Transcript: Eliquis, October 30, 2023 Medicare Drug Price Negotiation Program Patient-Focused Listening Session

MEDICARE DRUG PRICE NEGOTIATION PROGRAM
CENTERS FOR MEDICARE & MEDICAID SERVICES

Introductory Remarks

Meena Seshamani, MD, PhD, CMS Deputy Administrator and Director of the Center for Medicare

Greetings everyone. I'm Dr. Meena Seshamani, the Director of the Center for Medicare at the Centers for Medicare & Medicaid Services, or CMS. CMS administers Medicare, our country's federal insurance program for more than 65 million older Americans and people with disabilities. I deeply appreciate each one of you for taking the time to join us today. For the first time, Medicare is able to directly negotiate the prices of prescription drugs thanks to President Biden's lower cost prescription drug law, the Inflation Reduction Act. The benefits to consumers and patients from Medicare's new ability to directly negotiate drug prices are enormous. And alongside other provisions in the law that make healthcare and prescription drugs more affordable, negotiation strengthens Medicare's ability to serve people with Medicare now and for generations to come.

In August 2023, CMS announced the first ten drugs covered under Medicare Part D selected for negotiation, a significant and historic moment. Medicare's ability to negotiate directly with drug companies will improve access to some of the costliest drugs while driving market competition and fostering innovation. Our priority in negotiating with participating drug companies is to come to an agreement on a fair price for Medicare. Promoting transparency and engagement continues to be at the core of how we are implementing the new drug law and the Medicare Drug Price Negotiation Program. And that is why we set out a process for the first round of negotiation that engages you, the public. This patient-focused listening session is part of our effort to hear directly from patients and others and receive input relevant to the drugs selected for the first round of negotiations. But let me also remind you the law is about more than negotiation. Other provisions, including the $35 insulin copay cap and $0 out-of-pocket for certain recommended vaccines, are life changing and they are already impacting millions of people with Medicare across this country. Starting in 2024, the law expands the Extra Help program, which makes premiums and copays more affordable for people with limited resources with Medicare prescription drug coverage. And in 2025, the new $2,000 maximum out-of-pocket cap will provide additional help to those enrolled in a Medicare Part D plan.

Thank you again for joining us. Your input matters and we are here to listen. Next, stay tuned to hear from a senior CMS official to give you more details on what to expect during this patient-focused listening session.

00:03:32

Disclaimer

This patient-focused listening session is being live streamed. The session is listen-only and CMS will not respond to feedback during the session. Participation is voluntary and speakers acknowledged and agreed by participating in the listening session that any information provided, including individually identifiable

health information and personally identifiable information, will be made public during the listening session through a live stream broadcast. Clinicians should be mindful of their obligations under HIPAA and other privacy laws. CMS intends to make a redacted version of the transcript for the listening session available at a later date.

00:04:14

Welcome

Kristi Martin, Senior Advisor, Center for Medicare

Thank you so much, Dr. Seshamani, and welcome to those joining us to share their input as well as people who are watching the live stream. I'm Kristi Martin, a senior advisor with the Centers for Medicare & Medicaid Services. This is a virtual public listening session for the drug Eliquis, which was selected for the first cycle of negotiations with Medicare. We'll give more detail on this session and get going shortly.

First, I'd like to quickly provide context. We at CMS fall under the greater umbrella of the U.S. Department of Health and Human Services. CMS is tasked with implementing the new prescription drug law that helps save money for people with Medicare, improves access to affordable treatments, and strengthens the Medicare program. The law gives Medicare the ability to directly negotiate the prices of prescription drugs for the first time, as Dr. Seshamani mentioned.

In August, we announced the list of ten drugs covered under Medicare Part D selected for the first-round negotiations. This public listening session is one of a number of steps CMS is taking as part of the process for the first cycle of negotiation. The drug companies that manufacture all ten drugs selected for the first round of the Medicare Drug Price Negotiation Program signed agreements to participate in the negotiation program by October 1st. CMS will negotiate with these participating drug companies during 2023 and 2024 in an effort to reach agreement on maximum fair prices for the selected drugs that will become effective beginning in 2026.

This virtual, patient-focused listening session is an opportunity for the public to weigh in on this first round of the negotiation process. There are ten patient-focused listening sessions, one for each drug selected for Medicare negotiation. The goal of the listening sessions is to provide an opportunity for patients, beneficiaries, caregivers, consumer and patient organizations, and other interested parties to share input relevant to the drugs selected for the first cycle of negotiations and their therapeutic alternatives.

Another recent example of an opportunity for the public to share input on the selected drugs and their therapeutic alternatives was our data submission process, which invited manufacturers in the public with drugs selected for the first round of negotiation and other interested parties to submit data to inform the negotiation process.

In today's session, we are taking input from the community of people who utilize Eliquis in their own lives or the lives of those they serve and care for. Speakers who are joining us via Zoom registered for a chance to speak and underwent a random selection process. They've been asked to bring forward information related to the clinical benefit of the selected drug as compared to its therapeutic alternatives, how the selected drug addresses unmet need, and how the selected drug impacts specific populations.

Next, a few programming notes and reminders. For me and all of us at CMS, the purpose of today's session is

simple: it is to listen. I want to remind callers to stay on the topic at hand during the patient-focused listening session. On timing, every participant has a three-minute window. Other than to help keep time and stay on topic at hand and to help transition from speaker to speaker, you will not hear from me.

Now, on to the participants. Please welcome our first speaker, **[INFORMATION HAS BEEN REDACTED]**, who registered as a representative of a patient advocacy organization. **[INFORMATION HAS BEEN REDACTED]** reported a conflict of interest. Let's welcome **[INFORMATION HAS BEEN REDACTED]**.

