Beth Waldron

A statement for the record submitted to the House Committee on Oversight and Accountability

May 27, 2024

Dear Mr. Chair and Members of the Committee:

My name is Beth Waldron and I am a patient from Chapel Hill, North Carolina. I am sharing my experience of how the nation's largest pharmacy benefits manager (PBM)—who controls drug access for 1 in 3 Americans—non-medically forced heart patients off their stable medication despite 17 nonprofits warning them it was dangerous and risked patient safety.

I have a blood clotting disorder and have experienced life-threatening blood clots. To prevent future clots, I take an anticoagulant medication, commonly called a blood thinner. Anticoagulants are the #1 class of drug for adverse events, causing more emergency room visits annually than any other drug and nearly half are serious enough to require hospitalization. Their selection and management require great care because anticoagulants increase the risk of bleeding and are used in patients with an increased risk of clotting—both bleeding and clotting can be potentially fatal. At every appointment, my hematologist and I discuss my clot and bleed risks, changes in health and we make an informed decision together which drug I should take.

In November 2021, I received a letter from CVS Caremark informing me the anticoagulant I'd been taking for 8 years, Eliquis, was no longer going to be covered. (1) It said to ask my physician for a prescription for a different covered medication, either warfarin or Xarelto.

And that was it. The letter did not include a phone number to call if I had questions. Nor did it mention an appeals process.

I inquired and learned my doctor could ask for a prior authorization for Eliquis. But the written approval criteria required first taking and failing Xarelto. Failure on warfarin was not required. What does anticoagulant failure look like? Bleeding or clotting—both of which are potentially life-threatening.

I wasn't the only patient to receive such a letter. Eliquis was dropped from CVS Caremark's 3 national base formularies which covered approximately 30 million subscribers, impacting around 150,000 heart patients stable on Eliquis who were at-risk for either stroke due to atrial fibrillation (afib) or clots such as deep vein thrombosis (DVT).

Eliquis's sudden removal was viewed as so dangerously disruptive by the cardiovascular community that 17 nonprofits came out against it, writing letters to CVS Health's Chief Medical Officer citing published safety data showing the medication stable patients were being forced off, Eliquis, was clinically safer and more effective than the medication they were being moved to, Xarelto. (2,3)

Representatives from the American College of Cardiology (ACC) and the American Society of Hematology, (ASH)—who publish anticoagulation clinical care guidelines—met with CVS Health medical leadership on three separate occasions, the first on December 9, 2021 to express concerns and to ensure CVS was aware of the clinical data regarding those increased anticoagulation risks. ASH and ACC clinicians met again with CVS Health leadership on December 23, 2021. The company stood by their decision and proceeded with the Eliquis formulary exclusion, effective January 1, 2022.

The feared adverse bleeds and thrombotic events began to emerge soon after patients were non-medically switched. It is recorded in the February 9, 2022 Pharmacy and Therapeutics committee meeting minutes for my health plan—the State Health Plan of North Carolina—discussion of two thrombotic events occurring in patients at Duke Health. (4) The committee voted immediately in that meeting, in which CVS Caremark representatives were present, to reinstate the drug to the plan's formulary. However, nationally CVS Caremark still continued to keep the drug off formulary, despite meeting yet again with ACC and ASH clinicians on March 8, 2022 and being fully aware of the proliferation of adverse events.

During this same time, I and other impacted patients and clinicians were vocal on Twitter about what was happening and gave several media interviews. In April 2022, I received two unexpected calls from a man who said he was working on behalf of the office of CVS Health president and CEO Karen Lynch. (5) He wanted to know why I was so vocal on Twitter and referred to a drug prior authorization which the company had approved for me and other details which could only have been known by accessing my medical records. I filed a HIPPA complaint with HHS Office of Civil Rights, which they subsequently declined to investigate.

This experience worries me because as my PBM, CVS Caremark has complete control over not just my ability to access future prescription medications but also for my entire family. I feel trapped because there is no way for me to stop doing business with a PBM—my family is covered under an employer retiree plan which contracts out the pharmacy benefit management to CVS Caremark and thus, we have no say in who the PBM is for our insurance plan.

CVS Caremark quietly reinstated Eliquis effective July 1, 2022 to 2 out of 3 of its national formularies. However, this change was not communicated to patients. I learned it was returned to formulary solely by word of mouth. Several patients told me they only learned they had covered access again from my social media posts.

What is very clear from my experience is the drugs on a PBM's formulary might not be the ones clinically in the best interest of patients, but rather reflect non-transparent financial incentives. Greater consumer protections are needed to ensure patient safety.

Thank you for your time. Your consideration of these matters is greatly appreciated.

Sincerely,

Beth Waldron

References

1. Letter from CVS Caremark to Beth Waldron
2. Letter from the American Society of Hematology to CVS Health CMO Troyen Brennan
3. Letter from the Partnership to Advance Cardiovascular Health co-signed by 14 nonprofits to CVS Health CMO Troyen Brennan
4. State Health Plan of NC Pharmacy and Therapeutics Meeting Minutes
5. How a Formulary Change and a Few Tweets Led to a HIPAA Complaint, Managed Healthcare Executive, April 20, 2022