Transcript: Entresto, November 1, 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 Entresto, 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 an 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 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 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 Entresto 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 representative of a patient advocacy organization. **[INFORMATION HAS BEEN REDACTED]** reported no conflicts of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

00:08:11

Speaker Remarks

Speaker 1

Thank you and good morning. My name is **[INFORMATION HAS BEEN REDACTED]** and 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. Thank you for holding 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. 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. If there's one thing I want to be taken away from my comments is that every patient is unique and depends on the medical miracles that continue to be developed in this country every day. I'd also like to add that my husband is among those with cardiovascular disease, so access to medications for related conditions is an issue very close to my heart. Unrestricted access to the full breadth of life-changing medicines is critical to a patient's ability to function, contribute to society, and in many cases, even how long they live. Patients want to ensure that the development of life-changing medications continues and that they 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 or that work better for them due to more refined formularies that prioritize negotiated drugs above other options. As the negotiation progresses, we urge CMS to consider whether the price it negotiates protects patients who use the product while also 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 innovations for indications and existing cures. CMS should ensure that the negotiation does not spur greater restrictions to access or lead to stricter utilization management. Additionally, CMS should take great care to also protect patients using products off label or in different doses from being penalized or their care interrupted due to the negotiation process. This would be especially evident for people with chronic conditions and rare diseases who we represent. Thank you again for the opportunity to present these comments.

00:10:58

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 John, who registered in the category of other. John reported a conflict of interest. Welcome, John.

00:11:11

Speaker 2

Thank you. 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 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. The National Forum appreciates the opportunity to provide input today, as it will have a rippling effect on population health in the short and long term. Heart failure, the condition sacubitril/valsartan treats, makes everyday activities such as walking, climbing stairs, or carrying groceries difficult. People with heart failure that is not well managed often are swept into the revolving door of hospital readmissions, harming their well-being while raising costs to Medicare and the taxpayers who fund it. 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 over 70% of all patients hospitalized with heart failure are Medicare beneficiaries, it is essential that this policy improves and not reduces access to sacubitril/valsartan. It is imperative that this program not worsen access challenges for disadvantaged populations. The prevalence of heart failure among Medicare fee-for-service beneficiaries is highest among Black and American Indian Alaskan Natives. We recommend CMS work with the Office of Minority Health to achieve this requisite. We urge CMS to guard against potential unintended consequences. Price ceilings intended to benefit consumers 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 PBMs bigger rebates. Heart failure therapies are not interchangeable. In multiple clinical trials, treatment with sacubitril/valsartan achieved a relative risk reduction for hospitalization or death of 20% or more compared to alternative therapies. The magnitude of benefit was even higher in Black patients than Whites. 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 ensure the Medicare Drug Price Negotiation Program supports evidence-based strategies for appropriate care and protects beneficiary access, guards against potential unintended consequences such as utilization management that could result in reduced access to appropriate treatment and aligns incentives for all stakeholders. Thank you for this opportunity.

00:14:37

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

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

00:14:53

Speaker 3

Thank you and good morning. CMS, thank you so much for listening and trying to understand the major struggles and stresses of an everyday patient. My name is **[INFORMATION HAS BEEN REDACTED]**. I'm 70 years old, **[INFORMATION HAS BEEN REDACTED]**, New York, retired and have a beautiful family with four grandkids that I want to see grow up. I've been living with type 1 diabetes and its complications for over 51 years. I have worked within the healthcare RX systems we deal with for five decades. So my story covers some of how I dealt with these barriers of care over the years. Diabetes, leg amputation, and most recently suffering an emergency triple bypass. Believe me, this is a 24/7, 365 days a year job. I am always on high alert with all of my meds. Many do not realize what additional stress this presents, besides living with the disease itself. My fellow seniors and I every day worry about this. This should not be happening, as costs and access to drugs are out of control. I take a variety of drugs to stay alive. Two of the most expensive are insulin and Entresto and on the top ten drug list for negotiations. In 2020, I had an emergency triple bypass. After trying various different prescriptions and cardiologists, my new cardiologist prescribed Entresto 24/26, two times a day. This was a drug with no substitutes and revolutionary and the first drug that worked for me. After many adjustments, my ejection fraction finally rose to where my doctor was pleased. He had given me samples to try and I was on the road to recovery, I thought. First, fast forward, filling the first script and Entresto's list price today is $667. I received a 90-day supply, which is tier three drug under Medicare Part D. This year so far, I've paid $529, $565, and another $500 to come, equaling about $1800 out of my pocket. This revolutionary drug is way overpriced for most seniors, so they just take lower cost generic beta blocker and do not experience the advantage of Entresto. Entresto sales in 2022 was up 37% to $4.6 billion, while my out-of-pocket costs continued to increase. Does this seem to be a fair price? Usually, purchasers of high-volume products always get a better deal. Why not with high volume of Medicare recipients we offer the manufacturers? Just think of how many seniors with heart failure that could take advantage of Entresto if the price was lower. There are so many seniors that cannot afford this medicine to stay alive. The upshot of that is rationing of their drugs. How on earth can you stay on top of your health if you cannot afford the medicines prescribed for you to stay alive? This is an area where successful Medicare drug negotiations can shine. Better patient compliance leads to better outcomes in all areas. As a result, I struggle every month with my financials and my health. I can assure you this. Worrying –