Speaker Remarks

Speaker 1

Thank you. I'm **[INFORMATION HAS BEEN REDACTED]** an Afib patient and **[INFORMATION HAS BEEN REDACTED]** StopAfib.org, a nonprofit organization for those living with Afib. For me, warfarin meant bruises and bleeds, no gardening or kitchen knives, and an hour's drive up to twice a week for testing, but never being stable. The direct acting oral anticoagulants, the DOACs, ended that nightmare. We asked Afib patients in our community about their experiences, and over a thousand responded. For them compared to warfarin, Eliquis, and other DOACs, they had fewer side effects, less bruising and bleeding, few food and drug interactions, and it eliminated the stress of testing and created peace of mind. But cost is a massive issue. Medicare disallows coupons and vouchers, and patients on fixed incomes can't afford the huge copays. They're in the donut hole by the summer and split pills, take them every other day, or stop altogether, putting them at risk of stroke, which Medicare foots the bill for. Afib strokes cost Medicare about $47,000 the first year and about $140,000 over a lifetime, making this one of Medicare's most costly conditions. Estimated direct stroke cost in the U.S. in 2012 exceeded $71 billion and may triple by 2030. We patients need lower cost, but we're waiting for the other shoe to drop, as we already subsidize the payers and pharmacy benefits managers, the PBMs. The 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, and whether rebate practices discourage enrollment by certain beneficiaries. This is a health equity issue, as those who can least afford DOACs may be the most vulnerable. In just one example, the CDC says the risk of a first stroke is nearly double for non-Hispanic, Black adults as for White adults, and they have the highest rates of stroke death. But payers and PBMs are already preparing for the IRA. My 2024 Part D premium doubled, and others are seeing copays change to a percentage, costing them more. To compensate, 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 negotiate, please protect us from these costly, life-threatening tactics that will cause more strokes, especially in the underserved, and Medicare will pay more too. Thank you for protecting us patients.

00:11:50

Kristi Martin, Senior Advisor, Center for Medicare

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Now we'll move on to our next speaker. Please welcome our next speaker, Hussain, who registered as a healthcare provider who has experience prescribing, dispensing, or administering the selected drug or its therapeutic alternatives. Hussain reported no conflicts of interest. Let's welcome Hussain.

00:12:11

Speaker 2

Thank you. Good afternoon. My name is Hussain Lalani. I'm a board-certified primary care physician at Brigham and Women's Hospital and a health policy researcher at Harvard Medical School and the Program on Regulation, Therapeutics and Law, or PORTAL, a multidisciplinary academic research center that uses data to study the approval, regulation, use, and affordability of prescription drugs. As a primary care physician, I am all too familiar with my patients with Medicare being unable to afford the high cost of their medicines, specifically Eliquis. One of my patients had a cardiac arrest due to an abnormal heart rhythm while he was at home. His wife called 911, and paramedics shocked his heart back to life. He was rushed back to the intensive care unit at our hospital and spent many months recovering. Turns out he had multiple abnormal heart rhythms, including atrial fibrillation, for which he was prescribed Eliquis. When he got to the pharmacy, he learned that it would cost him about $500 per month. He doesn't qualify for the low-income subsidy or Extra Help program, and he was rejected from the manufacturer's patient assistance program. We couldn't sign him up for copay cards because he has Medicare, and he had very limited options to be able to access this life-saving drug. Turns out he ended up having to decide between switching medicines, borrowing monies from family, or purchasing the drug from an online pharmacy in Canada. The costs that my patients are asked to pay at the pharmacy strongly influence whether they can pick up a medicine. In a study conducted by researchers at PORTAL, we found that patients with atrial fibrillation were less likely to pick up their blood thinners, like Eliquis, if the cost of the medicine was more than $60, compared to less than $35. Patients with higher costs were also more likely to stop picking up their medicines in the future, thereby increasing their risk of stroke and death from blood clots. We also know from research that there are racial disparities in the prescribing of blood thinners. Research shows that Black patients with atrial fibrillation and Medicare are 25% less likely than White patients to receive a direct oral anticoagulant like Eliquis compared to warfarin. Multiple studies have also shown these 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. As CMS prepares to make this initial offer to Bristol Myers Squibb, it should know that the company has earned over $50 billion in global revenue since the drug was marketed. In 2022, the manufacturer reported $11.8 billion in global sales. Net sales were over $8 billion in the United States. Prescription drugs don't work if patients cannot afford them. That's why I'm glad that CMS is using the authority that Congress has given it to negotiate the price of Eliquis. I really hope this translates to lower prices for patients and ultimately to longer and healthier lives. Thank you.

00:15:21

Kristi Martin, Senior Advisor, Center for Medicare

Thank you for your comments, Hussain. Now we'll move to our next speaker. Please welcome **[INFORMATION HAS BEEN REDACTED]**, who is registered as a patient who has experience taking the selected drug or other treatments. **[INFORMATION HAS BEEN REDACTED]** reported no conflicts of interest, let's welcome **[INFORMATION HAS BEEN REDACTED]**.

00:15:38

Speaker 3

Thank you. I'm a Medicare patient, and I was diagnosed with Afib, tachycardia, and congestive heart failure in January of this year. I happened to be in Sweden at the time. I flew home, spent a week in the hospital where they got things under control, and I'll note that the same medications were prescribed in the U.S. as they were in Sweden, which was Eliquis along with a beta blocker and something to address the congestion. Since there were three clots in my atrium at the time, I was put on Eliquis immediately, actually in Sweden before I started my trip home, and they did not perform a cardioversion when I was in the hospital due to these clots. They've tried multiple cardioversion attempts, and in May, they decided to switch my anticoagulant from Eliquis to warfarin. I had significant problems with warfarin with bruising, bleeding, and an inability to maintain a therapeutic INR level. It kept bouncing up and down week after week, though my diet really had not changed. It was an hour drive from me to get to the hospital where they were doing the anti-coagulation clinic work, plus a ferry ride on a weekly basis, just to get it tested. Fortunately, I was cardioverted in late August, and in October, my heart function had improved. The cardiologist switched me back to Eliquis. Of note is, the problems that I experienced with warfarin, another anticoagulant, and there was a lack of problems with Eliquis. And this is similar to a survey conducted by the StopAfib.org organization where participants noticed significant issues like I had with warfarin, including bruising bleeding and the inability to maintain INR levels due to my CHA2DS2-VASc score, I'm going to be on an anticoagulant the rest of my life, and Eliquis has no side effects. I'll say that there is a fear among both patients and clinicians that the utilization management will significantly adversely affect seniors because there's a lack of guardrails and transparencies in the pharmaceutical beneficiary management industries. Most PBMs do not pass these negotiated discounts on to a patient. And though the Medicare Drug Price Negotiation Program aims to lower cost to patients, there's a genuine concern that it may indirectly increase barriers to access. There's a significant fear that while Medicare will negotiate a reduced cost to the Medicare program, PBMs will move Eliquis to a higher tier or remove it from the formulary, and the end cost to patients may increase, although Medicare would be saving money. This needs to be protected in negotiations. Utilization –

