

Transcript: Enbrel, October 31, 2023

Medicare Drug Price Negotiation Program

Patient-Focused Listening Session



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 Enbrel, 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 negotiations. 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, consumers 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 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 Enbrel 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]**.

00:08:43

Speaker Remarks

Speaker 1

Thank you. Enbrel was the second of nine biologics that I have been on in the last ten years. I was on it for six months to see if it would start working, but unfortunately for me, it didn't work at all. It wasn't the drug for me. I was on my third biologic for a year and a half, and then I was diagnosed with drug-induced lupus, which they believe was caused by the anti-TNFs and that drug in particular, the third one. Because I'm starting to run out of options, I'm currently on one again that has less chance of that particular side effect, but we're just hopeful that I won't get the drug-induced lupus again. This is why I think that it's so important to have Enbrel and as many other choices available so that every person can find the right one for them. I know many people on Enbrel now and many of them have been on it for over ten years. Enbrel was not the drug for me, but it may be the only drug that works for someone else. Until we can figure out what drug works best for each individual we need to have a wide variety to try. At the moment we never know what will work for us and how long it will work if it does.

00:10:14

Kristi Martin, Senior Advisor, Center for Medicare

Thank you, **[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]**.

00:10:34

Speaker 2

Good afternoon. My name is **[INFORMATION HAS BEEN REDACTED]**. I'm a 69-year-old retired **[INFORMATION HAS BEEN REDACTED]** from **[INFORMATION HAS BEEN REDACTED]**, Maine. I'm also a patient living with psoriasis and psoriatic arthritis for over 40 years. I have taken Enbrel to manage my symptoms since about 2007, along with the drug methotrexate. Enbrel has a list price of \$7,000 per month. Prior to my retirement, I had private insurance from my employer and took advantage of Amgen's patient assistance program and had an out-of-pocket cost of zero to \$60 per month. During this time, I was able to afford the medication I needed at no devastating cost to me. In 2019, when I retired and qualified for Medicare, I enrolled in a Medicare Assistance Medicare Advantage program. Currently, my copay for Enbrel is \$339 per month. However, at the beginning of each year, my copays are extremely high due to the donut hole in Medicare's coverage. This year alone, my first refill in January was \$2,000 and my second in February was \$1,100. This totals over \$3,000 in just the first two months of the year. This type of pricing, in my

opinion, unfairly takes advantage of people on Medicare, many of whom, like me, live on a fixed income. Even though I've been able to make it work, thus far, I am very aware of Enbrel's list price and I fear, the future, what the future may bring. If insurance were ever to fail to protect me, Enbrel's \$7,000 list price would be out of reach for me. The reality is that I cannot easily cut Enbrel from my medical treatment plan, as it has prevented me from having any serious arthritis flare for quite some time now. We have had to make some large sacrifices to deal with the financial stress my family and I now face with my medical bills. I admit that I have skipped doses here and there during times of high financial obligation to ration the medication a little bit longer. I have to carefully monitor my expenses, and rarely do my husband and I treat ourselves with unnecessary indulgences or entertainment. We simply have become more cost conscious. Seeing Enbrel on the list of drugs to be negotiated has allowed me to take a deep breath and have hope. Enbrel's high cost has been a burden. A constant anxiety. A lower price on this drug would be life changing for me and thousands of other patients. I can only imagine the stress relief I hope to feel in the future. Thank you for allowing me to speak.

00:14:10

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 **[INFORMATION HAS BEEN REDACTED]**. **[INFORMATION HAS BEEN REDACTED]** registered as a representative of a patient advocacy organization. **[INFORMATION HAS BEEN REDACTED]** has reported no conflicts of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

