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The Impact of Treatment Misclassification and Narrow Formularies on the Bleeding Disorder Community

What policies govern health plan formularies?

- The Affordable Care Act (ACA) created the **essential health benefits** (EHB) to define what services must be covered by health plans.
- EHB rules state that individual and small group health plans must cover at least: one prescription drug in every therapeutic category and class; or the same number of drugs in each category and class as the state's EHB-benchmark plan.
- The regulations also say that **plans must cover recommended drug treatment regimens that "treat all disease states."**



How does this harm people with bleeding disorders?

- Narrow formularies are when health plans significantly limit the medications they cover.
- For people living with bleeding disorders, narrow formularies may offer as few as **one treatment option across all bleeding disorders**.
- Since there are many differences among the products used to manage bleeding disorders (mechanism of action, half-life, administration route, and more) this means that some people can't access the medication that their physician believes is best for them or even one that can treat their condition.
- Since USP has all bleeding disorders treatments in a single category and class, insurers and health plans appear to comply with EHB rules even if they do not offer a treatment for each bleeding disorder.
- **HHS is not enforcing their regulation that requires plans to cover recommended drug treatment regimens that "treat all disease states."**



What players are involved?

- The **United States Pharmacopeia (USP)**, a non-governmental organization, defines drug categories and classes.
- Today, USP combines treatments for hemophilia A, hemophilia B, hemophilia with inhibitors, von Willebrand Disease and deficiencies of Factor VII, X, and XIII into a single category (Blood Products and Modifiers) and single class (Blood Component Deficiency/Replacement).
- The **Department of Health and Human Services (HHS)** is responsible for enforcing EHB rules and regulations.

The National Bleeding Disorders Foundation is calling on Members of Congress to sign a letter to HHS requesting enhanced enforcement of current essential health benefits (EHB) policies that would prevent narrow formularies that don't cover treatments for all bleeding disorders.

The National Bleeding Disorders Foundation (NBDF, formerly the National Hemophilia Foundation) is dedicated to finding cures for inheritable blood and bleeding disorders and to addressing and preventing the complications of these disorders through research, education, and advocacy, enabling people and families to thrive.