Signature of patient or patient's personal representative	Date
Patient's name	
Name of personal representative (if applicable)	Relationship to patient
HEALTH CARE PROVIDER MUST GIVE PATIENT AIREPRESENTATIVE A SIGNED COPY OF THIS FORM  The state of	M. Health care provider



PP-BEN-USA-0573

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# **Enroll in the BeneFix Trial Prescription Program**

To begin, please (1) read the terms and conditions, (2) complete parts 1 to 4 of this enrollment form, and (3) sign the authorization form before returning it to your health care provider. Health care providers, please retain the original signed authorization form with the patient's records and provide them with a copy. The remaining sections must be completed by a health care provider for complimentary products in accordance with the Prescription Drug Marketing Act of 1987. This program is intended for new BeneFix® Coagulation Factor IX (Recombinant) patients. See Terms and Conditions below. All products will be sent by the Pfizer Program Administrator.

Fax this completed form, along with the prescription for BeneFix and the patient authorization form, to 1-888-868-8660. Fax must be sent from a health care provider's office, or mail required documents to the Pfizer Factor Product Trial Prescription Program Administrator, Medvantx, PO Box 5736, Sioux Falls, SD 57117-5736. Please allow 1 to 3 weeks after submission of forms for processing and delivery.

#### BeneFix Trial Rx Terms and Conditions

OFFER TERMS: By enrolling in the 1-month trial program for Pfizer Factor Product, you acknowledge that you currently meet the eligibility criteria and will comply with the terms and conditions described below:

You (the patient) are currently covered by a private (commercial) insurance plan. The patient, or health care provider on the patient's behalf, must provide a completed enrollment form and a valid prescription to the Pfizer Factor Product Trial Prescription Program. The program is valid for one 1-month trial of up to 20,000 IU of factor. Trial cannot exceed 30 days. The patient, or the health care provider on the patient's behalf, must not submit any claim for reimbursement for product dispensed pursuant to this program to any third-party payer, including Medicaid, Medicare, or any other federal or state health care program. The patient must not apply the value of the free product received through this program toward any government insurance benefit out-of-pocket spending calculations, such as Medicare Part D True Out-of-Pocket Costs (Troop). The free trial offer is not valid for prescriptions that are eligible to be reimbursed by private insurance plans or health or pharmacy benefit programs that reimburse you for the entire cost of your prescription drugs. Patients who have already begun therapy with or who have been treated with Pfizer Factor Product are not eligible to participate in the program. Only new patients may use this offer. Only 1 program enrollment per person per lifetime. By enrolling in this program, you certify that you are not currently using Pfizer Factor Product. Program not available where prohibited by law. This free trial is not health insurance. This free trial is not intended to address delays or gaps in health insurance coverage for the specified prescription. This program cannot be combined with any other savings, free trial, or similar offers for the specified prescription. The free trial offer will only be accepted by participating factor providers. Offer good only in the United States and Puerto Rico. No purchase is necessary. Patients have no obligation to continue to use Pfizer Factor Product. This offer is not transferable. Pfizer reserves the right to rescind, revoke, or amend this free trial program without notice. This free trial program expires [12/31/21]. No membership fees. For questions about the Pfizer Factor Product Trial Prescription Program, please call 1-844-989-HEMO (4366) or write to us at Pfizer Factor Product Trial Prescription Program Administrator, Medvantx, PO Box 5736, Sioux Falls, SD 57117-5736.

#### PARTS 1-4: PATIENT INFORMATION (To be completed by patient or personal representative of patient)

y) (State) (ZIP
(State) (ZIP
certify that the patient is not currently receiving Benef
Date
Patient caregiver phone
r) (State) (ZIP
)

- patient weight, 1-month supply up to 20,000 IU.
- Will this trial be for once-weekly prophylaxis or on-demand use? \_\_\_\_ Once-weekly prophylaxis \_\_\_\_ On demand

(Signature of physician)

- Preferred vial sizes based on patient dosage (subject to availability) # 250 IU vials # 500 IU vials # 1000 IU vials # 2000 IU vials
- # 3000 IU vials 14 Signature of requesting licensed physician

(Date of request)

I agree that I will not resell or bill any third party, including Medicaid or Medicare programs, for any of the complimentary product provided under this trial prescription program. I acknowledge that any patient selected for this program is not currently receiving BeneFix therapy and has not been previously enrolled in the BeneFix Trial Prescription Program.





For questions about the BeneFix Trial Prescription Program, please call 1-844-989-HEMO [4366], Monday through Friday, 9:00 AM to 5:00 PM eastern time. Please see Indication and Important Safety Information on next page and accompanying full Prescribing Information.

#### **Indication**

BeneFix, Coagulation Factor IX (Recombinant), is a human blood coagulation factor indicated for the treatment of:

- Adults and children with hemophilia B (congenital factor IX deficiency or Christmas disease) for:
- On-demand treatment and control of bleeding episodes.
- Perioperative management of bleeding.
- Patients 16 years of age and older with hemophilia B (congenital factor IX deficiency or Christmas disease) for:
- Routine prophylaxis to reduce the frequency of bleeding episodes.

