



# NATIONAL HEMOPHILIA FOUNDATION

www.hemophilia.org

## Protecting Timely Access to Care The Need to Standardize Prior-Authorization

### Introduction

NHF leads the nationwide movement to ensure that all individuals living with hemophilia and related bleeding disorders have access to affordable medical care and services that are in accordance with physician guidelines. The Medical and Scientific Advisory Council (MASAC) – the leading council of medical experts on treatment of individuals with hemophilia and related bleeding disorders – has set forth a clear recommendation on access and care for members of the bleeding disorders community (MASAC #153<sup>1</sup>). Most notably, MASAC stipulates that members of our community experiencing medical emergencies should receive immediate access to treatment (with a wait no longer than 12 hours<sup>2</sup>), forgoing the prior-authorization process. NHF, however, acknowledges that prior-authorization is often the reality for our community members when seeking treatment. Without a *standardized* prior-authorization process, those affected as well as many who are part of other chronic disease groups risk being denied critical access to care. As a result, NHF supports a standardized prior-authorization process through which patients gain access to medically necessary prescription drug benefits and medical services within a suitable timeframe as determined by trained physicians.

### Background on Prior-Authorization

“One of the tools used by [Pharmacy Benefit Managers or] PBMs to manage prescription costs is requiring that certain drugs receive prior authorization (PA) from the PBM before dispensing.”<sup>3</sup> Prior-authorization is often applicable to medical services as well. Proponents of the prior-authorization process contend that its overarching goal is two-fold – “to encourage appropriate use of medications, both to reduce the incidence of preventable drug-related morbidity and to contain costs. The philosophy behind this mechanism, which intuitively seems to help promote the delivery of quality health care, is to target new, costly, or potentially toxic medications, and to encourage use of less-expensive, safer alternatives.”<sup>4</sup> In recent years there has been an “increasing requirement by insurers” across the

---

<sup>1</sup> “MASAC Document #153: MASAC Recommendation Concerning Reimbursement for Recombinant Clotting Factor Concentrates.” *The National Hemophilia Foundation*. 9 November 2003. You can access MASAC #153 [here](#).

<sup>2</sup> “MASAC Document #188: MASAC Recommendations Regarding Standards of Service for Pharmacy Providers of Clotting Factor Concentrates for Home Use to Patients with Bleeding Disorders.” *The National Hemophilia Foundation*. 16 November 2008. You can access MASAC #188 [here](#).

<sup>3</sup> Krieger, Leah. “Prescription for Prior Authorizations: A Better Way.” *PolicyMatters Journal: The Journal of the Goldman School of Public Policy University of California Berkeley* (Spring 2011). Web. <http://www.policymattersjournal.org/krieger.html>.

<sup>4</sup> MacKinnon, Neil J, and Ritu Kumar. “Prior Authorization Programs: A Critical Review of the Literature.” *Journal of Managed Care Pharmacy* Volume 7 number 4(July/August 2001): p 297. Web. <http://www.amcp.org/data/jmcp/review-297-302.pdf>



# NATIONAL HEMOPHILIA FOUNDATION

www.hemophilia.org

country to pre-authorize certain prescription drug benefits and medical services.<sup>5</sup> As such, NHF must take a position, in view of how the prior-authorization process presently affects the bleeding disorders community.

## **Issues with the Current State of Prior-Authorization**

The current prior-authorization process threatens timely access to treatment for patients. This access is vital to the health of individuals living with bleeding disorders, as lengthy wait times can quickly lead to a severely deteriorated condition. Hemophilia and related bleeding disorders occur when a person is deficient in or lacks one of several proteins necessary for the blood to clot. Many individuals experience spontaneous internal bleeding, which has resulted in severely damaged joints, various disabilities, and sometimes premature death. Treatment entails the infusion of clotting factor – often done at home through self-infusion – to compensate for missing or defective blood proteins. Clotting factor is derived either from human plasma or manufactured through recombinant technology; there are no generic alternatives to clotting factor. It is imperative that individuals with hemophilia and related bleeding disorders receive the prescribed treatment during the medically recommended timeframe.

Several factors contribute to delayed treatment. Confusion over multiple forms can result in a missed deadline or the correct forms not being submitted at all. This usually occurs when a patient is prescribed more than one prescription drug benefit or referred service that requires prior-authorization. There is then a need to complete a different form for each prescription drug benefit or service. The use of paper forms, as opposed to electronic ones, is another reason for delay. Processing a paper form takes longer than it would to process an electronic form. Lastly, a prolonged response time from PBMs can hinder timely access to medically necessary treatment.

