Transcript: Jardiance, November 8, 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 Jardiance, 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 of 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 our 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 Jardiance 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 help keep time and 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]**.

00:07:44

Speaker Remarks

Speaker 1

Thank you. Good afternoon. My name is **[INFORMATION HAS BEEN REDACTED]**. I'm a 74-year-old male who is extremely active and self-sufficient. In **[INFORMATION HAS BEEN REDACTED]** 2022, I suffered my second ventricular tachycardia attack. However, this one took the form of what is known as a storm and couldn't be controlled. I had to be med flighted off of **[INFORMATION HAS BEEN REDACTED]** to **[INFORMATION HAS BEEN REDACTED]**, where I spent the next 35 days in **[INFORMATION HAS BEEN REDACTED]** Hospital. When I returned home in **[INFORMATION HAS BEEN REDACTED]**, I began my recovery, and once I regained some strength, I attended the cardiac rehab at **[INFORMATION HAS BEEN REDACTED]** Hospital in **[INFORMATION HAS BEEN REDACTED]** '22. Over the next three months, I gained confidence and strength. My recovery was slow and frustrating. As I stated before, I'm extremely active and I couldn't walk up a hill without shortness of breath, leg cramps, my energy levels were low, and I was napping at various times during the day. Over time, things got marginally better. In June of 2023, I was still experiencing a lot of the same difficulties when it came to energy level, shortness of breath, and leg cramps. At my six-month appointment with my electrophysiologist, she prescribed a ten-milligram dose of Jardiance to be taken once daily. By the beginning of July, only three weeks later, there was a marked improvement in my condition. Over the next four weeks, almost all my issues with energy, shortness of breath, and leg cramps were diminished to the extent that they were unnoticeable. Both my friends and family were well aware of the changes taking place. I can only attribute this benefit to the addition of Jardiance in my daily routine. Thank you.

00:09:27

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

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

00:09:40

Speaker 2

Good afternoon. My name is **[INFORMATION HAS BEEN REDACTED]**, and I represent the Mended Hearts, the world's largest peer-to- peer cardiovascular patient support network, boasting over 100,000 members.

Personally, I live with a structural heart defect and have navigated three open heart surgeries, numerous medical interventions, and prescribed medications. 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 yearly, 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. The medication Jardiance has shown effectiveness in treating heart failure patients with both reduced and preserved ejection fractions, substantially lowering the rate of hospital admissions for heart failure patients. Its inclusion in the clinical arsenal is crucial to addressing the heart failure crisis, offering patients a chance for extended quality of life with minimal dependence on invasive procedures and treatments. 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, prescription payment plan, and expanded low-income subsidies strive to make drugs more affordable and accessible. However, as the new law unfolds, there are pressing concerns we urge CMS to address. Without safeguarding access or addressing formulary tiering issues that may result as unintended consequences from the price negotiations of selected drugs, there's a risk that medications like Jardiance could be relegated to non- preferred formularies, which will result in the opposite of the new law's intended effects, higher out-of-pocket costs for patients. We are also apprehensive about the law's potential ripple effect in the cardiovascular disease 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 cardiovascular drug development, such as high clinical trial expenses and comparatively low success rates. We urge CMS to assuage the concerns that the new law may limit access by categorizing them under non preferred formularies or that patients may experience unchecked utilization management practices that would result in fewer patients being treated by safe and effective drugs that are accessed by hundreds of thousands of Medicare beneficiaries. Thank you for your time and consideration.

00:12:30

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 Lubna, who registered as a healthcare provider who has experience prescribing, dispensing, or administering the selected drug or its therapeutic alternatives. Lubna declined to report whether they have a conflict of interest. Welcome, Lubna.

