Transcript: Imbruvica, November 6, 2023 Medicare Drug Price Negotiation Program Patient-Focused Listening Session

MEDICARE DRUG PRICE NEGOTIATION PROGRAM
CENTERS FOR MEDICARE & MEDICAID SERVICES

Introductory Remarks

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

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

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

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

00:03:32

Disclaimer

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

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

00:04:14

Welcome

Kristi Martin, Senior Advisor, Center for Medicare

Thank you, Dr. Seshamani, and welcome to those joining us to share their input as well as people who are watching the live stream. I'm Kristi Martin, a senior advisor with the Centers for Medicare & Medicaid Services. This is a virtual public listening session for the drug Imbruvica, 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 mentioned by Dr. Seshamani.

In August, we announced the list of ten drugs covered under Medicare Part D selected for 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 this first round of the negotiation process. There are ten patient-focused listening sessions, one for each drug selected for Medicare negotiation. The goal of the listening sessions is to provide an opportunity for patients, beneficiaries, caregivers, consumer and patient organizations, and other interested parties to share input relevant to the drugs selected for the first cycle of negotiations and their therapeutic alternatives.

Another recent example of an opportunity for the public to share input on the selected drugs and their therapeutic alternatives was our data submission process, which invited manufacturers with 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 Imbruvica in their own lives or the lives of those they serve and care for. Speakers who are joining us via Zoom registered for a chance to speak and underwent a random selection process. They've been asked to bring forward information related to the clinical benefit of the selected drug as compared to its therapeutic alternatives, how the selected drug addresses unmet need, and how the selected drug impacts specific populations.

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

simple: it is to listen. I want to remind participants 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]**.

00:08:37

Speaker Remarks

Speaker 1

Thank you for the opportunity to contribute to this important discussion on Imbruvica and therapeutic alternatives. I will be offering my perspective as both a registered nurse and professional patient advocate of nearly 25 years and **[INFORMATION HAS BEEN REDACTED]** CLL Society. My participation in this listening session and the contents of my statement is not influenced in any way by industry support. At CLL Society, **[INFORMATION HAS BEEN REDACTED]** fielding thousands of questions per year from patients through a program that we offer known as Ask the Experts. This service allows patients and their care partners the opportunity to submit questions about their disease and medications. And what I have consistently observed is that patient concerns are pretty universal in that they all want access to the best treatment possible that will result in them being able to live the best life to their fullest. Patients also trust that their healthcare providers will be able to prescribe the best treatment for them when it is their time to start a new treatment. And most patients are completely unaware that the treatments selected by healthcare providers are often driven, at least in part, by policies, cost considerations, and utilization management strategies. I've heard over and over from our patient community that having access to an oral blood cancer medication has been life changing for them. And when Imbruvica was first launched years ago, chemotherapy was one of the only options. Patients had no oral therapies to choose from. Even as an off-label use, we now know that a significant number of our patients have been able to remain on Imbruvica for years without disease progression. But over the years, there has also been a significant proportion of patients that have had to either reduce their dose significantly or completely discontinue the drug due to unmanageable side effects or disease relapse. If I were to think of one thing that CMS can do for all of those with CLL and SLL, it would be to make sure that treatment decisions are not driven by formularies or step therapy protocols, but rather through shared decision making between the healthcare provider and patient. Healthcare providers already have a tremendous administrative burden due to the many documentation hurdles that are required to ensure that their patients' treatment selections are driven by the unique needs of each individual patient's disease. They may decide not to jump through the additional documentation hoops that would be required for their patients to gain access to a drug that they believe will be the best treatment for their cancer. As CMS has repeatedly acknowledged, healthcare provider time is best spent on caring for patients, and right now, those with CLL and SLL can decide between several treatment options that will work best for their form of the disease. That would not be the case if Part D plans begin to restrict coverage or limit access to the other BTK inhibitors that are currently available. Also, my fear is that even more of our underserved patient populations might fall through the cracks if the plan's decision stands as is, resulting in a lack of access to the treatment that will be best for them. So I sincerely hope CMS will take the extra measures that are necessary to ensure that plans do the right thing for the patients, and that CMS quickly holds plans

accountable if they do not. Thank you for the opportunity to speak.

