Summer
2017

HANJournal

BDRN & HANJ

340B Bleeding Disorders Program

In association with:

Rutgers: Robert Wood Johnson Medical School

BDRN HANJ

Pharmacy Services In Your Hands

Bleeding Disorders Resource Network

BDRN's Mission is to improve the quality of life for people living with bleeding disorders.

At BDRN we are dedicated to serving and making a difference in the bleeding disorders community. We take a team approach to address each set of circumstances. Our commitment to improving the lives of those living with a bleeding disorder is what motivates us and is the essence of everything we do.

Hemophilia Association of New Jersey

HANJ's mission is to improve the quality of life for persons with a bleeding disorder by providing and maintaining access to highly qualified medical treaters and successfully proven medical regimens.

- Ensure access to care
- Secure more comprehensive insurance coverage
- Ensure the NJ Standards of Care are met
- Provide financial grants to hemophilia and bleeding disorder patients
- Provide financial grants in support of the HTC's
- Provide education programs and reimbursement support to patients of New Jersey

340B Program

The 340B Program is a federal drug discount program. It entitles certain safety net providers and clinics, including hemophilia treatment centers, to a discounted price for covered outpatient drugs. Rutgers/RWJ has registered to participate in the 340B Program as a Covered Entity. This will allow Rutgers/RWJ to purchase factor and other drugs at a discount. While other grant fundings suffer cutbacks, Rutgers/RWJ is able to use the cost savings and other program revenues to fund the services it provides to its patients. Rutgers has selected BDRN as one of its contract pharmacies under the 340B Program. BDRN and HANJ have agreed to work together to provide certain services for the Rutgers program, including patient education and financial assistance services.

Message from the President of HANJ
David Lechner

We have had a great few months and some great events at HANJ since our last newsletter.

We held our annual testimonial dinner where we had the pleasure to recognize Sal Rafanelli – CEO and Co-Founder of BiologicTx for his great work and long history of providing a critical link and service to our community.

At the HANJ Annual Meeting, we also had the opportunity to recognize some outstanding individuals that are part of and have supported our community for many years. We had the honor and privilege to give out the following awards; The Benefactors Award to John Halvey, two Special Recognition Awards to Bill Murray and Glenn & Eileen Rosenwald, two Humanitarian Awards to Ward Sanders and Dr. Franklin Desposito, The Unsung Hero Award to Vanessa Cullom, Congressman Dean Gallo Award to James Romano, The Past President's Award to George Keelty and the Kuhn Award to Dr. Katherine High.

On behalf of HANJ, I want to congratulate and thank again all of the individuals we had the opportunity to recognize for your hard work, dedication and commitment to our community. Each of you could not be more deserving of these awards for all you have done and continue to do.

In addition to Dr. Katherine High, President and Chief Scientific Officer of Spark Therapeutics, receiving the Kuhn Award at the Annual Meeting, she also presented on some of the new and exciting research and progress that is being made by Spark Therapeutics in the field of bleeding disorders; specifically, Hemophilia. We could not be more excited about the investments and research time that all of our industry partners are dedicating to bleeding disorders.

In addition to the Testimonial Dinner and Annual Meeting, In April we held our annual Hemophilia Awareness Walk at the RVCC campus where we had the opportunity to spend a great day together as a community. In June, we held our Annual Dennis Keelty Memorial Golf Tournament that brings together HANJ members with our industry partners to provide remembrance of individuals from our community and also raises money to continue to support all of the critical programs HANJ provides.

The turnout for all of these events was good, however it could and needs to be better. We understand everyone has a busy schedule and certain dates can conflict with plans, however these events provide many benefits to all of you and your participation, as always, is greatly needed. As a community we are stronger when we **ALL** work together.

I hope the summer is off to a great start for all of you and that you enjoy it. We do look forward to seeing you at some of the next events like Blood Brotherhood, Gourmet Dinner or Casino Night. Please remember, if you would like to attend an event and need assistance, please contact the HANJ office. Thank you again and I hope you enjoy the latest HANJ newsletter.

Best Regards,

David

HANJournal is published by the Hemophilia Association of NJ 197 Route18 So. Suite 206 North East Brunswick, NJ 08816.

Phone: 732-249-6000
Fax: 732-249-7999
E-mail: hemnj@comcast.net
Website: www.hanj.org

The Hemophilia Association of New Jersey was founded in August 1971 by 10 concerned families, and offers assistance to persons with hemophilia and their families from our office located in East Brunswick, New Jersey.
Our mission is to improve the quality of life for persons with a bleeding disorder by providing and maintaining access to highly qualified medical providers and successfully proven medical regimens.

Social Worker Update
By Neidy Olarte, MSW
Social Service Coordinator

Insurance Update

After several attempts from the GOP to repeal and replace the Affordable Healthcare Act (ACA), also known as Obamacare, the bill was not passed by the senate due to lack of votes needed to move the bill forward. While Obamacare is still in place, no one can know for sure how long it will remain intact and what will eventually replace Obamacare if the GOP is successful in repealing and replacing the ACA. It is also uncertain how Obamacare will survive without support from the President since he has vowed to let Obamacare fail. This can be extremely detrimental for families dealing with a chronic illness and particularly with families within the hemophilia community. HANJ continues to remain vigilant and continues to monitor any changes in the healthcare bill.

Insurance plans offered today have not only increased in premium cost, but have also increased in their co-pays, deductibles, and overall out-of-pocket costs. With these significant increases, individuals and families are obligated to pay more for their medical care. This can put a heavy burden and strain on families and individuals who have a chronic health condition. Through our insurance grant program, HANJ has expanded assistance to include co-pays and other out-of-pocket costs that are no longer covered through insurance. If you are in need of insurance assistance and feel that you may qualify to receive assistance through our insurance grant, please do not hesitate to contact HANJ for information.

Leaving your plan and what to know:

Were you currently terminated from your health insurance policy? Were you currently on Medicaid and no longer qualify to remain on your Medicaid plan? Did your income exceed the eligibility amount to remain on your health insurance plan through Medicaid? If you recently lost your health insurance, be aware that you have (60) days to enroll onto a policy through the marketplace, if that is the option you plan to take. Even if you are trying to enroll with our insurance grant program, if you do not secure a health insurance plan within the (60) day window, you will not be allowed to enroll into a plan through the marketplace until open enrollment which is usually after October. If you feel that you have been terminated from your insurance company in error, you have a right to appeal. Do not assume that you will be accepted to an insurance plan when you are ready to have a plan. If you do not seek insurance within the (60) day window you will not be eligible for insurance unless you feel you may qualify for a special enrollment period. Information on what consists as a special enrollment can be found on the healthcare website at www.healthcare.gov. This does not apply to those who have switched jobs and a new employer is offering insurance. Most employers have you wait (90) days before you are able to enroll under their health insurance plan. If you have any questions related to this matter you can contact HANJ for further assistance.

WHAT'S HAPPENING
New Jersey Hemophilia Treatment Centers

Rutgers Robert Wood Johnson Medical School Hemophilia Treatment Center

Rutgers RWJ Medical School 340B Program:
In order for the hemophilia program to maintain comprehensive hemophilia care in an era of increasing health care costs amidst dwindling levels of federal and state funding of hemophilia programs, the Rutgers Robert Wood Johnson Medical School Hemophilia Treatment Center has become a 340B covered entity as of October 1, 2015. Participation in the federal 340B program makes it possible for our HTC to continue to serve the hemophilia community with the high level of services and quality of care it expects. If you have questions about this program, please do not hesitate to contact the HTC directly at 732-235-6533.