00:12:49

Speaker 3

Thank you for the opportunity to address you today on a matter of great importance. I am Dr. Lubna Mirza, an endocrinologist practicing in Norman, Oklahoma. As we know, diabetes is a very serious and chronic disease that causes multiple serious complications, including blindness, kidney failure, foot amputations, heart attacks, and strokes. 37 million Americans are living with diabetes today. Many of them are elderly and need several medications, including multiple daily injections, insulin injections to control their blood sugars. It is difficult for many of my patients and their aging partners to administer multiple daily injections with weakened eyesight and hand grip. Some of these patients are requiring home health assistance for

administering these medications. Jardiance is an effective and generally well tolerated medication with very few side effects. It can help our patients control their blood sugars and reduce the risk for complications. Regrettably, it has remained beyond the reach of Medicare patients. While I was working on taking notes for my presentation today, my nurse advised me that the prescription I wrote yesterday for a patient was not able to be filled since it was costing them $400. We are dealing with this situation on a daily basis. Jardiance is taken by mouth. It's not an injectable, it's once daily. It improves adherence. Jardiance is not associated with weight gain, critical hypoglycemia, or gastrointestinal side effects, as we see with other medications that we have been prescribing for a long time, including glipizide, metformin, or even insulin, causes weight gain and severe hypoglycemia. Studies show that Jardiance not only improves blood sugars, but it also benefits in blood pressure reduction and weight reduction. Jardiance decreases the risk for heart failure. As one of the previous speakers mentioned, it reduces the risk for kidney failure and hospitalizations that can reduce cost over long term. So we should look at the long-term outcomes instead of short-term benefit of saving money. As a practicing endocrinologist taking care of my Medicare patients, I strongly believe that making Jardiance accessible and affordable is going to make a difference. It's going to help improve lives and reduce overall health costs by reducing complications, hospitalizations, and death. Let us remember that the price of medication should never be an obstacle for a patient and their well-being. It is our collective responsibility to ensure that all Medicare patients can access and afford this life changing medication, which includes my mother. She also takes Jardiance and I would be very happy if she can access this much needed medication. Thank you.

00:15:49

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

Thank you, Lubna. 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]** declined to report whether they have a conflict of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

00:16:03

Speaker 4

Hello, I'm **[INFORMATION HAS BEEN REDACTED]**. **[INFORMATION HAS BEEN REDACTED]** Survivors for Solutions. I want to thank CMS for engaging with patients who have to survive the policies we're discussing here today. I believe our experiences provide the missing perspective about the real risk 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 Jardiance and countless of other innovations are discovered at all. When I was diagnosed with an incurable, chronic, and progressive disease, there were zero 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. At age 28, MS basically fried my central 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, and into my parents' basement. Thankfully, around this time, a second MS therapy was approved by the FDA. I had hope, I had a plan B. Within five years, I went from being unable to work, walk, or swallow to rejoining a meaningful career I thought was over, meeting my future wife, and starting a family. I'm here today as living proof of this fact: that America's patients can't afford for that

pipeline of cures to end. I also know full well that costs can be a problem, but it's not the problem. Our illness is the problem. And the last thing we need are fewer options to fight disease. Had the IRA slowed innovation for me then, the way it's doing now, I would have spent my life as a ward of the state. We're discussing here today one of ten different drugs that all have one thing in common, they help a lot of people. Contrary to popular belief, this exercise is not 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 the people most in need, it hurts the whole country. Thank you for your time, and I look forward to sharing more about my patient experience next time.

00:18:44

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]**.

00:18:57

Speaker 5

Thank you. Hi, I'm **[INFORMATION HAS BEEN REDACTED]** with the Partnership to Fight Chronic Disease. Thank you so much for this opportunity. Type 2 diabetes is common in my family. We had a family elder die from diabetes-related complications, amputation by amputation. In the 20 years since his death, advancements in diabetes treatments have been remarkable. Recently, that man's nephew was advised that the metformin and glipizide he'd taken for years were no longer working to maintain recommended A1C levels. His options: insulin or try Jardiance. He opted for once daily Jardiance. Within a few weeks, his A1C levels were like those associated with people without diabetes and have remained there. He still takes dozens of pills daily to maintain his health, but Jardiance replaced multiple doses of another medicine and had no contraindications despite his complex regimen. In fact, Jardiance has the added benefit of heart and kidney protective effects, both critically important to him and the millions of beneficiaries living with diabetes and common heart or kidney comorbidities. Jardiance also represents the benefits of continuing innovation in exploring and gaining new indications. Since first gaining FDA approval in 2014 for type 2 diabetes, Jardiance has received additional approvals for heart failure and chronic kidney disease. For heart failure, Jardiance reduces the risk of death and hospitalization. For chronic kidney disease, Jardiance prevents decline in kidney function end-stage kidney disease, death, and hospitalization as well. One in three people with diabetes also has chronic kidney disease, and people with diabetes are twice as likely to have heart disease. Having a single medicine taken once a day that works across multiple conditions can help to improve adherence and outcomes for people with one or more of these illnesses or at risk of developing them. Research on Jardiance also has shown other improvements important to patients, including reduced symptoms, fewer physical limitations, and improved quality of life scores. Today's unanswered question is, what will CMS consider as unmet medical needs in the context of drug pricing? This spring, the Partnership released survey results of what older adults consider unmet medical needs when it comes to treatments. The priorities they identified are particularly relevant to Jardiance and include addressing reduced toxicity and side effects and promoting the ease of treatment, like fewer doses in easy

