Transcript: Farxiga, November 2, 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

Douglas Jacobs, MD, Chief Transformation Officer, 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 Dr. Doug Jacobs, the Medicare Chief Transformation Officer with the Centers for Medicare & Medicaid Services. This is a virtual public listening session for the drug Farxiga, 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 be effective beginning in 2026.

This virtual, patient-focused listening session is an opportunity for the public to weigh in on the 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 the data submission process, which invited manufacturers with the drugs selected for the first round of negotiations 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 Farxiga in their own lives or the lives of those they serve and care for. Speakers who are joining 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 keep time and to stay on the 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 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]**.

00:07:59

Speaker Remarks

Speaker 1

Thank you. Good morning, or early afternoon for most. **[INFORMATION HAS BEEN REDACTED]** I celebrate my 21st anniversary of having an open-heart surgery and a coronary bypass graft**.** My cardiologist at that time gave me four years. My wife told me at five that that's what he'd given me. It's been 21. I look at the benefits of medicine and the current drugs available to us as patients as being vital to the fact that I'm here talking with you today. My experience since taking specifically Farxiga – my cardiologist brought it up almost some three years ago, and at that time looked at the cost basis of it and realized that it was exceedingly expensive. Weighing the facts over the usage, he gave me a sample to take, and I did start noticing a benefit to me personally as far as viability and my ability to move around. The biggest thing at that point was actually going out and going through my prescription provider, and I use a mail service to keep my costs low. My first-year costs were $1,958.15. Part of that, some $436 is going to be rolled over already into this year's usage, which as of today amounts to $893.34. So with the $436, I'm still looking at $1,200. So, all of a sudden that was the primary focus three years ago, was, what's going on? Faced with inflation costs across the board, how am I going to afford this? Well, I'm affording it, but obviously not liking it. I would like to see this more in a general range. As far as pricing, it's exorbitant. I don't pay anything near that. And the rest of my drugs, I do those through Medicare. As far as access, it's been good, just dealing with the mail in. Benefits to my health – a gentleman yesterday when we were visiting patients at a local hospital said, "you're getting around better than you have in a long time." And I am. I physically feel much better. And I noticed that going back during the course of my moving into this and it's definitely a condition where I'm following the regards of my cardiologist. I'm just short of, I'm on my third AICD, which is a defibrillator pacemaker. The next step, and I do have a congestive heart failure doctor also, because my next step would be to go into an LVAD-type situation. So, anything will keep me from having to go there and make that type decision, it's definitely a benefit to me and my family. I think I'll end it there. It's worked for me. Everybody's different –

00:11:32

Douglas Jacobs, MD, Chief Transformation Officer, Center for Medicare

I'm so sorry, **[INFORMATION HAS BEEN REDACTED]**. Your three minutes are up. I'll give you a moment to finish up, okay?

00:11:37

Speaker 1

It's worked for me. It's worked for the benefit of my family. So I appreciate the opportunity to make some comments. Thank you.

00:11:45

Douglas Jacobs, MD, Chief Transformation Officer, Center for Medicare

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Now we'll move to our next speaker. Please welcome John, who registered in the category of other. John reported a conflict of interest. Welcome, John.

00:12:02

Speaker 2

Good afternoon. My name is John Clymer. I'm Executive Director of the National Forum for Heart Disease & Stroke Prevention, a nonprofit, nonpartisan 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 is appropriate for them. Thank you for this opportunity to provide input on the Medicare Drug Price Negotiation Program. 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. People with diabetes, heart failure, and chronic kidney disease have a much higher risk of more hospitalizations, more emergency department visits, and shorter life expectancy, not to mention reduced ability to engage in everyday activities like walking and carrying groceries. Dapagliflozin slows the progression of and is a guideline directed treatment for all three of these debilitating conditions. It is essential that the Price Negotiation Program does not worsen access to dapagliflozin for disadvantaged populations. The prevalence of diabetes, heart failure, and chronic kidney disease is highest among Blacks and American Indian, Alaskan Natives, Hispanics, and Asian Pacific Islanders. Compared with White people, these populations are between one and a half to four times more likely to develop end-stage kidney disease. We recommend CMS work with the Office of Minority Health to achieve this requisite. Healthcare costs to society and taxpayers are high and warrant containment. However, it is out-of-pocket costs that affect the individual's access to medications. Dapagliflozin's manufacturer reports that at current out-of-pocket costs, prescription abandonment is low and medication adherence is high. Therefore, we urge CMS to guard against potential unintended consequences. Price ceilings intended to benefit consumers and taxpayers could result in reduced access if pharmacy benefit managers drop medications from formularies or move them to higher out-of-pocket cost tiers because higher price drugs offer PBMs bigger rebates. We support the implementation of evidence-based care that aligns incentives for patients, providers, pharma innovators, and purchasers. In summary, the National Forum urges CMS to support evidence-based strategies for appropriate care and protect beneficiary access, guard against potential unintended consequences such as utilization management that could reduce access to appropriate treatment and align incentives for all stakeholders.