00:18:56

Kristi Martin, Senior Advisor, Center for Medicare

I’m sorry to interrupt **[INFORMATION HAS BEEN REDACTED]**, but we need to move on to our next speaker. We appreciate your comments. Thank you for joining us.

Please welcome our next speaker, **[INFORMATION HAS BEEN REDACTED]**, who registered as a patient who has experience taking the selected drug or other treatments. **[INFORMATION HAS BEEN REDACTED]** declined to report whether they have a conflict of interest. Let's welcome **[INFORMATION HAS BEEN REDACTED]**.

00:19:16

Speaker 4

Good morning. I want to thank CMS for the opportunity to speak about the Medicare Drug Price Negotiation

Program. Patient feedback is crucial to ensure negotiations reflect patient needs. I was diagnosed with atrial fibrillation in 1995, and fortunately, the condition can be easily treated and managed with a twice a day Eliquis. I was prescribed that in 2000, and I have been on it ever since. In 2021, I switched to Medicare, and in search of a more affordable drug price, I signed up for the plan that I thought was the best. I was astounded when I learned that it would cost me $700 for a 90-day supply, and out of sheer frustration, I stopped taking it. In just seven days, I developed a deep vein thrombosis in my calf. Thankfully, the clot dissolved when I started taking my prescription again. But I will never forget the stress and the anxiety of worrying if the clot would move and cause something more serious, like a stroke. Price can be one of the most critical barriers for patients. I appreciate Congress and CMS' pursuit of better access and affordability, but it is immensely important to ensure all seniors have access to innovative and affordable medicines. CMS needs to closely monitor utilization management practices used by pharmacy benefit managers. These practices can price patients out or even off of medications they're already on, like Eliquis, in my case. The switch happens without consultation with the doctor and patient. Medical decisions should be exclusively between the patient and the doctor. PBMs' utilization management practices, like prior authorization, step-therapy, and non-medical switching prioritize the profits at the expense of patients' health. CMS should look at these practices and keep the feedback at the forefront of negotiations. We can all agree that medication affordability is critical, but I am concerned price negotiations will result on unintended consequences to patient health. CMS must consider how the drug pricing could interrupt patient access to medically necessary, sometimes life-saving medications. It's time to move patients to the center of the conversation. Please do not keep patients from accessing their clinician prescribed medications that they need to keep them alive and stable. Thank you so much for your time and thank you for the opportunity to speak today.

00:22:01

Kristi Martin, Senior Advisor, Center for Medicare

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Now we'll move on to our next speaker. Please welcome our next speaker, Rajadhar, who registered as a healthcare provider who has experience prescribing, dispensing, or administering the selected drug or its therapeutic alternatives. Rajadhar has no reported conflicts of interest. Let's welcome Rajadhar.

00:22:22

Speaker 5

Thank you very much for the opportunity to provide you comments today. My name is Raj Reddy. I'm a medical student completing my third year of medical school. I've concluded all my core clinical training, and I'm currently completing a Master's in Health Policy, Planning and Financing at the London School of Economics and Political Science and London School of Hygiene & Tropical Medicine. After I return to medical school, I will apply into neurology, which is of course, very relevant to today's discussion of apixaban. I'm here speaking on behalf of Doctors for America, or DFA, where I serve as Vice Chair for Access to Affordable Care for the entire organization. I also speak having collected the perspectives of many of our physicians across specialties with experience using apixaban. Doctors for America mobilizes doctors and medical students to be leaders in putting patients over politics to improve the health of our patients, communities, and nation. We represent 27,000 physicians and medical students across all 50 states, representing all areas of specialization. DFA focuses solely on what is best for our patients, not on the

business side of medicine, and does not accept any funding from pharmaceutical or medical device companies. This uniquely positions DFA as an organization that puts patients over politics and patients over profits. DFA also hosts an FDA Advisory Task Force, a multi-specialty group that advocates regarding scientific and clinical integrity in FDA medication device approval and CMS coverage analysis processes. I'm also a member of that task force. DFA has also joined several amicus briefs on the side of the administration in the recent lawsuits regarding the Medicare Drug Price Negotiation Program. I have no other conflicts. DFA comes to you today with a simple message to CMS: stand firm on your principles in negotiation and negotiate the best possible price for our patients for apixaban or Eliquis, but I'll continue to refer to it by its non-brand name. The importance of apixaban is far and away the drug with the highest Medicare spending, exceeding the second highest drug by billions, is not lost to anyone. While we recognize that rivaroxaban or Xarelto will be discussed in a separate session, we also recognize the unique opportunity provided by including two medications in the same therapeutic class in Medicare negotiation, we strongly support CMS' efforts to negotiate the best deal for both drugs. As an aspiring neurologist, apixaban and direct oral anticoagulants hold a great deal of importance to me as one of our greatest tools against stroke, the fifth leading cause of death in the U.S. When I wrote to you in the newer intensive care unit with our patients experiencing severe strokes, nearly every single one of our patients was either already taking or was discharged on apixaban. However, we should also consider apixaban is a crucial medication for a number of life threatening cardiovascular and pulmonary conditions, including atrial fibrillation and pulmonary embolism. A game changer when approved in 2012, apixaban and direct oral anticoagulants were a major improvement over the numerous inconveniences noted with other drugs like warfarin. According to apixaban's manufacturer Bristol Myers Squibb themselves, the average month copay for apixaban is $55 a month, no small amount for a seniors on a fixed income, especially for a drug that's been available for over a decade and is often the primary choice within its therapeutic class. Furthermore, despite a generic being approved by the FDA in 2019 and this generic being rolled out in numerous other countries, Pfizer and Bristol Myers Squibb quickly filed suit to uphold a patent exclusivity, preventing a generic from being available until at least 2026 and likely not until 2031. How long must we wait to prevent stroke affordably? Thank you.

