



# HEMOGRAM

WESTERN PENNSYLVANIA CHAPTER OF THE NATIONAL HEMOPHILIA FOUNDATION

SUMMER 2021



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**UNITE FOR BLEEDING  
DISORDERS WALK**

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## BOARD OF DIRECTORS

*Interim President*

Brittani Spencer

*Secretary* John Yunghans

*Treasurer* Christina Miller

*Board Members*

R. Scott Domowicz

Melinda Perry

Jennifer Smith

## STAFF

*Executive Director* Kara Dornish

*Program Director* Janet Barone

*Development Director* Jessica Lee

Staff office hours are Monday-Friday from 9 a.m. until 4 p.m. Every attempt will be made to return calls received during regular office hours on the same day.

## MISSION STATEMENT

WPCNHF strives to enrich the lives of those with bleeding disorders in Western Pennsylvania and respond to the needs of the community in a dynamic environment.

Hemogram is published quarterly by the Western Pennsylvania Chapter of the National Hemophilia Foundation. The material in this newsletter is provided for your general information only. WPCNHF does not give medical advice or engage in the practice of medicine. WPCNHF under no circumstances recommends particular treatments, and always recommends that you consult your physician or treatment center before pursuing any course of treatment.

## DESIGNATE UNITED WAY GIFTS TO THE CHAPTER

If your company is participating in the United Way campaign, you may designate all or a portion of your gift to the Chapter.

**WPCNHF Contributor Agency Code Number is: 83**

## EVENTS CALENDAR

**July 15, 2021**

Outdoor Movie -  
Bombardier Blood  
Cranberry Township, PA

**July 22, 2021**

Annual Meeting & Walk  
Kick-Off  
Virtual Program

**August 8-14, 2021**

Camp Hot-to-Clot  
Fombell, PA

**August 26-28, 2021**

NHF Bleeding Disorders  
Conference  
Virtual Program

**September 11, 2021**

Ballers for Bleeding  
Disorders Paintball  
Tournament - Fundraiser

**September 18, 2021**

Unite for Bleeding  
Disorders Walk and  
Run for their Lives 5K -  
Fundraiser

**October 9, 2021**

Fall Program  
Erie, PA

**October 18-28, 2021**

HFA Symposium  
Virtual Program

**November 5, 2021**

New Parent Network  
Seven Springs, PA

**November 5, 2021**

Teen Program  
Seven Springs, PA

**November 6-7, 2021**

Education Weekend  
Seven Springs, PA

**November 23, 2021**

Advocacy Stakeholder Retreat  
Virtual Program

**December 4, 2021**

Take A Bough - Fundraiser  
Pittsburgh, PA

VISIT [WPCNHF.ORG](http://WPCNHF.ORG) FOR MORE INFORMATION ON OUR UPCOMING EVENTS.

12th Annual

**RUN  
FOR  
THEIR LIVES**  
Bleeding disorders can't stop us.

**Saturday, September 18, 2021**

North Park Swimming Pool Parking Lot  
S. Ridge Drive  
Allison Park, PA 15101

Check in begins at 7:30 A.M.

Race begins at 8:30 A.M.

Distance: 5K (3.1 miles)

Registration fee (Virtual and In-Person): \$30 (until  
September 17th)

Race Day Fee (In-Person): \$35

More information at: <http://bit.ly/runfortheirives12>



**We want to give a huge shout-out to Aberegg Army for raising \$720 for the 2021 Unite for Bleeding Disorders Walk!** They partnered with Bre's Cupcakin Around to raffle off a delicious Peanut Butter Chocolate Mega Cake! Tickets were \$5 each and the winner was pulled on May 6th.

Thank you so much to Mandy, Ryan, Cooper, Brooke and the entire team for your hard work and support of the Western PA bleeding disorders community!

Registration for the 2021 Unite for Bleeding Disorders Walk is now open! Register yourself or your team at: <https://uniteforbleedingdisorders.org/event/wpa>

## CONTACT US

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Chapter of the National  
Hemophilia Foundation**

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# LETTER FROM THE EXECUTIVE DIRECTOR

Dear Chapter Members & Friends,

I hope everyone is having a great start to the summer! As stay at home orders and mask mandates are being lifted, we are so excited to hold in-person events again! The past 15 months had its challenges, but it also showed how strong we are as a community. Stay at home orders did not stop us from coming together to advocate, learn, connect, and support each other. It forced us to become comfortable with virtual meetings and opened our eyes to the advantages of holding programs both in-person and virtually, so they are more accessible for all.

June marks the end of the Chapter's fiscal year and is a time I like to look back on what we accomplished and the work that lies ahead of us. This past year we increased our ability to provide emergency financial assistance. We started a COVID-19 Grocery Assistance Program which offered a streamlined way for us to get grocery gift cards to those in the community struggling with

food insecurity. Through this program, we provided \$13,900 to 36 families. Overall this year, we have provided over \$32,000 in emergency patient assistance to over 200 community members in need. If you need assistance, please do not hesitate to reach out to us or the social workers at the HCWP, this is what we are here for.

This fiscal year we held 25 virtual educational programs, 7 virtual fundraisers, and continued to keep our Advocacy Ambassador program going strong. As a result of our hard work, the PA budget was signed into law on June 30th with the hemophilia line item fully funded and language that ensures it will be distributed to all 7 Hemophilia Treatment Centers in PA. We want to continue building strong relationships with legislators and we need your help. If you would be interested in joining us in meeting with legislators, or would like to get involved by making phone calls or writing letters, please reach out to me at [kara@wpcnhf.org](mailto:kara@wpcnhf.org) or 724-741-6160.

We have many upcoming events including an outdoor screening of *Bombardier Blood* at Cranberry Park on



July 15th, our Annual Meeting being held virtually on July 22nd, and the Unite for Bleeding Disorders Walk and Run For Their Lives 5k on Saturday, September 18th. I hope to see you all there!

As always, please contact the office with any questions or concerns. It is truly an honor to be leading this organization.

*Kara Dornish*  
Kara Dornish  
Executive Director

# LETTER FROM THE BOARD PRESIDENT

Hello Chapter Members,

Summer is here and the Chapter staff has been rather busy planning and preparing for numerous events and programs; including the Young Adult Retreat, the New Parent Network Picnic, a screening of *Bombardier Blood* in the park, and, of course, the 12th Annual Run for Their Lives 5K and 13th Annual Unite for Bleeding Disorders Walk.

We hope that you plan on joining us for our upcoming Virtual Annual Meeting on July 22nd, which is open to Chapter members with bleeding disorders and their immediate family members. The Annual Meeting is an exciting time to learn about the past year and the vision moving forward as we continue to serve our members. You will hear from our newly elected board leaders and

have the opportunity to ask questions as well as provide feedback.

We are searching for talented and passionate members to join our Board of Directors. If you are interested in joining or would like to learn more, please contact Kara Dornish by email or phone at [kara@wpcnhf.org](mailto:kara@wpcnhf.org) or 724-741-6160.

I would like to thank the Board of Directors for their time and devotion to WPCNHF.

Wishing you the happiest and healthiest of summers.

Sincerely,  
Brittani Spencer  
Interim Board President



Bleed Have to cancel  
Late for school  
When will this bleed end?  
Another bleed  
Time Visit to ER  
Frustration Bleed



For the treatment of bleeding episodes in people\* with hemophilia A or B with inhibitors

## I'M READY TO MOVE ON

**Get rapid, predictable, and reliable bleed control with SEVENFACT 225<sup>†</sup>**



### Rapid effect: 3 hour

At 3 hours, 84% of mild/moderate bleeding episodes were controlled with a single dose



### Predictable\* response: 84%

At 9 hours, 84% of mild/moderate bleeding episodes treated achieved bleed control after a single dose



### Reliable control: 99.5%

At 24 hours, 99.5% of mild/moderate bleeding episodes were resolved



### Convenient home use: 98%

98% of bleeding episodes were treated at home

<sup>†</sup> 225 mcg/kg initial dosing regimen in the clinical trial.  
<sup>\*</sup> As seen in the clinical trial.

### Summary of Selected Safety Information

#### What is the most important information I should know about SEVENFACT?

The most serious possible side effect of SEVENFACT is abnormal clotting involving blockage of blood vessels, which include stroke, blockage of the main blood vessel to the lung, and deep vein blood clots.

#### You should know the signs of abnormal clotting and seek medical help immediately if they occur.

Signs of clotting in places other than your site of bleeding can include new onset of swelling and pain in limbs, new onset of chest pain, shortness of breath, loss of sensation or motor power, or altered consciousness or speech.

#### What is SEVENFACT?

SEVENFACT is an injectable medicine used for the treatment and control of bleeding episodes occurring in adults and adolescents 12 years of age and older with Hemophilia A or B with inhibitors.