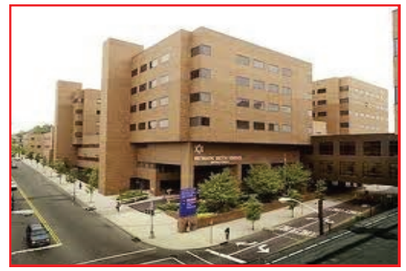
Educational & Programming Events:
The HTC will be hosting an infusion training program. Date and time to be decided. In addition, please do not hesitate to call the HTC to set up individual infusion training sessions (see contact information below).

School Visits:
The staff at the HTC continues to provide in-service programs to school personnel about a child's hemophilia. If you are in need of an in-service program at your child's school or camp, please contact Lisa Cohen, MSW at 732-235-6533. *Please do not wait to contact Lisa, as the slots for these visits fill up very quickly during this time of year!*

Ongoing Training:
The staff at the HTC continues to provide hands-on training in infusion procedures to parents and their children. A series of thirty minute sessions are held over a period of weeks/months depending on the families' needs, abilities and schedule. Please call Frances Maceren, RN at 732-235-6542, if you are interested in arranging infusion training.

General Information:
For information regarding women with bleeding disorders and/or a family history of hemophilia, clinical trials, genetic counseling, insurance issues, educational sessions or school visits, please call the Hemophilia Treatment Center at 732-235-6531.

Newark Beth Israel Medical Center and Children's Hospital of New Jersey



Happy Summer! The staff from the Comprehensive Hemophilia Treatment Center at Newark Beth Israel Medical Center and Children's Hospital of New Jersey would like to share some updates, current programs, and plans with you.

NEWS
New Staff:
We are happy to announce that Kim Roberts, MHA has joined our team as our new Data Analyst. Welcome Kim!

UPCOMING
Self-Infusion Workshops:
The process of learning how to self-infuse can be stressful. Our HTC will be offering self-infusion workshops for patients, and their parents or guardians, to learn how to properly and confidently self-infuse. The workshops, which will take place at the HTC, will enhance knowledge, educate, and empower both patients and their parents or guardians alike. At the end of the workshop, those who attend will be one step closer towards independence. These workshops have previously been one of our most attended workshops. To sign up for a workshop, please contact Erica, our Social Worker, at the HTC.

Hemophilia Camp:
The time for summer camp is quickly approaching. This year, like last year, we will have several children attending a hemophilia camp at either Double H Ranch or Hole in the Wall Gang Camp. Hemophilia camp is an integral part of our patients' journey towards independence. Learning how to self-infuse at camp is one of the many highlights of our camper's experience, and both camps have many supportive counselors who encourage our patients in that process. Both camps also offer family programming in the spring and fall. For more information about camp, or if your child or family is interested in attending camp in the future, please contact Erica, our Social Worker, at the HTC.

Travel Letters:
Are you going to be travelling? Are you going to need a travel letter? If you answered yes to either of those questions, this information is for you. Please remember to let the HTC staff know if you are going to need a travel letter at least two weeks prior to your scheduled trip so you can rest assured that your letter is in your hand as you embark on your journey.

ONGOING PROGRAMS
Hemophilia 340B Program:
We are excited to announce that our HTC participates in the Federal 340B Program. As a comprehensive care center, we have been improving the quality of life for individuals with bleeding disorders and providing cost effective care in the long term for many years. In an effort to help HTCs sustain themselves, and pro-

-vide better care for their eligible patients, Congress created the 340B Program as part of the Veteran's Health Care Act of 1992. Across the United States almost all of the HTCs participate in 340B Programs. Depending on your healthcare coverage, patients have a variety of pharmacy options to choose from. Our HTC has contracted with four different home care companies; Accredo, BDRN, Bioscrip, and Option Care. Patients who are not currently using one of these four companies may voluntarily switch, if their insurance company allows. Participation in the 340B Program is voluntary. Please contact our Program Manager Phyllis for further information.

My Life Our Future Carrier Testing:
The My Life Our Future program has been providing patients with hemophilia the opportunity to determine the genotype of their hemophilia. The program has now expanded to offer genotyping to potential and known carriers of hemophilia. The carrier testing will be available, for female family members of current participants of My Life Our Future, through the end of 2017. Please contact the HTC for more information.

School Visits:
School visits are a wonderful opportunity for our HTC to provide education and outreach to your child's school or daycare about hemophilia and other bleeding disorders. Whether the visit is with the staff at your child's school, the daycare staff, or even the child study team, a school visit opens the lines of communication between the child's school or daycare and the HTC.

If you are going to want a school visit scheduled for the fall for your child's school or daycare center, please contact the HTC so that a visit can be scheduled. In addition, if you will need any forms or letters for your child's school or daycare center completed, please be mindful that it may take up to two weeks for forms or letters to be completed. For more information, please contact us at the HTC.

Comprehensive Evaluations:
It is really important to schedule and attend an annual comprehensive evaluation at the HTC. The annual evaluation is an essential component in the provision of an individual's comprehensive care. Members of the HTC treatment team will complete medical, musculoskeletal, psychosocial and laboratory evaluations to assess the patient's current health and to develop a treatment plan for the upcoming year. Education and referrals for medical and psychosocial services will also be provided as needed. At the time of an annual evaluation, patients will be asked to participate in the ATHN (American Thrombosis & Hemostasis Network) Data Set. This is a voluntary program conducted by HTC's with support by ATHN to improve the health of people with coagulation disorders. Patients with hemophilia can also participate in My Life Our Future to determine the genotype of their hemophilia. **Please note that any individual receiving medication through the HTC to treat their bleeding disorder must be seen by the HTC on an annual basis.**

Manufacturer Factor Program:
Manufacturers of clotting factor

products have programs available to help patients continue to receive factor products during a lapse of insurance coverage. They also offer co-pay assistance programs. Each program has enrollment requirements and many require re-enroll ments and many require yearly re-enrollment. Enrollment in these programs can be beneficial. For more information, please contact your home care company or us at the HTC.

Please contact us at the Hemophilia Treatment Center to sign up for one of the above programs or to request further information on available groups or services for children and adults. We can be reached at (973) 926-6511.

St. Michael's Medical Center

Individualized session:
Our staff is always available for individual educational sessions on topics such as infusion and factor products. We always welcome suggestions from our patients. If you need assistance, please contact Dominique Joseph, RN at (973) 877-5340.

Educational Event:
We are pleased to announce that our center provided educational sessions throughout the months of May and June. Our topics were Nutrition, Exercise, Physical Therapy/ Arthropathy, Understanding Hepatitis, VWD, Hemophilia Awareness and Disease Management and Long Acting Factor/Q&A. Patients had the opportunity to voice their opinions, questions and concerns and were appreciative of all these sessions. We encourage our patients to call and give us suggestions on what they would like to hear next. We are always available and open to suggestions. For further information please call The Blood Research Institute and speak with Social Worker Joanne Rodriguez at (973)877-2967.

School Visits:
As we all know the school year has already ended but we want everyone to know that our staff is available for school visits with school personnel and nurses. To make arrangements for the next school year please contact Social Worker Joanne Rodriguez at (973) 877-2967

Looking Ahead:
For those starting or going back to college next year, please contact Joanne Rodriguez, Social Worker at (973) 877-2967 for scholarship information and preparation.

Please feel free to contact our treatment center to schedule appointments, education sessions or if you have any other questions, or concerns. We are committed to working together with you to provide individualized care. Our general number is (973) 877-5340. We hope you all have a wonderful and safe SUMMER!!!

Hemophilia Association of New Jersey Invites you to our Fall Educational Symposium

Please join us on Saturday, September 16, 2017 for our Fall Educational Symposium! Registration and brunch will be available at 10:00am and the Symposium will begin at 11:00am.

Date: Saturday, September 16, 2017

Time: 10:00am to 1:00pm

Place: Hilton Newark Penn Station
Gateway Center– Raymond Blvd.
Newark, NJ 07102-5107
(973) 622-5000

Our Presenters will be:

Phoebe Shagan, RN, CCM, a licensed independent Life and Health Insurance Agent. Phoebe will present information about Medicare and why you shouldn't wait until you are 65 to get the facts.

