YOU USE YOUR JOINTS MORE THAN YOU THINK.

That's why you need a Factor VIII treatment you can Count On to protect you and your joints from bleeds.

* ELOCTATE has been proven to help patients prevent bleeding episodes using a prophylaxis regimen.

In the A-LONG study, 64 previously treated adult and adolescent males with severe hemophilia A ages 12-66 received ELOCTATE either every 3 to 5 days, once weekly, or on demand.

†#1 prescribed based on HCP reported data as of September 2020.

**INDICATION AND IMPORTANT SAFETY INFORMATION**

**INDICATION**

ELOCTATE (Antihemophilic Factor [Recombinant], Fc Fusion Protein) is an injectable medicine that is used to help control and prevent bleeding in people with Hemophilia A (congenital Factor VIII deficiency). Your healthcare provider may give you ELOCTATE when you have surgery.

**IMPORTANT SAFETY INFORMATION**

Do not use ELOCTATE if you have had an allergic reaction to it in the past.

Tell your healthcare provider if you have or have had any medical problems, take any medicines, including prescription and non-prescription medicines, supplements, or herbal medicines, have any allergies, are breastfeeding, are pregnant or planning to become pregnant, or have been told you have inhibitors (antibodies) to Factor VIII.

Allergic reactions may occur with ELOCTATE. Call your healthcare provider or get emergency treatment right away if you have any of the following symptoms: difficulty breathing, chest tightness, swelling of the face, rash, or hives.

Your body can also make antibodies called “inhibitors” against ELOCTATE, which may stop ELOCTATE from working properly.

Additional common side effects of ELOCTATE are headache, rash, joint pain, muscle pain and general discomfort.

If you have risk factors for developing abnormal blood clots in your body, such as an indwelling venous catheter, treatment with Factor VIII may increase this risk.

These are not all the possible side effects of ELOCTATE. Talk to your healthcare provider right away about any side effect that bothers you or that does not go away, or if bleeding is not controlled after using ELOCTATE.

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 BRIEF SUMMARY OF PRESCRIBING INFORMATION ON THE PREVIOUS PAGE**

**YOU HAVE QUESTIONS. CoRes HAVE ANSWERS.**

Dedicated

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HI FRIENDS,

I hope you had a fantastic summer! I was busy enjoying the outdoors and soaking up all the sunny weather. My husband and I got the chance to head up to Canada for a few days to spend time with his family. It was so great to see my nieces and nephews—they grow up so fast!

We also did another backpacking trip for a few days in the Olympic National Park in Washington state. It was a beautiful route along a river in a valley. Luckily, that meant there wasn’t too much elevation to trek up! It was so great to get into nature for a few days and be without my phone and social media; I might try and take more breaks away from my phone even just on regular weekends. I hope you get some time to be outdoors, enjoy family and make joyful memories!

Family Planning

The cover article on page 22 focuses on how to have a healthy pregnancy and prepare yourself when you have a bleeding disorder or have a family history of bleeding disorders. While my husband and I aren’t starting a family just yet, we are looking forward to having kids one day. As a woman with a bleeding disorder, that means some extra planning to make sure that I have the best care team in place while I’m on that journey.

Care for women with bleeding disorders is often challenging, and I’ve encountered situations when there were not many options for treatment for my specific needs. HFA is committed to ensuring access to all treatments available for women, especially in regard to reproductive health.

Insurance Woes

An ongoing challenge for people with bleeding disorders is insurance. The word alone can cause headaches and stress before you even dive into the labyrinth/mess of insurance coverage. HFA staff is here to help you understand your insurance coverage and how to deal with insurance challenges. On page 14 is an article that outlines some of the hardships that still exist when dealing with insurance, despite all the successes of the Affordable Care Act. Learn about copay accumulators and other issues that you need to know in this article.

Please enjoy this issue of Dateline Federation. As always, if you have questions about anything included within these pages, please reach out to the HFA team. We are here to support you!

Allie Ritcey
Chair, HFA Board of Directors

Until then, we’re here for you and your family at www.hemophiliafed.org
Executive Corner
Allie Ritcey, chair of the HFA Board of Directors, shares how she spent her summer vacation.

Happening Highlights
Helping Hands needs your support. Save the dates for fall events.

Kids Corner
7 ways to get ready for back to school.

Member Organization Spotlight
The Tennessee Hemophilia and Bleeding Disorder Foundation celebrates its 47th year of Camp Freedom.

Inspiring Impact
Joana Baquero reflects on her journey with factor I deficiency via a TEDx Talk.

Insurance Challenges
Despite health insurance improvements of the past decade, hardships—like copay accumulators—remain.

Pregnancy Prep
With bleeding disorders, starting a family means planning ahead with a collaborative health care team.

Symposium 2022
It was a Texas-sized family reunion in April at the first in-person Symposium since the COVID-19 pandemic started.

Assisting, educating, and advocating for the bleeding disorders community since 1994.

Volume 23 • Issue 3 • SUMMER 2022

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Connect with us on social media for daily posts and updates about what’s happening at HFA.