00:18:15

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

I'm sorry to interrupt. **[INFORMATION HAS BEEN REDACTED]**, your three minutes are over. I'll give you a moment.

00:18:21

Speaker 3

That stress is not good for your health. The stress and strains of this cause a lot of mental distress which is not discussed. I am full support with Medicare negotiation, and it will be an historic move and help us save money. CMS, thank you for your hard work. We are on the tip of the iceberg for a better way of living with chronic illness. Thank you.

00:18:42

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 the patient advocacy organization. **[INFORMATION HAS BEEN REDACTED]** declined to report whether they have a conflict of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

00:18:58

Speaker 4

Good afternoon and thank you for the opportunity to comment on the CMS Drug Price Negotiation Program. My name is **[INFORMATION HAS BEEN REDACTED]** and **[INFORMATION HAS BEEN REDACTED]** of the Partnership to Advance Cardiovascular Health, or PACH. PACH is a cardiovascular patient and provider advocacy coalition that works to ensure that clinicians and patients' voices are represented in policy conversations concerning access to treatment. Our coalition is comprised of 17 different organizations from across the cardiovascular spectrum, so we believe we have a unique perspective on this program specifically, as five of the ten selected drugs have cardiovascular disease indications, and two others are under what we consider the cardiometabolic umbrella of treatments. Our country is at an inflection point when it comes to cardiovascular disease. After a half century of remarkable progress in cutting the death rate due to cardiovascular disease, America's progress has stalled. It was once believed that cancer would overtake cardiovascular disease as America's number one killer, but it clearly is no longer the case. The formula for our initial progress is well documented. Extraordinary public health efforts were put into campaigns for smoking cessation and other risk mitigating behaviors. Our understanding increased regarding the links of diet and exercise, and importantly, a veritable renaissance occurred where numerous medications and procedures came to market that truly changed the game for cardiovascular medicine. Entresto is one of those medications. For the 6.2 million Americans impacted by heart failure and the half million Part D beneficiaries who benefit from taking Entresto for their heart failure, many are fortunate to see a meaningful risk reduction of heart death and hospitalization. Unquestionably, this saves the healthcare system tens of millions of dollars. It's important to remember that cardiovascular disease disproportionately impacts vulnerable and historically underrepresented communities, including minorities, aging populations, rural communities, and those with lower socioeconomic status. For example, Black men and women have, respectively, a 70% and 50% higher risk of heart failure than their White counterparts and Medicare claims studies have shown that Black and Hispanic patients with atrial fibrillation, for instance, have a higher unadjusted risk for death and stroke. Obviously, treatments like Entresto offer immense value to the Americans who need it most. In human terms, what this all means is that treatments like Entresto give Americans more time with their family and their friends doing the things that give them joy and meaning in life. Gardening, time with grandkids, fulfilling life's ambitions and goals. I don't know how you put a price on that and therefore I don't envy your job. I mentioned at the beginning of my comments that America is at an inflection point when it comes to cardiovascular disease. Patients need access to these treatments and pipeline therapies in order to continue making progress on America's number one killer. I want to implore CMS to ensure that as this program is implemented, you meaningfully monitor utilization management of the medications that are being negotiated. We believe that many aspects of Part D redesign will help America's seniors with cost. However, we also believe that these policies could incentivize pharmacy benefit managers to make access to medications like Entresto all the more difficult. Ask any prescriber of cardiovascular medications their experience in the last ten years about the

difficulty getting their patients on therapy and they will tell you that utilization management for cardiovascular therapies has gotten out of control. One claims study showed that between 2014 and 2020, prior therapy protocols –

00:22:24

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

Sorry, **[INFORMATION HAS BEEN REDACTED]**. Your three minutes are up. I'll give you a moment to finish up.