Injecting medicines requires special training; do not attempt to self-infuse unless you have been taught how by your healthcare provider.

#### Who should not use SEVENFACT (coagulation factor VIIa)?

You should not use SEVENFACT if you are allergic to rabbits, or if you have known allergies to SEVENFACT or any of its components. Seek immediate medical help if you experience hives, itching, rash, difficulty breathing with cough or wheezing, swelling around the mouth and throat, tightness of the chest, dizziness or fainting, or low blood pressure after taking SEVENFACT.

Tell your healthcare provider prior to using SEVENFACT if you have begun treatment of a bleeding episode with another bypassing agent.

#### What should I tell my healthcare provider before I use SEVENFACT?

Tell your healthcare provider if you are pregnant, are nursing, or plan to become pregnant; if you have had prior blood clots, heart disease or heart failure, abnormal heart rhythms, prior pulmonary clots, or heart surgery; or if you have or have had any other medical conditions.

#### What are the possible side effects of SEVENFACT?

The most common adverse reactions for SEVENFACT are headache, dizziness, infusion-site discomfort, infusion-site hematoma, and infusion-related reaction and fever.

Seek immediate medical help if you have signs of a blood clot or an allergic reaction.

To report SUSPECTED ADVERSE REACTIONS or product complaints, contact HEMA Biologics at 1-855-718-4362. You may also report SUSPECTED ADVERSE REACTIONS to the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Please see Patient Product Information on the next page.



## WPCNHF SUPER SLEUTHS SOLVE THE CASE!

On Saturday, April 24th, the Western Pennsylvania Chapter of the National Hemophilia Foundation hosted their Virtual Murder Mystery Night! Over 40 people joined local Pittsburgh theater group, Mystery's Most Wanted, for an evening of entertainment and mystery as we celebrated Mother Fates' 100th birthday party! The cost to participate was \$25 per device and included the Zoom link and a themed event box. In this box, participants received a special clue sheet to help solve the mystery,

a detective book to keep notes during the investigation, a special birthday treat, and other birthday goodies.

At the end of Act II, each group decided who they thought the killer was and voted over Zoom. Those who correctly guessed the culprit won a Mystery's Most Wanted Coffee mug and a Unite for Bleeding Disorders shirt! Congratulations to our Super Sleuths, Emily H., Vera and Ihor M., Amanda L., and Rebecca B.!

Members of the audience were lucky enough to join the show and perform a few lines along side the characters.

Thank you to Jennifer B., who played the baker, Christina Y., who played the town

doctor, and Ethan W. who played a secret character (who we won't spoil here!)

Thank to our amazing sponsors for supporting this event; Our title sponsor, the Hemophilia Center of Western Pennsylvania, our Witness Sponsor, BioMarin, and our Clue Sponsor, CSL Behring! Thank you so much for your support of the bleeding disorders community!

Thank you to everyone who joined us at this event! We are pleased to announce that over \$6,000 was raised to support our emergency and medical patient assistance fund, educational programs, and support groups that benefit the bleeding disorders community in Western PA. We are grateful for your continued support during these uncertain times. We hope to see you at one of our events in the future!





## PATIENT PRODUCT INFORMATION

### SEVENFACT® (SEV-en-fact) coagulation factor VIIa (recombinant)-jncw

#### For Intravenous Injection After Reconstitution Only

#### PLEASE READ PATIENT PRODUCT INFORMATION AND THE INSTRUCTIONS FOR USE THAT COME WITH SEVENFACT BEFORE YOU START TAKING THIS MEDICINE AND EACH TIME YOU GET A REFILL. THERE MAY BE NEW INFORMATION.

This Patient Product Information does not take the place of talking with your healthcare provider about your medical condition and treatment. If you have questions about SEVENFACT after reading this information, ask your healthcare provider.

#### WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT SEVENFACT?

The most serious possible side effect of SEVENFACT is abnormal blood clotting involving blockage of blood vessels, which include stroke, blockage of the main blood vessel to the lung, and deep vein blood clots.

You should know the signs of abnormal clotting (thrombosis) described below and seek medical help immediately if they occur.

New onset of swelling and pain in the limbs or abdomen, new onset of chest pain, shortness of breath, loss of sensation or motor power, and altered consciousness or speech can all be signs of clot formation in places other than your site of bleeding. Seek immediate medical attention if you experience one or more of these symptoms.

SEVENFACT should be used as prescribed and directed by your healthcare provider.

#### WHAT IS SEVENFACT?

SEVENFACT is a recombinant human Factor VIIa protein for injection. SEVENFACT can allow adolescents and adults with Hemophilia A or B with inhibitors to create clotting at the site of bleeding without needing Coagulation Factor VIII or IX replacement.

SEVENFACT, coagulation factor VIIa (recombinant)-jncw, is indicated for the treatment and control of bleeding episodes occurring in adults and adolescents 12 years of age and older with Hemophilia A or B with inhibitors.

Injecting medications requires special training. Do not attempt to self-infuse unless you have been taught how by your health care provider or hemophilia treatment center. Once trained, you will need additional infusion materials along with your SEVENFACT so that you can successfully treat your bleeding episodes at home. Be sure to collect all necessary infusion materials before starting the reconstitution process.

SEVENFACT comes in a sterile dry powdered dosage form that must be reconstituted with sterile Water for Injection.

It is not known if SEVENFACT is safe and effective in children under 12 years of age.

#### WHO SHOULD NOT USE SEVENFACT?

You should not use SEVENFACT if you:

- Are allergic to rabbits.
- Have known allergies to SEVENFACT or any of its components.

Tell your doctor prior to infusing SEVENFACT if you have begun treatment of a bleeding episode with another bypassing agent such as activated prothrombin complex concentrate (FEIBA®).

#### WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE I USE SEVENFACT?

Tell your healthcare provider if you:

- Are pregnant, planning to become pregnant or nursing, as SEVENFACT has not been studied in patients with Hemophilia A or B with inhibitors who are pregnant or nursing.
- Had prior blood clots, heart disease, heart failure, abnormal heart rhythms, prior pulmonary clots or heart surgery.
- Have or have had any other medical conditions.

You and your doctor can then decide whether SEVENFACT is the right treatment for you, as well as the proper timing and doses you will need for SEVENFACT to control your bleeding episodes at home.

#### HOW SHOULD I USE SEVENFACT?

Treatment with SEVENFACT should be started by a healthcare provider who is experienced in the care of patients with Hemophilia A or B with inhibitors.

SEVENFACT is given as an injection into your vein.

You may infuse SEVENFACT at a hemophilia treatment center, at your healthcare provider's office, or in your home. You should be trained on how to infuse by your healthcare provider or hemophilia treatment center. Many people with inhibitors learn to infuse by themselves or with the help of a family member.

Treating at first sign of a bleed is important for bleed management. Your healthcare provider will tell you how much

SEVENFACT to use based on your weight and when to administer SEVENFACT.

#### To administer SEVENFACT:

- Collect all materials needed for your prescribed dose
- Follow the **Instructions For Use** guide to reconstitute the prescribed number of SEVENFACT vials
- Infuse following your healthcare provider's instructions, using infusion materials from your pharmacy

## CONTACT YOUR HEALTHCARE PROVIDER IF YOU:

- Miss a dose, or
- Administer more than your prescribed dose, or
- Think your bleed is not controlled within the expected time frame discussed with your healthcare provider.

## WHAT SHOULD I AVOID WHILE USING SEVENFACT?

- Avoid activity that can create more bleeding once you have completed your SEVENFACT infusion
- Avoid mixing SEVENFACT with other medications
- Avoid infusing SEVENFACT and other factor-containing therapies [such as activated prothrombin complex concentrate (aPCC) or other recombinant Factor VIIa products] at the same time. This increases your risk of having a disabling blood clot.

## WHAT ARE THE POSSIBLE SIDE EFFECTS OF SEVENFACT?

The most common adverse reactions reported in clinical trials for SEVENFACT were headache, dizziness, infusion-site discomfort, infusion-site hematoma, infusion-related reaction and fever.

A serious allergic reaction to SEVENFACT may occur. If you experience the severe symptoms of an allergic reaction after infusing SEVENFACT, seek immediate medical attention. Severe symptoms occur when your immune system reacts very strongly to foreign proteins or drugs.

- Hives, itching, rash, difficulty breathing with cough or wheezing, swelling around the mouth and throat, tightness of the chest, dizziness or fainting, and low blood pressure are all symptoms of a severe allergic reaction (anaphylaxis). Call 911 should you experience one or more of these symptoms.