Katie Verb, Director of Policy and Government Relations for the Hemophilia Federation of America, will present the topic, Staying Covered: Emerging Trends in the Insurance Landscape.

Diane Horbacz, Educator, will offer a hands-on program for children (ages 7-12) called "My Amazing Blood."

We hope you will be able to join us for this valuable symposium. You may RSVP by calling Cindy Hansen at HANJ at 732-249-6000 or by email to chansen561@comcast.net.

Parking will be paid for by HANJ. Upon registration, please request a paid parking voucher.

ALL Members!

The Hemophilia Association of New Jersey will be hosting several Pharmaceutical Educational Programs throughout the year

August 2017
Shire
Topic: Bullying Online and Offline
Teen/Adult
Thursday, August 17th

October 2017
Pfizer
Topic: Considerations for the Bleeding Disorder Community: Dealing with Persistent Pain
Thursday, October 12th

December 2017
Pfizer
Topic: Getting Real: Being a Teen or Young Adult (with Hemophilia)
Tuesday, December 5th

This information could change. Please check your mail for invitations with meeting dates and topics as well as RSVP instructions.

Meet the Board...

Jeff Lynch, MD
HANJ Medical Advisor

I have to admit that I spent most of my life not aware that there was a hemophilia community or a HANJ working on our behalf. As a child I had many unusually severe bruises and joint injuries which baffled our local physician. It wasn't until wisdom teeth extractions at age 16 that I was referred to a facility familiar with bleeding disorders. Finally diagnosed with mild/moderate hemophilia A and this being 1969, I received my first cryoprecipitate infusions while watching Neil Armstrong walk on the moon. For many years after that I received only intermittent and substandard treatment mostly due to my desire to ignore and deny the disease. Fortunately I made the effort and 10 years ago discovered the Cardeza Foundation HTC in Philadelphia. What a pleasant surprise to find physicians and nurses knowledgeable about hemophilia not to mention the availability of home infusion and adequate treatment. In addition this put me on the HANJ mailing list and started my interest in participating with our community. The Blood Brotherhood activities have given me a look at the variety of experiences we have with the disorder but also what we have in common trying to get by and stay healthy.

In my personal life I am a semi-retired Anesthesiologist. I am a graduate of Muhlenberg College and the UMDNJ New Jersey Medical School. My internship was in Internal Medicine at Morristown Memorial and I served an anesthesia residency at the University of Michigan Medical Center. For 30 years I have been practicing at what is now the Virtua Health System in Voorhees. I reside in Medford with my wife Linda and our dog Tasha{see photo} . We have two adult children. Dan works for Enterprise in Charlotte NC and Lindsay is a surgical resident at Thomas Jefferson University Hospital in Philadelphia.

I am very much looking forward being part of HANJ and its efforts to ensure quality of care and life for our members. The coming years seam to promise great advances in treatment as well as a political struggle to ensure access to these advances.

Jeff Lynch

Emergency Guidelines for Hemophilia
By Neidy Olarte, MSW
Social Service Coordinator

The Department of Health has released Emergency Guidelines for Hemophilia to all hospitals in the state of New Jersey. These guidelines were revised by the Medical Advisory board of the Hemophilia Association of New Jersey and will be a source to the hospitals particularly the emergency rooms to use when they a treating an individual with hemophilia. Please feel free to carry these guidelines with you should you need to show emergency personnel. If you feel that your nearest emergency room does not have these guidelines, please contact HANJ so that we can assure they have the guidelines available.

State of New Jersey
DEPARTMENT OF HEALTH
PO BOX 360
TRENTON, N.J. 08625-0360
www.nj.gov/health

CHRIS CHRISTIE
Governor

KIM GUADAGNO
Lt. Governor

CATHLEEN D. BENNETT
Commissioner

TO: Health Care Provider

FROM: Cathleen D. Bennett
Commissioner

SUBJECT: Emergency Guidelines for Hemophilia: General Guidelines

The New Jersey Department of Health is pleased to share the most recent version of Emergency Guidelines for Hemophilia: General Guidelines. Originally developed by representatives of the Medical Advisory Board of the Hemophilia Association of New Jersey in November 2005, this document was updated in July 2016. The guidelines are based on recommendations developed by various professional organizations including the October 15, 2006 Medical and Scientific Advisory Council of the National Hemophilia Foundation (document #175).

The guidelines are intended to assist Emergency Department staff in providing appropriate and expeditious care to individuals presenting with hemophilia. The guidelines seek to: promote understanding of the complexities of hemophilia treatment; provide guidance to emergency department personnel; and promote a consultative dialogue between an emergency department, New Jersey's Hemophilia Treatment Centers, and the patient/family.

The guidelines are for medical personnel who may be responsible for providing care to persons with hemophilia. The contents and recommendations of these guidelines are suggestions only. Attending physicians or other qualified healthcare providers such as physician assistants or nurse practitioners have the final responsibility for appropriate diagnosis and treatment.

The Department of Health, in partnership with the Hemophilia Association of New Jersey, hope that you find these guidelines useful in your care of patients with hemophilia.

I appreciate your continued commitment to providing New Jersey residents with quality health care and I look forward to continuing our efforts to improve the quality of life in New Jersey.

HEMOPHILIA ASSOCIATION OF NEW JERSEY

197 Route 18 South
Suite 206 North, East Brunswick, NJ 08816
Tel: 732-249-6000 • Fax: 732-249-7999
Web: www.hanj.org Email: hemnj@comcast.net

Emergency Guidelines for Hemophilia: General Guidelines

This document was updated and approved July 22, 2016 and originally developed in collaboration with Medical Advisory Board of the Hemophilia Association of New Jersey representatives in November 2005 called Emergency Guidelines for Hemophilia: General Guidelines and from various professional organizations including Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation in October 15, 2006 (document #175) for emergency personnel in New Jersey.

Red Flags in Hemophilia

- All patients are categorized as emergent
- Pain is often the first symptom of bleeding
- All trauma is significant
- **Believe the patient or parent that they are having a bleed.**
- The patient may appear well, yet may be having a significant bleed

1. TREAT HEMOPHILIA PATIENTS IMMEDIATELY.

2. Infuse with Factor BEFORE diagnostic studies, such as radiographs, CAT scans, suturing, or other procedures. For routine joint bleeding, no radiographic studies are indicated.

3. Contact the patient's Hemophilia Treatment Center or hematologist. However, do not delay treatment while waiting for a response. Most patients carry their factor and know their diagnosis or carry an ID card.

4. For patients with hemophilia who have illnesses or disorders that necessitate an invasive procedure (lumbar puncture, arterial blood gas, arthrocentesis, etc.) or surgery, factor replacement therapy must be administered beforehand.

5. A patient often has pain prior to obvious swelling of a joint. Believe and treat the patient. It is always better to err on the side of treatment rather than withholding factor replacement, since early treatment of joint bleeds can help prevent joint damage.

6. Factor Concentrate must be administered intravenously by IV push over 1-2 minutes.

7. Dose factor up to the "closest vial" and infuse the full content of each reconstituted vial.

8. In situations in which patients are hemodynamically stable and are not requiring volume replacement, the smallest gauge needle should be utilized for obtaining IV access (25g butterfly needles in young infants, 23g butterfly needles in older children and adults).

9. The most experienced IV therapist or phlebotomist should perform any venipuncture. Traumatic venipunctures and repeated needle sticks cause painful hematomas that may limit further IV access.

10. Intramuscular injections should be avoided if at all possible. If they must be given, factor replacement therapy should precede the injection. Tetanus immunizations may be administered subcutaneously.

