SUPPORT POLICIES THAT INCREASE AFFORDABILITY OF COVERAGE AND ACCESS TO CARE

NATIONAL HEMOPHILIA FOUNDATION
for all bleeding disorders

Bleeding Disorders Concerns About Affordability

People with bleeding disorders must have access to comprehensive health insurance that covers their life-saving treatments and expert care provided at hemophilia treatment centers (HTCs).

Annual treatment costs exceed $350,000 per year for a person with severe hemophilia. Therefore, people with bleeding disorders hit their annual out-of-pocket (OOP) maximum each year. For 2021, the OOP limit is **$8,550** for an individual and **$17,100** for a family.

Thus, many community members worry about:

- Having access to and affording comprehensive insurance coverage
- Paying their OOP costs for treatment
- Hitting their OOP limit, often in the first month
- Needing financial assistance to afford their OOP costs

What are Copay Accumulator Adjustor Programs and How do they Impact Patient Access?

- Many people with bleeding disorders and other chronic conditions need co-pay assistance programs to help them afford their high OOP costs.
- An increasing number of private health insurance plans are implementing co-pay accumulator adjustor programs that disallow co-pay assistance from counting towards a patient's OOP maximum.
- When co-pay assistance is not allowed, many patients cannot afford their treatments and stop taking them or reduce the prescribed dosage. This often leads to complications and has unintended consequences (i.e., increased ER visits, joint bleeds/damage, and missed days from work/school) that harm patients and increase overall costs.

Policies to Improve Access to Treatment and Prohibit Accumulator Adjustor Programs

Plans should be required to count all co-pays (regardless of who pays) towards a person's OOP maximum. This can be done via regulation by CMS.

Please support patient access to drugs by co-signing the McEachin-Davis letter to President Biden urging him to prohibit accumulator adjustor programs.

Contact Justin Goldberger with Rep. McEachin to be added to the letter.

Improving Access to Coverage during COVID-19 Public Health Emergency

Millions of Americans have lost their jobs and insurance coverage due to COVID-19 and the resulting economic crisis. We thank Congress for taking steps to address this urgent issue. We support COVID relief provisions that improve the affordability of quality, comprehensive health insurance, including:

- Financial incentives for states to expand Medicaid if they haven't
- Subsidies for people to pay for employer-sponsored coverage (via COBRA) if they lost their jobs
- Full subsidy on marketplace plans for people eligible for unemployment insurance but not COBRA

NHF urges Congress to pass these provisions into law and to enact permanent policies that will increase affordability for people with bleeding disorders and others with chronic conditions.

Co-sign the McEachin-Davis letter to President Biden to ensure that all co-pays count for patients.

Congress of the United States
Washington, DC 20515

March XX, 2021

The Honorable Joseph R. Biden, Jr
President
1600 Pennsylvania Ave, N.W.
Washington, D.C. 20500

Dear President Biden,

We write to thank you for your ongoing commitment to work with us to lower drug prices for Americans and to highlight a needed policy change that would bring us closer to that goal.

Millions of vulnerable Americans across the country rely on cost-sharing assistance to afford the medicines they need. Patients in the private health insurance market have increasingly relied on this assistance due to rising out-of-pocket costs for drugs. Historically, when a patient uses cost-sharing assistance, the amount has counted towards a patient's deductible and maximum out-of-pocket (OOP) limit. Recently, many health plans started designing benefits to exclude cost-sharing assistance from counting towards a patient's maximum OOP limit and deductible.

This problem can be rectified by reversing a policy adopted in the 2021 Notice of Benefit and Payment Parameters (NBPP).[1] The 2021 NBPP permits health insurance issuers and pharmacy benefit managers (PBMs) to adopt a practice referred to as a "copay accumulator adjustment program." These programs permit issuers to exclude cost-sharing assistance towards a patient's OOP maximum, making it difficult for patients to afford their medicines. Moreover, allowing PBMs to adopt these programs impedes patient access to treatment and increases OOP costs for patients in the midst of an unprecedented pandemic and economic crisis. We believe that the 2021 NBPP does not align with the U.S. Department of Health and Human Services' (HHS) own regulation defining cost-sharing – which includes payments made by or *on behalf of* an insured[2] – nor does it align with Congressional intent in defining cost-sharing and establishing the annual limit on cost-sharing.

Many of us wrote to then-Secretary Alex Azar to urge HHS to reverse this decision in the 2022 NBPP,[3] but the final rule released in January 2021 did not include this change[4]. We urge you to

[1] 45 CFR § 156.130 - Cost-sharing requirements.
[2] 45 CFR § 155.20, Definition of Cost-Sharing.
[3] https://edit-mceachin.house.gov/sites/mceachin.house.gov/files/Final%20NBPP%20Co-pay%20Accumulator%20Letter%20%5BSigned%5D%203.9.20.pdf
[4] https://s3.amazonaws.com/public-inspection.federalregister.gov/2020-10045.pdf

roll back the practice of copay accumulator adjustment programs and require health insurance issuers and PBMs to count all cost-sharing payments made by or on behalf of a patient toward that patient's annual deductible and OOP maximum.

With patient out-of-pocket costs increasing, we support regulatory changes that improve affordability. It is our fear that many patients will have to ration their medicines, or abandon their prescriptions altogether, which could lead to more serious health outcomes and higher costs. In addition, this is likely to have a disproportionate impact on individuals from vulnerable populations, people of color, and those with lower incomes and poorer health.

During a global pandemic, we should be doing everything we can to increase affordability of prescription drugs, not decrease it, and reversing the 2021 NBPP copay accumulator policy will help people save more money at the pharmacy counter. We urge you to consider reversing this policy to enable Americans to afford the lifesaving medication they rely on.