Until then, we’re here for you and your family at www.hemophilafed.org
1 Establish Communication Early.
Schedule an educational meeting with the school principal, teachers, school nurse and social worker so they can learn about your child’s bleeding disorder.

2 Plan Your Child’s Education.
There are support programs at the school, such as the 504 Plan or the Individualized Education Plan (IEP). A student with a bleeding disorder may be eligible for an IEP or a 504 plan, depending on their circumstances. These plans are:
- **IEP**: A project or plan for special education that a student will receive at school.
- **504 Plan**: A plan of how the school will support and eliminate the barriers faced by the student.

3 Wear a Medical Alert Bracelet.
It is recommended that your child always wear a medical alert bracelet. In an emergency, the bracelet will alert urgent care providers to your child’s medical condition and increased risk of bleeding.

4 Encourage Your Child to Seek Support at School.
Encourage your child to build trusting relationships with people at their school they can talk to about their bleeding disorder, especially in an emergency.

5 Talk About Any Ongoing Pandemic Concerns.
Your child may still have occasional questions or concerns related to the COVID-19 pandemic, such as changes in routine, new restrictions or mask rules. Be honest and answer questions with ideas your child can understand and are appropriate for their age level.

6 Embrace New Beginnings.
A new school year, with new routines, can be a good opportunity to teach life skills such as problem-solving, self-care and adaptation.

7 Establish Routines.
Establish daily routines for getting up, going to bed, homework time and school transportation. These habits will help your child feel ready for the day.

**Helping Hands Needs Your Support**
Helping Hands provides support to community members who are facing financial hardship directly caused by their bleeding disorder. In 2021, Helping Hands gave $345,340 to 588 families. Already in 2022, we have assisted 250 families or individuals with $154,260.

Helping Hands can help pay for household bills when someone loses income from missed work due to bleeds. It can also help cover the cost of transportation to or from doctors’ appointments and hotel stays if the family needs to stay while their child or spouse is treated medically. It also assists in purchasing refrigerators for factor, wheelchair ramps, comfy caps, orthopedic shoes/inserts, and specialty pain management products such as a cryo cuff.

Sometimes Helping Hands funding helps families avoid eviction from their homes or repossession of their primary vehicles. We are working hard to meet our goal of raising an additional $200,000 by the end of 2022. Join us by donating today at [www.hemophiliafed.org](http://www.hemophiliafed.org).

**Helping Hands in 2021**
$345,340 to 588 families

**Save the Dates!**

**Call to Action: Advocacy Week, Fly-In and Congressional Reception**
**September 11-12**
Washington, DC

**Gears for Good**
**September 23-25**
C&O Trail
Rosslyn, Virginia

**Dateline Live**
November 14-15
- Insurance Bootcamp > November 14
- Navigating Approved Products and Emerging Therapies > November 15
- Webinar event (Zoom)

**Symposium 2023**
April 13-16, 2023
Sea World Renaissance Hotel
Orlando, Florida
Camp Freedom of the Tennessee Hemophilia and Bleeding Disorder Foundation just celebrated its 47th year this summer. This weeklong camp of traditions bonds the next generation to the past. “Many of the counselors are former campers who choose to come back and spread their love of camp with new campers,” said Amanda Wilson, the Tennessee foundation’s executive director.

“We are a family,” Wilson said. “We support our brothers and sisters, wherever the need may be.”

While the COVID-19 pandemic has been a challenge for all of us, imagine taking on a new position with a new community. Over the past two years, many HFA member organizations welcomed new executive directors. We would like to recognize them here:

- Ashley Castello, Louisiana Hemophilia Foundation
- Leigh Goldstein, Arizona Bleeding Disorders
- Stephanie Hill, Central California Hemophilia Foundation
- Joy Linder, Southwestern Ohio Hemophilia Foundation
- Beth Mahar, Bleeding Disorders Association of Northeastern New York
- Andrea Orozco, Hemophilia Foundation of Northern California
- Sarah Pilacik, Eastern Pennsylvania Bleeding Disorders Foundation
- Anthony Llanes Rodriguez, Asociación Puertorriqueña de Hemofilia y Condiciones de Sangrado
- Kym Shaw, Snake River Hemophilia and Bleeding Disorders
- Mary Lou Warner, Hemophilia of Iowa

Welcome New Executive Directors!
Joana Baquero believes strongly that having afibrinogenemia, or factor I deficiency, has provided her with a resilient mindset, one that helps her tackle challenges head-on. She needed that mindset when she was diagnosed with breast cancer at age 35.

She had already had to deal with her rare bleeding disorder, which led to seven intracranial bleeds—the first at age 13, the last at age 31. At that point, she had a port inserted and started chemotherapy.

In 2022, Baquero was invited to present at TEDx Tulsa at the University of Tulsa in Oklahoma. The event theme was "new horizons." She decided to focus her talk on building a resilient mindset for everyday life.

"Having afibrinogenemia helped me shape a way of tackling challenges while still enjoying the rest of my life because if you think about any problem at you and thrive! Your bleeding disorder does not define you or the outcome of your life."