00:14:28

Speaker 3

Hello. Life without a biologic is extremely difficult. My pain intensifies, my joints stiffen. I need help doing very basic stuff. My fatigue overwhelms me. Day-to-day becomes more difficult because not only does my RA worsen, but so do my multiple comorbidities. Enbrel has allowed me to feel almost normal. I can do most things I want to, including some hobbies. I truly believe that Enbrel works better than the previous six biologics I've been on in the 20 years since I've been diagnosed with RA. Enbrel is my miracle drug. I've been told by several specialists of my other comorbidities, that getting RA under control will help control those comorbidities. I've been diagnosed with sleep apnea, high cholesterol, high blood pressure, neuropathy, chronic migraines, osteopenia, GERD, and several others. And I have noticed improvements in several of these since starting Enbrel. I started Enbrel a year and a half ago at the suggestion of my rheumatologist, when my previous biologic caused my white blood cells to drop way low, too low. I have several allergies and negative reactions to multiple medications. This limits the medications I can be on. Because of these reactions, I can only be on one disease modifier. A biologic is often paired with one or two disease modifiers to attain ultimate disease control. Being on a drug that works and doesn't cause bad side effects is both important and reassuring. Enbrel's injection mechanism is very user-friendly and easy on my arthritic hands. Enbrel works well for me. It is very important to my family because it allows me to be me. Thank you for this opportunity to speak about Enbrel and its importance to me.

00:16:57

Kristi Martin, Senior Advisor, Center for Medicare

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

00:17:12

Speaker 4

Thank you and good afternoon. My name is **[INFORMATION HAS BEEN REDACTED]**. I'm an advocate and patient living with chronic conditions, arthritis being one of them. **[INFORMATION HAS BEEN REDACTED]** the Chronic Care Policy Alliance. The 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 so much 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 plan, my doctors, and to find treatments that allowed me to resume my daily activities. If there is 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. For example, Enbrel is a life-changing treatment for many patients. However, other people may have serious side effects that we've heard about already today or find it to be ineffective. Additionally, those that get relief could see decreased effectiveness over time, making a change in treatment necessary. Therefore, individualized care decisions and treatment flexibility must be preserved through the process. Unrestricted 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 using Enbrel for their arthritis often regain the ability to do what many of us take for granted, including just sitting and standing comfortably. Patients want to ensure that the development of life-changing gene medications continues and that they have access to them, affordable access to them. A real concern is that the negotiation program might save Medicare money, but that patients will have to fight harder to access treatments they need or that work better for them due to more refined formularies that prioritize negotiated drugs above all other options. As negotiation processes and progresses, we urge CMS to consider whether the price it negotiates protects patients who use the product, by also preserving access to alternatives that work for people where the other drug doesn't. CMS should ensure that both the negotiation process and other policies within the IRA support ongoing research to both innovative new products and new indications for existing cures. CMS must not allow dollar signs and mass data to drive all decisions around these medications. Patients are individuals, so what works for many may not work for everyone. I want to thank you again for having these listening sessions and for allowing me to provide these comments.

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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 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]**.

00:20:26

Speaker 5

Hi, I'm **[INFORMATION HAS BEEN REDACTED]**, and I've had psoriatic arthritis for 40 years. For many years, I lived with constant joint and tendon pain as the meds that existed were not very effective. I then began to have damage to my joints. By the time I was in my late forties, I needed total knee replacement. Then Enbrel became available, and it was a game changer for me. My pain resolved and my inflammation markers returned to normal. Enbrel was given through a self-administered injection once a week, taking about a minute. The negotiated cost to my insurance company was \$3,700 a month, but my \$400 monthly copay was mostly covered through the pharmaceutical company's copay assistance program. The total cost to me was \$120 a year. Then seven years ago, I turned 65 and went on Medicare. Medicare has been wonderful, but because the pharmaceutical rates have not been negotiated, the monthly cost to my Part D plan for Enbrel would be probably about \$12,000. Because the federal anti-kickback statute prevents Medicare recipients from receiving copay assistance, the total annual cost me to be on Enbrel would be about \$30,000 a year. I only wish I were wealthy enough to afford this. I, like many other Medicare recipients with inflammatory arthritis, switched to an infusion medication which is billed through my Part B plan. The first medication that I tried required a four-hour intravenous infusion given at an infusion center every eight weeks. The medication initially worked, but it caused serious issues with my immune system. Then it stopped working altogether and my symptoms returned completely. I then was switched to a different infusion medication that takes an hour and a half every eight weeks at an infusion center. It's still much less convenient than the quick self-administered injection at home. So far, this medication is working. If it does stop working, though, like the previous medication did, I'm out of options. This leaves me terrified. When rates are negotiated for Enbrel and then there is a cap on out-of-pocket spending, or if the copay assistance becomes permissible, I could return to using Enbrel, which worked wonderfully for me and was a much more convenient option to use overall. It would give me another option. Thank you.