to take forms. People also rank the needs of underserved populations, including people disproportionately affected by disease, and accounting for the needs of people who have tried and failed on other treatments, as priorities. A singular focus on the drug at hand without that broader context and realities for beneficiaries has serious flaws and risks missing what patients consider unmet needs most meaningful to them. Thank you.

00:21:54

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 patient who has experience taking the selected drug or other treatments. **[INFORMATION HAS BEEN REDACTED]** reported a conflict of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

00:22:08

Speaker 6

Good afternoon. I'm **[INFORMATION HAS BEEN REDACTED]** and I'm grateful for this opportunity to speak on this important topic of CMS negotiations as both a patient and a healthcare advocate. I was 36 years old and five days postpartum when I suffered a massive heart attack that was misdiagnosed for an entire week. I dissected five coronary arteries and underwent an emergency quadruple bypass. In the months that followed, I had two additional heart attacks, suffered with recurrent pericarditis, developed arrhythmias, had an internal defibrillator and pacemaker placed, and eight months after my initial bypass, the grafts occluded. I had aneurysms all throughout my heart and my apex became aneurysmal. My ejection fraction was 21% and I was in heart failure. I required two additional open-heart surgeries where part of my heart was cut off and 15 laser holes were drilled in my heart. At 37 years old, despite being a former economist with the Department of Commerce, with undergraduate degrees in economics and business and finance, and a master's degree in business administration, I ended up on Social Security disability with Medicare as my coverage because I was too ill to work. First, it's a fact that drug affordability is a real concern for patients. I personally have had to choose between medicine and other basic necessities such as food, transportation, and housing. Second, I'm really concerned about the possibility that heart failure patients won't receive the standard of care as a result of these price negotiations. After recovering from my catastrophic illness, I became a healthcare advocate, and I've served as a member of the Advocacy Committee for the Heart Failure Society of America and on their inaugural Patient committee. I was board member and chair elect of Women Heart, the National Coalition for Women and Heart Disease, and I also served as a board member for two hospitals within the West Virginia University Healthcare System for six years. What each of these advocacy endeavors reaffirmed for me was the fact that heart failure patients are not receiving guideline directed medical therapy and that African Americans and other underserved populations are disproportionately impacted, as the previous speaker stated. SGLT2 inhibitors such as Jardiance, became the fourth pillar of care for heart failure in the spring of 2022 and they have additional benefits for comorbidities such as diabetes and kidney disease. I implore you to make sure that this standard of care remains available and accessible to all. And finally, medical innovation and cutting-edge therapy saved my life. My hope is that these negotiations will find an equitable balance between governmental cost savings and pharmaceutical company profit margins so that innovation and research

continue and that patients continue to reap the benefit from them. Thank you.

00:25:18

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 Letty, registered as a healthcare provider who has experience prescribing, dispensing, or administering the selected drug or its therapeutic alternatives. Letty reported no conflict of interest. Welcome, Letty.