11. Tourniquets should not be applied tightly to extremities because they may cause bleeding.

12. Aspirin, NSAIDs and aspirin-containing products are contraindicated in individuals with hemophilia. Acetaminophen and/or codeine may be used for analgesia.

BLEEDS REQUIRING TREATMENT

1. CRITICAL BLEEDS: significant injury to head, neck, face and throat, abdomen, iliopsoas muscle, gastrointestinal bleeding, deep laceration, compartment syndrome, new or unusual headache, severe pain or swelling at any site, acute fracture or dislocations
   Hemophilia A: **Factor VIII** 50 units /kg ***(100 %)***
   Hemophilia B: **Factor IX** 100 -120 units/kg (***100 -120%***)
   von Willebrand Disease: Factor VIII concentrate with von Willebrand factor 50 – 100 units ***VWF: RCo/kg***

   Admit the patient

2. SIGNIFICANT BLEEDS: are bleeding into joint and muscles, soft tissue, sprains, lacerations, hematuria, refractory nosebleeds, oral bleeds
   Hemophilia A: ***Factor VIII*** 15 - 50 units /kg ***(30 -100%)***
   Hemophilia B: ***Factor IX*** 30-100 units /kg ***(30-100%)***

Von Willebrand Disease:

a. Type I DDAVP 0.3 mcg/kg IV drip in 25-100 cc of normal saline (based on total dose of DDAVP) over 30 minutes **maximum dose is 20 micrograms** If not responsive to DDAVP and or for Type 2 A, 2B, and 3

    1. Factor VIII concentrate with von Willebrand factor 50 – 100 units VWF: RCo/kg

Out-patient follow up with hemophilia center should be arranged.

3. Mucosal bleeds, especially the mouth, that spontaneously stop. Usually re-bleed and almost always require treatment with antifibrinolytics agent such as Amicar (amino-caproic acid), 50 mg /kg/dose every 6 hours by mouth to maximum of 12 gm/day, are used in mucosal bleeds to enhance clotting.

RECOMMENDED PRODUCT

The treatment of choice for individuals with Hemophilia A (factor VIII deficiency) or B (factor IX deficiency) is recombinant factor VIII or else the patient's product of choice. Plasma-derived concentrate is a suitable alternative in an emergency situation when recombinant Factor VIII is not available. Cryoprecipitate and fresh frozen plasma are no longer recommended for treatment of individuals with hemophilia A or B.

Hemophilia A (Factor VIII Deficiency) Factor VIII Concentrates
- ***Recombinant***
  - ***Recombinate®***
  - ***Advate®***
  - ***Helixate FS ®***
  - ***Kogenate FS®***
  - ***Xyntha ®***
  - ***Novoeight®***
  - ***Eloctate (Long Acting VIII)***
- ***Monoclonal VIII (Plasma Derived)***
  - ***Hemofil M®***
  - ***Monoclate P®***
- ***Plasma Derived viral inactivated***
  - ***Alphanate®***
  - ***Koate DVI®***

Hemophilia B (Factor IX Deficiency) Factor IX Concentrates
- ***Recombinant***
  - ***Alprolix® (Long Acting IX)***
  - ***BeneFIX®***
  - ***Rixubus®***
- ***Monoclonal IX***
  - ***Mononine®***
- ***Plasma derived viral inactivated***
  - ***Alphanine***

FACTOR VIII INHIBITOR

Recombinate Factor VIIa NovoSeven®

For individuals with inhibitors (antibodies to factor VIII), treatment decisions may be more complicated. The care of inhibitor patients should be urgently discussed with the patient's hematologist. If an individual with an inhibitor presents in a life- or limb-threatening scenario, the safest immediate action is to prescribe recombinant factor VIIa (rFVIIa) NovoSeven® at a dose of 90 mcg/kg every 2 hours until bleeding resolves or Activated Prothrombin Complex Concentrates (FEIBA) at 75-100 units/kg.* The patient or family can also provide information on response to therapeutic bypassing agents.

FACTOR IX INHIBITOR

Do not give factor IX-containing products to patients with a history of factor IX inhibitors and anaphylaxis.

Give Recombinate Factor VIIa. NovoSeven®

For individuals with inhibitors (antibodies factor IX), treatment decisions may be more complicated. The care of inhibitor patients should be urgently discussed with the patient's hematologist. If an individual with an inhibitor presents in a life- or limb-threatening scenario, the safest immediate action is to prescribe recombinant factor VIIa (rFVIIa) NovoSeven®at a dose of 90 mcg/kg. every 2 hours until bleeding resolves. * The patient or family can also provide information on response to therapeutic bypassing agents.

VON WILLEBRAND DISEASE
- ***IV DDAVP***
- ***STIMATE INTRANASAL SPRAY***
- ***Factor VIII Concentrate containing VWF***
  - ***Humate P®***
  - ***Alphanate®***
  - ***Wilate ®***
  - ***Koate DVI®***

Factor V Deficiencies
- ***Fresh Frozen Plasma***
- ***Aminocaproic acid (Amicar)***

Factor VII Deficiencies
- ***Recombinant factor VIIa (rFVIIa) NovoSeven® 15-30 mcg/kg every 4 to 6 hours slow IV push***

Factor XI Deficiencies
- ***Fresh Frozen Plasma***
- ***Aminocaproic acid (Amicar)***

Hemophilia Association of New Jersey

37th Annual Testimonial Dinner Dance
Humanitarian "Man of the Year"
Honoring

Sal J. Rafanelli, R.P.h.
CEO/Co-Founder
BiologicTx
Saturday, April 15, 2017
Fiddler's Elbow Country Club

Indications for FEIBA [Anti-Inhibitor Coagulant Complex]

FEIBA is an Anti-Inhibitor Coagulant Complex indicated for use in hemophilia A and B patients with inhibitors for:

- Control and prevention of bleeding episodes
- Use around the time of surgery
- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes.

FEIBA is not indicated for the treatment of bleeding episodes resulting from coagulation factor deficiencies in the absence of inhibitors to coagulation factor VIII or coagulation factor IX.

Detailed Important Risk Information for FEIBA

WARNING: EVENTS INVOLVING CLOTS THAT BLOCK BLOOD VESSELS

- **Blood clots that block blood vessels and their effects have been reported during postmarketing surveillance following infusion of FEIBA, particularly following the administration of high doses and/or in patients with a risk of forming blood clots.**
- **If you experience any of these side effects, call your doctor right away.**

You should not use FEIBA if:

- You had a previous severe allergic reaction to the product (reactions causing discomforts that are damaging and life threatening)
- You have signs of development of small blood vessel clots throughout the body
- You have sudden blood vessel clots or blocked blood vessels, (e.g., heart attack or stroke)

Events involving blood clots blocking blood vessels can occur with FEIBA, particularly after receiving high doses and/or in patients with risk factors for clotting.

Infusion of FEIBA should not exceed a dose of 100 units per kg body weight every 6 hours and daily doses of 200 units per kg of body weight. Maximum injection or infusion rate must not exceed 2 units per kg of body weight per minute.

At first sign or symptom of a sudden blood vessel clot or blocked blood vessel (e.g., chest pain or pressure, shortness of breath, altered consciousness, vision, or speech, limb or abdomen swelling and/or pain), stop FEIBA administration promptly and seek emergency medical treatment.

Allergic-type hypersensitivity reactions, including severe, sometimes fatal allergic reactions that can involve the whole body, can occur following the infusion of FEIBA. Call your doctor or get emergency treatment right away if you get a rash, hives or welts, experience itching, tightness of the throat, vomiting, abdominal pain, chest pain or tightness, difficulty breathing, lightheadedness, dizziness, nausea or fainting.

Because FEIBA is made from human plasma it may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

The most frequent side effects observed during the prophylaxis trial were anemia, diarrhea, bleeding into a joint, signs of hepatitis B surface antibodies, nausea, and vomiting.

