  
**BEQVEZ**<sup>™</sup>  
fidanacogene elaparvovec-dzkt  
Suspension for intravenous infusion 1 × 10<sup>13</sup> vg/mL

**BEQVEZ is FDA approved as a one-time gene therapy infusion for eligible adults with moderate to severe hemophilia B**



Tim, who received the BEQVEZ infusion in 2021\*

\*Tim participated in the BEQVEZ clinical study. He was compensated for sharing his story. BEQVEZ is not approved for use in females.



## What is BEQVEZ?

BEQVEZ is a one-time gene therapy used for the treatment of adults with moderate to severe hemophilia B who are receiving routine prophylaxis, or have a current life-threatening bleed or a history of life-threatening bleeds, or have repeated serious spontaneous bleeds.

Before treatment with BEQVEZ, your healthcare professional will conduct a blood test to check for neutralizing antibodies to the AAVrh74var virus. The results of this testing will help determine if you may receive BEQVEZ.

## Important Safety Information

Before receiving BEQVEZ, tell your healthcare professional about all your medical conditions, including if you: have kidney or liver problems, including hepatitis; have factor IX inhibitors or a history of factor IX inhibitors; have an active infection.

Please see Important Safety Information throughout and full [Prescribing Information](http://www.BEQVEZ.com) at [www.BEQVEZ.com](http://www.BEQVEZ.com).



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For eligible adults with moderate to severe hemophilia B

## Welcome to BEQVEZ: a one-time gene therapy infusion\*



### Can BEQVEZ offer you a chance of bleed protection?

We understand getting gene therapy is an important decision. As with any new treatment, it's normal to have questions.

### This brochure is here to help you:



Learn more about BEQVEZ and how it works



Talk to your doctor about any questions you may have about what to expect, including safety, monitoring, and other lifestyle changes



Continue the conversation with your loved ones about what may be involved in the period leading up to and after gene therapy



Find out how to access the educational resources that are available to help support you and your loved ones throughout the treatment journey

### Important Safety Information (cont'd)

**BEQVEZ may cause serious side effects, including:**

**Increased Liver Enzymes.** Most patients treated with BEQVEZ developed elevated liver enzyme levels and most did not experience any symptoms.

Your healthcare professional will **monitor liver enzymes and factor IX activity levels** before administration of BEQVEZ and frequently following the administration to detect and identify possible elevations in liver enzymes and to monitor your response to BEQVEZ. Your doctor may prescribe a corticosteroid for the treatment of elevated liver enzymes.

**Always consult your doctor for treatment-related questions.**

**This brochure is not intended to replace the advice of your care team.**

\*Individual results and duration of effect may vary. The main BEQVEZ study is ongoing to assess the long-term efficacy and safety of BEQVEZ. On-demand factor IX (FIX) may still be required.

**Please see Important Safety Information throughout and full [Prescribing Information](#) at [www.BEQVEZ.com](http://www.BEQVEZ.com).**





## Gene therapy may help remove the need for factor IX prophylaxis (FIX prophy)\*

### The facts

Living with hemophilia B, depending on the severity, you may infuse FIX as often as 2 times per week, but may still need to treat on demand.



### The YOU factor

Gene therapy may help remove the need for FIX prophylaxis. It does this by helping your body make its own clotting factor.

That means instead of infusing routinely, you may have **bleed protection after just one infusion of BEQVEZ**.\*

\*Please see pages 7 to 8 to learn about how BEQVEZ performed in the clinical studies. Individual results and duration of effect may vary. The main BEQVEZ study is ongoing to assess the long-term efficacy and safety of BEQVEZ. On-demand FIX may still be required.



Scan the QR code to sign up now at [BEQVEZ.com](https://www.BEQVEZ.com)

Get emails with educational tools and materials to help support you on your BEQVEZ treatment journey

### Important Safety Information (cont'd)

**Limit alcohol consumption during the first year following BEQVEZ infusion**, as alcohol may reduce the effect of BEQVEZ and may increase liver enzyme levels.

**Infusion reactions, including hypersensitivity and severe allergic reactions (anaphylaxis) may occur. Alert your healthcare professional right away if you get any symptoms of hypersensitivity**, which may include but are not limited to low blood pressure, fever, heart palpitation, nausea, vomiting, chills, or headache.