**These are not all the possible side effects of SEVENFACT. For more information, ask your healthcare provider or pharmacist.**

**Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.**

## HOW SHOULD I STORE SEVENFACT?

- SEVENFACT should be stored in its product packaging to protect from light.
- Prior to reconstitution, the SEVENFACT kit should be stored at room temperature but can be stored between 36°F to 86°F (2°C to 30°C).
- After reconstitution, SEVENFACT should be stored at room temperature but can be stored between 36°F to 86°F (2°C to 30°C), for up to 4 hours.
- SEVENFACT should not be frozen.

## GENERAL INFORMATION ABOUT THE SAFE AND EFFECTIVE USE OF SEVENFACT

This leaflet summarizes the most important information about SEVENFACT.

Do not use SEVENFACT for a condition for which it was not prescribed. Do not give SEVENFACT to other people even if they have the same symptoms you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about SEVENFACT that is written for health professionals.

For more information, go to [www.SEVENFACT.com](http://www.SEVENFACT.com) or call 855.718.HEMA (4362).

## WHAT ARE THE INGREDIENTS IN SEVENFACT?

**Active ingredient:** coagulation factor VIIa (recombinant)-jncw

**INACTIVE INGREDIENTS:** ARGININE HYDROCHLORIDE, GLYCINE, ISOLEUCINE, LYSINE HYDROCHLORIDE, POLYSORBATE 80, TRISODIUM CITRATE DIHYDRATE, HYDROCHLORIC ACID, NITROGEN AND WATER FOR INJECTION.

## FOR INFORMATION CONTACT:

HEMA Biologics, LLC  
4441 Springdale Road  
Louisville, Kentucky 40241-1086

Manufactured by:  
Laboratoire Francais du Fractionnement et des Biotechnologies S.A. (LFB S.A.)  
Les Ulis, 91940  
France

Distributed by:  
HEMA Biologics  
Louisville, KY 40241  
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"SEVENFACT" is a trademark of LFB S.A.

PATENT Information: <https://hemabiodup.wputengine.com/patents/>

Approved 04/2020

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**HEMA**  
Biologics®

## Volunteer to make a difference.

We need your help! On Saturday, September 18, 2021, nearly 400 runners, and walkers will join us for our annual 5K Race and Unite for Bleeding Disorders Walk at the North Park Swimming Pool in Allison Park, PA. We have different shifts of volunteer opportunities available from 6:30 a.m. (set up) to 12:30 p.m. (tear down). Find out how you can volunteer on walk day by emailing Jessica at [jessica@wpcnhf.org](mailto:jessica@wpcnhf.org).

**Unite**  
for Bleeding Disorders

## HCWP CORNER

**KATHERINE BUSH, LCSW**

Hello to all WPCNHF Members and Your Families,

As spring ends and turns into summer, it's so refreshing to be out of the house and enjoying the outdoors. It was a long and hard winter for many in all sorts of ways, but we are so hopeful that brighter times are coming along with the warmer weather.

We are also hopeful that soon we can see each other more often in-person, rather than virtually. We are currently in the process of planning our annual summer camp program, which we unfortunately had to cancel last year. We also remain hopeful that we will be able to provide outreach clinics to our Amish population in the fall. We are so excited at the thought of resuming some of our traditions!

We continue to offer appointments both in-person and virtually, and you can also request factor refills

through our website (<https://hcwp.vitalant.org/Home.aspx>). We also continue to have our on-call number (888-990-4297) available when the center is not open.

Whenever possible, please call us before you arrive to the emergency room. Also, if you have a planned procedure, please reach out to us at least 10 days in advance so that we can arrange a plan to help keep you safe during your procedure.

And as always, please continue to reach out to us with any questions or concerns you may have about your care, or barriers that may keep you from receiving care. Please let us know what would make us better and what has been going well with your care. The more we know, the better we can be.

Sending our best wishes (along with a good dose of optimism for 2021!) to all of you,

The HCWP Staff



### CHRISTMAS IN JULY AT THE MALL AT ROBINSON

From July 1st - 31st, you can visit Christmas in July Tree Land at the Mall at Robinson (Pittsburgh, PA), located on the lower level Macy's wing across from Chocolate Boutique. Check out WPCNHF's tree and vote for it to win the *Best Tree Award*! The winning tree will receive \$500!

## ADVANCED STRESS MANAGEMENT



Thanks to the Hemophilia Federation of America (HFA), our members had the opportunity to participate in a virtual program, over Zoom, covering strategies to better manage stress, with Dr. Gary McClain, PhD, on May 23, 2021. Dr. McClain is a therapist, patient advocate, and author specializing in helping clients deal with the emotional impact of chronic and life-threatening illnesses. Resources and other helpful

information can be found on his website: [justgotdiagnosed.com](http://justgotdiagnosed.com)

Not only did Dr. McClain discuss the symptoms of stress, anxiety, and depression, but he also provided ways to cope, such as how to focus on your thoughts and change the way you think when you encounter a stressful situation.

Dr. McClain also shared important mental health resources. In addition, information on Mental Health Resources can be found on HFA's website: <https://www.hemophiliafed.org/news-stories/2021/04/mental-health-resources/>

A few important resources to note:

- National Suicide Prevention Lifeline: 1-800-273-8255 (1-888-628-9454 for Spanish-speaking callers)
- Crisis Text Line: Text HOME to

741741 to connect with a crisis counselor

- Therapist Locator: [www.therapistlocator.com](http://www.therapistlocator.com)

We thank HFA for sponsoring this important and informative program on stress management.

The Chapter sent window herb garden kits to families who registered for this program. We hope everyone is having success with their window gardens and are enjoying watching their seeds grow!





## WESTERN AND EASTERN PA HEMOPHILIA FOUNDATIONS HOLD STATE WIDE WORLD HEMOPHILIA DAY EVENT

April 17<sup>th</sup> was World Hemophilia Day, the day the whole bleeding disorders community comes together to celebrate the continuous advances in treatment, while raising awareness and bringing understanding and attention to the issues related to proper care to the wider public.

The Western and Eastern PA Hemophilia Foundations joined forces to hold a virtual event focusing on PA advocacy. Everyone who registered received a red light bulb to help spread awareness and light up their porch or room red. We started off the night with some friendly competition - asking in a poll what was better: Sheetz or Wawa, Primanti Brothers Sandwich or Philly Cheese Steak, and Yinz or Yous. We played kahoot trivia, heard from our sponsors, Representative Nick Pisciotto joined us and answered questions, and Miriam Goldstein of HFA led an education session on policy affecting the community and how to talk to your legislators. Thank you to everyone who attended and helped spread awareness of bleeding disorders this World Hemophilia Day.

Thank you to our sponsors:



# ADVOCACY UPDATE

## PENNSYLVANIA PASSES BUDGET WITH THE HEMOPHILIA LINE ITEM FULLY FUNDED

We are happy to let you know the Pennsylvania budget has passed with hemophilia fully funded at \$959,000.

In addition, the language in the fiscal code reads as follows:

"FUNDS APPROPRIATED FOR HEMOPHILIA SERVICES SHALL BE DISTRIBUTED TO GRANTEEES IN THE SAME PROPORTION AS DISTRIBUTED IN FISCAL YEAR 2019-2020."

This ensures hemophilia funding in the budget must be distributed to the 7 Hemophilia Treatment Centers in the same way it was last fiscal year and not based on a regional approach. The Pennsylvania General Assembly passed the budget and fiscal code bills on June 28th, 2021 and Governor Wolf signed them into law on June 30th, 2021.

### THANK YOU!

This could not have happened without your help. Thank you for contacting your legislators and sharing your stories of the importance of the Hemophilia Treatment Centers in Pennsylvania.

## ENDING CO-PAY ACCUMULATORS IN PENNSYLVANIA

In 2020, a federal regulation made it legal for insurers to implement "co-pay accumulator programs." But these programs effectively prevent drug manufacturers' co-pay assistance programs, such as cards or coupons that provide discounts on medications, from counting toward a patient's deductible. For patients who require costly specialty medications, these are a lifeline -

one that accumulators essentially cut off. Once the manufacturer payments run out, patients face their full deductible.

Several states have already eliminated accumulator programs, and we are working to eliminate them in Pennsylvania. Bipartisan legislation has been introduced that would protect patients from having their prescription drug co-pay assistance programs undercut by their health insurer or pharmacy benefit managers. Introduced by Reps. Barbara Gleim (R-Cumberland County) and Mark Longietti (D-Mercer County), HB 1664 along with Senate Bill 196, would eliminate co-pay accumulator programs statewide.

## PRIOR AUTHORIZATION AND STEP THERAPY

**SB 225:** Amends the Insurance Company Law by including a standard definition of prior authorization. It will also significantly streamline the process by requiring insurers to make available an electronic communications network that permits prior authorization requests to be submitted electronically, and authorizations and adverse determinations to likewise be returned electronically.