The serious side effects seen with FEIBA are allergic reactions and clotting events involving blockage of blood vessels, which include stroke, blockage of the main blood vessel to the lung, and deep vein blood clots.

Call your doctor right away about any side effects that bother you during or after you stop taking FEIBA.

Please see next page for Important Facts about FEIBA.
To see the Full Prescribing Information, including BOXED WARNING on blood clots, go to www.FEIBA.com.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

References: 1. Pergantou H, Matsinos G, Papadopoulos A, Platokouki H, Aronis S. Comparative study of validity of clinical, X-ray and magnetic resonance imaging scores in evaluation and management of haemophilic arthropathy in children. Haemophilia. May 2006;12(3):241-247. **2.** Gringeri A, Ewenstein B, Reininger A. The burden of bleeding in haemophilia: is one bleed too many? Haemophilia. Jul 2014;20(4):459-463. **3.** FEIBA Prescribing Information. **4.** Antunes SV, Tangada S, Stasyshyn O, et al. Randomized comparison of prophylaxis and on-demand regimens with FEIBA NF in the treatment of haemophilia A and B with inhibitors. Haemophilia. 2014;20(1):65-72.

S25994 12/16

Important Facts about FEIBA (Anti-Inhibitor Coagulant Complex)

What is FEIBA used for?

FEIBA (Anti-Inhibitor Coagulant Complex) is used for people with Hemophilia A or B with Inhibitors to control and prevent bleeding episodes, before surgery, or routinely to prevent or reduce the number of bleeding episodes. It is NOT used to treat bleeding conditions without inhibitors to Factor VIII or Factor IX.

When should I not take FEIBA?

You should not take FEIBA if you have had hypersensitivity or an allergic reaction to FEIBA or any of its components, including factors of the kinin generating system, if you have a condition called Disseminated Intravascular Coagulation, which is small blood clots in various organs throughout the body, or currently have blood clots or are having a heart attack. Make sure to talk to your healthcare provider about your medical history.

What Warnings should I know about FEIBA?

FEIBA can cause blood clots, including clots in the lungs, heart attack, or stroke, particularly after high doses of FEIBA or in people with a high risk of blood clots. Patients that have a risk of developing blood clots should discuss the risks and benefits of FEIBA with their healthcare provider since FEIBA may cause blood clots. FEIBA can cause hypersensitivity or allergic reactions and infusions site reactions, and these reactions can be serious. Because FEIBA is made from human plasma, it may carry the risk of transmitting infectious agents, for example, viruses, including Creutzfeldt-Jakob disease (CJD) agent, and the variant CJD agent. Although steps have been taken to minimize the risk of virus transmission, there is still a potential risk of virus transmission.

What should I tell my healthcare provider?

Make sure to discuss all health conditions and medications with your healthcare provider. If you are pregnant or are planning to become pregnant, or are a nursing mother, make sure to talk with your healthcare provider for advice on using FEIBA.

What are the side effects of FEIBA?

The most frequent side effects of FEIBA are: low red blood cell count, diarrhea, joint pain, hepatitis B surface antibody positivity, nausea, and vomiting. The most serious side effects of FEIBA include: hypersensitivity reactions, including anaphylaxis, stroke, blood clots in the lungs, and blood clots in the veins. Always immediately talk with your healthcare provider if you think you are experiencing a side effect.

What other medications might interact with FEIBA?

The use of other clotting agents with FEIBA is not recommended, for example, tranexamic acid and aminocaproic acid. Be sure to talk with your healthcare provider and pharmacist about all medications and supplements you are taking.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088

The risk information provided here is not comprehensive. To learn more, talk about FEIBA with your healthcare provider or pharmacist. The FDA-approved product labeling can be found at http://www.feiba.com/us/forms/feiba_pi.pdf or by calling 1-800-423-2090 and selecting option 5.

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MONEY SENSE

A Working Retirement

By Bill Hunter, Director of Personal Retirement Solutions for Bank of America Merrill Lynch

People's view of work and retirement has shifted greatly. While retirement was once synonymous with the end of working, nearly half (47%) of today's retirees say they either have worked or plan to work during their retirement. [1] But an even greater percentage (72%) of pre-retirees age 50+ say they want to keep working after they retire, and in the near future it will become increasingly unusual for retirees not to work.[2]

The decision to continue to work can affect your assets and requires careful strategies to manage your income while working in later years. Preparing in advance for a second-act career is essential.

New careers mean new costs
New careers may come with new startup costs. Ideally, it's best to prepare for those costs while you're in your first employment act and outlining your financial needs during your retirement years.

One of those costs may be additional training or education. Taking classes or training as soon as possible might give you a better sense of whether you actually want to spend the next few years doing what you had in mind, and whether it's a viable option in today's economy.

If you plan to start a business, such as opening a store, you may also have capital costs—and since you have fewer working years ahead of you, it may be harder to get a small business loan. However, with the current low interest rates, money is relatively cheaper, so another option is to open a low-interest line of credit while still employed.

You should consider both public and private sources of capital, as well. There are a number of public and private organizations that help startups get off the ground, including state and federal agencies and community development organizations. New, innovative forms of raising capital, such as crowdfunding sites that help you find large numbers of small donors, often without giving up any equity stake, can also prove useful—particularly if you're planning to start a nonprofit enterprise or a venture related to the arts.

Another option is to borrow against your eligible securities, if appropriate for you, or if you are at least 59 ½ years old, you may want to consider tapping IRA funds. You should consider all the pros and cons associated with these options, before you make a decision to employ either of them. Keep in mind that your startup budget should not depend entirely on funds you've set aside for necessary expenses in retirement.

Location, location, location
The best place to retire may not be the best place for your new business. If working in retirement is a priority for you, remember that location will have a major impact on expenses and quality of life.

[1]Work and Retirement – a Merrill Lynch retirement study in partnership with Age Wave, March 2014.
[2]Work and Retirement – a Merrill Lynch retirement study in partnership with Age Wave, March 2014.

Many popular retirement locales are heralded for having no state income tax, but they generally have higher sales and property taxes and may have municipal taxes to consider, as well. If your local taxes are high but you want to stay in the same area, consider moving to the next town or just across the state border.

Delay Social Security for better benefits
One of the possible advantages to a new job is that it may enable you to delay taking Social Security, which has rewards. More than 80 percent of Americans select to take Social Security as soon as they become eligible at age 62.[3] If your new paycheck allows you to, consider delaying taking Social Security. Postponing Social Security payments can boost your available retirement income when you do need it. Every year you delay, your total benefits could increase as much as 8 percent per year until age 70, when you earn the maximum.

Don't underestimate insurance costs
Health care expenses are people's top financial concern in retirement however, less than one out of six pre-retirees (15%) has ever attempted to estimate how much money they might need for health care and long-term care in retirement.[4]

If you are retiring before you are eligible for Medicare, health insurance costs can be a significant expense, as costs increase with age and health status changes. If you retire from your primary career before 65 to work independently, COBRA coverage may be available through your current employer's health plan. This may allow you to purchase as much as 18 months' worth potentially at a lower premium than what you'd pay on the open market.

If you plan to work elsewhere, negotiate health care compensation as part of your employment deal. If you plan to consult with the company in which you had worked full-time, discuss whether your current health care benefits can carry over into part-time compensation.

Make sure you assess any other insurance needs, such as disability or long-term care and budget for them.

Live your dream, but with eyes wide open
The key is to make sure you go into your second act with your eyes wide open. That means looking at how the various aspects of your proposed plan affect one another. Your financial advisor can help you run through the various life scenarios that may affect your plan and create a strategy that makes sense for your situation.

View every decision as part of another decision, and consider sitting down with a financial professional to plan out how they all tie together.