00:25:35

Speaker 7

Hello, my name is Letty Lara. I'm an emergency room nurse, so I am one of the first faces patients see when they present to the ER in acute heart failure exacerbation. Heart failure affects approximately five million Americans, results in nearly one million annual hospital stays, and is the top reason for Medicare hospital readmissions. More than 80% of ED patients with acute heart failure are admitted to the hospital and have a median inpatient length of stay of approximately 3.4 days. Of the $39.2 billion spent on heart failure care in the United States in 2010, hospital stay was the single largest proportion of this expenditure. Quite simply, these visits can be significantly decreased, if not altogether mitigated. As **[INFORMATION HAS BEEN REDACTED]** mentioned, the 2022 Guidelines for the Management of Heart failure, written by the American Heart association, the American College of Cardiology, and the Heart Failure Society of America, include the utilization of four critical medications, referred to as "Quad Therapy." Jardiance is one of those medications. In fact, three of the ten medications selected for price negotiation, excuse me, price negotiation, are used for Quad Therapy in the management of heart failure. The top reason for noncompliance, as we've all kind of mentioned with the guideline directed medical therapy, is cost. Patients simply cannot afford to access these lifesaving drugs. As a result, they go without and ultimately make frequent unnecessary hospital visits. Our hospitals are already overburdened, but more important than that is the fact that we have the resources to provide evidence-based care to this patient population, yet patients are simply priced out of having access to the medication. To the pharmaceutical companies, I'm aware that you have a lot of resources invested in R&D to safely introduce these medications to market, but you also have a responsibility to help people be healthier by supporting better access and care. Ensuring that this vulnerable population has access to guideline directed medical therapy is simply the right thing to do. Thank you.

00:27:40

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

Thank you for your comments, Letty. 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 no conflicts of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

00:27:54

Speaker 8

Good afternoon. Thank you. My name is **[INFORMATION HAS BEEN REDACTED]** and I'm an advocate and patient living with chronic conditions, one of which is type 2 diabetes. **[INFORMATION HAS BEEN REDACTED]** Chronic Care Policy Alliance. The CCPA brings together advocacy groups to make our voices louder as we work to improve the lives and health of those living with chronic disease. I became a health advocate because of my own struggle 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. Once you have a health issue that doesn't resolve, or in other words, a chronic condition, the struggles do not stop. Both my husband and I were placed on Jardiance to control type 2 diabetes. My husband is still on the medication and doing very well. His HBA1C dropped three points from nine to six in a relatively short time. I also felt great on Jardiance and it did bring down my A1C, but I had a major side effect and had to stop using it. I've tried two additional medications. The third is still working for me now and I'm doing well on it. My family's experience is a small illustration of how every patient is unique and depends on having a variety of medications to find out which one works for them. 37 million Americans, about one in ten, have diabetes, and approximately 95% of them have type 2 diabetes. Type 2 diabetes most often develops in people over the age of 45, so fast approaching the Medicare age. But recently more children, teens, and young adults are also developing it. There is currently no cure for diabetes. People with type 2 diabetes have cells that are insulin resistant. Older medications have more side effects, don't work, or continue to force the body to make more insulin for cells that are resistant to it. New medications work more effectively and have different approaches to managing blood sugar. Maintaining blood sugar levels is critical to avoiding increased costs of outpatient care, emergency room visits, hospitalization, and controlling the complications of diabetes such as vision and limb loss, heart disease, chronic kidney disease, nerve damage, and other problems with oral health, hearing, and mental health. As in my own care, access to new, better, and more effective medications is important to the patient's ongoing health as the patients require regular monitoring and ongoing treatment to maintain normal or near normal blood sugars levels so their disease does not progress. Medicines are medical miracles for many. We applaud the efforts to reduce the price of medications to better ensure access to them, but we ask CMS takes in the big picture of patient need for access to medication. Please take care to preserve innovation and access to innovation as you seek to make medications more affordable. We believe that making patients the center of the conversation during the negotiations is critical. Thank you for the opportunity to present these comments today.