A few years later, when her book sales plateaued, she realized she needed a new approach. "People today are always connected either on phones or computers, and I needed a way to reach people where they are," she said. "Going to a platform like TED enabled me to keep spreading the awareness of afibrinogenemia, while keeping the format short."

TED Talks aim to present one great idea in 18 minutes or less. Baquero began researching and applying to TEDx events, which are independent, grassroots events in which people get invited to present a TED Talk.

"Having afibrinogenemia helped me shape a way of tackling challenges while still enjoying the rest of my life because if you think about any problem that you have, and you only focus on that, then it burns you out," she said. "To me, factor I deficiency is part of my life, and I didn't want it to define what I was doing—when you get up, you can't be thinking of your bleeding disorder 24/7 because otherwise your life becomes just that. And that's not a way of living."

That already established resiliency was critical when Baquero was diagnosed with breast cancer. "I thought, this can't be happening. I couldn't believe it."

But then she reacted the same way she did when she would have a bleed: What do I need to do? Who do I need to talk to? Which doctors do I need to meet with? She also quickly realized that there are a lot more resources and information about breast cancer than afibrinogenemia, making it easier and faster to learn about it.

**Creating Her TEDx Talk**

Baquero developed her TEDx Talk after a lot of reflection. With an 18-minute limit, she knew she needed to present her ideas about resiliency in a concise but compelling format. She broke down her lessons into four steps:

1. Accept reality.
2. Focus on your end goal.
3. Find allies for your battle.
4. Cultivate hope despite your circumstances.

Before the event arrived, she practiced a lot and then, about two weeks before the event, she had to present to the organizers on Zoom so they could confirm she was ready.

In Tulsa, all participants rehearsed twice on the big stage before the final recording day. Coaches were on hand to give feedback, such as to stop pacing, where to look, what not to say. On the final day, Baquero had to do the presentation in one take to a full audience. However, because of the bright stage lights, she couldn't see the attendees. Only at the end, when they applauded, did she realize there were people in the room.

Baquero’s presentation has more than 13,000 views on YouTube (watch at www.youtube.com/watch?v=dU53bCvb-1c). She feels that her TEDx Talk was a way to give back to the bleeding disorders community by helping to generate awareness of factor I deficiency and other bleeding disorders.

Baquero has been inspired by Chris Bombardier, the first person with hemophilia to successfully climb the Seven Summits, including Mt. Everest. After watching his documentary, "Bombardier Blood," Baquero reflected on how everyone has their own unique "Everest" and what her Everest would be.

"The interpretation of Everest is different for every person," she said. "My Everest was writing a book and doing the TEDx talk, so I would encourage everyone to think, 'What is my Everest? What is my dream?'"
EVERY STEP HAS BEEN EVOLVING
THE SCIENCE OF GENE THERAPY
IN HEMOPHILIA B

We’re working to make gene therapy a reality for you.

Explore the advancing science behind gene therapy at HemEvolution.com
Figuring out how to obtain good, but affordable, health insurance can be a challenge for some in the U.S. But for people with bleeding disorders, there’s no question the overall situation is better now than it was a generation ago. More people now have health insurance coverage, and, at the same time, treatments for bleeding disorders have improved significantly. But nothing is ever as easy as it seems. As Mark Hobraczk, JD, MPA, HFA senior manager for policy and advocacy, said, “Getting insurance and actually being able to use it are two very different things.”

People with bleeding disorders face numerous challenges, even with health insurance. Read on to learn more about some of the hurdles and how HFA is working to surmount them.

The Affordable Care Act (ACA) expanded care and made major improvements to the health insurance landscape. People with bleeding disorders can no longer be charged higher premiums for having a bleeding disorder, nor can they be subjected to annual or lifetime caps on their medical care.

Insurance Challenges

Despite health insurance improvements of the past decade, hardships—like copay accumulators—remain.

BY JENNIFER LARSON, FREELANCE WRITER
The 12-year-old ACA made a real difference in the lives of people with bleeding disorders. The law was strengthened last year when Congress enacted the American Rescue Plan Act (ARPA). This legislation increased premium subsidies for people buying their own insurance through the ACA Marketplace and made the subsidies available to more people.

But some big challenges remain. Among others, trends in health insurance over the past decade have shifted toward putting more costs on the shoulders of patients.

“That shift is particularly painful in people with bleeding disorders because the costs of treatment are so high and they are lifelong,” said Miriam Goldstein, JD, HFA director of policy.

The medications are usually placed on a plan’s highest cost-sharing tier, often requiring co-insurance rather than a flat copay. A person with hemophilia or another bleeding disorder could lead to a series of bleeds that can result in a disorder can’t just take a different drug if their insurance plan without a copay accumulator, and Morrison learned that his employer-sponsored health insurance plan had processed his copay assistance but then refused to allow his patient assistance funds to count toward his deductible or out-of-pocket costs.

Morrison had been targeted by one of the biggest manufacturer’s copay assistance programs. He finished college, became a nurse practitioner, and a new job came along at the right time. His new employer offered an insurance plan without a copay accumulator, and Morrison gratefully signed up. Now he has a plan that allows his copay assistance program to actually help pay for his costs.

