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 AND/OR PATIENT'S REPRESENTATIVE A SIGNED COPY OF THIS FORM. Health care provider has verified patient representative's authority to act on patient's behalf. _____ (check)

xyntha® solofuse®
Antihemophilic Factor (Recombinant)

PP-XYN-USA-0471

May 2021

Pfizer

Enroll in the XYNTHA 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 product in accordance with the Prescription Drug Marketing Act of 1987. This program is intended for new XYNTHA® Antihemophilic Factor (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 XYNTHA 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.

XYNTHA 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)*

1 Name

2 Date of birth

3 Address
(Street) (Suite/Floor) (City) (State) (ZIP code)

(Please note that product cannot be shipped to PO boxes)

I, _____, certify that the patient is not currently receiving XYNTHA therapy.

If guardian, please state relationship to patient _____

(Signature of patient/parent/guardian) _____ Date _____

4 Telephone number ( ) ( )
Day Evening

☐ I am a patient caregiver Patient caregiver name _____ Patient caregiver phone _____

PARTS 5-10: PHYSICIAN INFORMATION

5 Name

6 Professional designation license # (required by law)

7 Name of treatment center*

8 Address
(Street) (Suite/Floor) (City) (State) (ZIP code)

9 Business telephone ( ) HTC telephone ( )

10 Fax ( ) Email address

*If not a treatment center, please fill in physician name and medical center affiliation.

PARTS 11-13: XYNTHA TRIAL PRESCRIPTION INFORMATION

11 Please note on the prescription whether patient has any allergies and/or is taking concomitant medications. Maximum quantity based on patient weight, 1-month supply, up to 20,000 IU.

12 Preferred IU† based on patient dosage. †Subject to availability.

#____250 IU XYNTHA SOLOFUSE #____500 IU XYNTHA SOLOFUSE #____1000 IU XYNTHA SOLOFUSE #____2000 IU XYNTHA SOLOFUSE #____3000 IU XYNTHA SOLOFUSE

☐ XYNTHA in vial form is available upon request. Please check this box and you will be contacted to confirm.

13 Signature of requesting licensed physician

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 XYNTHA therapy and has not been previously enrolled in the XYNTHA Trial Prescription Program.

_____
(Signature of physician) (Date of request)

For questions about the XYNTHA 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.**

xyntha® solofuse®
Antihemophilic Factor (Recombinant)

Indication

XYNTHA® Antihemophilic Factor (Recombinant) is indicated in adults and children with hemophilia A for on-demand treatment and control of bleeding episodes, for perioperative management, and for routine prophylaxis to reduce the frequency of bleeding episodes.

XYNTHA is not indicated in patients with von Willebrand's disease.

Important Safety Information

- Do not use in patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including hamster proteins.
- Allergic-type hypersensitivity reactions, including anaphylaxis, are possible with XYNTHA. Inform patients of the early signs or symptoms of hypersensitivity reactions (including hives, generalized urticaria, chest tightness, wheezing, and hypotension) and anaphylaxis. Discontinue XYNTHA if hypersensitivity symptoms occur and administer appropriate emergency treatment. XYNTHA contains trace amounts of hamster proteins. Patients may develop hypersensitivity to these proteins.
- Inhibitors have been reported following administration of XYNTHA. Monitor patients for the development of factor VIII inhibitors by appropriate clinical observations and laboratory tests.
- Clinical response to XYNTHA may vary. If bleeding is not controlled with the recommended dose of factor, determine the plasma level and administer a dose of XYNTHA sufficient to achieve clinical response. If the factor level does not increase or there is no response, suspect an inhibitor and perform appropriate testing.
- Across all studies, the most common adverse reactions (≥10%) with XYNTHA in previously treated adult and pediatric patients were headache (24% of subjects), arthralgia (23%), fever (23%), and cough (12%). Other adverse reactions reported in ≥5% of subjects were diarrhea, vomiting, and weakness.
- XYNTHA is an injectable medicine administered by intravenous (IV) infusion. Patients should be advised that local irritation may occur when infusing XYNTHA after reconstitution in XYNTHA® SOLOFUSE®.

Please see accompanying full Prescribing Information.

Xyntha PI Revised: 8/2020
Xyntha Solfuse PI Revised: 8/2020

xyntha® solofuse®
Antihemophilic Factor (Recombinant)

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 XYNTHA® Antihemophilic Factor (Recombinant) Trial Prescription Program, and its employees, representatives, and agents (collectively, "Medvantx") in connection with the XYNTHA 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

I, _____,
First Middle Last Name

hereby authorize _____
Name of physician/health care provider

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 XYNTHA 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 XYNTHA 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 XYNTHA Trial Prescription Program is not approved or (2) at the conclusion of my participation in the XYNTHA Trial Prescription Program, whichever is earlier.

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Antihemophilic Factor (Recombinant)

Acknowledgments

1. 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 XYNTHA 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 XYNTHA), 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 XYNTHA 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 XYNTHA Trial Prescription Program.
5. I understand that medicine received under the XYNTHA Trial Prescription Program shall not be sold, traded, bartered, or transferred. Pfizer reserves the right to change or cancel the XYNTHA Trial Prescription Program at any time.
6. 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 XYNTHA 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 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.

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