For more information, contact Merrill Lynch Financial Advisor, Cono T. Spinelli, of the Paramus, New Jersey office at 201.967.2730 or cono_spinelli@ml.com.

This material should be regarded as general or educational information on healthcare/Social Security considerations and is not intended to provide specific healthcare /Social Security advice. If you have questions regarding your particular situation, please contact your legal or tax advisor.

The investments or strategies presented do not take into account the investment objectives or financial needs of particular investors. It is important that you

[3]Health and Retirement – a Merrill Lynch retirement study in partnership with Age Wave, May 2014.
[4]Health and Retirement – a Merrill Lynch retirement study in partnership with Age Wave, May 2014.

consider this information in the context of your personal risk tolerance and investment goals.

Always consult with your independent attorney, tax advisor, investment manager, and insurance agent for final recommendations and before changing or implementing any financial, tax, or estate planning strategy.

All guarantees and benefits of an insurance policy are backed by the claims-paying ability of the issuing insurance company. They are not backed by Merrill Lynch or its affiliates, nor do Merrill Lynch or its affiliates make any representations or guarantees regarding the claims-paying ability if the issuing insurance company.

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Investment products offered through MLPF&S and insurance and annuity products offered through MLLA:

Are Not FDIC Insured	Are Not Bank Guaranteed	May Lose Value
Are Not Deposits	**Are Not Insured By Any Federal Government Agency**	**Are Not a Condition to Any Banking Service or Activity**

Blood Brotherhood For Adult Men with Hemophilia

The NJ Blood Brotherhood program holds free events for men with bleeding disorders. This group is open to anyone over the age of 21 who has a bleeding disorder. Each of our events incorporates a bit of education, socializing and a physical activity, but we typically use the time to get to know other guys in the community. The events are completely free and there is no commitment to attend every event.

If you'd like to join the Blood Brotherhood group and attend one of our events, please reach out to Joe Markowitz (Joe.Markowitz@gmail.com, 201-650-0335) or Peter Marcano (petermarcano@gmail.com, 201-401-7080) or HANJ directly.

HANJ has partnered with the Hemophilia Federation of America (HFA) to offer the Blood Brotherhood program. Blood Brotherhood is a men's group open to adult men (21+) with bleeding disorders. The purpose of this group is to provide an opportunity for older men with bleeding disorders to connect with their peers in a fun, relaxed setting. There is NO COST to attend any Blood Brotherhood event and once you sign up, there is no obligation to attend every event. Additionally, transportation assistance (gas cards or pre-paid Visa cards) may be available for each event, depending on our budget.

Hemophilia Association of New Jersey
Annual Meeting & Educational Forum
May 25th, 2017

Our Guest Speaker:

Katherine A. High, M.D.
Co-Founder, President & Chief Scientific Officer,
Spark Therapeutics
Topic: Gene Therapy: The Future of Hemophilia

Honorees

Benefactors Award	**John K. Halvey** **General Counsel** **Bridgewater Associates, LP**
Special Award	**William P. Murray** **Executive Vice President/National Director** **MWWPR**
Special Award	**Glenn & Eileen Rosenwald**
Humanitarian Award	**Wardell Sanders, Esq.** **President** **New Jersey Association of Health Plans**
Humanitarian Award	**Dr. Franklin Desposito** **Saint Michael's Medical Center**
Unsung Hero Award	**Vanessa Cullom** **Senior Director with the Strategy Team** **CareCentrix**
Congressman Dean A. Gallo Memorial Award	**James Romano** **Director of Government Relations & Advocacy for Patient Services Inc., (PSI)**
Past President's Award	**George Keelty**
Dr. L. Michael Kuhn Memorial Award	**Katherine A. High, M.D.** **Co-Founder, President & Chief Scientific Officer,** **Spark Therapeutics**

New Scholarships

Paul D. Amitrani Graduate Scholarship

Daniel Guerriero was awarded the Paul D. Amitrani Graduate Scholarship in memory of former HANJ President and honored member of our community for many years. Daniel will be attending NYU to pursue a Master's Degree in Public Health. Daniel is a graduate of The University of South Carolina and his volunteering has taken him to Thailand and currently to Peru and the Dominican Republic with LIG Global Foundation, which delivers reliable, excellent medical care to people who have little or no access to it. Daniel's ultimate goal is to "manage a non-profit organization aimed at providing healthcare for people in remote areas of the world."

HANJ Julie E. Frenkel Memorial Scholarship

Benjamin Cutler was awarded the HANJ Julie E. Frenkel Memorial Scholarship, which honors the memory of our beloved Hemophilia Association of New Jersey Assistant Executive Director who was fervent in her belief that continuing education is crucial for our community. Ben wil be attending The College of New Jersey and will be studying Economics and Finance.

Robert & Dennis Kelly Memorial Scholarship

Thomas Culp was awarded the Robert and Dennis Kelly Memorial Scholarship in memory of Robert and Dennis Kelly, beloved sons of longtime HANJ Board members Elaine and Robert. Thomas is a Sophomore at Rutgers University and is pursuing a degree of Food Science at the School of Environmental and Biological Sciences.

Hemophilia Association of New Jersey Annual Meeting & Educational Forum Exhibitors

May 25th, 2017

Accredo Specialty Pharmacy
Aptevo Therapeutics
BDRN, LLC
Bioverativ
BiologicTX
BioScrip Infusion Services
CSL Behring
Kedrion Biopharma
Novo Nordisk
Octapharma
Pfizer Inc.
Shire

Back-to-School Basics

Preparing your child for the school year
By Leslie Quander Wooldridge|08.04.2015
Originally Published August 2015
HEMAWARE, NHF

Follow these back-to-school suggestions for your child with a bleeding disorder:

Maintain perspective. Remember that school provides opportunities. "A child with a bleeding disorder should attend school every day like every other child," says Nancy G. Hatcher, LCSW, a clinical social worker at the Hemophilia and Thrombosis Treatment Center at -Valley Children's Hospital in Madera, California. Kids should participate in the classroom, and in physical education, field trips and other activities that promote peer relationships. "Children shouldn't worry about feeling different," she adds.

Talk with staff, and know your rights. When you register your child at school, note that he or she has a bleeding disorder, says Laurel J. Pennick, MSSW, LCSW, a licensed social worker at the Arizona Hemophilia and Thrombosis Center at the University of Arizona Health Sciences Center in Tucson.

Schedule a meeting with your child's teachers, school nurse or health aide, principal, physical education instructor and others, as needed. Talk about the basics of your child's bleeding disorder and how to recognize the signs of a bleed (e.g., limping, favoring one arm or swelling), and when to call you. Discuss first aid for simple bleeds, especially rest, ice, compression and elevation, or "RICE." And determine the need for extra time for tests or a set of books at home.

Prepare for sick days and emergencies. School staff should call you if they see signs of a bleed, bruise or other problem. "The main thing that usually happens at school is nosebleeds," says Pennick. For a serious issue, such as a head injury or a head, neck or large muscle bleed, staff should call you and 911, advises Hatcher.

If you have preferences about how or when to be contacted, advise the school. Also tell school staff in advance which hospitals have bleeding disorder medications so they know in case of emergency, says Pennick.

Develop a plan for absences. "We don't want children to fall behind," Pennick says. "It can affect them emotionally." Find out if your school will send classroom work home or have it available online, so your child can review it at home.

Establish a routine. Budget time for prophylaxis, or "prophy." "We suggest that you infuse in the morning, ideally before your child goes to school," says Pennick. That's because factor is at its highest efficacy during the active portion of the day. You may need an extra 30 to 45 minutes in the morning, so factor this time commitment in, whether you drive your child to school or send him or her on the bus.

At the end of the day, allow time for homework and relaxation. Ensure your child gets enough sleep. Children 6 to 13 years old typically need 9 to 11 hours per night, according to the National Sleep Foundation. Try to stick with a consistent bedtime every night of the week.