But Morrison remembers the shock he experienced when he learned his employer health plan expected him to pay $3,000 out of pocket each year, on top of his share of his monthly premium. He would have had to pay $4,200 annually just to get his one factor, a daunting prospect for a nurse in graduate school. “That doesn’t account for any other costs I might ring up, such as doctors’ visits,” he said.

“I would have had to front that money to them every year,” he continued. “We would not have been able to afford that every single year, on top of paying a premium for insurance. We just would not have been able to afford it.”

Unfortunately, thousands of other people don’t have the option to switch plans, for a variety of reasons. And even if they could switch, it might not matter because copay accumulators are becoming increasingly pervasive. In fact, Hobraczek said, more than 80% of commercial health plans sold today include copay maximizers.

“It really has a devastating impact on somebody who is going to have their care disrupted because they can’t afford $8,700—their potential out-of-pocket maximum for the year—up front,” Hobraczek said.

More Copay Accumulator Woes

It can be difficult to know if your plan even has an accumulator—until you confront an eye-popping bill for your next medication refill. Often, plans are not transparent about them, or the fine print is difficult to decipher.

Consider what happened to Britnie Nakai, a mother of two who lives in Salt Lake City. She and her nine-year-old daughter both have mild hemophilia A, and her 15-year-old son has severe hemophilia A. Every four days, her son receives an infusion of factor VIII. Nakai felt fortunate that the manufacturer’s copay assistance allowed her to meet the plan’s deductible—until she got a cryptic letter and a bill from her insurance company for $1,300 in April 2020.

The letter informed her that her son’s patient assistance didn’t count toward their deductible and out-of-pocket expenses. She was initially confused, as the insurance company actually used the phrasing “manufacturer coupon” instead of “patient assistance.” Plus, it was back-dated to January, but the company waited until April to inform her.

Essentially, the insurance company depleted her son’s patient assistance funds, which totaled about $12,000, then turned around and presented her with a bill. She had no prior knowledge this would happen. She had been hit retroactively with a copay accumulator.

Plus, the bad news was all coming down as COVID-19 was ramping up and everyone was already on edge. “It was devastating for a family that lives paycheck to paycheck,” Nakai said.

Copay Maximizers

You also have to watch out for the copay maximizer, which is a type of copay accumulator, or like a “cousin” to the copay accumulator. “It’s a form that’s a little less disruptive for the patient but still harmful,” Hobraczek said.

Copay maximizers mainly appear in employer-sponsored health plans, where they now actually outpace copay accumulator adjustments. Health plans with maximizers work by declaring that certain drugs don’t count as an essential health benefit. If you need one of these drugs, you can only get it by enrolling in a separate copay maximizer program, typically run by a separate company affiliated with the health plan. Through the maximizer program, you also have to sign up for manufacturer copay assistance. The maximizer program sets your monthly copay at 1/2 the total amount of assistance that is available from the manufacturer—but, as with an accumulator, none of those payments count toward your deductible or out-of-pocket limit. “In other words, you don’t benefit from the assistance,” Hobraczek said.

Randi Clites’ son Colton, 20, has severe hemophilia A and needs twice-weekly self-infusions of extended half-life clotting factor. He’s had regular access to clotting factor since he was 16 months old. “So now, he is totally benefiting from that,” said Clites, who lives in Ohio. “He has no joint damage. He is 100% physically like his peers. That is a true testament to the advocacy that was done in the generation before to make sure that people like him would have access to his treatment.”

Trouble with Copay Accumulators?

Report your insurance struggles to HFA via Project CALLS.org. An HFA initiative to collect stories from community members experiencing insurance issues that create barriers to care. HFA staff follows up on Project CALLS reports and, with permission, use these stories with lawmakers to illustrate trends and to support HFA’s advocacy for change.
So nearly every year, Clites and her husband pore over their options for health insurance: insurance through her husband’s employer, insurance through her employer, and plans offered through the ACA marketplace. They’ve switched plans when it became necessary. But it’s gotten harder, and the ongoing stress takes a toll.

“Typically, we can figure out a way to make it accessible and affordable, but we have to apply for assistance,” said Clites, who serves as the rare disease policy director at the Little Hercules Foundation in Dublin, Ohio. “And then we wait to see if that assistance will kick in.”

A copay maximizer means they’re often in limbo, waiting to see what happens next. They worry that they’re going to get a bill they can’t pay, followed by another bill. Clites is still waiting to see if a bill for $6,350 arrives for November and December 2021.

Clites’ advice for people with employer-sponsored plans: Read your benefits closely. “Now more than ever, it is crucial that patients read their summary of benefits at the beginning of the year so they can prepare for coverage gaps and apply for assistance programs available to them,” she said.

Changes Ahead … Hopefully

Without legislative changes, patients may continue to face a catch-22—they may have insurance, but their insurance doesn’t really help them pay for the care and medication they need.

