



NATIONAL HEMOPHILIA FOUNDATION
for all bleeding disorders

August 10, 2018

Drew Snyder
Executive Director
Mississippi Division of Medicaid
Walter Sillers Building
550 High Street, Suite 1000
Jackson, Mississippi 39201

Re: Pharmacy & Therapeutics Committee Review of Clotting Factor Products

Dear Director Snyder,

I am writing today on behalf of the National Hemophilia Foundation (NHF) to inquire about the upcoming August 14th Pharmacy and Therapeutics Committee (P&T) review of clotting factor products. NHF is the nation's leading advocacy organization for individuals with bleeding disorders. Our mission is 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 recognize that the complexities involved in treating hemophilia and related bleeding disorders can result in high medical expenses for patients and their health insurance plans. While the need to identify cost containment strategies is necessary, it is critical that such strategies not compromise continuity of care for those with complex medical conditions. Hemophilia and related bleeding disorders are rare, complex genetic conditions for which there are no known cures. Individuals often experience spontaneous and prolonged internal bleeding into the joints and soft tissues. To effectively manage these disorders, patients often require life-long infusions of clotting factor therapies that replace the missing or deficient blood proteins, thus preventing debilitating and life-threatening internal bleeding.

While today's therapies are safer and more effective than ever, they are also more costly than other types of medication. The average cost for a person with hemophilia can be around \$350,000 a year. For a patient with severe hemophilia, that annual cost can easily double. Developing an inhibitor (i.e., an immune response to treatment) or other complications such as HIV/AIDS, hepatitis, chronic joint disease, or bleeding as a result of trauma or surgery can increase those costs to over \$1 million.



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Clotting factor and non-factor replacement therapies are biological products derived from human blood plasma or by using recombinant technology for which there are no generic equivalents. Moreover, because of the nature of bleeding disorders, an individual's response and tolerability for a specific product is unique. For these reasons, NHF's Medical and Scientific Advisory Council (MASAC) recommends that individuals retain access to the full range of FDA-approved clotting factor products.¹ Limiting access through the use of restrictive drug formularies such as those requiring prior authorization, preferred drug lists, and fail first/step therapy, could have a negative impact on patient care and ultimately result in higher drug spends. Therefore, drug benefit designs employing these methods should be avoided, and the choice of product used by an individual should remain a decision between patient and physician.²

On behalf of individuals in the State of Mississippi affected by bleeding disorders, we urge you to prioritize the practice of allowing patient access to all FDA-approved therapies available to treat hemophilia and related bleeding disorders. However, if the state decides to manage clotting factor products we recommend the following: (1) new Medicaid patients be grandfathered in on their current medication; (2) the medication of existing Medicaid patients be included on the PDL; (3) any prior authorization criteria result in a clear, direct, and timely process that does not delay access to patient care. Also, because bleeding disorders are lifelong conditions without a cure we request that the authorization period be as long as is reasonable to prevent any negative consequences from patients running out of medication, e.g. six to twelve months. Adopting these policies will help mitigate any potential excess costs associated with our patients not having access to the medication they rely on.

Thank you for the opportunity to share our concerns. If you would like additional information or have questions, or would welcome the opportunity to further discuss these concerns, please feel free to contact me at 317-517-3032 or mrice@hemophilia.org.

Thank you,

Michelle Rice
Sr. Vice President, External Affairs
National Hemophilia Foundation

¹ MASAC Document #253 (2018) Recommendation Concerning Products Licensed for the Treatment of Hemophilia and Other Bleeding Disorders. www.hemophilia.org

² MASAC Document #166 (2005) MASAC Resolution Regarding Preferred Drug Lists. www.hemophilia.org