Thank you and we look forward to your response.

Sincerely,

A. Donald McEachin
Member of Congress

Rodney Davis
Member of Congress

SUPPORT FEDERAL FEDERAL BLEEDING DISORDERS PROGRAMS—FURTHER RESEARCH, ENHANCE PREVENTION AND ACCESS TO CARE

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National Institutes of Health (NIH)/National Heart Lung and Blood Institute (NHLBI)

Recognizing the devastating consequences of a person with hemophilia developing an inhibitor (when a patient's treatments stop working increasing the risk of bleeding, joint disease, and hospitalization), NHLBI held a State of the Science Workshop on Factor VIII Inhibitors in May 2018. The product of the workshop is a national blueprint for future basic, translational, and clinical research on the prevention and eradication of these inhibitors. NHF strongly supports furthering this area of critical research.

Request:

- Support funding for NHLBI to initiate high-priority research, as outlined in The National Blueprint for Factor VIII Inhibitor Research.
- Support overall NIH funding

Health Resources and Services Administration (HRSA)

HRSA's Maternal and Child Health Bureau provides funding to HTCs to provide multi-disciplinary services not typically reimbursed by insurance, such as physical therapy assessments, social work and case management services. As HRSA grantees, HTCs are also eligible to participate in the 340B Drug Discount Program, which allows for drugs to be purchased at a discount, and savings to be used to fund integrated care provided to all patients at the center.

Request:

- Maintain current funding levels for HRSA's hemophilia program at $4.9 million and ensure that HTC participation in the 340B program is maintained.

Centers for Disease Control and Prevention (CDC)

The CDC Division of Blood Disorders provides funding for HTC surveillance and prevention activities, and supports outreach and education programs provided by national bleeding disorders patient organizations. Recently, the CDC's work has focused on inhibitors, today's most challenging and harmful complication of hemophilia. Funding for the CDC hemophilia programs should be maintained to improve treatment and prevention strategies, especially those related to inhibitors, and to monitor blood and blood product safety for our community.

Request:

- Maintain current funding levels for hemophilia-related programs and budget lines in the CDC's Division of Blood Disorders - $5 million for hemophilia treatment centers and $3.5 million for hemophilia activities.

Maintain support for federal bleeding disorders programs at NIH, CDC, and HRSA

FAST FACTS ABOUT BLEEDING DISORDERS & HEMOPHILIA TREATMENT CENTERS

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About Hemophilia

- Hemophilia is a rare, genetic bleeding disorder that prevents the blood from clotting properly. The main symptom is uncontrolled and often spontaneous bleeding into the joints that can result in pain, swelling, and even permanent damage.
- About 20,000 people in the U. S. are affected by hemophilia, while the worldwide incidence is estimated to be roughly 400,000. Hemophilia occurs in roughly 1 in 5,000 live male births, of these 80% are hemophilia A (Factor XIII deficiency) and 20% are hemophilia B (Factor IX deficiency.)
- Currently, there is no cure for hemophilia. Individuals require lifelong treatment, including infusions of replacement clotting factor therapies, manufactured from human plasma or using recombinant technology.
- Treatment costs are typically $350,000 a year or more for a person with severe hemophilia. However, the development of an inhibitor (immune response to regular treatment), bleeding from trauma or surgery, and other complications can raise the annual cost to $1 million or more.
- In the 1980s, nearly 80% of Americans with severe hemophilia became infected with HIV, when the nation's blood supply was contaminated. More than 50% of people with hemophilia infected with HIV have died. Since 1986, there have been no reported cases of HIV transmission through factor concentrates in the U.S. The CDC estimates that up to 90% of people with hemophilia who used clotting factor prior to 1987 were exposed to Hepatitis C (HCV) through contaminated products. Current donor screening measures and improved viral inactivation methods have been integrated into the manufacturing process and dramatically improving the safety of plasma-derived products.

About Rare Bleeding Disorders

- There are a number of rare factor deficiencies, such as factor I, II, V, VII, X, XI, XII and XIII deficiencies. These very rare factor deficiencies were all discovered and identified in the 20th century.
- These conditions have similar symptoms as hemophilia and VWD and vary in treatments.

About Von Willebrand disease

- Von Willebrand disease (VWD), another inherited bleeding disorder that prevents the blood from clotting properly, is due to a deficient or defective blood protein known as von Willebrand factor.
- VWD occurs equally in men and women, and is estimated to affect more than three million Americans. Of the three main types, type I (the mildest form) accounts for approximately 70% of cases.
- Symptoms include frequent nosebleeds, a tendency to bruise easily, and excessive bleeding following surgery.
- In women, the disease can also cause heavy, prolonged bleeding during menstruation and excessive bleeding following childbirth. In addition, it is often undiagnosed or incorrectly attributed to a gynecologic condition; many have an extremely hard time being properly diagnosed.

About Hemophilia Treatment Centers (HTCs)

- In 1974, Congress authorized and funded the national network of HTCs within the Maternal and Child Health Block Grant's (MCH) Special Projects of Regional and National Significance (SPRANS). Today, the HTC network is comprised of a regionalized system of care with approximately 140 HTCs across the country that care for more than 70,000 patients throughout the lifespan.
- HTCs provide high-quality, multidisciplinary care furnished by a team of hematologists, pediatricians, nurses, social workers, physical therapists, orthopedists and dentists, all with specialize training in treating people with bleeding disorders.
- CDC studies show HTC patients have 40% lower mortality and morbidity rates compared with non-HTC patients, despite the fact that more severely-affected patients are more likely to use HTCs.
- A 2017 national patient satisfaction survey conducted by the HTC network found that 96% of patients reported being "always" or "usually" satisfied with their HTC, demonstrating the importance of this care model to our patient community.