Therefore, federal legislation changes are a key priority for HFA, Goldstein said. For example, ARPA expires at the end of 2022, which will create what Goldstein called “a financial shock” for people relying upon its enhanced subsidies to afford insurance. So HFA, in coalition with a host of allied patient advocacy groups, is calling on Congress to extend the subsidies.

Other efforts by HFA include:

- HFA is encouraging the 12 states that have not expanded Medicaid to do so. This would cover more people with bleeding disorders who currently don’t qualify for Medicaid or for ARPA subsidies. HFA is also encouraging a “federal fix” that would create a Medicaid-like alternative for the millions of people caught in the coverage gap.
- HFA, again in coalition, is asking federal regulators to adopt rules reigning in insurer use of copay accumulators and similar policies that interfere with people’s ability to use copay assistance to pay for their treatments.
- HFA is supporting state member organizations in their drive to get state legislation passed to ban copay accumulators. State laws only govern a subset of health insurance plans, “but they build pressure and momentum to apply to other health plans,” Goldstein said.

Looking back to the time before ACA passage, it’s clear how much the insurance landscape has improved for people with bleeding disorders. Gone are the days when people with preexisting conditions could be denied insurance, charged higher premiums based on their health or subjected to arbitrary dollar caps on their benefits.

Additionally, surprise medical billing protections also went into effect at the beginning of 2022, and skilled nursing facility care is now more readily available to people with bleeding disorders on Medicare.

Plus, a growing number of states are passing legislation to curtail or eliminate obstacles such as copay accumulators. Currently, 14 states and Puerto Rico have passed such bills. However, serious gaps remain, and much work remains to close loopholes and improve affordability. HFA and the bleeding disorders community remain committed to that work.

“Now more than ever, it is crucial that patients read their summary of benefits at the beginning of the year so they can prepare for coverage gaps and apply for assistance programs available to them.”

—Randi Clites

DOWN 1. Manageable, as an earworm 2. Devotee 3. Medical fluids 4. Prepare to propose, perhaps 5. PC’s “brain” 6. Votes 7. Concert venue 8. See Medication Guide 9. Winter hrs. in Havana and El Paso 10. HEMBLRA is the prophylactic treatment offered this way under the skin 11. Praeuro currency in Italy 12. Subway alternative 13. Human 14. New Orleans 15. Reduced 17. Spanish beers 18. Arcade enthusiasm 20. Bronde black tea 21. Old Portuguese coins 22. Hold 23. Feel bad 24. Feelness 25. Numbers in your face 27. Eye pain or swelling 28. Visible seating 29. Health hazard 30. Carbolic acid 31. Number of doses options HEMBLRA offers 32. Small hole in lace cloth 35. Central Plains tribe 36. Melodic 37. Towering 38. Reduce 39. Spanish cheers 40. Croquet 41. Concert venue 42. See Medication Guide 43. talk to your doctor about potential effects 45. Winter hrs. in Havana and El Paso 46. In the 47. Can’t wait to see more of the 48. Withhold until the 49. The most important information I should know about HEMBLRA. 50. A prescription medicine for people with hemophilia A with or without factor VIII inhibitors. 51. HEMBLRA increases the potential for your blood to clot. People who use activated prothrombin complex concentrates (aPCCs) (Felb®) to treat breakthrough bleeds while taking HEMBLRA may be at risk of serious side effects related to blood clots. 52. 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. 53. Your healthcare provider should show you or your caregiver how to prepare, measure, and inject your dose of HEMBLRA before you inject yourself the first time. Do not attempt to inject your own 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 HEMBLRA 1 week a month for the first 4 weeks. Your provider may adjust your maintenance dose as prescribed by your healthcare provider. 54. If you miss a dose of HEMBLRA 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 your next scheduled dose, and then continue with your normal dosing schedule. 55. Hemophilia 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.

**SOLUTIONS**

**INDICATION & IMPORTANT SAFETY INFORMATION**

What is HEMBLRA? HEMBLRA 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 HEMBLRA? HEMBLRA increases the potential for your blood to clot. People who use activated prothrombin complex concentrates (aPCCs) (Felb®) to treat breakthrough bleeds while taking HEMBLRA 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 damage 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 HEMBLRA: confusion; weakness; swelling of arms and legs; yellowing of skin and eyes; decreased urination; and/or blood clots (thrombotic events).

**Blood clots (thrombotic events)**, blood clots form in blood vessels in your arm, leg, lung, or head. Get medical help right away if you have any of the following signs or symptoms during or after treatment with HEMBLRA: confusion; weakness; swelling of arms and legs; pain or redness in your arms or legs; pain or redness in your face; numbness in your face; eye pain or swelling; and/or blood clots (thrombotic events).

Your body may make antibodies against HEMBLRA, which may stop HEMBLRA from working properly. Contact your healthcare provider if you notice that HEMBLRA has stopped working for you (e.g., increase in bleeds).

Solutions for these effects of HEMBLRA:**

For more information about side effects.

Before using HEMBLRA, 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 HEMBLRA may harm your unborn baby. Females who are able to become pregnant should use birth control (contraception) during treatment with HEMBLRA.
- Are breastfeeding. Women should not breastfeed while taking HEMBLRA. It is not known if HEMBLRA 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 HEMBLRA?