00:11:38

Kristi Martin, Senior Advisor, Center for Medicare

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

00:11:54

Speaker 2

Hi. Thank you for the opportunity to comment today. My name is **[INFORMATION HAS BEEN REDACTED]**. I am **[INFORMATION HAS BEEN REDACTED]** CLL Society, a 501c3 focused on advancing effective care for chronic lymphocytic leukemia and related blood cancers. As a nonprofit, we do rely on financial support from a diverse set of sources, but neither my participation in this listening session nor the content of my statements were influenced by financial support. We urge CMS to consider the downstream impact on both new therapies and additional indications for existing treatments as you go through this process, and we strongly urge CMS to acknowledge that how Part D plans respond to the agency's decisions will impact cancer patients. Our patients are relying on CMS to proactively protect access to all effective treatment options. Imbruvica was the first BTK inhibitor for CLL, and patients have benefited from having an effective treatment that they can take at home. Like most CLL treatments, it was first approved for a related B cell cancer, and it took two and a half years to get an indication for first line therapy in our patients. Like most cancer treatments, research on Imbruvica was far from over after initial approval. Post-approval research is crucial in cancers, particularly those that, like CLL, are now treated as chronic diseases with patients moving through lines of therapy. How will negotiations impact this research, especially post approval research? For example, a recent phase two study of Imbruvica and refractory hairy cell leukemia has shown promising results in a difficult to treat population. If approved for HCL, will CMS initiate a price renegotiation and require additional discounts? As CMS considers what constitutes a maximum fair price, we strongly urge you to consider the additional research leading to treatment for more patients. Most of our patients are now or soon will be Medicare beneficiaries, and patients newly started on a BTK inhibitor are increasingly prescribed one of the newer treatments, so we are concerned about the impact on the entire class sooner rather than later. Our concerns are unique to cancer because we can't just switch from a BTK inhibitor that's been successful for months or years to another one. For a patient like that, there are no therapeutic alternatives. Patients remain on the drug until they can't tolerate it or until their cancer progresses. If plans limit options to capsules, patients on proton pump inhibitors will in effect, be denied treatment. Also, patients can't step through failure on a preferred BTK inhibitor and expect that another one in the class will work. It likely won't, and the time before the patient runs out of options will be dramatically shortened. If CMS takes the passive role and simply monitors formularies over time, it will put our patients at risk of harms that cannot be undone. Again, I appreciate having the opportunity to speak today.

00:14:37

Kristi Martin, Senior Advisor, Center for Medicare

Thank you. 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 registers 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]**.

00:14:53

Speaker 3

Good morning, everyone. My name is **[INFORMATION HAS BEEN REDACTED]** and **[INFORMATION HAS BEEN REDACTED]** American Cancer Society Cancer Action Network, and ACS CAN really appreciate CMS holding these listening sessions on the new Medicare negotiation program, ensuring the voice of patients is considered. ACS CAN represents patients, survivors and loved ones impacted by cancer. Every Medicare beneficiary is either a cancer patient, survivor, or at risk of cancer. And the affordability and availability of prevention, early detection and treatment is critical to reducing the nationwide cancer burden. Advances in research have led to the development of more precise diagnostic tools and drug therapies that have significantly reduced cancer mortality. However, if patients face affordability or accessibility barriers, the goal of reducing death and suffering from cancer is greatly hindered. Access to a full range of affordable drug therapies is key for successful cancer outcomes. As CMS begins this negotiation for lower prices for select drugs in Medicare, there is the potential for real savings for millions of beneficiaries if the program is administered in a way that ensures that savings directly reach the patient. Medicare enrollees taking Imbruvica or future negotiated cancer drugs will only directly benefit from a price negotiation if they actually pay less than they were previously paying. Millions of cancer patients also need access to a specific drug like Imbruvica that is most effective for treating their personal cancer, so the Part D protected class policy must remain intact. As you know, cancer is hundreds of diseases and drugs are not interchangeable. Therefore, a patient's access to the right medicine at the right time is critical to their best outcome. Unfortunately, insurers are already financially incentivized to steer patients towards lower cost medicines, whether it's the best treatment for the patient or not. Negotiating lower prices for certain drugs could potentially create an even greater incentive for insurers to direct beneficiaries towards these lower priced drugs, and we want to ensure that CMS, as a result, are looking at these potential changes where plans are not steering patients towards potentially less effective drugs because of cost. While Imbruvica is currently the only oncology drug being negotiated, it is likely that future negotiations will include a number of cancer drugs. There remains an enormous unmet need for new therapies to treat cancer. Therefore, innovation for further lifesaving indications is critical to reducing the cancer burden. We urge CMS to work with FDA to monitor potential implications and consider the impact on long-term research, investment, and the unique characteristics of indication sequencing specifically when determining pricing for these cancer drugs. We know there will be many lessons learned from this first round of negotiation, and we urge CMS to continue to reach out to patients to find out directly about their experiences. Were real savings achieved? Did they maintain access to the drugs they needed? As well as having CMS monitor any shifts with FDA and innovation patterns of new cancer drugs. We really look forward to working with you as this new program is implemented on behalf of cancer patients and their families –

