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30 Oct 2023 | **Analysis**

Could Government Negotiated Prices Curtail Access? PBMs And Potential Perverse Incentives Dominate First Medicare Listening Session

by Sarah Karlin-Smith

Patients and advocacy groups tell Medicare they want lower cost drugs but are concerned that if government negotiations lower list prices, rebate-focused PBMs may preference higher list-price competitors.

Patients and patient advocates raised a potentially concerning paradox at the first Medicare public listening session on the drugs that will be subject to US government price negotiations under the new Inflation Reduction Act – that the government's ability to get lower list prices for selected drugs might lead pharmacy benefits managers to make the medications more inaccessible to patients.

The Centers for Medicare and Medicaid kicked off the first of 10 days of listening sessions 30 October with public testimony regarding the selection of *Bristol Myers Squibb Company*/*Pfizer Inc.*'s anticoagulant Eliquis (apixaban). (*See boxes for two of our preview stories about the process.*)

One of the most repeated requests – made by at least nine speakers – was for Medicare to protect patients from perverse incentives that pharmacy benefits managers may have to negatively impact formulary status of the drug because a lower list price might mean less ability for the PBMs to pocket big rebates from the drug.

As Medicare Drug Negotiation Patient Sessions Kick Off, Advocates Already Eyeing Improvements

By

Sarah Karlin-Smith

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Negotiated drugs must be covered on plan formularies under the law, but the law doesn't specify the terms of coverage, meaning PBMs could change the preferred status, tiering or utilization management restrictions of the medication. (Also see "*Rebates In Part D: HHS Argues Scrutiny Of Impact On Formularies, Beneficiaries Not Needed Now*" - Pink Sheet, 6 Sep, 2023.)

PBMs could also try to negotiate for additional rebates to reduce the government negotiate price even further in return for better formulary placement but they'd be working from a lower list price which historically has made it harder, not easier, for companies to get better placement from PBMs (Also see "*Humira Horsepower: AbbVie's Brand Retains 98% US Market Share*" - Scrip, 11 Oct, 2023.)

Melanie True Hills, the founder and CEO of StopAfib.org, and an afib patient testified that patients "need lower cost" drugs but they are "waiting for the other shoe to drop."

26 Oct 2023
Patient advocates see IRA patient listening sessions as an opening to push CMS to have more conversations on access issues in general, but first they want to work on improving the current process.

Read the full article here

CMS Seeking Patient Comments On Negotiated Drugs Similar To US FDA's PFDD Program

By

Derrick Gingery 29 Aug 2023
Statements on patient experience with the diseases treated by the drugs subject to price negotiation and how they impact their lives are requested; 10 meetings are planned for the fall.

Read the full article here

"We already subsidize the payers and pharmacy benefits managers, the PBMs. The US Government Accountability Office just reported that Medicare Part D plans paid less for highly rebated drugs than the beneficiaries did. They recommended CMS monitor the effect of rebates, especially with the coming Inflation Reduction Act.... If the IRA erodes margins PBMs may move our meds to higher tiers or even exclude them and we won't be able to afford our meds yet again. As you're negotiating, please protect us from these costly, life-threatening tactics that will cause more stress, especially in the underserved," True Hills said.

Sue Peschin, president and CEO of the Alliance For Aging Research, raised concerns that CMS "only pledges to monitor utilization management by Part D plans and not develop guardrails to protect patient access." She said there can be negative health consequences from switching stable patients from one anticoagulant to another.

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Vague Conflict Of Interest Disclosures

The Alliance for Aging Research receives funding from many pharmaceutical companies. But the Medicare public comment sessions only asked – not mandated – conflicts of interest be disclosed.

When people like Peschin did voluntarily disclose a conflict, all Medicare's moderator told the public was that they had indicated a conflict. There was no public communication as to what those conflicts were.

Another unique feature of the meetings was that Medicare introduced patients by their first name only and if the person did not introduce themselves by their full name, there was only minimal identification of who was speaking.

These listening sessions are a rare foray for CMS into this type of public interaction and the kinks may be worked out over time.

CMS has set aside 90-minutes of public interaction for each of the 10 drugs on its list providing up to 20 speakers with three minutes of speaking time each.

Those 20 slots were not all filled for Eliquis, and the meeting ended a half hour early. Despite the extra time, Medicare still cut off each public speaker at the three-minute mark. For US Food and Drug Administration and Centers for Disease Control and Prevention meetings it is common for the time blocks for public testimony to vary in length depending on how many speakers sign up to testify.

Unpalatable, Less Effective Alternatives

Eliquis patients who spoke at the meeting often focused their remarks on the benefits they receive from the drug versus other anticoagulants, particularly warfarin.

One patient, Charles, said he had bruising and an inability to maintain a therapeutic INR level with warfarin. He also said he had to take an hour drive plus a ferry ride to get the weekly blood testing he needed while on warfarin.

"I'm going to be on an anticoagulant the rest of my life and Eliquis has no side effects," he said.

Other patients raised issues with frequent dose adjustments, dietary restrictions and severe bleeding on warfarin.

High Price Leads To Inequities

Hussain Lalani, a primary care physician and health policy researcher at Harvard Medical School

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raised concerns about the health inequities that may be occurring due to the higher costs of direct oral anticoagulants like Eliquis compared to the cheaper generic warfarin.

“Research shows that black patients with atrial fibrillation and Medicare are 25% less likely than white patients to receive a direct oral anticoagulant, compared to warfarin. Multiple studies have also shown health inequities, and this leads to higher rates of stroke and death for black patients. While there are many reasons why this may be happening, cost is very likely one of the factors,” Milani said.

One patient, David Mitchell, president and founder of Patients for Affordable Drugs brought up *Bayer AG*/*Johnson & Johnson*’s Xarelto (rivaroxaban), because when he was prescribed Eliquis his Part D plan required him to “fail first” on Xarelto.

Xarelto would have cost him $85.75 out of pocket for a 90-day supply, while Eliquis would have cost $798 out of pocket for a 90-day supply.

“There are a couple of big problems with this arrangement. One is that Eliquis is a superior drug with better results in clinical trials on prevention of clots, prevention of strokes and prevention of death. It also has a lower incidence of bleeding. So fail first for this drug would have meant for me that I have had a blood clot, had a stroke or was dead. So fail first makes no sense for this class of drugs,” Mitchell said.

“Second, Xarelto and Eliquis have roughly the same list price, their makers have in fact been raising prices in lockstep since they were introduced in 2011. There’s no real reason to deny me Eliquis, except that the plan is making more money Xarelto. In other words, plan profit is being put ahead of my health,” Mitchell said.

ICER Gets Hit

The Alliance for Aging Research’s Peschin and Candance DeMattesi, VP of policy & advocacy at the Partnership to Fight Chronic Disease, which also has connections to the drug industry, used parts of their public testimony to try and deter CMS from relying too heavily on analyses from the Institute for Clinical and Economic Review (ICER).

ICER conducted an evidence assessment of Eliquis and Xarelto, which was also selected for negotiation and submitted it to Medicare as public comment. (Also see "*ICER Hands CMS A Drug Price Negotiation Cheat Sheet On Eliquis, Xarelto*" - Pink Sheet, 2 Oct, 2023.)

DeMattesi took issue with ICER’s use of quality adjusted life year calculations and argued that ICER discounts benefits important to patients such as reduced side effects and ease of use. She also said ICER relied on older clinical trials, not more up-to-date real-world evidence, to inform its work on the two blood thinners subject to negotiations.

“Make no mistake – [for] anything that includes a life, your calculation will show less value for people with fewer life years remaining. That’s the entire Medicare population,” DeMattesi said.