See the detailed "Instructions for Use" that comes with your HEMBLRA. For information on how to prepare and inject a dose of HEMBLRA, and how to properly throw away (dispose of) used needles and syringes. Use HEMBLRA exactly as prescribed by your healthcare provider. Your healthcare provider will prescribe your dose based on your weight. If your weight changes, tell your healthcare provider. You will receive HEMBLRA 1 week a month for the first 4 weeks. Your provider may adjust your maintenance dose as prescribed by your healthcare provider.

Stop (discontinue) prophylactic use of bleeding agents before starting HEMBLRA prophylaxis. You may continue prophylactic use of aPCCs for the first week of HEMBLRA prophylaxis.

HEMBLRA is given as an injection under your skin (subcutaneous injection) by you or a caregiver.
Diane Bruno was 26 when she discovered she was a carrier of hemophilia, six months after giving birth to her son. Ten years later and living in Methuen, Massachusetts, the mom of three lives with mild bleeding disorder symptoms.

“We didn’t have any history of bleeding disorders in my family when my son was born,” Bruno explained. “He was diagnosed at four days old with severe hemophilia A, and it was only after the fact that some of my own symptoms during delivery made more sense.”

Bruno knew she wanted more children, but her experience with heavy bleeding and a third-degree tear requiring multiple surgeries postpartum made her more hesitant. She and her husband had several conversations with her son’s hematologist and her ob-gyn to be sure they were being proactive about bleeding risks.

“We didn’t have any history of bleeding disorders in my family when my son was born,” Bruno explained. “He was diagnosed at four days old with severe hemophilia A, and it was only after the fact that some of my own symptoms during delivery made more sense.”

Bruno knew she wanted more children, but her experience with heavy bleeding and a third-degree tear requiring multiple surgeries postpartum made her more hesitant. She and her husband had several conversations with her son’s hematologist and her ob-gyn to be sure they were being proactive about bleeding risks.

“Once we had a pretty good handle on our son’s bleeding disorder, we decided we would go all in and take a big risk in hopes that the outcome would outweigh the risks,
and it certainly did," Bruno said. "I trusted [my ob-gyn’s] judgment and had two successful C-sections with both of my daughters. Although there was a bit more bleeding during the process of stitching the incisions, I did not need factor and I healed successfully."

One of the most important things Patricia Huguelet, MD, clinical medical director of the Spots and Dots bleeding clinic and associate professor at the University of Colorado School of Medicine and Children’s Hospital Colorado, wants people to understand is they can still have a safe and healthy pregnancy despite a bleeding disorder.

"So many women live in fear because they’ve struggled their whole lives with bleeding," Huguelet explained. "They assume pregnancy is something they can’t do or that would be catastrophic."

The key is having a diagnosis and planning in advance. While a person may be young and healthy, there are still increased chances for bleeding, from first-trimester complications, second and third-trimester placental problems, and postpartum hemorrhage at delivery, Huguelet said.

Academic medical centers are usually well-equipped to manage high-risk pregnancies in collaboration with hematology. If a clinic doesn’t have this type of multi-disciplinary care, it’s a matter of having an ob-gyn and hematologist working together, to nail down a plan for any pregnancy complications and develop a plan for delivery.

Sometimes though, that planning can be difficult for women to advocate for, as Brandi Worthington knows. Living in Lake Elsinore, California, the 38-year-old mother of four is a carrier of and has mild hemophilia A. But she bleeds heavier than someone with mild hemophilia, she said, which was only discovered when she was seven months pregnant with her third child.

Worthington said she didn’t get the care she should have had. All of her pregnancies were considered high risk due to a number of different health complications. Having grown up with “outrageous” periods, doctors told her she wasn’t anemic and didn’t have hemophilia, but they didn’t know what was going on with her. Despite having a nephew with hemophilia, she and her twin were never tested. It wasn’t until she was pregnant with her third child, a son, that her doctor decided to have her tested.

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"Historically, carriers were under-recognized and undervalued," said Patricia Huguelet, MD. But some in the medical community are starting to realize carriers don’t have normal factor levels and can have significant bleeding.

Genetic Testing
It’s hard to say if genetic testing before pregnancy would have helped prevent Worthington’s complications. But having a plan after birth would have been crucial, she said. After he was born, her son was bruised all over from multiple needle pokes. When the medical staff wanted to give him the vitamin K shot, Worthington asked them not to.

“I had some inkling,” Worthington said. She told the staff she’d prefer someone knowledgeable in hemophilia assess him first. “They gave him the shot and had a hematoma right away. I’m like, boom, he’s a hemophiliac.”

Despite her concerns, Worthington was dismissed. As a female, she had the impression hemophilia wasn’t a concern for the medical staff. They appeared to assume that only males could have hemophilia. “It was a struggle.”

Kaylee Dollerschell, MS, is a certified genetic counselor at the Hemophilia and Thrombosis Center at the University of Colorado. She regularly meets with families to provide genetic education about hereditary bleeding and clotting disorders.