00:25:26

Kristi Martin, Senior Advisor, Center for Medicare

Thank you for your comments. Moving on to our next speaker, please welcome **[INFORMATION HAS BEEN REDACTED]**, who registered as a representative of a patient advocacy organization. **[INFORMATION HAS BEEN REDACTED]** reported a conflict of interest. Let's welcome **[INFORMATION HAS BEEN REDACTED]**.

00:25:41

Speaker 6

Thank you. Good afternoon. My name is **[INFORMATION HAS BEEN REDACTED]**, and I'm representing the Mended Hearts, the world's largest peer-to-peer cardiovascular patient support network, boasting over 100,000 members across 20 countries. Personally, I live with a structural heart defect, having navigated three open heart surgeries, numerous medical interventions, and prescribed medications. Heart disease tragically remains the primary cause of death in America, with nearly 700,000 deaths each year. It is critical for Medicare beneficiaries to have access to these critical medications, like Eliquis, as they play a vital role in

preventing life threatening cardiovascular events. We at Mended Hearts champion the ideals of the Medicare Price Negotiation Program, designed to lessen the financial burden on Medicare beneficiaries. Key provisions, like Part D out-of-pocket maximum, the Prescription Payment Plan, and expanded low-income subsidies, strive to make drugs more accessible and affordable. However, as the new law unfolds, there are pressing concerns we urge CMS to address. Without safeguarding preferential access or rectifying formulary tiering issues that may result from price negotiations for the selected drugs, there is a risk that medications like Eliquis could be relegated to non-preferred formularies. This jeopardizes access that countless cardiovascular disease patients depend on to mitigate heart attack and stroke risks. We also are apprehensive about the new law's ripple effects in the cardiovascular sector. Five out of the ten drugs selected for price negotiation this year are used in treating heart patients. This new reality could hinder the development of novel treatments, especially given the inherent challenges in the cardiovascular drug development process, such as high clinical trial expenses and comparatively low success rates. Lastly, the introduction of Eliquis and other direct oral anticoagulants have revolutionized cardiovascular disease care. My personal care journey saw years on warfarin demanding regular clinic visits and consistent dose adjustments. A severe bleeding episode led to an emergency room visit and multiple follow ups with my doctor. This eventually drove, in my case, the decision to discontinue warfarin. Direct anticoagulants like Eliquis have undoubtedly spared countless hours in travel and medical monitoring and saved millions in healthcare costs associated with warfarin's unpredictable nature. We urge CMS to assuage the concerns regarding the new law's potential limiting access by categorizing these drugs under non-preferential formularies. Additionally, please consider the impact that the new Part D plans' reimbursement structure may have on impeding progress for innovative cardiovascular treatments for breakthrough drugs like Eliquis, which have transformed patient care, providing safer, more efficient alternatives to medications such as warfarin. Thank you for your time and consideration.

00:28:39

Kristi Martin, Senior Advisor, Center for Medicare

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Now we'll move to our next speaker. Please welcome **[INFORMATION HAS BEEN REDACTED]**, who registered as a patient who has experienced taking the selected drug or other treatments. **[INFORMATION HAS BEEN REDACTED]** has reported no conflicts of interest. Let's welcome **[INFORMATION HAS BEEN REDACTED]**.

00:28:55

Speaker 7

Hi, I'm **[INFORMATION HAS BEEN REDACTED]**. I'm a Medicare patient with a Medicare Advantage plan. **[INFORMATION HAS BEEN REDACTED]** Mended Hearts, I visit our patients. I've been on Eliquis for about one year as a result of needing another stent. I also have a history of Afib, other stents, and I have an aortic valve replacement. While on Eliquis, I've noticed no side effects, no bruising issues. I also have two cousins. They're in their 70s. They have Afib issues, and they say it's working fine with them. One issue I'd like to bring up is the cost. I order my medications through a three-month pharmacy. Every three months, I order my meds through the mail. The most expensive medications are $30 a month, excuse me, $30 every three months. But my Eliquis is $70 every three months. That's something I can afford, that I don't know if everybody can. And I think I would appreciate it if something could done to bring at least the cost of that

down more on par with the other medication. Thank you.

00:30:17

Kristi Martin, Senior Advisor, Center for Medicare

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Now we'll move to our next speaker. Please welcome **[INFORMATION HAS BEEN REDACTED]**, who registered as a patient who has experienced taking the selected drug or treatments. **[INFORMATION HAS BEEN REDACTED]** reported no conflicts of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

00:30:32

Speaker 8

Thank you. Yes. My name is **[INFORMATION HAS BEEN REDACTED]**. I'm 75, and I **[INFORMATION HAS BEEN REDACTED]**. Five years ago, I was diagnosed with Afib and prescribed warfarin. For the first two years, I had random nosebleeds that required me going to the ER to have my nose packed several times. I also had severe bleeding episodes three times where I had to go in to be treated immediately. My INR was never able to keep stable, so I was at the anti-coagulation clinic about every two weeks, average, if not every one week, for constant changes to the dosing. By year three, I changed my cardiologist, and he suggested switching to Eliquis. From friends who took it, I knew it was more than I could afford. My doctor knew of my financial situation and suggested I apply for patient assistance from Bristol Myers Squibb Foundation, which I was approved for. So, thankfully, I was able to switch, and my nose bleeds stopped and of course, no more INR testing and no more watching the diet and how much greens you were having. Also, before and after surgery is so much better with Eliquis, I stop taking it ahead as advised by the doctor, and start again a day or two later with no issues and no INRs to try to get it back into the range. Each year when I reapply for assistance, I have to meet a 3% of my income deductible in order to qualify. I meet that requirement by buying a 30-day supply of Eliquis at my preferred pharmacy using Part D. This year, the cost was $544. I don't have a single friend or relative that can afford to pay that each month. By the generosity of Bristol Myers Squibb, I'm fine for now. But should they discontinue the program or change the max income, I would be back on warfarin and all the problems that came along with it. I have a close friend who will be retiring in February of 2024, and his biggest concern is how he will continue taking Eliquis, which he now has been taking for five years. Currently, under his employer's insurance, he pays $50 for a three-month supply. He knows from talking to me and other friends that are recipients that the cost will rise to $1,500 for that same amount of time. His Social Security income and pension will total a bit more than mine than what I receive, so he won't qualify for any assistance. He will likely be forced to go off of it. Thank you.

