



September 1, 2023

Katie Merritt
Director of Policy and Planning
Office of the Insurance Commissioner
1326 Strawberry Square
Harrisburg, PA 17120

[submitted via email to: ra-in-policyoffice@pa.gov]

RE: Commonwealth Essential Health Benefits Benchmark Plan—Public Comment Period; [Notice 2023-14](#)

Dear Director Merritt:

Hemophilia Federation of America (HFA) and the National Bleeding Disorders Foundation (NBDF) are national non-profit organizations that represent individuals with bleeding disorders across the United States. Our missions are to ensure that individuals affected by hemophilia and other inherited bleeding disorders have timely access to quality medical care, therapies, and services, regardless of financial circumstances or place of residence. We thank you for the opportunity to provide comments to inform future decision-making regarding the Essential Health Benefits (EHB) benchmark plan for the Commonwealth of Pennsylvania. Both our organizations have signed onto group comments urging the Commonwealth to make its benchmark plan (BMP) as generous as possible. We write separately here to highlight an issue with specific relevance for Pennsylvanians with bleeding disorders.

About Hemophilia and Other Bleeding Disorders

Hemophilia is a rare, genetic bleeding disorder affecting about 30,000 Americans that impairs the ability of blood to clot properly. Without treatment, people with hemophilia bleed internally, sometimes as a result of trauma, but sometimes simply as a result of everyday activities. This bleeding can lead to severe joint damage and permanent disability, or even – with respect to bleeds in the head, throat, or abdomen – death. Additional related bleeding disorders include Von Willebrand disease (VWD), another inherited bleeding disorder, which is estimated to affect more than three million Americans.

People with bleeding disorders have complex, lifelong medical needs. They depend on ongoing use of prescription medications (infused clotting factors or injectable factor mimetics) to treat or avoid debilitating bleeding episodes that can lead to advanced medical issues or even death.¹ Current treatments and medical care, **when accessible**, are highly effective and allow individuals to lead healthy and productive lives. However, current treatment regimens are also extremely expensive, costing anywhere from \$250,000 to \$1 million or more annually, depending on the severity of the disorder and whether complications such as an inhibitor, which prevents hemophilia treatments from being effective, are present. As a result, people with bleeding disorders depend on access to quality health coverage, including robust EHB and affordability protections.

¹ Gene therapy for hemophilia may eventually reduce or eliminate the need for ongoing factor replacement, but that is many years off for the overwhelming majority of patients, notwithstanding the FDA's recent approvals of a first gene therapy for Factor IX deficiency in November 2022 and for Factor VIII deficiency in June 2023.



Pennsylvania's Benchmark Plan

Pennsylvania's current BMP (2017-2024) covers prescription drugs, including generics, preferred brand drugs, non-preferred brand drugs, and specialty drugs. The Commonwealth's [summary information sheet](#) on file with the U.S. Centers for Medicare and Medicaid Services, however, lists 0 products in the category and class of "Blood Products and Modifiers/Hemostasis Agents" and 5 (unspecified) products in the category and class of "Blood Products and Modifiers/Blood Products and Modifiers, Other." Publicly available documents make no reference to coverage of clotting factor or other products essential for the treatment of bleeding disorders.

Even though the current BMP does not explicitly list infusible or injectable hemostasis agents, it is our understanding that Pennsylvanians with Marketplace insurance *do* currently have access to their essential bleeding disorders medications. We urge the Commonwealth, as it develops an updated BMP, to expressly assure patient access to these essential drugs. Given the high cost and life-saving nature of clotting factor and related hemophilia treatments, it is particularly important that people be able to ascertain that their treatments will be covered, and what their co-payment or co-insurance will be for their medications.

We also fear that omitting specific reference to bleeding disorders products from the BMP could create an opening for issuers to discourage enrollment by high-cost individuals living with a bleeding disorder. Current EHB standards² for drug coverage hinge, in part, on the US Pharmacopeia (USP), requiring coverage of at least one drug per USP category and class. The USP classification comprises drugs covered under Medicare Part D; since clotting factor and other bleeding disorders therapies are covered under Medicare Part B, they are not included in the USP. In the absence of express coverage requirements in the BMP, a health plan that excludes coverage for all available bleeding disorders medications could nonetheless argue that it satisfies EHB drug coverage standards.

Patients in Tennessee are encountering this scenario today. As of January 1, 2023, Tennessee's dominant commercial insurer has implemented formularies that exclude many and in some cases **all** available treatments for a variety of bleeding disorders. The excluded drugs are effective, long-used, and clinically necessary to prevent or treat painful, debilitating, and even life-threatening bleeding episodes. Even though this radically abridged Tennessee formulary discriminates against vulnerable populations, leaving them with with no treatment options, the insurer asserts that its plans satisfy EHB coverage requirements. We urge the Commonwealth to adopt robust EHB standards that would prevent adoption of similarly deficient formularies by Pennsylvania issuers.

Conclusion

Our organizations work to ensure that individuals with bleeding disorders have full access to the treatments they need to lead healthy, productive lives. For all the reasons set forth above, we urge Pennsylvania's Insurance Department to protect coverage of the prescription drugs that our community members need by including them in the BMP. Thank you for considering these comments, and if you

² 45 CFR § 156.122



NATIONAL
BLEEDING DISORDERS
FOUNDATION
Formerly NHF

would like any additional information, please contact Miriam Goldstein, HFA's Interim Vice President for Public Affairs, m.goldstein@hemophiliafed.org, and Nathan Schaefer, NBDF's Senior Vice President of Public Policy and Access, nschaefer@hemophilia.org.

Sincerely,

Miriam Goldstein, JD
Acting Vice President of Public Affairs
Hemophilia Federation of America

A handwritten signature in black ink that reads 'Miriam Goldstein' in a cursive script.

Nathan Schaefer, MSW
Senior Vice President, Public Policy & Access
National Bleeding Disorders Foundation

A handwritten signature in black ink that reads 'Nathan M. Schaefer' in a cursive script.