On June 23, SB 225, as amended, passed unanimously out of the Senate Banking and Insurance Committee. Thank you to the members of the Senate Banking & Insurance Committee for helping us take this important step forward. Please urge your legislators to continue this progress when the bill is up for a vote in the full Senate.

VISIT [HTTPS://WWW.WPCNHF.ORG/GET-INVOLVED/ADVOCACY/](https://www.wpcnhf.org/get-involved/advocacy/) TO STAY UP TO DATE ON ADVOCACY ISSUES, SIGN UP FOR ACTION ALERTS, AND LEARN MORE ABOUT BECOMING AN ADVOCACY AMBASSADOR!





# EXPERIENCE MATTERS

BeneFix is FDA approved for once-weekly prophylaxis and on-demand use to fit your dosing needs—from the only recombinant factor IX supporting individuals with hemophilia B for more than 20 years.\*

Not actual patients.



**More than 20 years\* of experience**—the first recombinant treatment for individuals with hemophilia B



**Dosing options to meet your needs**—for once-weekly prophylaxis and on-demand use



Designed with viral safety in mind. More than 150 quality control tests are done on each batch of BeneFix



The convenience of the BeneFix Rapid Reconstitution (R2) Kit with a range of vial sizes



## What Is BeneFix?

BeneFix, Coagulation Factor IX (Recombinant), is an injectable medicine that is used to help control and prevent bleeding in people with hemophilia B. Your doctor might also give you BeneFix before surgical procedures.

BeneFix is **NOT** used to treat hemophilia A.

**ASK YOUR DOCTOR WHICH BENEFIX  
DOSING OPTIONS MAY BE RIGHT FOR YOU**

## 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.
- Call your health care provider right away if your bleeding is not controlled after using BeneFix.
- Allergic reactions may occur with BeneFix. Call your health care provider or get emergency treatment right away if you have any of the following symptoms: wheezing, difficulty breathing, chest tightness, your lips and gums turning blue, fast heartbeat, facial swelling, faintness, rash, or hives.
- Your body can make antibodies, called “inhibitors,” which may stop BeneFix from working properly.
- If you have risk factors for developing blood clots, such as a venous catheter through which BeneFix is given by continuous infusion, BeneFix may increase the risk of abnormal blood clots. The safety and efficacy of BeneFix administration by continuous infusion have not been established.
- Some common side effects of BeneFix are fever, cough, nausea, injection site reaction, injection site pain, headache, dizziness, and rash.

Please see the Brief Summary for BeneFix on the next page.



**BeneFix®**

**Coagulation Factor IX (Recombinant)**

Room Temperature Storage

\*BeneFix was approved February 11, 1997.



R<sub>x</sub> only

### Brief Summary

See package insert for full Prescribing Information. This product's label may have been updated. For further product information and current package insert, please visit [www.Pfizer.com](http://www.Pfizer.com) or call our medical communications department toll-free at 1-800-438-1985.

Please read this Patient Information carefully before using BeneFix and each time you get a refill. There may be new information. This brief summary does not take the place of talking with your doctor about your medical problems or your treatment.

### What is BeneFix?

BeneFix is an injectable medicine that is used to help control and prevent bleeding in people with hemophilia B. Hemophilia B is also called congenital factor IX deficiency or Christmas disease. Your doctor might also give you BeneFix before surgical procedures.

BeneFix is **NOT** used to treat hemophilia A.

### What should I tell my doctor before using BeneFix?

Tell your doctor and pharmacist about all of the medicines you take, including all prescription and non-prescription medicines, such as over-the-counter medicines, supplements, or herbal medicines.

Tell your doctor about all of your medical conditions, including if you:

- have any allergies, including allergies to hamsters.
- are pregnant or planning to become pregnant. It is not known if BeneFix may harm your unborn baby.
- are breastfeeding. It is not known if BeneFix passes into the milk and if it can harm your baby.

### How should I infuse BeneFix?

The initial administrations of BeneFix should be administered under proper medical supervision, where proper medical care for severe allergic reactions could be provided.

### See the step-by-step instructions for infusing in the complete patient labeling.

You should always follow the specific instructions given by your doctor. If you are unsure of the procedures, please call your doctor or pharmacist before using.

### Call your doctor right away if bleeding is not controlled after using BeneFix.

Your doctor will prescribe the dose that you should take.  
Your doctor may need to test your blood from time to time.  
BeneFix should not be administered by continuous infusion.

### What if I take too much BeneFix?

Call your doctor if you take too much BeneFix.

### What are the possible side effects of BeneFix?

Allergic reactions may occur with BeneFix. Call your doctor or get emergency treatment right away if you have any of the following symptoms:

wheezing	fast heartbeat
difficulty breathing	swelling of the face
chest tightness	faintness
turning blue (look at lips and gums)	rash
	hives

Your body can also make antibodies, called "inhibitors," against BeneFix, which may stop BeneFix from working properly.

Some common side effects of BeneFix are fever, cough, nausea, injection site reaction, injection site pain, headache, dizziness and rash.

BeneFix may increase the risk of thromboembolism (abnormal blood clots) in your body if you have risk factors for developing blood clots, including an indwelling venous catheter through which BeneFix is given by continuous infusion. There have been reports of severe blood clotting events, including life-threatening blood clots in critically ill neonates, while receiving continuous-infusion BeneFix through a central venous catheter. The safety and efficacy of BeneFix administration by continuous infusion have not been established.

These are not all the possible side effects of BeneFix.

Tell your doctor about any side effect that bothers you or that does not go away.

### How should I store BeneFix?

DO NOT FREEZE the BeneFix kit. The BeneFix kit can be stored at room temperature (below 86°F) or under refrigeration. Throw away any unused BeneFix and diluent after the expiration date indicated on the label.

Freezing should be avoided to prevent damage to the pre-filled diluent syringe.

BeneFix does not contain a preservative. After reconstituting BeneFix, you can store it at room temperature for up to 3 hours. If you have not used it in 3 hours, throw it away.

Do not use BeneFix if the reconstituted solution is not clear and colorless.

### What else should I know about BeneFix?

Medicines are sometimes prescribed for purposes other than those listed here. Do not use BeneFix for a condition for which it was not prescribed. Do not share BeneFix with other people, even if they have the same symptoms that you have.

If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about BeneFix that was written for healthcare professionals.

This brief summary is based on BeneFix® [Coagulation Factor IX (Recombinant)] Prescribing Information LAB-0464-12.0, revised June 2020.





# Explore **HEAD-TO-HEAD** Pharmacokinetic (PK) Study Data

See half-life, clearance and other  
PK data from the crossover study  
comparing **Jivi®** and **Eloctate®**

Visit **PKStudies.com** to find out more.

► **Pharmacokinetics** is the study of the activity  
of drugs in the body over a period of time.

  
antihemophilic factor  
(recombinant) PEGylated-aucI  
**LET'S GO**





ON WORLD HEMOPHILIA DAY, THE ENTIRE BLEEDING DISORDERS COMMUNITY CAME TOGETHER TO CELEBRATE THE CONTINUOUS ADVANCES IN TREATMENT WHILE RAISING AWARENESS TO THE ISSUES AND CHALLENGES THAT WE FACE EVERY DAY.

BUILDINGS AND LANDMARKS IN PHILADELPHIA, BETHLEHEM, HARRISBURG, AND PITTSBURGH WERE LIT RED IN HONOR OF WORLD HEMOPHILIA DAY. IN PITTSBURGH, LANDMARKS LIT RED INCLUDED PITTSBURGH'S CITY-COUNTY BUILDING, GULF TOWER, KOPPERS BUILDING, FIFTH AVENUE PLACE SPIRE, CARNEGIE SCIENCE CENTER AND HEINZ HALL'S GARDEN PLAZA WATERFALL.



This year, to celebrate Bleeding Disorders Awareness Month in March, 61 members of the Western PA Chapter decorated mini canvases to be part of a collage that we debuted on World Hemophilia Day.





# GO SEEK. GO EXPLORE. GO AHEAD.

PEOPLE LIKE YOU. STORIES LIKE YOURS.  
Explore more at [HEMLIBRAjourney.com](https://HEMLIBRAjourney.com)



## Discover your sense of go. Discover HEMLIBRA.

### What is HEMLIBRA?

HEMLIBRA is a prescription medicine used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children, ages newborn and older, with hemophilia A with or without factor VIII inhibitors.