The benefit of meeting with a genetic counselor prior to pregnancy, explained Dollerschell, is that not everyone will need genetic testing because not all bleeding disorders are inherited. If it’s suspected that a bleeding disorder is hereditary, Dollerschell supports families through the challenges of having a child with a genetic bleeding disorder.

“There’s a benefit in being able to prepare for delivery,” she said, “not only for Mom, if she’s affected, but also for the baby.” Knowing someone’s bleeding status in advance can help the clinical team and pregnant person plan for special considerations during delivery or postpartum care.

“People can feel guilt for passing on a disorder to their children,” Dollerschell said. “There’s no control over what we pass on, but those things don’t necessarily get addressed by other providers [but] can potentially get addressed by genetic counselors.”

Understanding how a genetic disorder is inherited can help people discover if other family members or future children may have the same condition and how to best test them. If a family is interested, genetic counselors can also review family planning options related to hereditary disorders.

As a genetic counselor, Dollerschell respects that testing options might feel like a fit for some families and not for others. “We just provide the information,” she said. Genetic counselors provide support and guidance to help patients decide if or which genetic testing option feels best for their family.

Being Proactive
Ashley Fox, 29, always knew she was a carrier because her father had lived with hemophilia A. Fox has two sons and lives in Pittsburgh. Her infant son has mild hemophilia A, while her older son does not have hemophilia. As a symptomatic hemophilia carrier, Fox said her youngest son’s pregnancy was a pleasant surprise after two heartbreaking miscarriages.

Still, Fox was concerned about her bleeding risk and whether her son would inherit hemophilia. She and her husband declined prenatal testing and decided to wait until he was born to find out.
“Maybe finding out his diagnosis during pregnancy would have made it a little easier, maybe not.”
—Ashley Fox

“Operative delivery puts a lot of force on the fetal head, which can result in scalp trauma and potential subdural and intracranial hemorrhage,” Huguelet said. If there isn’t progress in labor, providers may move to a Cesarean delivery faster because of the increased risk of complications with the baby during operative deliveries. Fox had blood work done at the local hemophilia treatment center (HTC) to check her factor levels in anticipation of the Cesarean delivery. The levels came back high enough that her care team was comfortable that she wouldn’t experience complications. The HTC also provided Fox with a cord blood kit to take with her to the hospital because she had declined prenatal genetic testing. Cord blood kits can quickly diagnose hemophilia in newborns by medical staff drawing blood from the umbilical cord and getting rapid results from the test sample. She ended up using the kit and found out two days after her son was born that he had hemophilia A.

“Maybe finding out his diagnosis during pregnancy would have made it a little easier, maybe not,” Fox said. Despite the challenges faced, she, along with Worthington and Bruno, agreed: Having a bleeding disorder does not have to interfere with having a healthy pregnancy.

How to Plan Ahead
If you’re living with a bleeding disorder and you’re thinking about getting pregnant, there are plenty of resources to help you make the best decision for your family. Here’s what you need to know.

ASK QUESTIONS
“Be proactive and ask questions,” Bruno said. “If your ob-gyn doesn’t have the answers, find someone who does. You can have a successful pregnancy and delivery with the right monitoring and open communication between you and your care team.”

“Keep in close contact with your HTC,” Fox said. “They’re your best ally and will support you every step of the way.”

CONNECT WITH COMMUNITY
“I never realized how valuable having allies who know what you’re going through can be,” Bruno said. “This community is very supportive and always willing to share the name of an outstanding doctor. You can get the care you need, but it may mean more advocating and educating along the way.”

ADVOCATE FOR YOURSELF
Sometimes, women “have to fight from the get-go before they even find out they’re pregnant,” Worthington said. Find a bleeding disorder community and talk to people. Figure out a plan and work closely with your providers. Know where you’ll deliver and if they have the level of care you need. “Don’t be scared to voice your opinion.”

CREATE A CARE PLAN
Getting care in place before you’re pregnant can help alleviate the fear and worry. Your provider will look at your factor levels and ask about your past medical and surgical history. They will want to know if you’ve had any major bleeding complications. People with bleeding disorders do have an increased chance of heavy first-trimester bleeding, but having a plan before pregnancy is ideal, Huguelet said.

REFRAME YOUR MINDSET
“Once you have a handle on what living with a bleeding disorder looks like, if you have another child with a bleeding disorder it can actually benefit the family because the kids have each other to lean on,” Bruno said. Worthington’s son who has hemophilia is treated the same as her other kids, even if the experience is a little different. “If you want to have a baby, I don’t think hemophilia should stop you.”

In her second trimester, Fox went to the emergency department with excessive bleeding and was diagnosed with a subchorionic hemorrhage (SCH), in which blood collects in the space between the placenta and uterus. This can cause bleeding, sometimes significantly. Fox was relieved to see her baby healthy and moving on the ultrasound. Fox was placed on modified bed rest, and the SCH resolved in six weeks. “I tried to take it easy, but I never fully got over the fear of something going wrong,” Fox said.