00:32:58

Kristi Martin, Senior Advisor, Center for Medicare

[INFORMATION HAS BEEN REDACTED], thank you for your comments. Now we'll move to our next speaker. Please welcome **[INFORMATION HAS BEEN REDACTED]**, who registered as a patient who has experience taking the selected drug or other treatments. **[INFORMATION HAS BEEN REDACTED]** reported no conflicts of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

00:33:14

Speaker 9

Well, thanks for allowing me to speak today. I'm a relatively new user of Eliquis. I had my first atrial fibrillation event that happened this last July. I wasn't excited when the emergency room doctor told me I had to go on blood thinners because I'd heard of stories that people had over the years, issues related to the medicine that they were taking, the blood thinners. When I went to see my regular doctor, he immediately said that I was going to be on Eliquis for the long term, and I was even less excited. But he made it really clear that Eliquis is different than the previous generation of blood thinners, in particular warfarin, because I'd heard all the horror stories of warfarin, and it turns out my doctor was right. I've been on Eliquis now for four months, and to be honest with you, it hasn't made any change in my daily regimen. I take the pills twice a day and haven't noticed any complications, which is great. There was no need for testing, no need for any dietary changes. All those horror stories that I had heard from before, it turns out that there really wasn't an issue at all. I am aware of the cost. When I went to pick up my first Eliquis prescription, they initially quoted me $600 to walk away. Fortunately, I have a good prescription Part D Medicare plan, and as a result, my cost is less than $30 per month. I am aware, however, for some people, that's a significant issue and the ability to pay $30 every month could be a problem for some people. Fortunately, once again, I have a good plan, and I don't have to worry about skipping medications. One of my greatest concerns, quite frankly, is moving forward, whether the patient experience is going to be considered as part of whether Eliquis is prescribed and ultimately paid for by Medicare. In reading the Inflation Reduction Act, it says that when it comes to negotiating the price of a drug, the Secretary of Health and Human Services must consider whether the condition the drug targets can be treated with alternative therapies, how much the drug cost to produce, the cost of research and development, and other factors. And what I'm really hoping, and what I really want to speak to is the fact that the other factors should include patient experience. Because while drugs like warfarin could potentially accomplish the same goal, the patient experience of Eliquis is something that is significantly different. And because it's such a better patient experience, that needs to come into play. And I would hope that the negotiations with regard to the cost and the price of Eliquis would not do anything to reduce or restrict access to Eliquis. It just so happens I'm on another medication that is actually even more expensive than the Eliquis. I mean, it's upwards of $50,000 a year if I had to pay it out-of-pocket. So, I'm one of those people who's looking forward to the 2025 price cap of $2,000. However, what I don't want to see is that my out-of-pocket costs are affecting the way I have the ability to get access to it. I don't want to see my costs go down and my ability to get access to certain medications go down as well. So back to my key point: I really hope that the patient experience is a key factor in determining how drugs are priced and how they're prescribed in the future. Thanks for your time.

00:36:20

Kristi Martin, Senior Advisor, Center for Medicare

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Now we'll move to our next speaker. Please welcome **[INFORMATION HAS BEEN REDACTED]**, who registered as a patient who has experience taking the selected drug or other treatments. **[INFORMATION HAS BEEN REDACTED]** reported a conflict of interest. Let's welcome **[INFORMATION HAS BEEN REDACTED]**.

00:36:25

Speaker 10

Thank you, Ms. Martin. My name is **[INFORMATION HAS BEEN REDACTED]**. I'm a patient with the incurable blood cancer, multiple myeloma, and I'm prescribed Eliquis to prevent blood clots. I'm at high risk of blood clots for four reasons. One of my cancer drugs causes blood clots. I have Afib, which can cause blood clots. I have had a deep vein thrombosis, a blood clot, and I'm close to 75 years old, which is an additional risk factor. When I was diagnosed with Afib back in April of this year and I was prescribed Eliquis, I called my Part D drug plan to inquire about getting it and the price. I was told my out-of-pocket for Eliquis would be $798 for a 90-day supply. But there was a catch. I couldn't have Eliquis because my plan required me to use Xarelto and to fail first on that before I could get Eliquis. Xarelto was available for $85.75 out-of-pocket for a 90-day supply. I was also told my doctor could appeal the requirement to fail first on Xarelto. Now, 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 failed first for this drug would have meant for me that I had had a blood clot, had a stroke, or was dead. So failed first makes no sense for this class of drugs. Patients should be able to get the drug that their doctor thinks will work best for them. 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 on Xarelto. In other words, plan profit is being put ahead of my health. I must also mention that the list price of Eliquis is a problem because of gaming of our patent system to extend monopolies and block competition. Bristol Myers Squibb and Pfizer, who manufactured the drug, have applied for 48 patents on Eliquis and have been granted 27. Negotiation on these drugs is going to break these extended monopolies and lower prices for patients like me. So, back to my story. What did I do? Well, I bought Eliquis from a certified pharmacy in Canada where there is a generic on the market called apixaban. Instead of $798 out-of-pocket for a 90-day supply, I pay $261, including shipping, an annual savings to me of $2,148. Patients should not have to jump through these hoops because of cost. Patients should be able to afford the drug they need, and that is best for them. Negotiation on Eliquis is going to help millions of patients like me have both better health and improved financial well-being. Thank you.