## BEQVEZ aims to deliver a working gene to help your body make its own FIX



### How BEQVEZ works

Discover how BEQVEZ may help your body create FIX on its own, after a one-time infusion.



#### Before BEQVEZ

In hemophilia B, your FIX gene is changed or mutated. As a result, your body doesn't make enough clotting FIX protein.

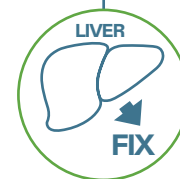


#### Introducing BEQVEZ

BEQVEZ is designed to give your body the healthy (working or functioning) FIX gene it lacks.



BEQVEZ uses a vector to carry the working gene to the liver.



#### After the one-time BEQVEZ infusion

After BEQVEZ gets to the liver, it aims to help your body make more clotting FIX proteins.

After receiving the BEQVEZ infusion, regular post-infusion monitoring is required and it is important to keep FIX on hand. Talk with your doctor about whether you are able to stop FIX prophylaxis or resume, and actions you may need to take for surgeries, procedures, injuries, and bleeding events.

Please see Important Safety Information throughout and full [Prescribing Information](#) at [www.BEQVEZ.com](https://www.BEQVEZ.com).



## The efficacy and safety of BEQVEZ were studied for several years

### The main BEQVEZ study

- **45 participants** were enrolled in an ongoing study
  - Before the BEQVEZ infusion, all had at least 6 months of routine FIX prophylaxis
- The study compared the number of bleeds participants experienced following the BEQVEZ infusion versus the bleed rate with routine FIX prophylaxis before the BEQVEZ infusion (the lead-in period)\*

This ongoing study aims to follow each participant's results for up to **6 YEARS**

### The initial BEQVEZ studies

These studies looked at the safety of BEQVEZ. The study started with 15 participants, and includes data for 5 participants up to **YEAR 6**

\*The efficacy evaluation period was from Week 12 (Day 82) to data cutoff.



### Important Safety Information (cont'd)

BEQVEZ can insert itself into the DNA of cells in the human body. The effect that insertion may have on those cells is unknown but **may contribute to a theoretical risk of cancer**. There have been no reported cases of cancer caused by treatment with BEQVEZ.

The most common side effect of BEQVEZ is increased liver enzymes. These are not all the possible side effects of BEQVEZ. For more information, ask your healthcare professional.

Please see Important Safety Information throughout and full [Prescribing Information](http://www.BEQVEZ.com) at [www.BEQVEZ.com](http://www.BEQVEZ.com).

## BEQVEZ is a one-time gene therapy that may offer a chance of bleed protection without the need for FIX prophylaxis in eligible patients



In the main BEQVEZ study, BEQVEZ helped participants achieve:



### Reduction in bleeds

**44%**  
Reduction

Participants had a **44% decrease in the number of bleeds per year on BEQVEZ vs routine FIX prophylaxis**

In the efficacy evaluation period, participants experienced an average of **2.5** bleeds per year following BEQVEZ, compared to **4.5** while they were on routine FIX prophylaxis during the lead-in period.



### ZERO bleeds

**60%**

**60% of participants had ZERO bleeds during the efficacy evaluation period (27 out of 45)**

While on routine FIX prophylaxis, **29%** of participants (**13 out of 45**) had zero bleeds in the lead-in period.



### A chance to live prophylaxis free

**87%**

**87% of participants were prophylaxis free during the efficacy evaluation period (39 out of 45 participants)**

**13%** of participants (**6 out of 45**) returned to routine FIX prophylaxis from **0.4 to 1.7** years after the BEQVEZ infusion.



### Important to note

**Individual results and duration of effect may vary. The main BEQVEZ study is ongoing to assess the long-term efficacy and safety of BEQVEZ. On-demand FIX may still be required.**

**BEQVEZ™**  
fidanacogene elaparvovec-dzkt  
One-time gene therapy



## The safety of BEQVEZ has been studied since 2017

Meet **TIM**, who received the BEQVEZ infusion in 2021

### The longest-running clinical development program of any approved gene therapy for hemophilia B



#### The most common side effect seen in $\geq 5\%$ of participants following treatment with BEQVEZ was raised liver enzymes

- 53.3% of participants (24 out of 45) in the main BEQVEZ study
- 13.3% of participants (2 out of 15) in the initial BEQVEZ studies

These cases were treated with corticosteroids.