### What is the most important information I should know about HEMLIBRA?

**HEMLIBRA increases the potential for your blood to clot. People who use activated prothrombin complex concentrate (aPCC; Feiba®) to treat breakthrough bleeds while taking HEMLIBRA may be at risk of serious side effects related to blood clots.**

**These serious side effects include:**

- **Thrombotic microangiopathy (TMA)**, a condition involving blood clots and injury to small blood vessels that may cause harm to your kidneys, brain, and other organs
- **Blood clots (thrombotic events)**, which may form in blood vessels in your arm, leg, lung, or head

Please see Brief Summary of Medication Guide on following page for Important Safety Information, including **Serious Side Effects**.

**HEMLIBRA**  
emicizumab-kxwh | 150  
injection for subcutaneous use | mg/mL



**Medication Guide**  
**HEMLIBRA® (hem-lee-bruh)**  
**(emicizumab-kxwh)**  
**injection, for subcutaneous use**

**What is the most important information I should know about HEMLIBRA?**

**HEMLIBRA increases the potential for your blood to clot. Carefully follow your healthcare provider's instructions regarding when to use an on-demand bypassing agent or factor VIII (FVIII) and the recommended dose and schedule to use for breakthrough bleed treatment.**

**HEMLIBRA may cause the following serious side effects when used with activated prothrombin complex concentrate (aPCC; FEIBA®), including:**

- **Thrombotic microangiopathy (TMA).** This is a condition involving blood clots and injury to small blood vessels that may cause harm to your kidneys, brain, and other organs. Get medical help right away if you have any of the following signs or symptoms during or after treatment with HEMLIBRA:
  - confusion
  - weakness
  - swelling of arms and legs
  - yellowing of skin and eyes
  - stomach (abdomen) or back pain
  - nausea or vomiting
  - feeling sick
  - decreased urination
- **Blood clots (thrombotic events).** Blood clots may form in blood vessels in your arm, leg, lung, or head. Get medical help right away if you have any of these signs or symptoms of blood clots during or after treatment with HEMLIBRA:
  - swelling in arms or legs
  - pain or redness in your arms or legs
  - shortness of breath
  - chest pain or tightness
  - fast heart rate
  - cough up blood
  - feel faint
  - headache
  - numbness in your face
  - eye pain or swelling
  - trouble seeing

**If aPCC (FEIBA®) is needed, talk to your healthcare provider in case you feel you need more than 100 U/kg of aPCC (FEIBA®) total.**

See **"What are the possible side effects of HEMLIBRA?"** for more information about side effects.

**What is HEMLIBRA?**

HEMLIBRA is a prescription medicine used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children, ages newborn and older, with hemophilia A with or without factor VIII inhibitors.

Hemophilia A is a bleeding condition people can be born with where a missing or faulty blood clotting factor (factor VIII) prevents blood from clotting normally.

HEMLIBRA is a therapeutic antibody that bridges clotting factors to help your blood clot.

**Before using HEMLIBRA, tell your healthcare provider about all of your medical conditions, including if you:**

- are pregnant or plan to become pregnant. It is not known if HEMLIBRA may harm your unborn baby. Females who are able to become pregnant should use birth control (contraception) during treatment with HEMLIBRA.
- are breastfeeding or plan to breastfeed. It is not known if HEMLIBRA passes into your breast milk.

**Tell your healthcare provider about all the medicines you take,** including prescription medicines, over-the-counter medicines, vitamins, or herbal supplements. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

**How should I use HEMLIBRA?**

**See the detailed "Instructions for Use" that comes with your HEMLIBRA for information on how to prepare and inject a dose of HEMLIBRA, and how to properly throw away (dispose of) used needles and syringes.**

- Use HEMLIBRA exactly as prescribed by your healthcare provider.
- **Stop (discontinue) prophylactic use of bypassing agents the day before starting HEMLIBRA prophylaxis.**
- **You may continue prophylactic use of FVIII for the first week of HEMLIBRA prophylaxis.**
- HEMLIBRA is given as an injection under your skin (subcutaneous injection) by you or a caregiver.

- Your healthcare provider should show you or your caregiver how to prepare, measure, and inject your dose of HEMLIBRA before you inject yourself for the first time.
- Do not attempt to inject yourself or another person unless you have been taught how to do so by a healthcare provider.
- Your healthcare provider will prescribe your dose based on your weight. If your weight changes, tell your healthcare provider.
- You will receive HEMLIBRA 1 time a week for the first four weeks. Then you will receive a maintenance dose as prescribed by your healthcare provider.
- If you miss a dose of HEMLIBRA on your scheduled day, you should give the dose as soon as you remember. You must give the missed dose as soon as possible before the next scheduled dose, and then continue with your normal dosing schedule. **Do not** give two doses on the same day to make up for a missed dose.
- HEMLIBRA may interfere with laboratory tests that measure how well your blood is clotting and may cause a false reading. Talk to your healthcare provider about how this may affect your care.

**What are the possible side effects of HEMLIBRA?**

- See **"What is the most important information I should know about HEMLIBRA?"**

**The most common side effects of HEMLIBRA include:**

- redness, tenderness, warmth, or itching at the site of injection
- headache
- joint pain

These are not all of the possible side effects of HEMLIBRA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How should I store HEMLIBRA?**

- Store HEMLIBRA in the refrigerator at 36°F to 46°F (2°C to 8°C). Do not freeze.
- Store HEMLIBRA in the original carton to protect the vials from light.
- Do not shake HEMLIBRA.
- If needed, unopened vials of HEMLIBRA can be stored out of the refrigerator and then returned to the refrigerator. HEMLIBRA should not be stored out of the refrigerator for more than a total of 7 days or at a temperature greater than 86°F (30°C).
- After HEMLIBRA is transferred from the vial to the syringe, HEMLIBRA should be used right away.
- Throw away (dispose of) any unused HEMLIBRA left in the vial.

**Keep HEMLIBRA and all medicines out of the reach of children.**

**General information about the safe and effective use of HEMLIBRA.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use HEMLIBRA for a condition for which it was not prescribed. Do not give HEMLIBRA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about HEMLIBRA that is written for health professionals.

**What are the ingredients in HEMLIBRA?**

**Active ingredient:** emicizumab-kxwh

**Inactive ingredients:** L-arginine, L-histidine, poloxamer 188, and L-aspartic acid.

Manufactured by: Genentech, Inc., A Member of the Roche Group,  
1 DNA Way, South San Francisco, CA 94080-4990  
U.S. License No. 1048

HEMLIBRA® is a registered trademark of Chugai Pharmaceutical Co., Ltd., Tokyo, Japan

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For more information, go to [www.HEMLIBRA.com](http://www.HEMLIBRA.com) or call 1-866-HEMLIBRA.

This Medication Guide has been approved by the U.S. Food and Drug Administration  
Revised: 10/2018



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**Genentech**  
A Member of the Roche Group

# SPRING HAS SPRUNG AT WPCNHF'S MOTHER'S DAY PAINT 'N SIP

On Sunday, May 9th, WPCNHF celebrated Mother's Day with a Paint 'N Sip fundraiser! Mickayla Poland, a local artist based in St. Marys, PA, spent the afternoon with us and showed us how to paint a beautiful flowery field on our wine glasses. The cost to participate was \$25 to pick-up your painting kit at the Chapter office or \$35 and your kit would be shipped to your home. Each kit included a wine glass, 2 paint brushes, 5 paint cups, and care instructions for the finished glass.

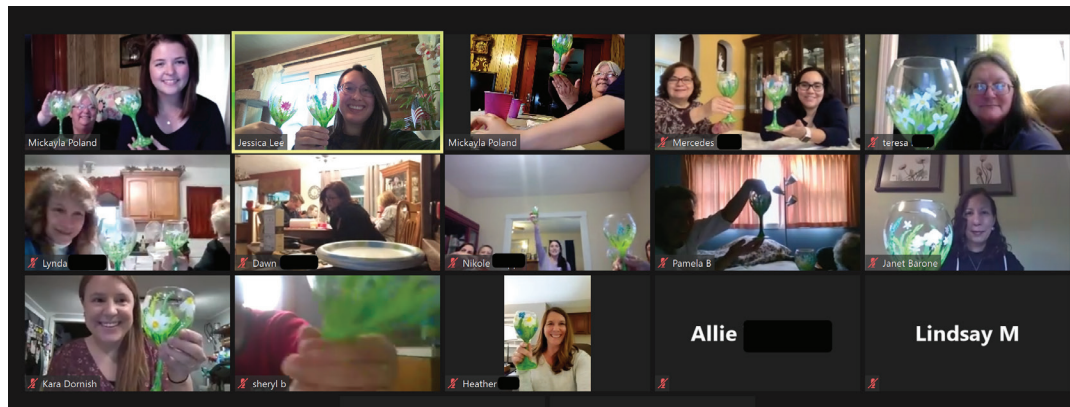
Over 40 people joined to celebrate Mother's Day with us and helped raise nearly \$1,500 for the bleeding disorders community of Western Pennsylvania! All the money raised from this event will go toward

providing medical and emergency assistance to our members in need, as well as providing support groups, and free educational programs to anyone affected by bleeding disorders in Western PA! WPCNHF also partnered with One



Hope Winery to help raise even more funds for our community. Between April 20th and May 11th, 10% of all wine sales, minus taxes and shipping, went back to the Chapter.