00:39:33

Kristi Martin, Senior Advisor, Center for Medicare

[INFORMATION HAS BEEN REDACTED], thank you for your comments. Now we'll move on to our next speaker. Please welcome **[INFORMATION HAS BEEN REDACTED]**, who registered as a representative of a patient advocacy organization. **[INFORMATION HAS BEEN REDACTED]** reported a conflict of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

00:39:49

Speaker 11

Thank you. Hi, everyone. My name is **[INFORMATION HAS BEEN REDACTED]** Alliance for Aging Research. Thank you to CMS for the opportunity to comment. Since 2018, the Alliance has consistently opposed Medicare Drug Price Negotiation policies because they all rely on significant cuts to beneficiary access in order to reach projected CBO savings. While political messaging claims that price negotiation is going to help rein in high drug prices, the process instead captures drugs that serve millions of Medicare beneficiaries at comparatively modest costs, such as Eliquis, rather than drugs that induce sticker shock. So,

what is cutting access going to look like in practical terms? Well, while the IRA guarantees formulary inclusion for all ten selected drugs being discussed in these sessions, it doesn't guarantee formulary placement for any of them. So starting in 2026, Medicare beneficiaries and family caregivers are going to need to check their plan formularies. If their plan has switched formulary tier placement for a selected drug, beneficiaries can either pay out-of-pocket to stay on it, switch to a preferred drug in the same class, or switch to a new plan. Insurance plans are also likely to restrict access to selected drugs through utilization management practices such as prior authorization and step therapy. But unfortunately, CMS only pledges to monitor utilization management by Part D plans and not develop guardrails to protect patient access. Switching stable patients off anticoagulant therapy like Eliquis is alarming for patients reliant on blood thinners to manage clot risk. A September 22 survey from the American Journal of Preventive Cardiology found that, of respondents that were taking anticoagulants who were non-medically switched by their payers, 70% of their health plans' explanations for the switches were financial, but many led to serious health consequences. A reported 28% of patients experienced side effects, 7% had heart attacks, 4% had strokes, and 20% actually stopped taking their blood thinners. These are patients at very high risk for deep vein thrombosis, pulmonary embolism, stroke, and heart attack. It's vital that Medicare create actual safeguards to prevent these potentially dangerous impacts. The government's lack of transparency about its price setting methodology is also concerning to us. We may or may not hear today from the Institute for Clinical and Economic Review, or ICER, about their special report on Eliquis. ICER reports are indeed special in that they are payer-centric, not patient-centric. Arnold Ventures is the largest funder of ICER, and we think Arnold funding should be reported as a conflict by other groups participating here, such as PORTAL and DFA. ICER uses its own equal value of life years, known as the evLY or the evLYG metric in its report. However, claims by ICER that the evLY fixes the biases of the QALY and complies with the law as described in the IRA –

00:43:01

Kristi Martin, Senior Advisor, Center for Medicare

I'm sorry to interrupt, but we need to move on to our next speaker. Your three minutes are up. We really appreciate your comments and thank you for joining us.

Speaker 11

Thank you.

00:43:11

Kristi Martin, Senior Advisor, Center for Medicare

Please welcome our next speaker, Seth, who registers a healthcare provider who has experience prescribing dispensing or administering the selected drug or its therapeutic alternatives. Seth declined to report whether they have a conflict of interest. Welcome, Seth.

00:43:27

Speaker 12

Thank you for the opportunity to comment on the Medicare Drug Price Negotiation Program's impact on the treatment of cardiovascular disease and future drug innovation. My name is Dr. Seth Baum, and I am an

Eliquis patient. I have practiced cardiology for more than 30 years, and I currently serve as the chief scientific officer of a large clinical trials company. I have a unique perspective here. Medicines have literally saved my own life. I prescribe therapies to prevent heart attacks and strokes in my patients, and I have been intimately involved in clinical trials for drug development. Therefore, I have had a remarkable front row seat to witness what is possible through unimpeded science. As a patient, I experienced multiple life-threatening bleeds on warfarin. Consequently, for over three years, I had to inject myself in the abdomen twice daily with a blood thinner until Eliquis became available and my Harvard hematologist prescribed it. Eliquis for me has been a godsend. As a clinician, I have seen patients live longer, happier, healthier lives because of innovative medicines like Eliquis. As you know, oral anticoagulants are a game changer for patients at risk for stroke and other clotting events. The value Eliquis has brought to my patients and to the healthcare system is immense. I implore you to ensure that as this program is implemented, you do everything in your power to keep patients on their medications. Please do not allow utilization management schemes to get in the way of doctors and their Medicare patients. Please understand that any gap in adherence for an oral anticoagulant can be devastating, leading to stroke, DVT, pulmonary embolism, or even death. As a clinical researcher, I want to warn everyone that this drug price negotiation program, as it stands, will likely disincentivize investment, specifically in America's number one killer, cardiovascular disease. A recent study from Avalere shows that the IRA's Medicare Drug Price Negotiation Program is expected to have a disproportionate impact on cardiovascular drug development and innovation. Cardiovascular drug trials are unique in that they demand nearly two times more patients than other disease states, demand almost 50% more clinical trial sites, take longer to conduct than do trials for other drugs, and they are simply more costly than their counterparts in other therapeutic areas. The vast majority of cardiovascular medications are small molecules, and as the law is currently written, small molecule development is severely disincentivized by the IRA negotiation timeline. It is simply riskier and costlier to bring new cardiovascular drugs to market than it is for drugs in other disease states. I fear scientists and manufacturers will be forced to make difficult decisions about drug development, resulting in fewer options for patients and ultimately worse outcomes for the American public. We must find a way to lower out-of-pocket costs for seniors without sacrificing unfettered drug access and robust drug development innovation. Thank you very much.

00:46:31

Kristi Martin, Senior Advisor, Center for Medicare

Thank you for your comments Seth. Now we'll move to our next speaker. Please welcome John, who registered under the category “Other.” John reported a conflict of interest. Let's welcome John.