#### Zero participants in the BEQVEZ studies experienced serious side effects

These are not all the possible side effects of BEQVEZ. Your care team will monitor you for possible infusion reactions on the day of your infusion.

Your healthcare professional will monitor liver enzymes and FIX activity levels before administration of BEQVEZ and frequently following the administration to detect and identify possible elevations in liver enzymes and to monitor your response to BEQVEZ. Your doctor may prescribe a corticosteroid for the treatment of elevated liver enzymes.

Infusion reactions, including hypersensitivity and severe allergic reactions (anaphylaxis) may occur. Alert your healthcare professional right away if you get any symptoms of hypersensitivity, which may include but are not limited to low blood pressure, fever, heart palpitation, nausea, vomiting, chills, or headache.

### Important Safety Information (cont'd)

Talk to your healthcare professional before receiving any vaccinations if you are taking a corticosteroid.

Talk to your doctor about any medications you plan to take including over the counter medications, herbal supplements, and vitamins as certain substances can affect the liver and may reduce the effectiveness of BEQVEZ.

Your healthcare professional will test your factor IX activity levels and for factor IX inhibitors.



"SINCE BEQVEZ, I'VE HAD ZERO REGRETS AND ZERO BLEEDS\*\*"

#### About Tim:

- Diagnosed with severe hemophilia B as a baby
- Lives an active life traveling with his band
- Before BEQVEZ, needed FIX prophylaxis infusions 2 times per week and sometimes needed on-demand treatment for breakthrough bleeds
- Now, he's living life prophylaxis free

\*60% of participants (27 out of 45) had zero bleeds during the efficacy evaluation period. While on routine FIX prophylaxis, 29% of participants (13 out of 45) had zero bleeds in the lead-in period.

Individual results and duration of effect may vary. It is not possible to predict who will respond and how long the treatment response will continue.



Learn more about Tim at [BEQVEZ.com](https://www.BEQVEZ.com)

Please see Important Safety Information throughout and full [Prescribing Information](https://www.BEQVEZ.com) at [www.BEQVEZ.com](https://www.BEQVEZ.com).