00:31:09

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

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

00:31:20

Speaker 9

Good afternoon. My name is John Clymer. I am 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 Collaborative, 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. The National Forum appreciates the opportunity to provide input today. We urge CMS to ensure its Drug Price Negotiation Program provides beneficiary access to the right treatment for the right patient at the right time. People who have cardiorenal metabolic conditions are at higher risk for worse health outcomes, hospitalizations, and early death. I know from my family's experience what some of the previous speakers today have attested to, that these often-interconnected conditions harm people's everyday lives. Empagliflozin slows the progression of, and, as pointed out previously, is a guideline directed treatment for all three debilitating conditions. The Price Negotiation Program must not worsen access to empagliflozin for populations disproportionately affected by CRM conditions. The prevalence of CRM conditions is highest among Blacks and American Indian/Alaska Natives, Hispanics, and Asian Pacific Islanders. Disparities are also present based on sex and socioeconomic status. We recommend CMS work with the Office of Minority Health to achieve this imperative. The heart failure population accounted for 41% of Medicare inpatient admissions, 55% of readmissions, and 50% of skilled nursing facility admissions. It's better for beneficiaries to treat them with medications that keep them out of hospitals' revolving doors, and it's less costly for Medicare. A person with heart failure costs Medicare more than triple what the general population costs. However, out-of-pocket costs affect the individual's access to medications. Among SGLT2s, empagliflozin users have significantly higher adherence and persistence rates, which are important for CRM management. 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 priced drugs offer the PBMs bigger rebates. Finally, we support the implementation of evidence-based care that aligns incentives for patients, providers, pharma innovators, and purchasers.

00:34:42

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

Thank you for your comments, John. Now we'll move to our final speaker. Please welcome Bich-May, who registered as a healthcare provider who has experience prescribing, dispensing, or administering the selected drug or its therapeutic alternatives. Bich-May reported no conflicts of interest. Let's welcome Bich-May.

00:35:01

Speaker 10

Thank you for inviting community members to speak about the impact of high drug prices. I'm a family physician with over ten years of clinical experience. I serve on the Board of Doctors for America, a nonpartisan advocacy organization made up of 27,000 physicians and medical students in all 50 states. DFA focuses on what is best for our patients and does not accept any industry funding. When I was a medical student first rotating through hospitals, I saw a lot of patients who were hospitalized for diabetes and complications from diabetes, such as dialysis for chronic kidney disease and amputations for bone infections. We had to use insulin to get their diabetes under control, and it wasn't until my family medicine rotation that I understood that people could take pills to manage their diabetes. Since I graduated from medical school, there are now more classes of drugs that treat diabetes, and empagliflozin one of those drugs, a once daily pill. First, we should consider how effective is empagliflozin. It lowers the hemoglobin

A1C 0.5 to 1 percent, and it can help with outcomes that matter to patients. One study that added empagliflozin, or placebo, to existing type 2 diabetes treatment in older patients who had preexisting cardiovascular disease demonstrated lower all-cause mortality, a number needed to treat of 38 over 3.3 years, cardiovascular mortality, an NNT of 45 over 3.3 years, and hospitalization for heart failure, an NNT of 71 in the empagliflozin group versus the placebo group. There are no long-term data on morbidity mortality benefits in patients without pre-existing cardiovascular disease, and this benefit has not been documented with other drugs in this class. It's also important to consider side effects. Some people may experience weight loss about three to four pounds. Rare serious side effects include low levels of blood or fluids in the body and low blood pressure. The number of people taking this medication for one person to develop one of these serious side effects, or number needed to harm, NNH, is 335. It's generally well tolerated, with no greater discontinuation rate than placebo. Over three years of treatment, about 10% of women or an NNH of 14, and 5% of men or an NNH of 29, report a genital yeast infection. Another important note is that empagliflozin was FDA approved for type 2 diabetes in 2014 and there are no generic alternatives available. The price for a 30-day supply of empagliflozin ranges from $578 to $1,000 on a price comparison website. Yesterday during the sitagliptin session, I shared statistics about America's drug price problems and pharmaceutical R&D that I won't repeat today. Instead, I want to draw your attention, as other speakers have to how high drug prices for diabetes are a health equity issue. Diabetes is prevalent in a high proportion of Native American, Alaska Native, Black, and Latino adults in this country. Differences in diabetes prevalence are also seen by socioeconomic position, which is defined by a level of education attained and the income to poverty ratio. Historically marginalized populations bear disproportionate burden of this disease, and to achieve health equity and care and improve outcomes of this complex chronic condition that can impact the body in so many debilitating ways, we must address high prescription drug prices. While there is benefit with empagliflozin reducing risk for death due to heart disease or hospitalization for heart failure, American taxpayers have helped to subsidize its development. I'm not sure why we have to pay such high drug prices for these drugs once they're available, so I'm glad the drug makers negotiate with CMS. Thank you very much for your time.

00:38:04

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

Thank you for your comments, Bich-May, and 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.