MASAC offers clear recommendations on access to care for members of the bleeding disorders community – recommendations which the current prior-authorization process fails to consider. MASAC Recommendation 153 focuses on patients who are treated with recombinant factor.<sup>6</sup> It states that “there are specific considerations in prescribing a product for any individual patient. Therefore MASAC recommends that insurance companies and other third-party payers...cover whichever recombinant factor product is prescribed by the patient’s treating physician.”<sup>7</sup> MASAC stresses the need for affected individuals to have access to the medically recommended form of treatment, as well as the importance of maintaining the patient-doctor relationship.

Even when there are standardized processes in place, these processes should never outweigh the necessity for individuals with bleeding disorders to have emergency access to their lifesaving medications. Thus, NHF will always advocate in accordance with MASAC 188.<sup>8</sup> We advise that there be

---

<sup>5</sup> Morley, Christopher P. et al. “The Impact of Prior Authorization Requirements on Primary Care Physicians’ Offices: Report of Two Parallel Network Studies.” *Journal of the American Board of Family Medicine* Volume 26 number 1 (January-February 2013). Web. <<http://www.jabfm.org/content/26/1/93.long>>

<sup>6</sup> Ibid. MASAC 153.

<sup>7</sup> Ibid.

<sup>8</sup> Ibid. MASAC 188.



# NATIONAL HEMOPHILIA FOUNDATION

www.hemophilia.org

a plan in place to ensure that, in case of emergency need, patients can have access to their factor in 3-12 hours.<sup>9</sup> In regards to a person with a bleeding disorder, their physician's recommendation is final. There is no need to delay treatment in search of an alternative or cheaper form of care; neither one exists.

## **NHF Supported Courses of Legislative Action**

NHF supports legislation that standardizes the prior-authorization process. We advocate for a single, standardized prior-authorization form that is used by all payers. The form should be available to be submitted electronically, and via facsimile. In addition, NHF recommends that a time limit for a response from the PBM be stipulated. This time limit delineates how long an insurer has to approve or reject a prior-authorization, or to request more information. If there is no response by the end of the given time period, then the request is automatically authorized, and the patient receives the requested prescription drug benefit or service. Specifying a page limit for the standard prior-authorization form also cuts down on confusion. Finally, NHF recommends that the legislation define a standard length of time for which the prior-authorization remains valid after approval.

There is precedent for prior-authorization legislation at the state-level. An example of successful legislation is in Texas. Governor Rick Perry signed SB 1216 and SB 644 into law on June 14, 2013. Together these bills spurred the development of a committee that advises Texas' Insurance Commissioner on the creation of a single, standard prior-authorization form. Furthermore, SB 1216 "require[s] that the department and a health benefit plan issuer or the agent of the health benefit plan issuer that manages or administers health care services benefits make the form available in paper form and electronically..."<sup>10</sup> This addition is a key factor in maximizing convenience, thereby shortening the processing and wait time for prior-authorization. Implementation of the standard form in Texas must begin by January 1, 2015. Similar legislation was passed in California, Minnesota, Michigan, Iowa, and Washington.

## **Conclusion**

Individuals with hemophilia and related bleeding disorders should never be subjected to delays in physician-prescribed treatment, including those delays inevitably caused by prior-authorization requirements. (This is especially true in the case of a medical emergency).<sup>11</sup> Since prior-authorization remains a reality for members of our community, a streamlined process in which one standard form is used by all insurers would be a great help in eliminating issues of long wait times and delayed access to necessary care. In keeping with the access standards recommended by MASAC, NHF supports the standardization of the prior-authorization process. NHF will work with our chapters to encourage states to pass legislation that creates a single standard form that can be submitted electronically. To maximize patient protection, NHF recommends that prior-authorization legislation also include:

---

<sup>9</sup> Ibid

<sup>10</sup> "SB 1216: An Act Relating to the Creation of a Standard Request Form for Prior Authorization of Medical Care or Health Care Services." *Texas State Legislature*. 14 June 2013. Web. <<http://www.capitol.state.tx.us/tlodocs/83R/billtext/pdf/SB01216F.pdf#navpanes=0>>.

<sup>11</sup> Ibid. MASAC 188.



# **NATIONAL HEMOPHILIA FOUNDATION**

[www.hemophilia.org](http://www.hemophilia.org)

1. A page limit for the form;
2. A time limit for an insurer approval, denial, or request for more information;
3. The length of time for which the approval is valid.

NHF is open to legislation that either specifically delineates these requirements in the bill language or that establishes a commission or other dedicated group (i.e. practitioners, insurers and patient advocates) to recommend a specific form, so long as the bill sets parameters for the recommendations that include the above elements.

The implementation of prior-authorization legislation (similar to that enacted in Texas) goes a long way in ensuring timely access to critical medical care and services for members of the bleeding disorders community, and other individuals for whom timely access to treatment may ultimately be a matter of life and death.