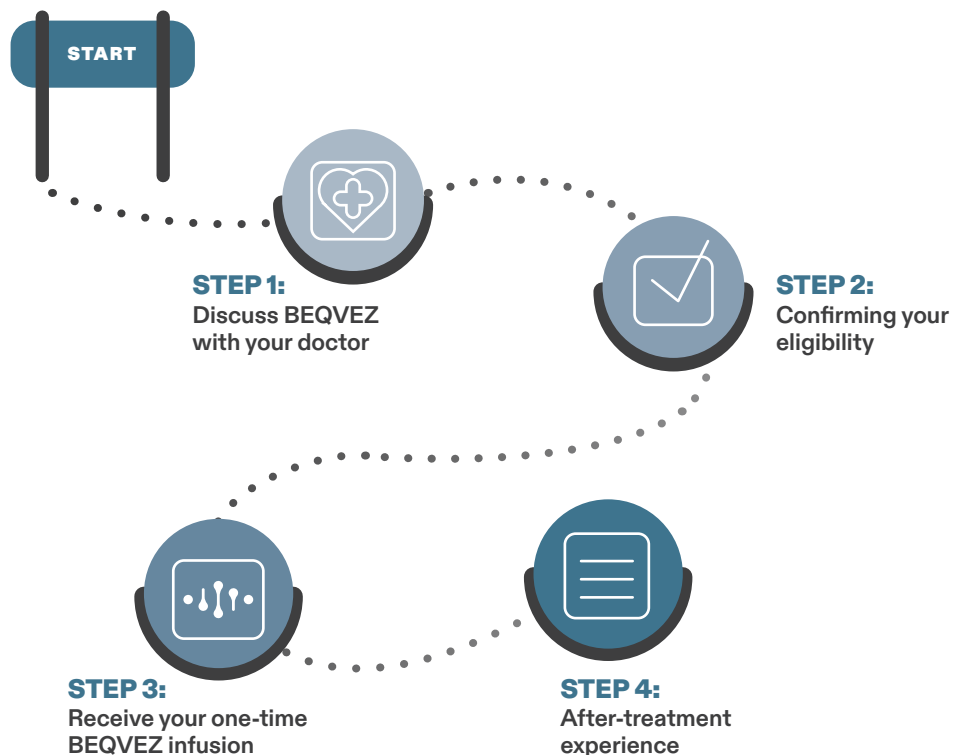
  
**BEQVEZ™**  
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One-time gene therapy

# Here's what you can expect with the BEQVEZ treatment journey

## Beginning the BEQVEZ treatment journey



No matter where you are in your journey, we're here to give you educational support, tools, and resources to help



### STEP 1: Discuss BEQVEZ with your doctor

If you are an adult with moderate to severe hemophilia B, you may be wondering if BEQVEZ is an option for you. To find out, the first step is to talk to your doctor. Together, you can decide if BEQVEZ is a good choice for you and your treatment goals.

You may want to discuss:

- 1 What goals are most important to you when choosing a treatment?
- 2 What are your short- and long-term plans after treatment?
- 3 Are you able to commit to potential temporary lifestyle changes?



### STEP 2: Confirming your eligibility

To find out if BEQVEZ is right for you, you and your doctor will talk about considerations like potential lifestyle changes. You will also need lab testing and confirmation of your access and insurance coverage to see if you're eligible for BEQVEZ.

Your doctor will check your eligibility with various tests to confirm if BEQVEZ may be a treatment option for you. These tests include, but are not limited to, checking your liver health, checking for FIX inhibitors, and seeing if you have any neutralizing antibodies (NABs) to BEQVEZ. Your care team will talk to you about your results and whether BEQVEZ is right for you.

You will get the results from your NAb test after about 7 to 10 days.

### Important Safety Information (cont'd)

After receiving BEQVEZ, your doctor will discuss whether and when you are able to stop prophylaxis, if you need to resume prophylaxis, and actions you may need to take for surgeries, procedures, injuries, and bleeding events.

Do not donate blood, organs, tissues, or cells for transplantation following administration of BEQVEZ.

Please see Important Safety Information throughout and full [Prescribing Information](#) at [www.BEQVEZ.com](http://www.BEQVEZ.com).



# The BEQVEZ treatment journey continued



## STEP 3: Receive your one-time BEQVEZ infusion

On the day of your infusion, you should plan to spend all day at the gene therapy infusion center.

This includes preparation time for your infusion. You may need to fill out some paperwork.

The process before, during, and after the infusion may vary across centers.



The infusion takes about 1 hour



After the infusion, you'll stay at the infusion center for at least 3 hours for monitoring

- Your care team will check your vital signs, like your heart rate and temperature
- They will also check if you have an infusion-related reaction
- When your care team is sure you are ready to leave the infusion center, you can go home

Your care team will give you a follow-up plan to monitor your liver and FIX activity levels routinely.

## Important Safety Information (cont'd)

BEQVEZ is not intended for administration to women. **Males should not donate sperm and should use a male condom or not have sexual intercourse** for up to 6 months after receiving BEQVEZ.

**Patients and caregivers should ensure proper handling of any materials that have come into contact with the patient's urine, feces, saliva, mucus, or semen** in the first 6 months after BEQVEZ infusion.

Please see Important Safety Information throughout and full [Prescribing Information](http://www.BEQVEZ.com) at [www.BEQVEZ.com](http://www.BEQVEZ.com).



## STEP 4: After-treatment experience

It will be important to see your care team for post-infusion monitoring routinely after the infusion.



You will have blood tests to assess your liver health and FIX activity levels.

In the clinical trial for BEQVEZ, some participants had raised liver enzyme levels and/or a decrease in FIX activity levels. Depending on their levels, these participants were prescribed corticosteroids.

Your care team will also remind you about:

- Limiting alcohol during the first year after the BEQVEZ infusion
- Not donating sperm and being abstinent or using a male condom for the first 6 months after your infusion

Talk to your doctor about enrolling in a registry to assess the long-term efficacy and safety of treatments for hemophilia.