00:15:21

Douglas Jacobs, MD, Chief Transformation Officer, Center for Medicare

Thank you for your comments, John. Now we'll move 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]**.

00:15:36

Speaker 3

Thank you. Good afternoon. My name is **[INFORMATION HAS BEEN REDACTED]** and I represent the Mended Hearts Inc., the world's largest peer-to-peer cardiovascular patient support network, hosting over 100,000 members. Personally, I live with a structural heart defect, navigated three open heart surgeries, numerous medical interventions, and prescribed medications. As I spoke to you yesterday, heart failure has become a health crisis in the United States. Heart failure affects over six million Americans and is a leading cause of death in the United States. With almost a million new cases annually, the percentage of people with heart failure is expected to rise by 46% by 2030, a projected eight million people. Mortality is also high, with one in three patients with heart failure dying within one year of hospitalization and 40% to 50% within five years of diagnosis. We at Mended Hearts support the ideals of the Medicare Price Negotiation Program, designed to lessen the financial burden on Medicare beneficiaries. Key provisions like Part D max out-of-pocket spending, the Prescription Payment Plan, expanded low-income subsidies, all strive to make drugs more accessible and affordable. However, as the new law unfolds, there are pressing concerns we urge you to address. Without safeguarding access or addressing formulary tiering issues that may result as an unintended consequence from the price negotiations of selected drugs, there's a risk that drugs like Farxiga could be relegated to nonpreferred formularies and may result in the opposite of the new law's intended effects: higher out-of-pocket costs for patients. We're also apprehensive about the law's potential ripple effects in the cardiovascular disease sector. Five out of the ten drugs selected for negotiation this year are used in treating heart patients. The new reality could hinder the development of novel treatments, especially given the inherent challenges of cardiovascular drug development, such as high clinical trial expenses and comparatively low success rates. I want to highlight the stringent nature of primary endpoints in numerous clinical trials for cardiovascular medications. These trials often hinge on assessing major adverse cardiac events, also known simply as MACE, a composite measure encompassing cardiovascular mortality and significant cardiac incidents. Take, for example, the drug Farxiga, whose trial findings indicated a marked decline in cardiovascular fatalities, hospital admissions, and urgent care visits related to heart failure. The benchmark that MACE sets for cardiovascular drugs is notably high, ensuring that only drugs with significant impacts on outcomes reach patients. The stringent threshold, however, while ensuring quality, concurrently poses obstacles to introducing new cardiac medications. This challenge could be exacerbated as the incentives decrease for developing chronic condition drugs that impact a broad swath of the Medicare population. We urge CMS to work to assuage our concerns and that the new law may limit medication access by categorizing them under non preferred formularies, or patients may experience unchecked utilization management practices –

00:19:05

Douglas Jacobs, MD, Chief Transformation Officer, Center for Medicare

Your three minutes are over. Please take a moment to wrap up.

00:19:08

Speaker 3

Sure. Unchecked utilization management practices that would result in fewer patients being treated by safe and effective drugs that are being accessed by hundreds of thousands of Medicare beneficiaries. Thank you.

00:19:21

Douglas Jacobs, MD, Chief Transformation Officer, 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 representative of a patient advocacy organization. **[INFORMATION HAS BEEN REDACTED]** reported a conflict of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

