May 25, 2022

The Honorable Lina Khan
Chair, Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580


Dear Chair Khan,

I am writing on behalf of the American Society of Hematology (ASH) in response to the Federal Trade Commission’s (FTC) solicitation for public comments on the business practices of pharmacy benefit managers (PBMs). Specifically, ASH would like to comment on the PBM practice of non-medical switching, when a PBM forces a patient to change medications for non-clinical reasons. These changes can cause significant clinical and safety concerns. ASH opposes non-medical switching because of its negative impact on patients and providers.

ASH represents more than 18,000 clinicians and scientists worldwide who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as non-malignant conditions such as sickle cell anemia, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the field of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy.

The PBM practice of removing a drug from a formulary, often in the middle of the patient’s plan year, for non-clinical reasons is becoming more common and is having detrimental effects on patient health and compliance with their recommended treatment plan. When this occurs, individuals may be forced to switch from a drug on which they were stable, to a less effective drug. Many times, this is done without the knowledge of, or notice to, the prescribing physician. While PBMs sometimes allow for exemptions – meaning an individual can remain on the drug being removed from the formulary – it requires the prescribing physician to submit a prior authorization request. These requests are time-consuming, lack transparency, and add to the already significant administrative burden on physicians and other medical staff.

Recently, ASH was notified of a major U.S. PBM that engaged in non-medical switching and removed all but one direct-oral anticoagulant (DOAC) – drugs critical for the treatment of venous thromboembolism (VTE) – from a commercial health plan formulary. The result was such that patients across the country received letters informing them that they would no longer be able to receive the medication they had been using for years due to loss of coverage and beginning in the new year, they would be forced to switch to a different drug. In this situation, there were significant clinical and safety concerns related to patients being forced to switch to a different DOAC than the one...
they were purposefully prescribed by their physician. For example, the DOAC removed from the formulary has a lower bleed risk and studies show that it is safer in patients with advanced age, baseline active cancer, chronic kidney disease, and venous thromboembolism.\(^1\) Patients were put at risk when they lost access to the medication that was most clinically appropriate. In addition to the impact on patients, physicians were faced with a significant increase in paperwork to attempt to keep their patients on the drug that was most clinically appropriate.

ASH believes treatment decisions should be made between a physician and the patient and opposes PBM policies, such as non-medical switching, that can impede this process. The PBM practice of non-medical switching should be prohibited. At the very least, there should be new regulations around transparency to help provide clarity as to the rationale behind the change and the process for seeking an exemption for patients that must stay on their prior medication. For example, in the scenario described above, the PBM did not make public the clinical criteria that would qualify a patient for an exemption. This resulted in multiple prior authorization requests being written and denied. Additionally, patients receiving letters informing them they must switch medications are not typically told that there is an exemption process, leading to fear, confusion, and uncertainty. PBMs that engage in non-medical switching should be required to make public the clinical criteria used when approving formulary exemptions and to inform patients about their exceptions process.

ASH appreciates the opportunity to submit these comments and thanks the Federal Trade Commission for issuing the Request for Information. If you have any questions or if the Society can ever serve as a resource to you, please reach out to Suzy Leous, ASH Chief Policy Officer, at sleous@hematology.org.

Sincerely,

Jane Winter, MD
President

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