Learn to let go. Allow your child to try new classes and new pursuits. Encourage new friendships.

Be open to safe activities and sports. "If a child has severe hemophilia and is on a regular prophy dose schedule, his or her clotting factor levels should be high enough that he or she can participate in all but the most aggressive activities," says Hatcher. Although soccer can be too physical as kids get older, some kids successfully play tennis and even team sports like volleyball. Just check with your HTC about any recommended restrictions. That way you and your child will have a good school year.

Your Hemophilia Treatment Center can do School Visits!

This information is based on Heidi's experience. Different patients may have different results. Talk to your doctor about whether IXINITY® may be right for you.

INDICATIONS AND IMPORTANT SAFETY INFORMATION

What is IXINITY®?

IXINITY [coagulation factor IX (recombinant)] is a medicine used to replace clotting factor (factor IX) that is missing in adults and children at least 12 years of age with hemophilia B. Hemophilia B is also called congenital factor IX deficiency or Christmas disease. Hemophilia B is an inherited bleeding disorder that prevents clotting. Your healthcare provider may give you IXINITY to control and prevent bleeding episodes or when you have surgery.

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

IMPORTANT SAFETY INFORMATION for IXINITY®

- You should not use IXINITY if you are allergic to hamsters or any ingredients in IXINITY.
- You should tell your healthcare provider if you have or have had 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 hamsters, are nursing, are pregnant or planning to become pregnant, or have been told that you have inhibitors to factor IX.
- You can experience an allergic reaction to IXINITY. Contact your healthcare provider or get emergency treatment right away if you develop a rash or hives, itching, tightness of the throat, chest pain, or tightness, difficulty breathing, lightheadedness, dizziness, nausea, or fainting.
- Your body may form inhibitors to IXINITY. An inhibitor is part of the body's defense system. If you develop inhibitors, it may prevent IXINITY from working properly. Consult with your healthcare provider to make sure you are carefully monitored with blood tests for development of inhibitors to IXINITY.
- If you have risk factors for developing blood clots, the use of IXINITY may increase the risk of abnormal blood clots.
- Call your healthcare provider right away about any side effects that bother you or do not go away, or if your bleeding does not stop after taking IXINITY.
- The most common side effect that was reported with IXINITY during clinical trials was headache.
- These are not all the side effects possible with IXINITY. You can ask your healthcare provider for information that is written for healthcare professionals.

You are encouraged to report side effects of prescription drugs to the Food and Drug Administration. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see accompanying brief summary of Prescribing Information on next page.

Aptevo™ Therapeutics

Aptevo BioTherapeutics LLC, Berwyn, PA 19312

IXINITY®
coagulation factor IX
(recombinant)
Factoring in your world™

IXINITY® [coagulation factor IX (recombinant)]

Brief Summary for the Patient

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.IXINITY.com.

Please read this Patient Information carefully before using IXINITY. This brief summary does not take the place of talking with your healthcare provider, and it does not include all of the important information about IXINITY.

What is IXINITY?

IXINITY is a medicine used to replace clotting factor (factor IX) that is missing in people with hemophilia B. Hemophilia B is also called congenital factor IX deficiency or Christmas disease. Hemophilia B is an inherited bleeding disorder that prevents clotting. Your healthcare provider may give you IXINITY when you have surgery.

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

Who should not use IXINITY?

You should not use IXINITY if you:

- Are allergic to hamsters
- Are allergic to any ingredients in IXINITY

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

What should I tell my healthcare provider before using IXINITY?

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 hamsters
- Are breastfeeding. It is not known if IXINITY passes into your milk and if it can harm your baby
- Are pregnant or planning to become pregnant. It is not known if IXINITY may harm your baby
- Have been told that you have inhibitors to factor IX (because IXINITY may not work for you)

How should I infuse IXINITY?

IXINITY is given directly into the bloodstream. IXINITY should be administered as ordered by your healthcare provider. You should be trained on how to do infusions by your healthcare provider or hemophilia treatment center. Many people with hemophilia B learn to infuse their IXINITY by themselves or with the help of a family member.

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

Your healthcare provider will tell you how much IXINITY to use based on your weight, the severity of your hemophilia B, and where you are bleeding. You may have to have blood tests done after getting IXINITY to be sure that your blood level of factor IX is high enough to stop the bleeding. Call your healthcare provider right away if your bleeding does not stop after taking IXINITY.

What are the possible side effects of IXINITY?

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

- Rash
- Hives
- Itching
- Tightness of the throat
- Chest pain or tightness
- Difficulty breathing
- Lightheadedness
- Dizziness
- Nausea
- Fainting

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

The most common side effect of IXINITY in clinical trials was headache.

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

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

How should I store IXINITY?

250 IU strength only; store at 2 to 8°C (36 to 46°F). Do not freeze.

500, 1000, 1500, 2000 and 3000 IU strengths; store at 2 to 25°C (36 to 77°F). Do not freeze.

Do not use IXINITY after the expiration date printed on the label. Throw away any unused IXINITY and diluents after it reaches this date.

Reconstituted product (after mixing dry product with Sterile Water for Injection) must be used within 3 hours and cannot be stored or refrigerated. Discard any IXINITY left in the vial at the end of your infusion.

After reconstitution of the lyophilized powder, all dosage strengths should yield a clear, colorless solution without visible particles. Discard if visible particulate matter or discoloration is observed.

What else should I know about IXINITY?

Your body may form inhibitors to factor IX. An inhibitor is part of the body's immune system. If you form inhibitors, it may stop IXINITY from working properly. Consult with your healthcare provider to make sure you are carefully monitored with blood tests to check for the development of inhibitors to factor IX. Consult your doctor promptly if bleeding is not controlled with IXINITY as expected.

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

Always check the actual dosage strength printed on the label to make sure you are using the strength prescribed by your healthcare provider.

Aptevo™ Therapeutics

Manufactured by:
Aptevo BioTherapeutics LLC
Berwyn PA, 19312
U.S. License No. 2054

Part No: 1000973_1
CM-FIX-0078

Biotherapies for Life® **CSL Behring**

For adults and children with hemophilia A

REACH HIGHER

With the Long-lasting Protection of AFSTYLA

2x WEEKLY AVAILABLE
FDA-approved for dosing 2 or 3 times a week

ZERO BLEEDS (median AsBR*)
In clinical trials, whether dosed 2 or 3 times a week

COMPARABLE TO **NATURAL FACTOR VIII**
Identical to natural Factor VIII once activated

Zero inhibitors observed—Low incidence of side effects in clinical trials

In clinical trials, dizziness and allergic reactions were the most common side effects.

Visit AFSTYLA.com to sign up for the latest news

*Annualized spontaneous bleeding rate in clinical trials (interquartile range [IQR]=0–2.4 for patients ≥12 years; 0–2.2 for patients <12 years).

Important Safety Information

AFSTYLA is used to treat and control bleeding episodes in people with hemophilia A. Used regularly (prophylaxis), AFSTYLA can reduce the number of bleeding episodes and the risk of joint damage due to bleeding. Your doctor might also give you AFSTYLA before surgical procedures.

AFSTYLA is administered by intravenous injection into the bloodstream, and can be self-administered or administered by a caregiver. Your healthcare provider or hemophilia treatment center will instruct you on how to do an infusion. Carefully follow prescriber instructions regarding dose and infusion schedule, which are based on your weight and the severity of your condition.

Do not use AFSTYLA if you know you are allergic to any of its ingredients, or to hamster proteins. Tell your healthcare provider if you previously had an allergic reaction to any product containing Factor VIII (FVIII), or have been told you have inhibitors to FVIII, as AFSTYLA might not work for you. Inform your healthcare provider of all medical conditions and problems you have, as well as all medications you are taking.