Thank you to everyone who joined us at this event and supported us through wine sales! We are so grateful you joined us to celebrate the amazing women in your lives. We hope to see you at one of our events in the future!



The Hemophilia Center of Western Pennsylvania clotting factor program was established in 2000 as a complement to the Center's other comprehensive care services. The clotting factor program allows the Center the opportunity to offer clotting factor to its patients, thereby supplementing its comprehensive treatment care model and providing the best possible care for its patients.

## **Factor Program Services**

- All factor product brands available
- Online factor ordering available
- 24 – 48 hour delivery
- Same day courier service for emergent needs
- On-call services, 24/7
- Home treatment supplies
- Lot tracking for recall notification
- Online home treatment records
- Insurance benefit information assistance

## **Patient Benefits**

- Direct communication and service from the Center's treatment team
- Support of the Center's operations
- Expansion of patient services

Please contact the Center at (412) 209-7280 for more information about how this program can benefit you and the entire bleeding disorder community.

The Hemophilia Center of Western Pennsylvania supports patient choice consistent with the Veterans Health Care Act of 1992 and maintains a freedom of choice policy where patients are informed of their choices regarding factor replacement products.



# HEMOPHILIA A IS A PIECE OF YOU. NOT ALL OF YOU.

ADYNOVATE® is a treatment that can be personalized to fit your lifestyle so you have more time to spend doing the other things that also make you, you. It has a simple, twice-weekly dosing schedule on the same 2 days every week.<sup>1,2</sup>

\*In clinical trials, ADYNOVATE demonstrated the ability to help prevent bleeding episodes using a prophylaxis regimen.

No actual patients depicted.

## ADYNOVATE twice-weekly prophylaxis prevented or reduced the number of bleeds<sup>2</sup>

ADYNOVATE was proven in 2 pivotal clinical trials to prevent or reduce the number of bleeding episodes in children and adults when used regularly (prophylaxis)<sup>2</sup>

- **Children Under 12 Years:** This study evaluated the efficacy of ADYNOVATE twice-weekly prophylaxis and determined the ability to treat bleeding episodes for 6 months in 66 children under 12 years old who received 40–60 IU/kg of ADYNOVATE prophylaxis treatment<sup>2</sup>
  - During the 6-month study in children under 12, those receiving twice-weekly prophylaxis treatment experienced a median<sup>1</sup> overall ABR<sup>4</sup> of 2.0
  - 0 bleeds in 38% (25 out of 66 patients) during 6 months on twice-weekly prophylaxis

<sup>1</sup>Median is defined as the middle number in a list of numbers arranged in numerical order.

<sup>4</sup>ABR=annualized bleed rate, the number of bleeds that occur over a year.

<sup>5</sup>Per-protocol patients were assigned to the prophylactic group and treated with their originally assigned dose for the entire duration of the study.

## ADYNOVATE Important Information

### What is ADYNOVATE?

- ADYNOVATE is an injectable medicine that is used to help treat and control bleeding in children and adults with hemophilia A (congenital factor VIII deficiency).
- Your healthcare provider (HCP) may give you ADYNOVATE when you have surgery.
- ADYNOVATE can reduce the number of bleeding episodes when used regularly (prophylaxis).

ADYNOVATE is not used to treat von Willebrand disease.

## DETAILED IMPORTANT RISK INFORMATION

### Who should not use ADYNOVATE?

Do not use ADYNOVATE if you:

- Are allergic to mouse or hamster protein.
- Are allergic to any ingredients in ADYNOVATE or ADVATE® [Antihemophilic Factor (Recombinant)].

Tell your HCP if you are pregnant or breastfeeding because ADYNOVATE may not be right for you.

### What should I tell my HCP before using ADYNOVATE?

Tell your HCP if you:

- Have or have had any medical problems.
- Take any medicines, including prescription and non-prescription medicines, such as over-the-counter medicines, supplements or herbal remedies.
- Have any allergies, including allergies to mice or hamsters.
- Are breastfeeding. It is not known if ADYNOVATE passes into your milk and if it can harm your baby.
- Are or become pregnant. It is not known if ADYNOVATE may harm your unborn baby.
- Have been told that you have inhibitors to factor VIII (because ADYNOVATE may not work for you).

- **Adolescents and Adults 12 Years and Older:** This study evaluated the efficacy of ADYNOVATE in a 6-month study that compared the efficacy of a twice-weekly prophylactic regimen with on-demand treatment and determined hemostatic efficacy in the treatment of bleeding episodes in 137 patients. These adolescents and adults were given either ADYNOVATE prophylaxis twice-weekly at a dose of 40–60 IU/kg (120 patients) or on-demand treatment with ADYNOVATE at a dose of 10–60 IU/kg (17 patients). The primary study goal was to compare ABR between the prophylaxis and on-demand treatment groups<sup>2</sup>
  - 95% reduction in median overall ABR (41.5 median ABR with on-demand [17 patients] vs 1.9 median ABR with prophylaxis [120 patients])
  - 0 bleeds in 40% (40 out of 101 per-protocol<sup>5</sup> patients) during 6 months on twice-weekly prophylaxis

### What important information do I need to know about ADYNOVATE?

- You can have an allergic reaction to ADYNOVATE. Call your healthcare provider right away and stop treatment if you get a rash or hives, itching, tightness of the throat, chest pain or tightness, difficulty breathing, lightheadedness, dizziness, nausea or fainting.
- Do not attempt to infuse yourself with ADYNOVATE unless you have been taught by your HCP or hemophilia center.

### What else should I know about ADYNOVATE and Hemophilia A?

- Your body may form inhibitors to factor VIII. An inhibitor is part of the body's normal defense system. If you form inhibitors, it may stop ADYNOVATE from working properly. Talk with your HCP to make sure you are carefully monitored with blood tests for the development of inhibitors to factor VIII.

### What are possible side effects of ADYNOVATE?

- The common side effects of ADYNOVATE are headache and nausea. These are not all the possible side effects with ADYNOVATE. Tell your HCP about any side effects that bother you or do not go away.

**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 Facts about ADYNOVATE on the following page and discuss with your HCP.**

**For Full Prescribing Information, visit [www.adynovate.com](http://www.adynovate.com).**

**References:** 1. Valentino LA. Considerations in individualizing prophylaxis in patients with haemophilia A. *Haemophilia*. 2014;20(5):607-615. 2. ADYNOVATE Prescribing Information.

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## Patient Important facts about

### **ADYNOVATE® [Antihemophilic Factor (Recombinant), PEGylated]**

This leaflet summarizes important information about ADYNOVATE. Please read it carefully before using this medicine. This information does not take the place of talking with your healthcare provider, and it does not include all of the important information about ADYNOVATE. If you have any questions after reading this, ask your healthcare provider.

#### **What is the most important information I need to know about ADYNOVATE?**

Do not attempt to do an infusion to yourself unless you have been taught how by your healthcare provider or hemophilia center.

You must carefully follow your healthcare provider's instructions regarding the dose and schedule for infusing ADYNOVATE so that your treatment will work best for you.

#### **What is ADYNOVATE?**

ADYNOVATE is an injectable medicine that is used to help treat and control bleeding in children and adults with hemophilia A (congenital Factor VIII deficiency). Your healthcare provider may give you ADYNOVATE when you have surgery. ADYNOVATE can reduce the number of bleeding episodes when used regularly (prophylaxis).

ADYNOVATE is not used to treat von Willebrand disease.

#### **Who should not use ADYNOVATE?**

You should not use ADYNOVATE if you:

- Are allergic to mice or hamster protein
- Are allergic to any ingredients in ADYNOVATE or ADVATE® [Antihemophilic Factor (Recombinant)]

Tell your healthcare provider if you are pregnant or breastfeeding because ADYNOVATE may not be right for you.

#### **How should I use ADYNOVATE?**

ADYNOVATE is given directly into the bloodstream.

You may infuse ADYNOVATE at a hemophilia treatment center, at your healthcare provider's office or in your home. You should be trained on how to do infusions by your healthcare provider or hemophilia treatment center. Many people with hemophilia A learn to infuse their ADYNOVATE by themselves or with the help of a family member.

Your healthcare provider will tell you how much ADYNOVATE to use based on your individual weight, level of physical activity, the severity of your hemophilia A, and where you are bleeding.