00:23:05

Kristi Martin, Senior Advisor, Center for Medicare

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

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Speaker 6

Thank you. I am **[INFORMATION HAS BEEN REDACTED]** AiArthritis, which is the International Foundation for Autoimmune & Autoinflammatory Arthritis, a person living with the conditions as well that are treated by Enbrel. So, I am also speaking on behalf of the millions of people in the United States whose lives have improved because of access to Enbrel. I'd like to start by just explaining that our diseases, these autoimmune and autoinflammatory arthritis diseases, are heterogeneous. And so that means they are unique to individuals and to subgroups because they are molecular level. They start in our immune system

and they're triggered often by something environmental plus a genetic factor. So of course, we're all going to be slightly different. It's really important to understand because the issues that are caused within this immune system, it's complex. It's going to require regulation when overactivity of this inflammation goes away. So even people with the same diagnosis, like rheumatoid arthritis or psoriatic arthritis, they're not going to possibly respond all the same to any given drug that's approved by the FDA indicated to treat that one disease. So, the process to find the right medication is extremely complicated and often requires this lengthy trial and error process. So once a patient finds the biologic that works, there should be no alternatives or disruption of continuity of care, but only by pulling them from it when it naturally stops working. The American College of Rheumatology recommends that many of our diseases be initially treated with TNF inhibitors, which Enbrel is, as the first line treatment. And while it may not work for everyone, for those it does, having access to it early in the disease course will help prevent disease progression and increase the rate of remission. And that is a word that is very rarely heard in our community. Over half of us will develop comorbidities, like dual diagnosis heart disease, Alzheimer's, as a result of the uncontrolled inflammation, again as a result from not being matched to the right treatment. If a different biologic or biosimilar targets the same thing, there are also other factors to consider. So, switching should not be an alternative option. Method of application. We've heard from infusion versus injection if there's any sensitivities to it, all of these things need to be considered. Regarding the prevalence, one in ten people live with AiArthritis diseases. And the average onset is 20 to 40 in adults, any age in children, and a new subgroup, late onset or elderly onset in 65 or older. So there are subgroups that data is showing that Enbrel and other diseases may work better in them than others, and that data does need to be considered. While Enbrel contributes to the top 20% of costs for Medicare Part D. We do encourage CMS to consider other factors that lend to that position (i.e., step therapy, placement on formularies, forced use). Enbrel is the first drug that is often recommended to use in these diseases, so it's very possible its high cost is in conjunction with its extensive use. AiArthritis would like to stress –

00:26:36

[Kristi Martin, Senior Advisor, Center for Medicare](#)

Apologies [**INFORMATION HAS BEEN REDACTED**], your three minutes have expired. I'll give you a moment to wrap up and then we'll move on.

00:26:42

[Speaker 6](#)

And there's no such thing as an alternative therapy. And just please remember, if Enbrel is a miracle drug, please keep access for the people it works for. Thank you.

00:26:51

[Kristi Martin, Senior Advisor, Center for Medicare](#)

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

00:27:07

Speaker 7

Hi, and thank you for letting us speak today. I'm just going to start off with telling you what life without a biologic, which I have spent the 14 years I have had RA and Sjogren's. I'll say I've been on biologics half the time because of other health issues. But life without a biologic makes everything difficult. The pain, the fatigue, all the other symptoms are unbearable some days. Getting ready for a doctor's appointment is like running a marathon. Enbrel was my favorite. Enbrel is the only biologic I've been on that had no unpleasant side effects and made me balanced enough so I could work and take care of myself more easily. All others have been infusions. Well, since Medicare, all others have been infusions, which are time consuming and can come with negative side effects. A couple left permanent damage behind. I took Enbrel for five years when diagnosed in 2007. My disease, at that time, was moderate. My rheumatologist diagnosed me by a physical exam before my labs even got back. Prior to diagnosis, I felt like I had the flu for five years. Weighing in at 98 pounds, I was 47 years old, and I had been dealing with back pain from a car accident five years prior. Enbrel was my first and I took it along with methotrexate. That's what they advised when it first came out. And it worked so well for me. I started Enbrel, I had asked my rheumatologist about Enbrel because I had been researching that Enbrel and methotrexate worked well together, and she agreed. I went on it the first month. Thankfully, the patient support program helped me afford it and it was amazing. I think I was on Enbrel for about five years. It stopped working, I think, because of delays in having back and neck surgery. So, I was off all immunosuppressants for months. And most importantly, I just want to get through to everyone that every single one of us is different. There's no one-size-fits-all medication for autoimmune issues. It's best to find a biologic that works for you. You stick with it. Medication hopping and delaying meds can give you the risk of them not working as well or not at all in many cases. I can't express enough that early diagnosis and quick, aggressive treatment is a must for quality of life and chances of remission. I've been doing this for 14 years and I, over the last five years, am seeing remission. And that's amazing –