Immediately stop treatment and contact your healthcare provider if you see signs of an allergic reaction, including a rash or hives, itching, tightness of chest or throat, difficulty breathing, lightheadedness, dizziness, nausea, or a decrease in blood pressure.

Your body can make antibodies, called inhibitors, against FVIII, which could stop AFSTYLA from working properly. You might need to be tested for inhibitors from time to time. Contact your healthcare provider if bleeding does not stop after taking AFSTYLA.

In clinical trials, dizziness and allergic reactions were the most common side effects. However, these are not the only side effects possible. Tell your healthcare provider about any side effect that bothers you or does not go away.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit **www.fda.gov/medwatch**, or call 1-800-FDA-1088.

Please see the following brief summary of full prescribing information on the adjacent page, and the full prescribing information, including patient product information, at AFSTYLA.com.

AFSTYLA®
Antihemophilic Factor (Recombinant), Single Chain

AFSTYLA®, Antihemophilic Factor (Recombinant), Single Chain
For Intravenous Injection, Powder and Solvent for Injection
Initial U.S. Approval: 2016

BRIEF SUMMARY OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use AFSTYLA safely and effectively. Please see full prescribing information for AFSTYLA, which has a section with information directed specifically to patients.

What is the most important information I need to know about AFSTYLA?

- Your healthcare provider or hemophilia treatment center will instruct you on how to do an infusion on your own.
- Carefully follow your healthcare provider's instructions regarding the dose and schedule for infusing this medicine.

What is AFSTYLA?

- AFSTYLA is a medicine used to replace clotting Factor VIII that is missing in patients with hemophilia A.
- Hemophilia A is an inherited bleeding disorder that prevents blood from clotting normally.
- Does not contain human plasma derived proteins or albumin.
- Your healthcare provider may give you this medicine when you have surgery.
- Is used to treat and control bleeding in all patients with hemophilia A.
- Can reduce the number of bleeding episodes when used regularly (prophylaxis) and reduce the risk of joint damage due to bleeding.
- Is not used to treat von Willebrand disease.

Who should not use AFSTYLA?

You should not use AFSTYLA if you:

- Have had a life-threatening allergic reaction to it in the past.
- Are allergic to its ingredients or to hamster proteins.

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

What should I tell my healthcare provider before using AFSTYLA?

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 hamster proteins.
- Have been told you have inhibitors to Factor VIII (because this medicine may not work for you).

How should I use AFSTYLA?

- Administer directly into the bloodstream.
- Use as ordered by your healthcare provider.
- You should be trained on how to do intravenous injections by your healthcare provider or hemophilia treatment center. Once trained, many patients with hemophilia A are able to inject this medicine by themselves or with the help of a family member.
- Your healthcare provider will tell you how much to use based on your weight, the severity of your hemophilia A, and where you are bleeding.
- You may need to have blood tests done after getting to be sure that your blood level of Factor VIII is high enough to clot your blood.
- Call your healthcare provider right away if your bleeding does not stop after taking this medicine.

What are the possible side effects of AFSTYLA?

- Allergic reactions may occur. Immediately stop treatment and call your healthcare provider right away if you get a rash or hives, itching, tightness of the chest or throat, difficulty breathing, light-headedness, dizziness, nausea, or decrease in blood pressure.
- Your body may form inhibitors to Factor VIII. An inhibitor is a part of the body's defense system. If you form inhibitors, it may stop this medicine from working properly. Your healthcare provider may need to test your blood for inhibitors from time to time.
- Common side effects are dizziness and allergic reactions.
- These are not the only side effects possible. Tell your healthcare provider about any side effect that bothers you or does not go away.

What else should I know about AFSTYLA?

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

Please see full prescribing information, including full FDA-approved patient labeling. For more information, visit www. AFSTYLA.com

Manufactured by:
CSL Behring GmbH
35041 Marburg, Germany

for:
CSL Behring Recombinant Facility AG
Bern 22, Switzerland 3000
US License No. 2009

Distributed by:
CSL Behring LLC
Kankakee, IL 60901 USA

BAYER
access solutions

Don't let insurance or financial challenges get between you and your treatment

Free Trial Program*

- Enroll today for up to 6 free doses†
- KOVALTRY®, Antihemophilic Factor (Recombinant), or KOGENATE® FS, Antihemophilic Factor (Recombinant), is delivered to your home free of charge
- Any patient who has not taken KOVALTRY® or KOGENATE® FS is able to participate, regardless of type of insurance or if you have insurance

Access to Therapy

Concerned about maintaining access to treatment?

We might be able to provide KOVALTRY® or KOGENATE® FS at no cost if you are‡:

- Experiencing challenges getting insurance coverage for KOVALTRY® or KOGENATE® FS
- Uninsured or underinsured
- Between jobs and experiencing a gap between insurance coverage

$0 Co-pay Program§

If you have private insurance, you may be eligible for the $0 Co-pay Program.

- You may be able to receive **up to $12,000 in assistance** per year, regardless of income
- **Assistance is awarded per patient.** Multiple members of the same household can apply
- Enrollment can be started and completed in **one short phone call**

Live Helpline Support

- Consult with an expert in insurance
- Spanish-speaking Case Specialists are also available

Call **1-800-288-8374** 8:00 AM–8:00 PM (ET) Monday–Friday.

*The Free Trial Program is available to newly diagnosed patients and patients who are currently using other therapy. Patients currently using KOVALTRY® or KOGENATE® FS are not eligible for the respective Free Trial programs. Participation in the Free Trial Program is limited to 1 time only per treatment. The medication provided through this program is complimentary and is not an obligation to purchase or use KOVALTRY® or KOGENATE® FS in the future. Reselling or billing any third party for the free product is prohibited by law.

†The Free Trial Program includes up to 6 free doses to a maximum of 5,000 IU for new patients and 40,000 IU for previously treated patients.

‡The program does not guarantee that patients will be successful in obtaining reimbursement. Support medication provided through Bayer's assistance programs is complimentary and is not contingent on future KOVALTRY® or KOGENATE® FS purchases. Reselling or billing any third party for free product provided by Bayer's patient assistance programs is prohibited by law. Bayer reserves the right to determine eligibility, monitor participation, determine equitable distribution of product, and modify or discontinue the program at any time.

§People with private, commercial health insurance may receive KOVALTRY® or KOGENATE® FS co-pay or co-insurance assistance based on eligibility requirements. The program is on a first-come, first-served basis. Financial support is available for up to 12 months. Eligible patients can re-enroll for additional 12-month courses. The program is not for patients receiving prescription reimbursement under any federal-, state-, or government-funded insurance programs, or where prohibited by law. All people who meet these criteria are encouraged to apply. Bayer reserves the right to discontinue the program at any time.

Kogenate® FS
antihemophilic factor (recombinant)

Kovaltry®
Antihemophilic Factor (Recombinant)

Hemophilia Association of New Jersey

Upcoming Events

HANJ Fall Educational Symposium
Hilton Newark Penn Station
Saturday, September 16, 2017

Gourmet Dinner
Il Tulipano
Cedar Grove, NJ
Monday, September 18, 2017

Kelly Brothers Annual
Scholarship Benefit
Saturday, September 23, 2017

Casino Night
Pines Manor
Edison, NJ
Saturday, October 14, 2017

PACT Workshop
December 2017

25 years

Kelly Brothers Scholarship Benefit
In Memory of Bob & Dennis

Saturday, September 23, 2017
2—6 PM

Friendly Sons of the Shillelagh
15 Oak Street
Old Bridge, NJ

$25 per Adult (Children free)

Includes:
Food, Keg Beer, Wine, Soda, Water
DJ & Games for Kids

If unable to attend, donations greatly appreciated.
Checks can be made out to:

Hemophilia Association of New Jersey

Or
H.A.N.J.

Any questions please call 732-679-1922