00:22:28

Speaker 4

Yeah. Thank you. These medications do no one any good if patients can't access them. Please implement this program in such a way that this burden does not increase. Thank you for your time.

00:22:39

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]**.

00:22:53

Speaker 5

Thank you. Good afternoon. My name is **[INFORMATION HAS BEEN REDACTED]**, representing Mended Hearts, Inc., the world's largest peer-to-peer cardiovascular patient support network, boasting over 100,000 members. Personally, I live with a structural heart defect, navigated three open heart surgeries, and 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 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 between 40% and 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 the 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 that we urge you to address. Without safeguarding access or addressing formulary tiering issues that may result as an unintended consequence from the price negotiations for the selected drugs, there is a risk that medications like Entresto could be regulated to non-preferred formularies. Entresto is demonstrated to be accessible to beneficiaries with a recent HHS ASPE report showing that beneficiaries only pay approximately $29 per patient per month. Please ensure that we don't take a step backwards in terms of access. We are also apprehensive about this law's potential ripple effects in the cardiovascular sector. Five out of the ten drugs selected for price negotiation are used in treating heart patients. This 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. My heart condition, known as a single ventricle heart disease with Fontan circulation, unfortunately has a natural history course that often leads to heart failure. Currently, some patients with unrelated heart failure are treated off label with Entresto. To determine the effectiveness of this drug, clinical trials are necessary, but the Medicare Price Negotiation Program might hinder sponsors from conducting trials for additional indications, putting patients like myself in the dark about the potential benefits of existing drugs on rare disease populations. We urge CMS to work to assuage the concerns that the new law may limit medication 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.

00:25:57

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

00:26:16

Speaker 6

Hello. Thank you so much. My name is Ray, or Dr. Ray, as some of my pediatric patients call me. I'm a pediatric cardiologist, and for those who don't know kind of the breadth of that specialty, I take care of pediatric patients, but also adult patients because many of our patients have complex heart disease, as the last speaker was mentioning, and require pediatric cardiology to care for them for the duration of their life. And as they either have heart failure that stems from their congenital heart disease or from adult style heart disease, more traditional heart disease, we use medicines including Entresto, to treat this disorder. And Entresto has been shown independently from other types of medicine for heart failure to have effects that greatly benefit patients, both in terms of how productive they can be during their lives, but also how productive they can be in their personal lives. It makes them more efficient, it makes them have higher energy, and it's important that these patients stay on their medications so that their heart failure doesn't return and that they don't have unintended consequences from stopping medicine. I want to say that in addition to caring for patients, I am an active member of my medical societies, both on the state and national level, and participate in their democratic policy making. We have discussions around these medicines on an annual or twice annual basis, and there are a number of patient stories that we hear during these discussions that are quite disheartening, where patients have not been able to access medicines or have not been able to stay on medicines because of cost. And I'll mention just a couple of patients at our institution specifically, aside from all the stories that I've heard, our institution specifically, we were caring for a 63-year-old patient who had a congenital heart disease and required Entresto. But after a number of prescriptions, their insurance maxed out, and they weren't able to cover the so-called donut hole where they have to pay out-of-pocket until they reach their deductible. This resulted in the patient having decreased heart function, and by chance, because we didn't anticipate this, they required a surgery for their

GI tract or their stomach, and this puts them at higher risk. And this is just one example of a number of ways that loss of medications and decrease in heart function can have serious consequences. What CMS has done and the IRA has done to increase or attempt to increase affordability and increase access for these medicines is crucially important. And I would say simply that although regulation oftentimes attempts to increase benefits for all participants in the medical system, I think the IRA's focus on patients in this instance is crucially important, and very admirable. I support what they are doing, and I will tell my patients to look forward to these regulations coming into place. Thank you so much.