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Kristi Martin, Senior Advisor, Center for Medicare

Apologies, **[INFORMATION HAS BEEN REDACTED]**. Three minutes have run out. I'll give you a moment to have a closing remark and then we'll move on.

00:30:32

Speaker 7

Thank you.

00:30:33

Kristi Martin, Senior Advisor, Center for Medicare

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

00:30:50

Speaker 8

Thank you. So, I just basically want to tell you the story about how I started taking Enbrel. I was a poker dealer out in **[INFORMATION HAS BEEN REDACTED]**, many moons ago, and my thumbs started hurting. They had found out they had psoriatic arthritis. And my thumbs were just swelling up so much that they were red and I could barely deal. So, when you pitch cards, there goes my career. So, I had to switch over from dealing. I actually went back to school. Found out I had psoriatic arthritis, and I thought, well, I'm stuck being done dealing. They put me on methotrexate. Methotrexate not only did it not work, it hurt my liver, so I was done with that. Then I went to Enbrel. Now for ten years, from 2013 till actually last month, I took Enbrel. During that time, I experienced my swelling has gone down a lot. The damage to my joints has stopped. Even in 2019, I had to come off of it for about four or five months because I had a surgery. I needed time to recover, so I had to come off of it for four or five months. And during that time, I didn't have any pain with my joints. My joints didn't become inflamed, and it was even in the middle of winter. So Enbrel got me to a point where I don't know if I was in remission, I'd have to ask a doctor, but I got to a point where it wasn't progressing. So, when I went back on Enbrel, it kept on working. Fast forward a couple more years, after the pandemic, I needed a job and they were hiring poker dealers. And I was able to go back to poker and deal poker because I needed to just earn a living. So, I was even able to go back to dealing poker. So basically, I just want to talk about how Enbrel is a good part of staying productive in your life, and staying productive, as a productive part of society. So, it did give me my life back and I was able to deal poker again, and now I'm able to basically sit and stand and just do all the little things that you can't do when you suffer from some of these autoimmune and auto inflammatory diseases. It is important to keep people on Enbrel. If they are on Enbrel, if they have to switch, they have to switch. None of these are going to last forever. None of these solutions last forever. But as long as they are helping, we should try to do our best to keep people on Enbrel. Thank you very much.

00:33:14

Kristi Martin, Senior Advisor, Center for Medicare

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

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Speaker 9

Hello, I'm **[INFORMATION HAS BEEN REDACTED]**, **[INFORMATION HAS BEEN REDACTED]** Survivors for Solutions. I want to thank CMS for engaging patients who have survived these policies we're discussing here today. I believe our experiences here provide the missing perspective of the real risk this is putting on real patients. I regrettably believe this effort delivers blunt force trauma to a finely balanced medical discovery ecosystem. This policy knowingly risks how Enbrel, and countless other innovations, are discovered at all. Most troubling is it endangers the hope that people who most need it. When I was diagnosed with incurable autoimmune disease, there were zero disease modifying treatments, DMTs, to slow my path to complete



disability. That soon changed thanks to public policy that encouraged both cutting edge treatments and low-cost generics. Research could rationally take risks based on a predictable public policy. At 28, MS basically fried my central nervous system. The first DMT, which worked for many, didn't work 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, it 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, meeting my future wife, and starting a family. I'm here today so you can look at patient in the eye who has needed four different breakthrough drugs over 35 years. America's patients can't afford this 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. Illness is the problem. And the last thing we need are fewer options to fight those diseases. Had the IRA slowed innovation for me, 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. Thank you for your time, and I look forward to sharing more of my patient experience during future sessions.

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[Kristi Martin, Senior Advisor, Center for Medicare](#)

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Now we'll welcome 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]**.

