ISSUE BRIEF:

NON-MEDICAL SWITCHING AND STEP THERAPY

Some third-party payers – private insurers, self-insured entities, and government health programs, including Medicaid – are adopting restrictive drug utilization management policies in the pursuit of cost savings. In some cases, payers have forced patients to switch from their current medication to a different product for reasons wholly unrelated to the patients' health, a practice known as "non-medical switching."

For many other disease states, payers have implemented "step therapy" protocols, requiring patients to first try (and fail on) a payer-preferred drug before the patient is allowed to obtain a non-preferred medication. While we have yet to see bleeding disorders therapies managed in this way, the increased use of formularies and preferred drug lists sets the stage for payers to implement these policies. With both non-medical switching and step therapy, third-party payers are putting cost control efforts ahead of the clinical judgment of the patients' physicians, and are denying patients access to necessary, doctor-selected treatments.

HFA strongly maintains that non-medical switching and step therapy are inappropriate tools in the context of hemophilia care.[1]

GENERAL BACKGROUND

The use of step therapy and non-medical switching has increased significantly in recent years, extending now to products used to treat a range of chronic, complex, and rare conditions. Payer practices can include:

- Eliminating coverage for certain drugs altogether;
- Not covering new FDA-approved products, or automatically excluding new products at launch;
- Establishing onerous fail-first step therapy and prior authorization prerequisites before patients can get approval to use the drugs their doctor has prescribed; and/or
- Raising co-pays for and/or placing non-preferred drugs in higher cost-sharing tiers.

Payers argue that these practices allow them to make the best use of limited healthcare dollars, but patient advocates counter that step therapy and non-medical switching policies obstruct access to care. These policies can harm patient health and weaken the doctor-patient relationship – often without actually yielding real cost savings.

A recent study concluded that non-medical switching is "more often associated with **negative or neutral** effects on clinical and economic outcomes, health resource utilization, and medication-taking behaviors than positive effects."[2] Step therapy and non-medical switching practices also discriminate against patients who have expensive chronic conditions (for example, discouraging them from signing up or remaining with a particular insurer). And these practices may have a disproportionate impact on consumers who "churn" between different health plans – e.g., move between Medicaid and private insurance – requiring those patients to switch medication with each change in coverage.[3]

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[1] While we refer to hemophilia and hemophilia care throughout this issue brief, please note that our discussion and arguments apply equally with respect to the treatment of severe von Willebrand disease.

[2] Elaine Nguyen, Erin R. Weeda, Diana M. Sobieraj, Brahim K. Bookhard, Catherine Tak Piech, Craig I. Coleman, *Impact of Non-Medical Switching on Clinical and Economic Outcomes, Resource Utilization and Medication-Taking Behavior: A Systematic Literature Review,* Current Medical Research and Opinion (2016) (emphasis added), http://dx.doi.org/10.1185/03007995.2016.1170673.

[3] See Report of Consumer Representatives to the National Association of Insurance Commissioners, *Promoting Access to Affordable Prescription Drugs: Policy Analysis and Consumer Recommendations for State Policy Makers, Consumer Advocates, and Health Care Stakeholders* 24 (August 2016), http://consumersunion.org/wp-content/uploads/2016/08/Promoting-Access-to-Affordable-Prescription-Drugs_Aug-2016.pdf.

IMPACT ON HEMOPHILIA CARE

While hemophilia treatment is undeniably expensive, subjecting hemophilia patients to step therapy or non-medical switching is neither therapeutically appropriate nor an effective way for payers to manage this class of patients. Clotting factor used by hemophilia patients to prevent and stop bleeding is a specialty drug with no generic counterpart. Clotting factors vary in a number of important respects, including half-life and immunogenicity, and as such are not interchangeable or therapeutically equivalent. Patient bleeding patterns and responses to different clotting factors vary widely.

