



NATIONAL HEMOPHILIA FOUNDATION
for all bleeding disorders

October 24, 2017

Bradley Henry, MD, Chair
West Virginia Medicaid Pharmaceutical and Therapeutics Committee
Bureau for Medical Services
Pharmacy Services
350 Capitol St., Room 251
Charleston, WV 25301-1542

Re: Therapeutic Class Reviews – Antihemophilic Agents

Dear Mr. Chairman and Committee Members,

I am writing today on behalf of the National Hemophilia Foundation (NHF) to inquire about and comment on the proposed actions by the Pharmaceutical and Therapeutics Committee (P&T) at its October 25 meeting regarding antihemophilic clotting factor. 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 understand that clotting factor products will be reviewed by the Committee to be included on the state's Preferred Drug List effective January 1, 2018.

NHF recognizes 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. For example, cost of treatment for a person with severe hemophilia can reach \$250,000 per year or more.

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 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 (PDL), 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

According to the state's current generic non-preferred drug prior authorization form it appears that a patient must "fail" on a preferred product before they can access a non-preferred product. We respectfully ask that you to re-consider this approach. It is difficult for a patient to "fail" on a prescribed bleeding disorders medication. Typically, if a patient experiences breakthrough bleeding, the protocol would be to increase the quantity and frequency of dosing to overcome an accelerated half-life response. This may result in unintended consequences such as more frequent infusions, which often leads to more missed days of work or school, decreased adherence and overall quality of life. Collectively, these would result in greater long-term health care costs. In this scenario, a longer half-life product, which may be non-preferred, could result in a better outcome for the patient and at a lower cost. Alternatively, rather than a "fail" requirement, we suggest you consider a physician's attestation as to why the patient should be prescribed a non-preferred product sufficient to ensure access to the necessary medication.

Regarding the process for accessing non-preferred products would you please clarify some things? 1) Does the state intend to use the Non-Preferred Drug Prior Authorization form for hemophilia patients? 2) If so, how will the state define "failure" for a patient using a preferred clotting factor product? 3) The prior authorization process requires the attestation of the prescribing pharmacist. Since in most instances blood clotting factors are prescribed by a physician, can this be amended to add: or the patient's prescribing physician?

On behalf of individuals in the State of West Virginia 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.



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

Thank you,

Michelle Rice

Sr. Vice President, External Affairs

National Hemophilia Foundation

¹ MASAC Document #250 (2013) 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