00:18:19

Kristi Martin, Senior Advisor, Center for Medicare

I apologize **[INFORMATION HAS BEEN REDACTED]**, I'm sorry to interrupt. Your three minutes are over. Please take a moment to wrap up.

00:18:26

Speaker 3

I'm done. Thank you.

00:18:27

Kristi Martin, Senior Advisor, Center for Medicare

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

00:18:43

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 that we are discussing here today. I believe our experiences will provide the missing perspective about real risks 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 Imbruvica 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 progressive disease, there were zero disease modifying treatments 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 the 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 to live into my parent’s basement. Thankfully, around this time, a second MS therapy was approved by the FDA. I had hope and a plan B. And I can say without exaggeration that it saved my life. Within five years, I went from being unable to work, walk, or swallow to rejoining a career I thought was over, meeting my future wife, and starting a family. I'm here today so you can look a patient in the eye who has needed four different break-through drugs over 35 years. Americas 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. 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 burden and a ward of 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 popular belief, this exercise is not to lower patient costs, 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 productivity, reduced revenue, increased suffering, and despair across the country. Thank you for your time. I look forward to sharing more of my patient experience.

00:21:30

Kristi Martin, Senior Advisor, Center for Medicare

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

00:21:44

Speaker 5

Yes, thank you. And I reported a conflict of interest because while I'm an employee of the CLL Society, I'm speaking to you today as a patient with CLL. In May of 2021, I went to my doctor for my annual physical, walked in feeling healthy except for a swollen lymph node on my neck. And that lymph node turned out to be a symptom, which was confirmed over the coming weeks as chronic lymphocytic leukemia, CLL, which I found out was an incurable disease that would affect my blood, my immune system, and my overall health. In the time since my diagnosis, I've learned a lot about the disease that I will host for the rest of my life. I even started working at the nonprofit CLL Society so that I could help others like me. Yes, there are treatments, and there are some people who live many years with CLL without needing treatment. My testing has confirmed that I will not be one of those people. I will need treatment soon. And while the treatment options now are better than they were 15 years ago, no one knows how these medications will work over a longer period of time. So what do we know? The demographic for CLL falls heavily into Medicare. It's clear that CLL patients relying on Part D drug coverage will hit the new out-of-pocket maximum and will benefit from the IRA's payment option plan. But negotiating prices down will also have zero impact on what CLL patients pay for their treatments. The Medicare program will save money, and beneficiaries may find that premiums are lower, and those are legitimate objectives. But as a patient, I have to hope CMS will ensure that cost savings are achieved without impacting CLL patients' access to current medications, or the discovery of new treatments. For thousands of patients now doing well in one of the existing drugs approved for CLL any chance that these plans would require them to switch to an alternative therapy is an absurd risk. CLL is unlike many other diseases in that it presents itself very differently in each patient. This is why a diverse array of treatment options is essential. Patients like me know that our lives literally depend on being able to receive the right medication for our unique case, and there is no single right answer that works for all of us. There's a bright side, though. Research on combining BTK inhibitors with Venetoclax, for example, open new possibilities for shorter treatment durations. And Jaypirca, which was recently approved for treatment of mantle cell lymphoma, is being studied for CLL as well. This research is costly, though, and is less likely to occur when the result would selection for price negotiation. So I and thousands of others like me wait and hope for progress. The drug development process takes long, and many simply don't have that much time. But for the 18,000 people who are newly diagnosed each year with CLL, we must continue to offer hope for better treatments for a cure, and hope that we can live out our lives. Thank you.