00:29:37

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

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

00:29:53

Speaker 7

Hi. My name is **[INFORMATION HAS BEEN REDACTED].** I'm a mom, first-time grandparent, writer, patient advocate, **[INFORMATION HAS BEEN REDACTED]** the Global Healthy Living Foundation. But most importantly, I'm a six-time heart failure survivor who is here today to share how Entresto contributed to another chance at a productive life. In 2019, I unexpectedly found myself struggling to breathe while experiencing swelling throughout my entire body. It was so extensive, I could barely fit on a pair of shoes. I was rushed to the hospital, then admitted for further testing. Hours later, I had to be relocated to the ICU for heart failure. I was only 41 years old at that time and a single parent with two kids who were still dependent on me. Even as I was gasping for air to breathe, and being told flight for life was on standby if my vitals did not improve, the only thought that crossed my mind was needing to survive so that my children would not be motherless. That terrifying ordeal was brief and required a few days in the ICU to recover. Once I was released to go home, there was a variety of medications to take daily and follow up appointments with a cardiologist to keep me on the mend and hopefully back to my life as it was before. Lifestyle changes were made by implementing healthier eating habits along with moderate exercise. I was even switched off one prescription, added in some new ones, while incurring array of symptoms like weight gain, nausea, lightheadedness, and anxiety. Unfortunately, those lifestyle alterations I made only failed. Over a span of a year and a half, I would find myself going into heart failure an additional five times and back into the ICU each time. I was mentally exhausted and frustrated from making great progress one month and then the next going back into the hospital. I fought even harder to find a treatment that could help me attend events with my kids and getting back to one of my favorite pastimes, which was traveling to new destinations. It was not until I began receiving consultation from another cardiologist that we decided to see if Entresto could lessen those unresolved stress on my heart. With the help of a nurse, I was able to fill out the file a request for patient assistance to be able to afford this medication. Within three months after my initial use of this medication, I noticed fewer issues with swelling in my legs and feet. I stopped feeling so fatigued doing the simplest tasks, like walking to my vehicle in the parking lot to go inside the grocery store. The part that proved my health had drastically improved, was the change in not having to make as many phone calls

to my cardiologist's office. This September has been two years I had been heart failure free. During that time, I was able to travel on several occasions across country and make fun memories with my grandson. A few months ago, I watched my youngest of three walk across the stage to receive his high school diploma, then helped him get established on campus where he started college this fall. With all those moments I created what I even was more grateful for was being able to celebrate my 46th birthday because my heart has benefited from adding Entresto as a preventative treatment for better health. Thank you for listening to my story.

00:32:49

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]**.

00:33:05

Speaker 8

Hi. Thank you so much. I'm **[INFORMATION HAS BEEN REDACTED]** the Partnership to Fight Chronic Disease and so appreciate you hosting these listening sessions. During our lifetimes, we've gone from having a few medicines to treat heart failure to having many, including Entresto. That innovation addresses significant unmet needs for the more than six million adults living with heart failure in the United States. In my life, heart failure has transformed a refusing to retire 82-year-old to an 85-year-old who loses his breath when tying his shoes. A walk up any stairs or incline requires multiple stops. Though extremely frustrating for him, he is alive and has avoided hospitalization, which are the two main clinical outcomes for heart failure. But clinical measures like ejection fraction mean little to him. It's his daily inability to catch his breath and the frustration and anxiety that causes that are most important. Studies have shown that Entresto positively affects these quality-of-life scores for people with heart failure, as well as improving clinical measures that are so important. Heart failure is expensive. Almost $2 out of every $3 spent on heart failure are for hospitalizations. Medicare covers most people with heart failure, and it is the most common hospital admission diagnosis and readmission cause within Medicare. Health inequities drive significant disparities in outcomes despite advances in heart failure therapy and survival overall. African Americans have the highest five-year risk of death after diagnosis and the highest hospitalization rates. They are also disproportionately diagnosed with heart failure, are often younger at diagnosis, and experience significantly higher death rates. Having multiple chronic conditions is also common. About 40% of Medicare beneficiaries with heart failure have five or more non-cardiac comorbidities, so optimizing outcomes requires having a variety of drug treatment options. Prescribers must not only consider contraindications, but also the heterogeneity of treatment effects, patient needs and preferences, and side effect profiles. Polypharmacy is a real issue. My loved one takes more than 25 pills a day. Today I close with an important unanswered question related to this, and that's how this effort will affect medicine access and choices for patients. Entresto costs Medicare around $400 a month for each person using it before any rebates. For Entresto the high prevalence of heart failure and the preferences of patients and providers are driving spending and its presence among the first ten drugs for Medicare pricing. Though CMS requires plans to

cover drugs subject to pricing, they are not now requiring better access or passing along the savings to patients at the pharmacy counter. Previous listening sessions and today have highlighted how PBMs and plans rely on rebates they negotiate to determine formulary placement and the fact that they tend to charge patients list price during deductibles and when calculating coinsurance. With no guarantee for better access or direct savings for patients, how access will be affected remains unclear and seriously concerning. Thank you again for the opportunity to provide comment.