Reconstituted product (after mixing dry product with wet diluent) must be used within 3 hours and cannot be stored or refrigerated. Discard any ADYNOVATE left in the vial at the end of your infusion as directed by your healthcare professional.

You may have to have blood tests done after getting ADYNOVATE to be sure that your blood level of factor VIII is high enough to clot your blood.

#### **How should I use ADYNOVATE? (cont'd)**

Call your healthcare provider right away if your bleeding does not stop after taking ADYNOVATE.

#### **What should I tell my healthcare provider before I use ADYNOVATE?**

You should tell your healthcare provider if you:

- Have or have had any medical problems.
- Take any medicines, including prescription and non-prescription medicines, such as over-the-counter medicines, supplements or herbal remedies.
- Have any allergies, including allergies to mice or hamsters.
- Are breastfeeding. It is not known if ADYNOVATE passes into your milk and if it can harm your baby.
- Are pregnant or planning to become pregnant. It is not known if ADYNOVATE may harm your unborn baby.
- Have been told that you have inhibitors to factor VIII (because ADYNOVATE may not work for you).

#### **What are the possible side effects of ADYNOVATE?**

You can have an allergic reaction to ADYNOVATE.

Call your healthcare provider right away and stop treatment if you get a rash or hives, itching, tightness of the throat, chest pain or tightness, difficulty breathing, lightheadedness, dizziness, nausea or fainting.

The common side effects of ADYNOVATE are headache and nausea. Tell your healthcare provider about any side effects that bother you or do not go away.

These are not all the possible side effects with ADYNOVATE. You can ask your healthcare provider for information that is written for healthcare professionals.

#### **What else should I know about ADYNOVATE and Hemophilia A?**

Your body may form inhibitors to Factor VIII. An inhibitor is part of the body's normal defense system. If you form inhibitors, it may stop ADYNOVATE from working properly. Consult with your healthcare provider to make sure you are carefully monitored with blood tests for the development of inhibitors to Factor VIII.

Medicines are sometimes prescribed for purposes other than those listed here. Do not use ADYNOVATE for a condition for which it is not prescribed. Do not share ADYNOVATE with other people, even if they have the same symptoms that you have.

#### **The risk information provided here is not comprehensive.**

**To learn more, talk with your health care provider or pharmacist about ADYNOVATE. The FDA-approved product labeling can be found at [www.ADYNOVATE.com](http://www.ADYNOVATE.com) or 1-877-825-3327.**

**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.**

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Issued 05/2018



# CURRENTLY RECRUITING BLEEDING DISORDERS STUDIES

**DANA IVANCO, CCRC**

Please feel free to contact any of our Research Staff for any questions on a study you are interested in hearing more about.

Our research team email is:  
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Megan Rode, Research Coordinator,  
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**INHIBIT PHASE III INHIBITOR CLINICAL TRIALS  
PLATFORM: INHIBITOR ERADICATION TRIAL  
COMPARING ELOCTATE IMMUNE TOLERANCE**

## INDUCTION (ITI) PLUS EMICIZUMAB VS. ELOCTATE ITI ALONE TO ERADICATE INHIBITOR FORMATION IN INDIVIDUALS WITH SEVERE HEMOPHILIA A

Overview: This is a multi-center randomized phase III clinical trial, the Inhibitor Eradication Trial, in which Eloctate ITI plus Emicizumab will be compared with Eloctate ITI alone to eradicate inhibitors in patients with severe hemophilia A. This adaptive design is necessary as randomized trials in rare diseases are often not possible. The INHIBIT Clinical Trials Platform includes two linked trials, the Inhibitor Prevention Trial (Prevention Trial) and the Inhibitor Eradication Trial (Eradication Trial) that will be conducted at up to 41 U.S. hemophilia treatment centers (HTCs) affiliated with universities. The Inhibitor Eradication Trial is a 48-week randomized phase III trial, in which 90 previously treated patients (PTPs) with severe hemophilia A and high-responding inhibitors (anti-VIII > 0.6 B.U.), will be enrolled. Subjects will include individuals with severe hemophilia A who develop inhibitors during the linked Inhibitor Prevention Trial and adults or children at the same HTCs refractory to or never undergoing immune tolerance induction (ITI). Once enrolled, subjects who meet all the inclusion and none of the exclusion

criteria, will be randomized to weekly Eloctate ITI plus weekly Emicizumab vs. weekly Eloctate ITI alone to eradicate inhibitor formation, defined as anti-FVIII < 0.6 B.U.

More information: <https://clinicaltrials.gov/NCT04303572>

**INHIBIT PHASE III INHIBITOR CLINICAL TRIALS  
PLATFORM: INHIBITOR PREVENTION TRIAL  
COMPARING ELOCTATE (RFVIII-Fc) VS. EMICIZUMAB  
(HEMLIBRA) TO PREVENT INHIBITOR FORMATION  
IN INDIVIDUALS WITH SEVERE HEMOPHILIA A**

Overview: This is a multi-center randomized phase III clinical trial, the Inhibitor Prevention Trial, in which consecutive hemostatic agents will be compared using adaptive design to prevent inhibitors in patients with severe hemophilia A. This adaptive design is necessary as randomized trials in rare diseases are otherwise not possible. This adaptive design is necessary as randomized trials in rare diseases are otherwise not possible. The INHIBIT Clinical Trials Platform includes two linked trials, the Inhibitor Prevention Trial (Prevention Trial) and the Inhibitor Eradication Trial (Eradication Trial) that will be conducted at up to 41 U.S. hemophilia treatment centers

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# DRIVE-THRU NONPROFIT NIGHT AT WIGLE WHISKEY AND THREADBARE CIDER

On Thursday, May 20th, the Western Pennsylvania Chapter of the National Hemophilia Foundation partnered with Wigle Whiskey to host a Drive-Thru Nonprofit Night at their location in the Strip District. For every online order made on May 20th on Wigle's website, they donated 9.99% of all food and drink sales back to the Chapter!

On Thursday, July 10th, we hosted another Nonprofit Night with Threadbare Cider, located

in Pittsburgh. Threadbare Cider donated 9.99% of their pizza and cider sales! Participants could order online or dine-in and mention WPCNHF. There was no limit on the number of cider bottles purchased, so the more you bought, the more we raised!

Thank you to everyone who joined us at our Wigle Whiskey and Threadbare Cider Nonprofit Nights! All the money raised will provide education, patient assistance, and support groups for our members



affected by bleeding disorders in Western Pennsylvania!

## CURRENTLY RECRUITING BLEEDING DISORDERS STUDIES

CONTINUED FROM PAGE 17...

(HTCs) affiliated with universities. The Inhibitor Prevention Trial is a 48-week randomized phase III trial, in which 66 previously untreated patients (PUPs) with severe hemophilia A will be enrolled. Subjects will include children from 4 months of age up to 4 years of age who have not been previously treated with clotting factor. Once enrolled, subjects who meet all the inclusion and none of the exclusion criteria will be randomized to preemptive weekly Eloctate (rFVIII Fc) vs. weekly Emicizumab (Hemlibra) to prevent inhibitor formation, defined as anti-FVIII  $\geq 0.6$  BU.

More information: <https://clinicaltrials.gov/NCT04303559>

**RFVIII Fc-VWF-XTEND; BIVV001- EFC16295- A PHASE 3 OPEN-LABEL, MULTICENTER STUDY OF THE SAFETY, EFFICACY AND PHARMACOKINETICS OF INTRAVENOUS RECOMBINANT COAGULATION FACTOR VIII Fc-VON WILLEBRAND FACTOR-XTEN FUSION PROTEIN (RFVIII Fc-VWF-XTEN; BIVV001)**

### IN PREVIOUSLY TREATED PEDIATRIC PATIENTS <12 YEARS OF AGE WITH SEVERE HEMOPHILIA A

**Overview:** This study is being conducted to determine the safety, efficacy, and pharmacokinetics (PK) of BIVV001 administered as once-weekly (QW) prophylaxis treatment in previously treated pediatric patients <12 years of age with severe hemophilia A.

### THE VON WILLEBRAND DISEASE AGING AND BLEEDING CORRELATION STUDY: VWD ABC STUDY

**Overview:** This study is being done to see if people with type 1 VWD experience age related increases in VWF levels and what effect this has on bleeding in this population. In order to discover this, the study will examine medical history, blood and genetic tests for VWD and bleeding and collect information about bleeds from the subjects.

**PROSPECTIVE, RANDOMIZED, CROSSOVER TRIAL COMPARING RECOMBINANT VON WILLEBRAND FACTOR (RVWF) COMBINED WITH TRANEXAMIC ACID (TA) VS. TRANEXAMIC ACID (TA) ALONE TO MINIMIZE MENORRHAGIA IN WOMEN WITH VON WILLEBRAND DISEASE: THE VWD MINIMIZE STUDY**

**Overview:** The purpose of this research study is to compare the use of recombinant von Willebrand factor (rVWF) and tranexamic acid (TA, Lysteda®) in women with von Willebrand Disease (VWD) who have heavy monthly periods (also called menorrhagia).