00:46:49

Speaker 13

Good afternoon. My name is John Clymer. I'm Executive Director of the National Forum for Heart Disease & Stroke Prevention, a non-profit, non-partisan organization dedicated to health, equity, and optimizing cardiovascular health and well-being throughout the lifespan. Through our Value and Access Collaboration, patient, provider, payer, purchaser, public health and pharma organizations collaborate to enhance health and well-being by supporting people's access to evidence-based care that's appropriate for them. The National Forum appreciates this opportunity to provide feedback on the Medicare Drug Price Negotiation Program, as it will have a rippling effect on population health in the short and long term. We urge CMS to

make sure its drug price negotiation program ensures beneficiary access to appropriate evidence-based care. That is: the right treatment for the right patient at the right time. Given that stroke reduces mobility in more than half of survivors aged 65-plus, it's essential that this policy improves and not reduces access to apixaban. It is imperative that this program not exacerbate access challenges for disadvantaged populations. For example, non-Hispanic Blacks have far higher rates of first stroke and death from stroke, an event that apixaban helps prevent. We recommend CMS work with the Office of Minority Health to achieve this requisite. We urge CMS to guard against potential unintended consequences, which have been cited by many of the speakers before me, such as utilization management that could result in reduced access to appropriate treatment. As **[INFORMATION HAS BEEN REDACTED]** pointed out, price ceilings intended to benefit consumers could have the unintended consequence of reducing access if pharmacy benefit managers drop medications from formularies or move them to higher out-of-pocket cost tiers because higher priced drugs offer PBMs bigger rebates. Anticoagulant therapies are not interchangeable. Multiple studies have found different event rates for people on different anticoagulants. We support the implementation of evidence-based care that aligns incentives for patients, providers, pharma innovators, and purchasers. In summary, the National Forum for Heart Disease and Stroke Prevention, on behalf of its more than 100 non-profit, for-profit and public sector member organizations, urges CMS to ensure that Medicare Drug Price Negotiation Program: (1) supports evidence-based strategies for appropriate care and protects beneficiary access; (2) guards against potential unintended consequences such as utilization management that could result in reduced access to appropriate treatment; and (3) aligns incentives for all stakeholders. Thank you for this opportunity.

00:50:02

Kristi Martin, Senior Advisor, Center for Medicare

Thank you for your comments, John. Now let's move on to our next speaker, **[INFORMATION HAS BEEN REDACTED]**. **[INFORMATION HAS BEEN REDACTED]** registered as a representative of a patient advocacy organization. **[INFORMATION HAS BEEN REDACTED]** reported a conflict of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

00:50:18

Speaker 14

Thank you. I'm **[INFORMATION HAS BEEN REDACTED]**, Partnership to Fight Chronic Disease. Thank you so much to CMS for the opportunity to comment. Eliquis reduces clotting and stroke risks associated with Afib and other conditions. Without proper treatment, more than half the people diagnosed with Afib will die within five years of symptom onset. Health disparities are common, as are multiple co-morbidities, since 98% of people with Afib have at least one other chronic condition, building treatment regimens that work and meet individual patient needs depends on having a variety of treatment options available. Compared with warfarin, Eliquis doesn't require constant blood tests and dose adjustments or dietary restrictions and has fewer drug interactions. Those are critically important unmet medical needs this drug addresses. Eliquis is on this list because physicians and beneficiaries favor it. Medicare has identified the initial ten drugs by gross Part D drug spending. Per CMS data, Eliquis costs Medicare, before rebates, less than $400 a month per person using it. A recent GAO report notes that the anticoagulants are among the classes of drug with the highest rebates and that patients do not see those savings at the pharmacy counter. It's on the list

simply because a lot of people use it. And although CMS requires plans to cover these drugs, there's no requirement where they will be placed on the formulary or the limits on access barriers. That means less access and is not what's being advertised to the public about these drug pricing efforts without change. I have been fortunate enough to be selected to speak at nine of these listening sessions, and I plan to close each with a key unanswered question. Today I ask on what information will CMS rely in considering the benefits and values of these medicines? The patient community has serious concerns about the use of ICER reports, for example. Those concerns include their stubborn reliance on the discriminatory QALY, evLY, and evLYG. Make no mistake, anything that includes a life year calculation will show less value for people with fewer life years remaining; that's the entire Medicare population. Assessing value also means making choices on evidence used and its weight applied. ICER regularly makes decisions that discount benefits important to patients, such as reduced side effects, less testing, fewer diet limits, ease of use, fewer drug interactions. For example, ICER recently released an analysis that includes Eliquis despite the accumulation of a decade's worth of real-world evidence since the FDA approved Eliquis, ICER relied on older clinical trial data instead to draw conclusions about value. That's really troubling, and without greater transparency, we won't know what CMS is going to rely on or the weight placed on this type of evidence. Thank you so much for the opportunity again to comment.

00:53:19

Kristi Martin, Senior Advisor, Center for Medicare

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Please welcome our next speaker, **[INFORMATION HAS BEEN REDACTED]**. **[INFORMATION HAS BEEN REDACTED]** registered as a representative of a patient advocacy organization. **[INFORMATION HAS BEEN REDACTED]** reported no conflicts of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

00:53:24

Speaker 15

Thank you and good afternoon. My name is **[INFORMATION HAS BEEN REDACTED]**. I'm an advocate and patient living with chronic conditions. **[INFORMATION HAS BEEN REDACTED]** the Chronic Care Policy Alliance. The Chronic Care Policy Alliance is a network of state and regional advocacy organizations advancing public policy that improves the lives of those living with chronic conditions and diseases. I became a health advocate because of my own struggles to get my health condition taken seriously by my health insurance plan, my doctors, and to find treatments that allowed me to resume my daily activities. If there's one thing I want to be taken away from my comments, it is that every patient is unique and depends on medical miracles that continue to be developed in this country. And recently, I have a family member diagnosed with Afib. I really want to thank you for these listening sessions so that patients can speak directly about the issues impacting their care. I often say that policies should not be about us without us. Every unique patient must be considered in the negotiation process. Unrestricted access to the full breadth of life changing medicines is critical to patients' ability to function, contribute to society, and in many cases, even how long they will live. Patients want to ensure that the development of life-changing medications continues and that they'll have access to them. A real concern for patients is how the negotiation program might save Medicare money, but that patients will have to fight harder to access the treatments they need due to formulary changes that prioritize negotiated drugs above all other options. As negotiation