00:24:43

Kristi Martin, Senior Advisor, Center for Medicare

Ron, thank you for your comments. Moving on to our next speaker, please welcome **[INFORMATION HAS BEEN REDACTED]**, who registered as a representative of a patient advocacy organization. **[INFORMATION**

HAS BEEN REDACTED] reported no conflicts of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

00:24:58

Speaker 6

Thank you so much. Good afternoon. My name is **[INFORMATION HAS BEEN REDACTED]**. I'm an advocate and a patient living with chronic conditions. **[INFORMATION HAS BEEN REDACTED]** the Chronic Care Policy Alliance. The CCPA is a network of state and regional advocacy organizations advancing public policy that improves the lives of those living with chronic conditions and diseases. We advocate for patients because most of us have seen and felt the devastation chronic diseases can bring to individuals, their families, and loved ones, even when diagnosis, medications, and treatments are readily available. Together through CCPA, our voices can speak up to say that every patient is unique, every patient is important, and every patient and their loved ones depend on the medical miracles that continue to be developed in this country every day. Access to the full breadth of life-changing medicines is critical to a patient's ability to function, contribute to society, and even how long they will live. Patients want to ensure they have access to affordable medication, but also the development of life changing medications continue and that patients have access to them. Very few among us have not had cancer touch our lives or the life of someone we know and love. The medication everyone is talking about today targets chronic lymphocytic leukemia, CLL, or mantle cell lymphoma, which are rare cancers. They are also not curable, but they can go into remission. People with rare diseases and these cancers must live on hope. Hope that treatment will slow their cancer. Hope that they will be able to live a relatively normal life. Hope that their cancer does not grow quickly. Hope that there will one day be a cure. These people's lives depend on medications, that those medications often fail after a time or they may fall out of remission. In these cases, they need access to a different medication. Access to a variety of medications are necessary to meet this need. Access to variety of medications are important to identify the best ones to fight the disease in that individual. And don't forget their hope for a cure. New treatments are being developed. We need the development to continue. We want new treatments that work better, longer, with fewer side effects and we want that cure. This is critical information to make part of your discussion in these negotiations. We ask that patients, their needs, and care remain the center of the conversation as you negotiate. Please keep in mind that what works for many might not work for everyone. We really appreciate you holding these listening sessions. Look forward to working with you and thank you for the opportunity to present these comments.

00:27:48

Kristi Martin, Senior Advisor, Center for Medicare

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Now we'll move on to our next speaker. Please welcome **[INFORMATION HAS BEEN REDACTED]**, who registered in the category of other. **[INFORMATION HAS BEEN REDACTED]** reported no conflicts of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

00:28:03

Speaker 7

Hello. My name is **[INFORMATION HAS BEEN REDACTED]**, as you heard, and I am a Waldenstrom's Macroglobulinemia patient. I do volunteer work for both the LLS and for the International Waldenstrom's

Macroglobulinemia Foundation, which I'll refer to Waldenstrom's as WM for convenience. I was diagnosed in 2006 as a result of some anomalies on a routine blood test and I was in watch and wait for eight years. And then I started to develop peripheral neuropathy. It was unusual because it was not sensory neuropathy, but motor neuropathy, and it became harder and harder for me to walk, and I ended up in a walker and then I was treated for the Waldenstrom's, which they weren't sure for quite a while whether the motor neuropathy was related to the Waldenstrom's. And turned out it was and I was treated with cyclophosphamide, Rituxan, and dexamethasone. So I had a chemo cocktail treatment with a monoclonal antibody and it was successful. My motor neuropathy went away. I have some residual sensory neuropathy in my feet, particularly in my right toes, but it is not debilitating, and I haven't needed treatment since 2015. However, I'm looking ahead, and I will need more treatment in the future, probably. By the way, Waldenstrom's is even rarer than CLL. About 1,500 people diagnosed per year in the U.S. And the Bing Center at the Dana Farber Cancer Clinic, which is dedicated to research to Waldenstrom's and helping patients with Waldenstrom's, developed Imbruvica in working with Pharmacyclics and they did the whole genome testing and discovered the gene that gets mutated in Waldenstrom's and other cancers and that the BTK inhibitor could block that mutation. However, of course, the drugs that were developed are expensive, and Part D does not cover it all. The chemotherapy I had was covered 100% by Part B, 80% by Medicare, and 20% by my Medigap policy. But the oral therapies are quite expensive, as you know, and I am looking ahead to using a BTK inhibitor rather than having another round of chemo. And of course, the problem is that you have to take it for the rest of your life, and it's quite expensive and it's been very effective, although, as you've heard, sometimes people have side effects, or it no longer works, and they have to use all their alternatives. But they are very effective drugs, the BTK inhibitors, and I'm concerned that Imbruvica has side effects –