Recognizing this diversity of clotting factor products, the Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF) emphasizes that product selection for bleeding disorder patients "require[s] a complex decision making process" between a patient and his or her physician and that "it is critical that the bleeding disorder community has access to a diverse range of therapies and that prescriptions for specific clotting factor concentrates are respected and reimbursed."[4] Because the selection of the medically-optimal clotting factor product for each patient is so individualized and medically important, MASAC urges third-party payers to cover whichever factor product is prescribed by the patient's treating physician rather than resorting to a formulary approach.[5]

Non-medical switching contravenes the MASAC standards. It allows a payer to dictate the use of a potentially less effective and/or therapeutically inappropriate clotting factor product regardless of the patient's medical needs and the clinical judgment of his or her doctor, and threatens continuity of care for patients who are stable on their existing therapies. In a recent study (across a variety of disease states), researchers found there were **no positive outcomes** associated with non-medical switching of patients who were stable on their existing medications. Instead, the study found negative impacts on clinical outcomes, healthcare utilization, and medication-taking behavior.[6] In the hemophilia context, this could mean less effective control of bleeding, irreversible deterioration of bleeding-damaged joints, a need for additional factor or medical services to resolve increased bleeding, and/or greater challenges for patient adherence to doctor-prescribed therapy.

Step therapy policies are similarly unacceptable in the context of hemophilia treatment and raise a number of questions:

- How is treatment "failure" defined for purposes of hemophilia care – and whose definition prevails?
- Does failure mean "X" number of breakthrough bleeding episodes, or a single serious bleed that resists treatment with the approved product?
- If forcing a specific treatment regimen results in a patient's inability to comply because of challenges in using the formulary-listed product, does that constitute a "failure"?

[4] National Hemophilia Foundation, Medical and Scientific Advisory Council. *MASAC Recommendation Regarding Factor Concentrate Prescriptions and Formulary Development and Restrictions,* Document #159.
Accessed July 12, 2016. MASAC Document #159.

[5] National Hemophilia Foundation, Medical and Scientific Advisory Council. *MASAC Recommendation Regarding Factor Concentrate Prescriptions and Formulary Development and Restrictions,* Document #153.
Accessed July 12, 2016. MASAC Document #153.

[6] Nguyen et al., op cit. The researchers cautioned, too, that the time periods in which outcomes were evaluated in the underlying studies were probably shorter than optimal for assessing outcomes in chronic disease states: "For instance, negative outcomes in medication-taking behavior in the short-term may have long-term consequences on disease progression or the ability to control symptoms."

Any of the foregoing could cause irreparable harm or even death to bleeding disorder patients. Such treatment failures would moreover raise payer costs (via additional doctors' visits, hospitalization, and/or extra required factor usage) while exacting an intolerable human toll.

CONCLUSION

Non-medical switching and step therapy allow cost control efforts to trump clinical judgment and interfere with the doctor-patient relationship. Non-medical switching has been shown to undermine patient adherence to therapy and worsen patient outcomes, potentially raising payer costs (via additional doctors' visits, hospitalization, extra required drug usage, and/or permanent injury). For these reasons, non-medical switching is inappropriate and potentially dangerous in the context of hemophilia care. Bleeding disorder patients who are **stable on an existing drug therapy** should be allowed to continue on that drug (whether they are continuing on an existing health plan or transitioning to new coverage). At the bare minimum, a third-party payer should not be able to force a hemophilia patient to switch products for non-medical reasons during a plan year, nor should it be allowed to increase patient out-of-pocket costs (or move that drug to a higher cost-sharing tier) within that period.

Hemophilia patients, too, should not be subjected to **step therapy requirements** (whether continuing on an existing health plan, or beginning on or transitioning to new coverage; whether continuing on an existing clotting factor product, or beginning use of a new product). Fail-first policies with respect to hemophilia treatment are unacceptable because the consequences of a treatment "failure" are so serious. The risks of a major bleed (or of cumulative damage from repeated bleeding episodes) are too high to expose hemophilia patients to potentially ineffective treatments, or to delay their access to the therapies prescribed by their treating physicians, all in the pursuit of cost savings.