00:36:38

[Speaker 10](#)

Thank you. Hi, I'm **[INFORMATION HAS BEEN REDACTED]**, **[INFORMATION HAS BEEN REDACTED]** the Partnership to Fight Chronic Disease, and we so appreciate you hosting these sessions. Enbrel is FDA approved for three different autoimmune arthritis conditions. As you've heard, these conditions attack multiple joints and connective tissue, causing inflammation, redness, and pain. Left untreated, the inflammation damages joints and other tissues, which can lead to chronic pain, affect balance, cause joint deformities, disability, and affect the skin and other organs. All of these conditions are associated with pain and utter exhaustion, during flares, with long-lasting remission as the goal. Symptomology can vary significantly, so the journey to an accurate diagnosis and working treatment regimen can be a long one, involving multiple specialists and taking years. Too often, patients, primarily women, are not believed or have their symptoms discounted. Once a person develops one autoimmune condition, she is likely to develop others. Disparities are common. For example, non-White individuals with rheumatoid arthritis tend to experience more treatment delays and suffer from poorer outcomes as a result. Once diagnosed, patients face multiple hurdles to accessing treatments and maintaining that access. Stories of having to requalify for treatment or health plan changes that restart step therapy requirements are common. A recent study, by Let My Doctors Decide, showed that most Medicare plans receive failing scores on patient access to

medicines for rheumatoid arthritis and psoriatic arthritis because of the significant severe access barriers those plans impose. Treatment is nuanced for autoimmune arthritis. What works well for one person may not work for another. For some treatments, they can lose their effect over time, and people can develop comorbidities, both of which may require treatment changes. So having options among drug administration, and different choices, are critically important. For example, arthritis may limit self-administration of injections, leading a patient to prefer a physician administered medicine. People without easy access to infusion centers may need a self-administered biologic, like Enbrel. These unmet needs are important to patients and should be considered. The availability and access to Enbrel, that results in remission, have been life changing for many, as you've heard today. Addressing the significant unmet medical needs of people living with autoimmune arthritis have altered the course of these disabling conditions and paved the way for innovation and new options. I close by posing a key unanswered question, and that is, how is CMS going to consider these patient specific treatment experiences and the need for options when weighing therapeutic alternatives? As I mentioned, people with autoimmune arthritis may present the same clinically but have very different responses to the same treatment. Patient access and ability can factor into preferred routes of administration. And those differences are meaningful and should weigh heavily in your consideration of what is a legitimate therapeutic alternative, if there are, or if it should be just looked at broadly and consider those patient specific considerations. Thank you again for the opportunity to speak today.

00:39:55

[Kristi Martin, Senior Advisor, Center for Medicare](#)

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

00:40:16

[Speaker 11](#)

Thanks very much. And thank you, CMS, for your work. I'm the Access to Medicines Director at Public Citizen, a consumer group with 500,000 members across the United States. Amgen's unfair exploiting of patent loopholes, extending its monopoly by an extra decade, has cost Medicare a billion dollars so far and will cost another billion by the time negotiated prices take effect. We documented this in a new report today. In our view, when negotiating maximum fair prices to deliver just prices for Medicare enrollees, CMS should consider patent abuses that deprive the public of more affordable therapeutic alternatives and should not consider the facial value of acquisitions, as R&D expenditures. So costs, Medicare enrollees who rely on Enbrel face exorbitant costs. Out-of-pocket for this drug is over \$2,000 annually for almost half the enrollees who need the treatment. Amgen has blocked cost saving biosimilars until at least 2029, 30 years after the drug was initially approved in 1998. We estimate that if Medicare's enrollees had access to biosimilars, Medicare could have saved nearly \$2 billion by the time negotiated prices take effect in 2026. How do we get this figure? We looked at gross spending. We factored in expected rebates from the academic literature, including for anti-TNF inhibitors, 36% and 37%. We estimated 18.4% price reductions by looking at European experience with these same biosimilars conservatively, not accounting for rebates. And then we