00:31:28

Kristi Martin, Senior Advisor, Center for Medicare

Hi **[INFORMATION HAS BEEN REDACTED]**. I apologize for interrupting. The three minutes have expired. Please take a moment and finish your final thoughts.

00:31:36

Speaker 7

Yeah, the final thought is that Afib is a side effect of Imbruvica, and a lot of doctors, including mine, are recommending Zanubrutinib, or BRUKINSA and I'm concerned about the impact of negotiating drug prices for Imbruvica and what effect it will have on other BTK inhibitors like Zanubrutinib. Thank you.

00:32:01

Kristi Martin, Senior Advisor, Center for Medicare

Thank you, **[INFORMATION HAS BEEN REDACTED]**. We appreciate your comments. Now we'll move to our next speaker. Please welcome James, who registered as an academic researcher or other subject matter expert not affiliated with the manufacturer of the selected drug or its therapeutic alternatives. James reported no conflicts of interest. Welcome, James.

00:32:24

Speaker 8

Oh, thank you very much. My last name is Love, James Love. My family's been impacted by cancer, but I am not an Imbruvica patient. I work for Knowledge Ecology International, known by its initials KEI, and we filed two comments on this drug. I'll highlight a few points from our previously submitted comments. The pre-clinical research that led to the development and FDA approval of Imbruvica benefited from studies and research by companies now owned by the drug sponsors, as well as independent research funded by the U.S. National Institutes of Health, the NIH, the German government, the European Union, the Cancer Prevention and Research Institute of Texas, the CLL Global Research Foundation, the Leukemia and Lymphoma Society, the Howard Hughes Medical Institute, and the D. Warren Brown Foundation. Number two point is that the Orphan Drug Tax Credit provided a significant subsidy for the clinical studies. The FDA granted 14 orphan designations for Imbruvica, including eight indications that have received FDA approval. The credit was equal to 50% of the qualifying expenditures on clinical trials through the end of 2017 and 25% thereafter. Three, the NIH clinicaltrials.gov database lists companies owned by AbbVie and J&J as a sponsor and funder of 21% of all the trials involving Imbruvica. The NIH is identified as one of the funders of Imbruvica trials 17% of the time. The largest funder of clinical trials in the database is “other.” Number four in August 2022, the FDA asked AbbVie to undertake three small studies of Imbruvica on pediatric populations. The request was made under 21 USC 355a, which grants a six-month extension of Imbruvica’s patent and regulatory exclusivities. The FDA did not have to request the study, but it did. The requested enrollment in the studies was just 100 patients in total. The cost of this discretionary request by the FDA is expected to be massive. The 2021 Medicare and Medicaid outlays of Imbruvica were $3.2 billion, and the U.S. expenditures of the drug by other payers is also substantial. The government, this is my last comment, the government should not use the pediatric extension for small studies that impose large costs on society, when the government could fund the studies directly at far less cost to society. Thank you.

00:35:31

Kristi Martin, Senior Advisor, Center for Medicare

James, thank you for your comments. Moving on to our next speaker, please welcome **[INFORMATION HAS BEEN REDACTED]**. **[INFORMATION HAS BEEN REDACTED]** 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]**.