More information: <https://clinicaltrials.gov/NCT02606045>

### PROSPECTIVE, RANDOMIZED TRIAL COMPARING RECOMBINANT VON WILLEBRAND FACTOR (RVWF) PLUS TRANEXAMIC ACID (TA) VS. RVWF ALONE TO REDUCE POSTPARTUM HEMORRHAGE IN WOMEN WITH VON WILLEBRAND DISEASE: THE VWD-WOMAN TRIAL

**Overview:** This is a prospective, randomized single-center phase III pilot clinical trial comparing recombinant von Willebrand factor (rVWF, Vonvendi®) plus tranexamic acid (TA, Cyclokapron®) vs. rVWF alone to reduce postpartum hemorrhage (PPH) in women with von Willebrand disease (VWD).

More information: <https://clinicaltrials.gov/NCT04344860>

## GETTING TO KNOW HCWP STAFF



**NICOLE MYERS**  
RESEARCH NURSE

**Birthplace:** Ellwood City, PA

**First job:** Subway, in high school

**Accomplishment you're proudest of:**  
My family and being a nurse

**What three words describe you best?**  
Punctual, loyal, compassionate

**Dream vacation:** I love to travel, so I am happy to go anywhere that allows me to be a tourist.

**Things you can't do without:**  
Television and shoes

**Person you'd most like to have dinner with:** Dr. Temple Grandin

**Movie you could see anytime:**  
Legends of the Fall

**TV show you try not to miss:** I

don't watch much TV but I listen to podcasts every day and I try not to miss *The Daily* by the New York Times.

**Three things that can always be found in your refrigerator:** almond milk, coffee, leftovers

**Secret vice:** I pick and bite at my nails (ugh!)

**Who would play you in the movies?**  
Zoey Deschanel

**Your pet peeve about Pittsburgh:**  
The weather

**People may be surprised to know that:** Before my family, I sold all of my belongings in my apartment, drove to and lived in Jackson, Wyoming, where I spent lots of time hiking around the Tetons and Yellowstone.



# STUDY LOOKS AT NEURAXIAL ANESTHESIA AND POSTPARTUM COMPLICATIONS IN HEMOPHILIA

Findings from a recently published study in the Journal of Anesthesia suggest that pregnant patients with hemophilia whose factor VIII or IX levels drop below 50% at the time of receiving neuraxial anesthesia are more likely to experience postpartum complications. Neuraxial anesthesia refers to the administration of local anesthetics and analgesia to targeted locations in the spinal area. Epidurals are a commonly utilized form of neuraxial anesthesia, often used as a method of pain relief during labor.

Investigators were led by Brandon Togioka, MD, Associate Professor, Department of Anesthesiology and Perioperative Medicine at the Oregon Health & Science University in Portland. Togioka and his colleagues conducted two sets of literature reviews in October 2019. The first review, which included 13 articles, encompassed individual case reports and case series that described neuraxial techniques in patients with hemophilia—regardless of sex, age, or pregnant status. The second review, which included 19 articles, looked for case reports and series that outlined bleeding outcomes among pregnant patients.

Findings from the first review showed that 3 of 134 patients had neuraxial hematoma with paraplegia (paralysis of the legs and lower body). All three of these patients presented with a factor level of 1%. The second review showed that out of 2,712 deliveries, postpartum hemorrhage occurred

in 193 patients (7.1%), which necessitated blood transfusion in 60% of these patients. Overall, postpartum bleeding complications were nearly “twice as likely” where factor levels were below 50%.

“In summary, we found low level evidence (Level 4) that factor VIII and IX levels should be greater than 50% for delivery and neuraxial techniques. In our review of 134 neuraxial placements and 2,712 deliveries, neuraxial hematomas were found with a factor level of 1% and hemorrhagic complications were higher when factor activity was <50%,” explained Togioka and his fellow authors. “Therefore, factor levels should be assessed and increased above 50% prior to neuraxial technique and delivery.”

The review, “Delivery and Neuraxial technique Outcomes in Patients with Hemophilia and in Hemophilia Carriers: A Systematic Review,” was published March 2021 in the Journal of Anesthesia.

Please note that earlier this year, NHF’s Medical and Scientific Advisory Council (MASAC) issued MASAC Document #265 which provides recommendations for the diagnosis and management of women with bleeding disorders during pregnancy, labor, and delivery. It also addresses the critical postpartum period with specific treatment recommendations designed to both mitigate the risk of bleeding-related complications in women and to enable the early diagnosis of affected infants. The document also does include recommendations on the appropriate use of neuraxial anesthesia.

View and download MASAC Guidelines for Pregnancy and Perinatal Management of Women with Inherited Bleeding Disorders and Carriers of Hemophilia A or B at: [bit.ly/masacguidelines](https://bit.ly/masacguidelines)

Source: *Hematology Advisor*, April 6, 2021

## WPCNHF’S CHARITY LIVE STREAM

On Friday, June 18th, WPCNHF partnered with Colin Domowicz, a chapter member diagnosed with von Willebrand Disease, to host a Charity Live Stream to benefit the bleeding disorders community of Western Pennsylvania. On Twitch, Colin goes by Draagax and has built a large audience playing video games. Video games have been a big part of his life for over a decade, and he wanted to use his platform to share his story and give back to the bleeding disorders community.

WPCNHF joined the stream for the first two hours. Thank you to Tracy S., Mindy S., and Mason B. for joining the stream live at the Chapter office and virtually to play games and share your story! Throughout the stream, there were raffles and challenges for Colin to complete when certain fundraising goals were hit such as taking a shot of pickle juice, taking a pie to the face, and eating a Carolina Reaper! Colin continued streaming for over 12 hours and raised a total of \$1001.69 for WPCNHF! All proceeds of this event will support our educational programs, social programs, and patient assistance fund to help families in need during the COVID-19 pandemic.

We are so thankful for Colin’s hard work and support and for bringing awareness to bleeding disorders!



# WE'RE IN THIS TOGETHER.

**Thursday 3:24 pm**

Practicing yoga with  
her mom

Mariana, living with  
von Willebrand disease

Not an actual patient

## Let's make today brilliant.

Takeda is here to support you throughout your journey and help you embrace life's possibilities. Our focus on factor treatments and educational programs, and our dedication to the bleeding disorders community, remain unchanged. And our commitment to adult patients with von Willebrand disease is stronger than ever.

*Not all activities are appropriate for all individuals.  
Consult your doctor prior to engaging in any activity.*

 [bleedingdisorders.com](https://bleedingdisorders.com) | 

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WPCNHF'S

# ANNUAL MEETING



AND WALK KICK-OFF

THURSDAY, JULY 22ND | 6:00 PM

Join us virtually for our Annual Meeting and Walk Kick-Off! Learn more about the services the Chapter offers, help us recognize our top volunteers, hear from our sponsors, and help us kick off the Unite for Bleeding Disorders Walk!

Dinner Gift Cards and Event Boxes with sponsor giveaways will be sent to those who **register by Friday, July 16th.**

This event is open to members of our Chapter with bleeding disorders and their immediate family. RSVP with your first and last name and the number of people in your household attending by emailing **[rsvp@wpcnhf.org](mailto:rsvp@wpcnhf.org)** by July 22nd at 3pm to receive a dinner gift card. You must RSVP by July 16th to receive an event box. Please include Annual Meeting in the subject line. The Zoom link and call in information will be sent to those who register.

## THANK YOU TO OUR SPONSORS:



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THE HEMOPHILIA  
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of Western Pennsylvania

CVS specialty

octapharma  
For the safe and optimal use of human proteins



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CSL Behring



WESTERN PENNSYLVANIA CHAPTER OF THE NATIONAL HEMOPHILIA FOUNDATION

20411 Route 19, Unit 14  
Cranberry Township, PA 16066

# Unite

for Bleeding Disorders



## 13th Annual Unite for Bleeding Disorders Walk

**When:** Saturday, September 18, 2021

**Where:** North Park Swimming Pool Loop  
S Ridge Drive  
Allison Park, PA 15101

**Questions:** [jessica@wpcnhf.org](mailto:jessica@wpcnhf.org)  
724-741-6160



[uniteforbleedingdisorders.org/event/wpa](https://uniteforbleedingdisorders.org/event/wpa)



# HEMOGRAM

WESTERN PENNSYLVANIA CHAPTER OF THE NATIONAL HEMOPHILIA FOUNDATION

20411 Route 19, Unit 14

Cranberry Township, PA 16066

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