projected out. How did Amgen game the system? Amgen acquired Enbrel by buying out Immunex all the way back in 2002, did not otherwise contribute to the invention. Immunex had licensed unsuccessful patent applications from Roche in '99. Five years later, the corporations entered a new agreement that practically gave Amgen ownership. Amgen reworked the patent applications to unfairly duplicate and extend patent protection of Enbrel. Now, normally, patent law prohibits an inventor from repeatedly patenting, but courts held that due to the licensing arrangement, Roche actually owned the patent applications. So, Amgen was not double patenting. It was a legal trick and an absurd situation. Amgen and Immunex are the effective owners when they earn billions off of Enbrel, but not effective owners of the patents for purposes of the law. Again, this delayed the entrance of biosimilars in the United States. Biosimilars entered in Europe in 2016. So, what does that mean? What lessons should we take? What should CMS do in negotiations? Well, do consider that where there's patent gaming, and spoiler alert that may be the case for most IRA drugs, CMS should consider the prices that would be in place under generic or biosimilar competition, proper competition, had the gaming not occurred and the excessive revenues unfairly obtained. Do not consider the facial value of acquisitions as R&D costs. In the Enbrel case, acquisition bears no relationship to R&D costs, but rather their projected value monopoly power. This is in our comments and report. Look, taxpayers are losing billions to pack gains, while more affordable alternatives are available to people in other countries. So, feel empowered. You aren't taking anything from Amgen. You'll be getting back for taxpayers what Amgen and other corporations unfairly took. Thanks for your time.

00:43:25

[Kristi Martin, Senior Advisor, Center for Medicare](#)

Thank you for your comments, Peter. 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]**.

00:43:41

[Speaker 12](#)

Hi, thanks for allowing us to speak today. My name is **[INFORMATION HAS BEEN REDACTED]**. I am in Wisconsin and I wanted to share a little bit of my journey. I was diagnosed with rheumatoid arthritis at the age of 13, so I've had this disease for over 40 years. I was on less effective medications for my first 20 years of my journey and I am still fixing what the first 20 years created in my situation. I have now, since the onset of biologics, my last 20 years of my journey have been significantly better. I will say that I have been on every biologic. Enbrel was my first and it sadly did not work for me but I want to express what many others have said on this call today, that we are all individuals. Every one of us will react to these medications differently. And what is my miracle medication may not be somebody else's miracle medication. Biologics have been a miracle for me. My amount of destruction has significantly stopped. So, for the last 20 years, I've had no increased damage to my joints and things like that. So, I want to express just how much and how life changing these biologics have been for people like me who are diagnosed really early. My diagnosis came after a foot surgery, so that was what my initial trigger was. And I will say that I have never, in these 40 years of having this disease, achieved remission. I can pretty much say that I probably never will. I am difficult to treat. I've been on every biologic. And I'm on the second trial of several. So, hoping for new medications to

reach the market. And I will say that my quality of life is so much better. I'm actually able to be a active participant in life. I am a medically retired dietitian, but I do a lot of work with research and patient participation and a lot of things to get the word out that these medications really do work for many. And look forward to new ones to hit the market. Thank you very much for your time.

00:46:44

Kristi Martin, Senior Advisor, Center for Medicare

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

00:47:01

Speaker 13

Hi, thank you for having me. I began experiencing symptoms of autoimmune arthritis diseases at the age of 14. Throughout my teens and twenties, I had bouts of joint pain, fevers, and swelling. But it wasn't until the age of 31 that a rheumatologist finally looked at me and said, we think you have connective tissue disease and Sjogren's syndrome. Over the next seven years, I took disease modifying drugs which provided some relief, but I had been wearing braces on my wrists, my ankles, using a cane from time to time. My mobility really suffered. Seven years later, my rheumatologist changed, and I was officially diagnosed with rheumatoid arthritis. At that time, I was finally prescribed my first biologic drug and the difference in my pain level was drastic. I went from needing braces to support my arms, my wrists for driving, to not needing braces at all. And I no longer needed a cane most of the time to walk. Sadly, after two years, that first biologic drug stopped working, and that's when I was switched to Enbrel. After two months, on Enbrel, again, my joints were flaring. I was back to wearing braces on my wrists, and on my ankles, and on my knees, to try to get through the day. I was switched to Enbrel and after two months my doctor and I both realized it was no longer working. However, my doctor did submit for a change in biologic drugs, but my insurance rejected it, and I was required to stay on Enbrel an additional four months, taking the drug every week instead of the every other week as is normally prescribed. When asked why I was unable to change, my insurance told me that it was the safer choice for me, and it was more cost effective for my insurance. They didn't take the advice of the rheumatologist, who I felt was the expert in my disease. And so, for another four more months, I struggled severely with pain and fevers and joint swelling. Although Enbrel did not work for me, it is an effective treatment for many people, people who live with varying diseases. The difference in quality of life that Enbrel can bring to people is life changing. I can say for myself, once a biologic drug was introduced into my treatment plan, my life changed for the better. I'm lucky that I have private insurance. Although, over the years it has created barriers. Job changes or insurance changes through work, most often has been a nightmare for me to get the new insurance companies to allow me to continue to stay on a biologic drug that I'm currently taking. At this point, I'm on my 9th biologic, and I can say honestly, right now, I'm doing better than I've ever done taking a biologic drug. My current insurance is through my employer, but as I'm getting closer to retirement age, my biggest fear is losing my ability to pay for a drug that I need. I'm currently seeing that with my mother, who is on Medicare, who is struggling to afford the medication she needs for her COPD. I believe that patients deserve a chance to take a medication that will