00:35:49

Speaker 9

Good afternoon. My name is **[INFORMATION HAS BEEN REDACTED]**. I'm 73 years old. I live in **[INFORMATION HAS BEEN REDACTED]**, New York, and I am enrolled in traditional Medicare. In 2012, I was diagnosed with CLL, for which I began taking Imbruvica in 2015. I am taking the Imbruvica successfully now for eight years. I have not suffered any side effects. It has afforded me a very good quality of life. However, at a cost of $17,000 per month, it is not affordable. I depend on grants and state assistance to pay for my medication, and I worry every year if I will be eligible. I worry about my life without my medication and know certainly that my disease would progress, and I would succumb. Sadly, there are no generics and there are no biosimilars. I would like to thank CMS for including Imbruvica as one of the ten drugs eligible for price negotiations. It is my hope that future negotiations will make these meds affordable to more seniors. It is my very strong belief that negotiated pricing will not affect, hinder, or impede research or new drug

innovations in any way, as this is funded the majority by the American taxpayers. Ultimately, drugs do not work if they are not taken and ultimately if they are not affordable.
I urge CMS to continue vigorous negotiations to make all cancer medications affordable to all seniors. Thank you for your time.

00:38:02

Kristi Martin, Senior Advisor, Center for Medicare

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Now we'll move on to our final speaker today. Please welcome our final 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]**.

00:38:24

Speaker 10

Good afternoon. My name is **[INFORMATION HAS BEEN REDACTED]**, and I'm here to express my appreciation for your addition of Imbruvica, or as I call it, Ibrutinib, as one of the first drugs to be on the Medicare price reduction program. I was diagnosed with CLL in April of 2000, and at that time, I was given a ten-year survival time. Because CLL, or chronic lymphocytic leukemia, has no cure yet, we as patients start out in what is called watch and wait, where hematologists monitor patients' blood, usually every three to six months. We always think of any cancer as once you have a treatment you're cured. But that's never the case with CLL, and it causes a tremendous amount of stress for patients. In April of 2004, I began my first treatment in a clinical trial at Ohio State University. At that time, the only option was chemotherapy, which at its completion left me in remission, but with a breathing problem of shortness of breath upon exertion that I have to this day. In 2009, I started coming out of remission and started back in watch and wait. By 2011, I needed treatment again, but I was very fearful of chemotherapy furthering my breathing issues. Fortunately, there was a phase two trial recruiting patients for Ibrutinib at the National Institute of Health, and I was luckily chosen to participate. Ibrutinib proved to be a fantastic drug. It was the first pill form of treatment for CLL that was in a trial instead of chemotherapy. How amazing is that? Initially, my blood counts increased, but over a period of months, it came back to normal range. I only had minor side effects throughout the course of my treatment. NIH is a phenomenal institution, and they were very caring, and I stayed on Ibrutinib until May of 2023, when I was advised to stop treatment. I had been in remission for many of those years at that point, and just by taking the pills. I truly believe that Ibrutinib saved my life. I no longer am in fear of CLL and losing my life because of this disease, as there are so many new treatments available now. Additionally, I have what's called familial CLL, as both my mother and her brother have. And I have two children, and now I'm not as concerned if they get this disease. I am so pleased that Ibrutinib was included on President Biden's list, because I try to help a lot of new patients that are on a Facebook CLL group, and one of their biggest concerns is the cost of the drugs to treat CLL. Cancer treatments are very expensive, especially the newer treatments such as Ibrutinib and other BTK inhibitors. How are they going to afford it? Especially retirees on a fixed income? Other blood cancers use Ibrutinib as well. Additionally, there was a recent study that compared to chemotherapy –

00:41:51

Kristi Martin, Senior Advisor, Center for Medicare

Hi **[INFORMATION HAS BEEN REDACTED]**. I'm sorry to interrupt. Your three minutes are over. Please take a moment and wrap up your final thoughts. Thank you.

00:41:58

Speaker 10

Ok, I'm just – and versus Ibrutinib, and the result was very positive and that Ibrutinib patients had a longer time in remission. It was easier for them. Thank you for this opportunity.

00:42:10

Kristi Martin, Senior Advisor, Center for Medicare

Thank you, **[INFORMATION HAS BEEN REDACTED]**.

And thank you all so much for taking the time to participate in today's 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.