progresses, CMS should consider whether the price it negotiates protects patients who use the product while still preserving access to alternatives for those who don't. Further, CMS should ensure that both the negotiation process and other policies within the IRA support ongoing research into both new products and new indications for existing cures. CMS should ensure that the negotiation does not spur greater restrictions to access or lead to stricter utilization management. Great care we need is to protect patients using product off label or in different doses from being penalized or their care interrupted to the negotiation process. This would be especially evident for people with chronic conditions and rare diseases. CMS must ensure that best interests of patients drive decisions around these medicines, not financial savings or one size fits all data analysis. Patients are individuals, so what works for many may not work for everyone. Therefore, a negotiated price that supports individualized care decisions and treatment flexibility must be preserved through this process. I want to thank you again for the opportunity to present these comments.

00:56:29

Kristi Martin, Senior Advisor, Center for Medicare

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Please welcome our next speaker, Gina, who registered under the category “Other.” Gina reported no conflicts of interest. Welcome, Gina.

00:56:41

Speaker 16

Thank you for allowing me to be here to speak today. I am talking to you from a personal, with family members being on Eliquis, to also a professional where I work at a federally qualified health center, and I help people sign up for insurance. I live in a rural area. We are the only office, doctor office in our county. We have one pharmacy in our county, so we are very rural. To say about Eliquis, about the price negotiation, I think that is a very good thing that we are looking at. But my concern is this: I think Eliquis is an excellent medicine. I have seen it with family members and then my providers here at our facility. My concern is, I don’t think Eliquis is the problem. I think it’s the drug plans. Nobody in this country has a coverage gap, a doughnut hole, except people on Medicare. Even negotiating the prices for lower amounts on these medicines for 2024, open enrollment has already started. I’m looking at plans that majority of them are 16% to 25% the cost of the medicine for Eliquis, it is falling into the tier three and tier four. So negotiating is great, but until you change the plan also, they have their preferred pharmacies. My little local pharmacy here in my county is never preferred, so that’s actually hurting business too, for your local mom and pop shops that are trying to make a living. They have to go to Walmart, Walgreens, CVS, to the big chains. You have to also look at the people that I deal with in our area. Majority of the people are getting $1,500 or less a month, Social Security, pay for Part B, then pay for your drug plan. The wording on the drug plan says cost before deductible. You have a $200 deductible. So then why are you having to pay $900 the first month for your medicine? If you have a $200 deductible, you should pay $200. You've met your deductible. Anybody that's on Eliquis is going to hit the coverage gap, the donut hole, because of the cost of it. That's the same with diabetics. You might have lowered the insulin, but the medicine they're still showing is very expensive so they still hit that coverage gap. I think negotiations are great, but I do feel that changes need to be on the plans. People can't afford right now, $562 –

00:59:57

Kristi Martin, Senior Advisor, Center for Medicare

I'm sorry to interrupt, Gina, but your three minutes have expired, and we need to move on to our last speaker. Thank you for your comments, Gina. I appreciate it.

Speaker 16

I appreciate it, thank you very much.

01:00:07

Kristi Martin, Senior Advisor, Center for Medicare

Please welcome our last speaker, **[INFORMATION HAS BEEN REDACTED]**. **[INFORMATION HAS BEEN REDACTED]**, who is registered as a patient who has experience taking the selected drug or other treatments. **[INFORMATION HAS BEEN REDACTED]** reported no conflicts of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

01:00:21

Speaker 17

Thank you. Thank you for having me speak. About a year and a half ago, I was diagnosed with Afib. At the time, I was having kidney problems also. My doctor, my cardiologist, suggested that I go on a blood thinner and suggested that I look into Eliquis or warfarin. She told me that Eliquis was very expensive. I have a son that had been on Eliquis for about a year, and he was paying $10 a month to get his prescription. So I thought, well, I can go on Eliquis because I can use the same thing. But when I called Eliquis to verify that I qualified for this offer that they were making, I found out that because I was on Medicare, I was not qualified, that they only allowed people that had commercial insurance to be on this program that they had. So my out-of-cost would have been about $600 and something dollars to begin with, and over $200 a month after that. So, my cardiologist put me on warfarin. Well, about six months ago, I went on dialysis for my kidneys, and I had to have a catheter put in to support the dialysis. And about two months after I had that done, I got an infection. So, my kidney doctor started me on antibiotics, and the next thing I know, my INR was just going off the chart, and it was because of the antibiotics did not work with the warfarin. So, we tried a second antibiotic, but it was still the same thing. So, next we took me off of warfarin until the time that I got all the antibiotics taken and got this infection cleared up. So, I've had that problem with warfarin not working with certain other medications. Right now, again, I've looked into Eliquis, and it's still at a very high cost. And with our Social Security and with the small pension plan that we have, it's just not possible for me to have it. And I do have problems with bleeding excessively if I get a cut or a scrape or what have you. So it's been really hard on warfarin. So that's why I am really hoping that all this goes through for the Eliquis. I think it was kind of sad to me to know that the people that are under 65, that most of them are on commercial insurance, are eligible for this. But people over 65, which I would have thought would be the biggest patient file that they would have are not eligible for any program to help them bypass the cost.

01:03:42

Kristi Martin, Senior Advisor, Center for Medicare

Hi, **[INFORMATION HAS BEEN REDACTED]**. I'm sorry to interrupt. Thank you so much for your comments.

And that concludes our patients who are participating in speaking today.

Thank you all for taking the time to participate in this listening session. Your input will be discussed internally as we continue to thoughtfully implement the new law in our efforts to lower prescription drug prices. Thank you and have a great day.

For a list of the drugs selected for the first cycle of the Medicare Drug Price Negotiation Program, click here.

For more information on the Medicare Drug Price Negotiation Program, please click here.