Not knowing the status of her son and his own risk for bleeding, Fox scheduled a Cesarean delivery. “In case he did have hemophilia, they felt it was a safer option for him due to the risk of cranial hemorrhaging with vaginal delivery.”

“Frequently, women experience lacerations with delivery, particularly during the first delivery,” Huguelet said. “But your average patient isn’t going to have a vulvar or vaginal hematomata because they have the ability to stop themselves from bleeding.” In someone with a bleeding disorder, though, those chances can be higher.

If it’s not known if a baby has a bleeding disorder, but it’s suspected in the mother, providers aim to avoid two birthing interventions: invasive fetal monitoring and operative vaginal delivery, Huguelet said.

Fetal heart tones can be traced using a monitor on the woman’s abdomen. However, it’s not perfect because the woman’s heartbeat can be picked up instead of the baby’s. The most accurate method is a fetal scalp electrode in which a clinician places a small electrode on the fetal scalp. However, Huguelet said, this can also cause a significant hematomata on the baby if the baby were to have a bleeding disorder, so it is generally recommended to use the less invasive external monitoring in these situations.

The same goes with an operative vaginal delivery, such as vacuum-assisted deliveries or the use of forceps. “Operative delivery puts a lot of force on the fetal scalp, which can result in scalp trauma and potential subdural and intracranial hemorrhage,” Huguelet said. If there isn’t progress in labor, providers may move to a Cesarean delivery faster because of the increased risk of complications with the baby during operative deliveries.

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We hosted a Texas-sized family reunion in April at Symposium, the first in-person HFA event since the COVID-19 pandemic started.
Save The Dates!

Upcoming HFA Events

SEPTEMBER 17-19
HFA Advocacy Week, Fly-In and Congressional Reception

SEPTEMBER 23-35
Team Resilience Gears for Good National Bike Ride

NOVEMBER 14-15
Dateline Live Virtual Event

Symposium 2022

For more information on all upcoming HFA events, go to www.hemophiliafed.org
IMPORTANT FACTS ABOUT ELOCTATE® (ANTIHEMOPHILIC FACTOR [RECOMBINANT], FC FUSION PROTEIN)

Please read this information carefully before using ELOCTATE® and each time you get a refill, as there may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

WHAT IS ELOCTATE®?
- ELOCTATE® is an injectable medicine that is used to help control and prevent bleeding in people with Hemophilia A (congenital Factor VIII deficiency).
- Your healthcare provider may give you ELOCTATE® when you have surgery.

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT ELOCTATE®?
- You should not use ELOCTATE® if you are allergic to ELOCTATE® or any of its other ingredients. Tell your healthcare provider if you have had an allergic reaction to any Factor VIII product prior to using ELOCTATE®.
- You can have an allergic reaction to ELOCTATE®. Call your healthcare provider or emergency department right away if you have any of the following symptoms: difficulty breathing, chest tightness, swelling of the face, rash or hives.
- Your body can also make antibodies called, “inhibitors” against ELOCTATE®. This can stop ELOCTATE® from working properly. Your healthcare provider may give you blood tests to check for inhibitors.
- If you have risk factors for developing abnormal blood clots in your body, such as an indwelling venous catheter, treatment with Factor VIII may increase this risk.

THE MOST COMMON SIDE EFFECTS OF ELOCTATE INCLUDE:
- Joint pain, general discomfort, muscle pain, headache, and rash, in previously treated patients, and Factor VIII inhibition, device-related blood clotting, and rash in previously untreated patients.

TALK TO YOUR HEALTHCARE PROVIDER FOR MORE INFORMATION AND ABOUT ANY SIDE EFFECT THAT BOTHERS YOU OR DOES NOT GO AWAY.

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE STARTING ELOCTATE®?
Tell your healthcare provider about all your health conditions, including if you:
- Have or have had any medical problems.
- Are taking any prescription and non-prescription medicines, including over-the-counter medicines, supplements, or herbal medicines.
- Are pregnant or planning to become pregnant. It is not known if ELOCTATE® may harm your unborn baby.
- Are breastfeeding. It is not known if ELOCTATE® passes into breast milk and if it can harm your baby.

AFTER STARTING ELOCTATE®:
- If your bleeding is not controlled and you experience a lack of clinical response to Factor VIII therapy, call your healthcare provider right away.
- Medicines are sometimes prescribed for purposes other than those listed here. Do not use ELOCTATE® for a condition for which it was not prescribed. Do not share ELOCTATE® with other people, even if they have the same symptoms that you have.

HOW SHOULD I USE ELOCTATE®?
ELOCTATE® should be administered as ordered by your healthcare provider. You should be trained on how to do infusions by your healthcare provider. Many people with hemophilia A learn to infuse ELOCTATE® by themselves or with the help of a family member. See the booklet called “Instructions for Use” packaged in your ELOCTATE® for directions on infusing. If you are unsure of the procedure, please ask your healthcare provider.

QUESTIONS?
The risk information provided here is not comprehensive. To learn more, talk about ELOCTATE® with your healthcare provider or pharmacist. The FDA-approved product labeling can be found at www.eloctate.com or 1-855-MyELOCTATE (693-5628). 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.

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