect is a personalized patient support program to help you throughout your treatment journey

Whether you're considering treatment, ready to start, or looking for more information about DEB, Krystal Connect is here to help you.

When you contact and enroll in Krystal Connect, you will be connected to a dedicated team including your Patient Access Liaison (PAL) and Care Coordinator\*. Your team is available to:

- ▶ Provide education about VYJUVEK and DEB
- ▶ Help you navigate the insurance process
- ▶ Inform you about financial assistance programs. For eligible patients, Krystal Connect may be able to reduce out-of-pocket costs or help locate assistance options
- ▶ Support treatment planning and administration. In preparation for your first appointment, your PAL will be in touch to make sure you have all the information you need and know what to expect
- ▶ Provide information to help you locate a treating doctor in your area



**Eligible patients may pay as little as \$0 for VYJUVEK.**

\*PALs and care coordinators do not direct patient care or provide medical advice.

Setting up Administration >>

### IMPORTANT SAFETY INFORMATION (cont'd)

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## Getting set up for VYJUVEK administration

VYJUVEK can be administered at a healthcare setting or at your home, depending on your doctor's instructions, your insurance plan coverage, and your preference.



**If you and your doctor decide you will receive VYJUVEK in your home,** your Krystal Connect Patient Access Liaison (PAL) will introduce you to the services offered by Option Care Health<sup>®</sup>, a national in-home nursing and pharmacy service. Together, your PAL and Option Care Health team will ensure you have everything needed for in-home administration. They will coordinate the weekly shipping of VYJUVEK to your home and weekly nurse visit to administer it.



**If you and your doctor decide you will receive VYJUVEK in a healthcare setting,** Krystal Connect will work with your healthcare office to schedule your weekly VYJUVEK delivery to the office. You will then work directly with the office to schedule your weekly appointments.

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# Experience VYJUVEK: the **FIRST** and **ONLY** treatment that

- ▶ Addresses the **genetic cause of DEB**
- ▶ Provides **powerful wound healing** in a topical gel

Ask your doctor about VYJUVEK.

**Vyjuvek**<sup>®</sup>  
beremagene geperpavec-svdt  
5x10<sup>9</sup> PFU/mL single-use vial

Sign up for more information  
at [VYJUVEK.com](https://VYJUVEK.com) or call  
1-844-5-KRYSTAL.



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VYJ-2200039 v3.0 February 2024



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## Indication and Usage, and Important Safety Information

### INDICATION AND USAGE

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