00:36:22

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

00:36:37

Speaker 9

Hello, I'm **[INFORMATION HAS BEEN REDACTED]**. I'm **[INFORMATION HAS BEEN REDACTED]** Survivors for Solutions. I want to thank CMS for engaging with patients who have to survive these policies we're discussing here today. I believe our experiences provide the missing perspective about real risks 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 Entresto and countless other innovations are discovered at all. Most troubling to me is it endangers the hope of people who need it most. When I was diagnosed with incurable progressive chronic disease, there were zero disease modifying treatments or DMTs, to slow my path to total 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 years old, 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 parent's basement. Thankfully, around this time, a second MS therapy was approved by the FDA. I had hope, I had a plan B. I can say this without exaggeration that this drug saved my life. Within five years, I went from being unable to work, walk, or swallow to rejoining a meaningful career I thought was over, and me and my future wife started a family. I'm here today so you can look a patient in the eye who has needed four different breakthrough drugs over 35 years. My point here is most patients can't afford for this pipeline to end. I can't. No one knows better than me 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. And the last thing we need is 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 burden, a ward to the state. We're discussing today one of ten different drugs that all have one thing in common, they help a lot of people. Contrary to public 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 people most in need, it hurts the whole country. Whole country? Why? Less productivity, less innovation, less tax revenue, and slows our path to lowering suffering. I want to thank you for the time here. I look forward to sharing more about my patient experience in future sessions. Thank you.

00:39:51

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 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]**.

00:40:08

Speaker 10

Hi there. I'm **[INFORMATION HAS BEEN REDACTED]**, and I'm a patient living with heart failure. And **[INFORMATION HAS BEEN REDACTED]** Mended Hearts chapter **[INFORMATION HAS BEEN REDACTED]**, California. For over 25 years, **[INFORMATION HAS BEEN REDACTED]**, Maryland **[INFORMATION HAS BEEN REDACTED]**. A sudden cardiac arrest at work after hours when I was alone in my office led to my diagnosis of heart failure. Remarkably, miraculously, I should say, my heart managed to restart itself, and I'm here today. So following that diagnosis, I received an AICD, which was a safety net in case I had a future sudden cardiac arrest. And at that time, when I was diagnosed with heart failure, my research looked into heart failure, looked really grim. It seemed like maybe the average life expectancy was five years, and that was pretty frightening to me. But fortunately, my doctor prescribed Entresto to me in 2016 and this was key for my treatment and for much improvement in my condition. In the seven years since my diagnosis, even though I've had other heart related things go on, I have never been hospitalized for heart failure, and in fact, my current cardiologist says I'm well compensated with it because of the Entresto treatment. I'm really grateful for Entresto and the ability to manage my condition through this medication, which has allowed me to enjoy a post-retirement fulfilling life with family nearby in California. The transition from my school retirement insurance program to Medicare was a little bit shocking to me, as my medication costs went way up for the same prescription for the same condition. That really surprised me. However, my copays remain manageable for me because I have a good retirement system as a former educator, so I can continue to access this medication. I don't know if that would be true for other people who don't have the same kind of safety net insurance that I have. Thankfully, from the day that I was prescribed Entresto, I didn't have any hurdles in terms of receiving it. Like I said, the cost did go up when I switched to Medicare, but it's still within my budget and it really changes my life and what I'm able to do. I truly believe that Entresto was transformative for me. I'm really grateful for the doctor that first prescribed it for me. And I feel like he and that prescription really made a big change in my life. And I hope that it remains within reach and affordable to others, because I think it is a really helpful medication and I think people should be able to afford it and use it to change their lives. So I hope that others with a similar diagnosis will be able to have that same access that I have. Thank you for listening to my comments today.

00:43:22

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.