treat their symptoms and that barriers such as –

00:50:22

Kristi Martin, Senior Advisor, Center for Medicare

Hi **[INFORMATION HAS BEEN REDACTED]**. Apologies, your three minutes have expired. I'll give you a moment to finish your final thought.

00:50:29

Speaker 13

That's basically it. Thank you so much for having me.

00:50:31

Kristi Martin, Senior Advisor, Center for Medicare

Thank you, **[INFORMATION HAS BEEN REDACTED]**. We appreciate your comments. We'll move on to our final speaker for today's session. 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]**.

00:50:50

Speaker 14

Thank you. My name is **[INFORMATION HAS BEEN REDACTED]**, and I live in **[INFORMATION HAS BEEN REDACTED]**, Colorado, and I'm here to share my experience with Enbrel on behalf of the Global Healthy Living Foundation and thousands of Colorado patients who also use Enbrel. I was diagnosed with ankylosing spondylitis, or AS, after eight years of recurrent unexplained bouts of hip and lower back pain that sent me to multiple different primary care providers, orthopedic surgeons, sports physicians, and eventually six different rheumatologists. It wasn't until several years and three other medications that I found my current specialist who recommended Enbrel. With the help of a specialty nurse, we navigated through the prior authorization and patient assistance to obtain the medicine within about a month of getting the prescription at a huge discount, which made it feasible for me to take. About 1.7 million Americans, or roughly 1% of adults, live with AS, which is roughly the same prevalence as rheumatoid arthritis. AS affects the spine and sacroiliac joints that connect the lower spine to the pelvis. And can spread up the spine and to peripheral joints like knees, ankles, shoulders, feet, and cause other digestive, skin, and autoimmune inflammatory diseases and symptoms like brain fog. An estimated 3.2 million more have axial spondyloarthritis, which is more broadly defined and makes the disease far more likely than is probably diagnosed. The delay in diagnosis for me, and many more people like me, had a huge impact on my quality of life. And it can lead to permanent joint damage and disability. Before my diagnosis and treatment with Enbrel, I missed about 100 hours of work in just over a year due to fatigue and difficulty moving, walking, sitting, standing in one place, and even just getting out of bed. After a couple of months of taking Enbrel, my hips, back and neck inflammation was reduced so much that I could move, walk, and look over my shoulder again in the normal range of motion, maybe for the first time ever. I could finally roll over in bed and take my first few steps of the morning without excruciating pain and stiffness. And I had started to measure my

life by very different standards before taking Enbrel, such as getting through the day with only one nap. And some days it was hard to even walk the quarter mile into my office from the parking garage, and I began to wonder when I would need to give in and get a cane. After starting Enbrel, I regained parts of my former life back and it felt like being given a second chance. I can't reverse the permanent joint damage from the years of not being on proper treatment, but it improves symptoms so much that I have the ability to do yoga and even run again sometimes, something I hadn't done in years due to the joint pain and stiffness and fatigue. I'm from Colorado, and I live to get outside in the mountains and hike, snowshoe, and cross-country ski, and it took a huge toll on me and my family to have this otherwise invisible condition. I lost not just work productivity, but my kids lost a sense of having a normal mom that could do regular weekend activities or even just vacuum the house. It's been a huge effect on my happiness and well-being just to do chores again and go outside and be an active Coloradoan. Thank you.

00:54:20

[Kristi Martin, Senior Advisor, Center for Medicare](#)

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**, 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 and our efforts to lower prescription drug costs. Thank you and have a great day. Bye.

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](#).