#### Limitation of use:

BeneFix is not indicated for induction of immune tolerance in patients with hemophilia B.

### **Important Safety Information**

- BeneFix is contraindicated in patients who have manifested life-threatening, immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including hamster protein (CHO).
- Hypersensitivity reactions, including anaphylaxis, have been reported with BeneFix. Closely monitor patients for signs and symptoms of acute anaphylaxis, particularly during the early phases of initial exposure to the product. Immediately discontinue the administration of the product and initiate appropriate treatment if symptoms occur.
- Patients may develop hypersensitivity to hamster protein as BeneFix contains trace amounts.
- BeneFix has been associated with the development of thromboembolic complications, including in patients receiving continuous infusion through a central venous catheter. The safety and efficacy of BeneFix administration by continuous infusion have not been established.
- Neutralizing antibodies (inhibitors) have been reported following the administration of BeneFix. If expected plasma factor IX activity levels are not attained, or if the patient presents with an allergic reaction, or if bleeding is not controlled following an expected dose of BeneFix, perform an assay that measures factor IX inhibitor concentration
- The most common adverse reactions (>5%) from clinical trials were fever, cough, nausea, injection site reaction, injection site pain, headache, dizziness, and rash.

Please see accompanying full Prescribing Information.

Benefix PI Revised: 4/2021



## **Patient Authorization Form**

This Patient Authorization Form authorizes your health care provider to disclose your health and personal information to Medvantx, the administrator of the BeneFix® Coagulation Factor IX (Recombinant) Trial Prescription Program, and its employees, representatives, and agents (collectively, "Medvantx") in connection with the BeneFix Trial Prescription Program in accordance with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and related federal regulations and rules. The support provided through this program is not contingent on any further purchase.

#### **Authorization**



to disclose my individually identifiable health and medical information described below to Medvantx solely for the authorized purposes described in this authorization form.

## Description of Health and Medical Information That May Be Disclosed

My health care provider may disclose individually identifiable health and other information that supports my participation in the BeneFix Trial Prescription Program. Information disclosed may include my name, address, date of birth, diagnosis/disease treatment, financial information, medical records, and the specialty of my health care provider. For details about how we collect and use personal information, including applicable US state privacy rights and notices for California residents, please visit www.pfizer.com/privacy.

## **Authorized Purposes**

The authorized purposes are: (1) to evaluate my eligibility for inclusion in the BeneFix Trial Prescription Program and (2) if my participation in the program is approved, to administer the program to me.

## **Expiration of Authorization**

My authorization shall expire (1) when my participation in the BeneFix Trial Prescription Program is not approved or (2) at the conclusion of my participation in the BeneFix Trial Prescription Program, whichever is earlier.



Coagulation Factor IX (Recombinant)
Room Temperature Storage
\*BeneFix was approved February 11, 1997.

## **Acknowledgments**

- I understand that once my health care provider gives Medvantx information about me based on this authorization, my medical and health information may be subject to redisclosure and no longer protected by federal privacy regulations. I further understand and agree that Medvantx may retain my medical and health information as disclosed under this authorization after this authorization expires for the purposes related to the administration of the BeneFix Trial Prescription Program. I also understand that in the event of an audit, and only for the purposes of such an audit, some information may also be disclosed to Pfizer (the manufacturer of BeneFix), even after this authorization has expired, so long as the audit is for a period of time when this authorization was in effect.
- 2 I understand that I may refuse to sign this authorization form and that, unless allowed by law, my refusal to sign will not affect my ability to obtain treatment from my health care provider or to seek payment or my eligibility for benefits. However, I understand that I may not be included in the BeneFix Trial Prescription Program if I refuse to sign this authorization form.
- 3 I understand that I may revoke my authorization at any time by providing a written notice of the same to my health care provider that refers to (or with a copy of) this authorization form. However, I understand that if I revoke this authorization, it will not affect prior disclosures made by my health care provider to Medvantx in reliance of this authorization.
- 4 I understand that completing this enrollment form does not guarantee that I will qualify for the BeneFix Trial Prescription Program.
- 5 I understand that medicine received under the BeneFix Trial Prescription Program shall not be sold, traded, bartered, or transferred. Pfizer reserves the right to change or cancel the BeneFix Trial Prescription Program at any time.
- I understand and agree to the following:
  I agree to communications from Pfizer, Medvantx, and/or parties acting on their behalf to determine my eligibility for the BeneFix Trial Prescription Program and for other non-marketing purposes related thereto. I agree to be contacted by Pfizer, Medvantx, or parties working on their behalf for these purposes using an autodialer or prerecorded voice at the telephone number(s) provided. If I have a caregiver, they have also agreed to receive such communications from Pfizer, Medvantx, and/or parties acting on their behalf for the purposes described above and I hereby give my permission for Pfizer, Medvantx, and/or other parties acting on their behalf to

Medvantx, and/or other parties acting on their behalf to contact my caregiver for such purposes. I understand that I (and, if applicable, my caregiver) can opt out of these communications at any time by contacting Medvantx Pharmacy at 1-844-229-8444.