00:19:35

Speaker 4

Good afternoon. I'm **[INFORMATION HAS BEEN REDACTED]** the Partnership to Fight Chronic Disease. Thank you so much for this opportunity. Farxiga is an FDA approved medicine that treats three common chronic conditions: chronic kidney disease, type 2 diabetes, and heart failure. Having a medicine taken once a day that treats more than one condition and a regularly occurring constellation of them addresses an important unmet need. Within Medicare, more than three out of four people with type 2 diabetes or with heart failure or with chronic kidney disease live with three or more chronic conditions. Living with multiple chronic conditions makes everything more difficult. People are left to comply with complex treatment regimens and manage it all with limited coordination among providers. Polypharmacy is a real issue. I have a loved one with type 2 diabetes and heart failure. He takes more than 25 pills a day. At any age, that is hard, but at 85, it's overwhelming. These diseases are common and costly. Heart failure is the leading diagnosis for Medicare hospital admissions and readmissions. Chronic kidney disease goes undiagnosed until it reaches the severe stage for 90% of people affected. End-stage kidney disease means dialysis or transplant and costs Medicare $66,000 to $95,000 a year per person living with it. On average, 130,000 new people begin dialysis every year in the United States. Compared with their White peers, African Americans are four times more likely to develop end-stage kidney disease. Hispanic and American Indian patients are twice as likely. These realities speak to the significant unmet needs for protective treatments that prevent dialysis, hospitalization, and death. Farxiga also represents the benefits of continuing innovation and exploring and gaining new indications. Since first gaining FDA approval in 2014, Farxiga has received four more approved indications. Having a single medicine taken once a day that works across multiple conditions can help improve adherence and outcomes for people with one or more of these illnesses or at risk of developing them. Today, my key unanswered question is, with the conditions treated by Farxiga among the most common comorbidities in Medicare, how will CMS weigh the benefits of medicines across multiple chronic conditions? The total benefit is more than the sum of the parts. Medication options that are easy to use and reduce polypharmacy have benefits for each condition treated individually, as well as benefits associated with treating comorbid conditions and risk factors. The extent to which CMS considers unmet needs relating to commonly co-occurring conditions will have an immediate impact on its evaluation of Farxiga. It will also encourage or discourage others to pursue research into additional indications that address unmet needs for

people living with more than one chronic condition. Thank you so much for considering these comments and the opportunity to present them.

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Douglas Jacobs, MD, Chief Transformation Officer, Center for Medicare

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Now we'll move to our final speaker. Please welcome **[INFORMATION HAS BEEN REDACTED]**, who registered as a representative of a patient advocacy organization. **[INFORMATION HAS BEEN REDACTED]** declined to report whether they have a conflict of interest. Let's welcome **[INFORMATION HAS BEEN REDACTED]**.

00:22:55

Speaker 5

Hello. My name is **[INFORMATION HAS BEEN REDACTED]**. I'm **[INFORMATION HAS BEEN REDACTED]** Survivors for Solutions. I want to thank CMS for engaging with patients to discuss the policy impact of the policies we're talking about today. I believe our experiences here provide the missing perspective about the real risk that this is putting on real patients. Regrettably, this effort delivers blunt force trauma to a finely balanced medical discovery ecosystem. This policy knowingly risks how Farxiga and countless other innovations are discovered at all. Most troubling is it endangers the hope of people who need it most. When I was diagnosed with an incurable chronic and progressive disease, there were zero disease modifying treatments or DMTs to slow my path to complete disability. That soon changed thanks to public policy that encouraged both cutting edge treatments and low-cost generics. Research could rationally take risks based on predictable public policy. At 28, MS basically fried my nervous system. The first DMT, which worked for many, wasn't working for me. Out of options, my father checked me out of the nursing home I now required into my parents' basement. Thankfully, around this time, a second MS therapy was proved by the FDA. I had hope and a plan B. And I can say without reservation, it saved my life. In five years, I went from being unable to walk or swallow to rejoining a meaningful career I thought was over, meeting my future wife, and starting a family. I'm here today so you can please look a patient in the eye who has needed four different breakthrough drugs over 35 years. Most patients can't afford for that pipeline to end. No one knows better than me that these treatments don't grow on trees. I know cost can be a problem, but it's not the problem. Our illness is the problem. The last thing we need are fewer options to fight disease. Had the IRA slowed innovation for me then, the way it is now, I would have spent my life as a burden or a ward of the state. We're discussing one of the ten different drugs that all have one thing in common, they have helped a lot of people. Contrary to popular belief, this is not an effort to lower patient cost, but to target successful therapies that the government doesn't want to pay for. When a solution goes undiscovered, it doesn't just harm people most in need, it hurts the whole country. Lost revenue, lost productivity, lost lives. Thank you for your time and I hope to look forward to sharing more of my patient experience during future sessions.

00:25:56

Douglas Jacobs, MD, Chief Transformation Officer, Center for Medicare

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Thank you all so much 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.