## After the infusion, when do you need to have scheduled follow-ups?



Your care team may suggest that you visit the same lab for all your tests. This may help minimize any potential variability in results.

You can also speak to your doctor and nurse who may be able to help guide you to resources and tools after your BEQVEZ infusion.





## Educational support and resources to help you navigate your BEQVEZ treatment journey



Pfizer  
**genetogether™**

Pfizer GeneTogether is here to help answer your coverage and logistics questions throughout your BEQVEZ journey. If you and your doctor decide BEQVEZ is the right treatment choice for you, your care team will work with you to enroll you in Pfizer GeneTogether.

### The program includes:

- Information and resources to support you before, during, and after treatment
- Dedicated Patient Case Managers ready to answer questions you may have about the planning needed to receive BEQVEZ

Your Pfizer GeneTogether care team will help you get ready for your infusion by:

- Assisting you with travel logistics required for your treatment
- Confirming the date of the infusion and any preparation or planning needed beforehand
- Checking with your care team to make sure you're all set for your infusion



To get started and see the support available:

**Call us at 1-855-4BEQVEZ (1-855-423-7839)**

9:00 AM to 7:00 PM ET Monday to Friday

**Visit us at [pfizergenetogether.com](https://www.pfizergenetogether.com)**

### Important Safety Information (cont'd)

Before receiving BEQVEZ, tell your healthcare professional about all your medical conditions, including if you: Have kidney or liver problems, including hepatitis; have factor IX inhibitors or a history of factor IX inhibitors; have an active infection.

## Find more support in your community



### Reaching out to your hemophilia community may help you find more support and resources

These organizations are neither owned nor controlled by Pfizer. Pfizer does not endorse and is not responsible for the content or services of these organizations.



The **National Bleeding Disorders Foundation** (formerly the National Hemophilia Foundation) is dedicated to finding cures for inheritable blood and bleeding disorders, and to addressing and preventing the complications of these disorders through research, education, and advocacy, enabling people and families to thrive.



The **Coalition for Hemophilia B** strives to make quality of life the focal point of treatment for people with hemophilia B and their families through education, empowerment, advocacy, and outreach.



The **Hemophilia Federation of America** is a patient advocacy organization serving the rare bleeding disorders community. It advocates for safe and effective therapies and quality, affordable health coverage. Ultimately, it seeks a better quality of life for all persons with bleeding disorders.

Please see Important Safety Information throughout and full [Prescribing Information](#) at [www.BEQVEZ.com](https://www.BEQVEZ.com).







**BEQVEZ™**

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Suspension for intravenous infusion 1 • 10<sup>11</sup> vg/mL

- ✓ **One-time infusion**
- ✓ **Offers a chance of bleed protection without the need for FIX prophylaxis\***
- ✓ **Known safety profile, studied since 2017**

\*Individual results and duration of effect may vary. The main BEQVEZ study is ongoing to assess the long-term efficacy and safety of BEQVEZ. On-demand FIX may still be required.



**Scan the QR code to sign up now at BEQVEZ.com**

Get emails with educational tools and materials to help support you on your BEQVEZ treatment journey

Pfizer has over **25 years** of commitment to the hemophilia community



**One-on-one patient support and information is here for you**

Call **1-855-4BEQVEZ (1-855-423-7839)** 9:00 AM to 7:00 PM ET Monday to Friday



**Our commitment to you includes a Pfizer Patient Affairs Liaison**

Dedicated to providing support for the community, your Pfizer Patient Affairs Liaison (PAL) is available to help you access the support and information you need. Sign up to connect at **togetherforrare.com**

Pfizer PALs are not measured or awarded based on sales performance nor will they ask you to switch products.

## Important Safety Information (cont'd)

**BEQVEZ may cause serious side effects, including:**

**Increased Liver Enzymes.** Most patients treated with BEQVEZ developed elevated liver enzyme levels and most did not experience any symptoms.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

**Please see Important Safety Information throughout and full [Prescribing Information](http://www.BEQVEZ.com) at [www.BEQVEZ.com](http://www.BEQVEZ.com).**

