

# Transcript: Stelara, November 14, 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 Stelara, which was selected for the first cycle of negotiations with Medicare. We'll give more detail on this session and get going shortly.

First, I'd like to quickly provide context. We at CMS fall under the greater umbrella of the U.S. Department of Health and Human Services. CMS is tasked with implementing the new prescription drug law that helps save money for people with Medicare, improves access to affordable treatments, and strengthens the Medicare program. The law gives Medicare the ability to directly negotiate the prices of prescription drugs for the first time, as Dr. Seshamani mentioned.

In August, we announced the list of ten drugs covered under Medicare Part D selected for the first round of negotiations. This public listening session is one of a number of steps CMS is taking as part of the process for the first cycle of negotiation. The drug companies that manufacture all ten drugs selected for the first round of the Medicare Drug Price Negotiation Program signed agreements to participate in the negotiation program by October 1<sup>st</sup>. 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 Stelara 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 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 help transition from speaker to speaker, you will not hear from me.

Now, on to our participants. Please welcome our first speaker, Madelaine, who registered as a healthcare provider who has experience prescribing, dispensing, or administering the selected drug or its therapeutic alternatives. Madelaine reported a conflict of interest. Welcome, Madelaine.

00:08:23

## Speaker Remarks

### Speaker 1

Thank you for the opportunity to share some brief remarks with you. At the outset, I should point out that the issues I plan to discuss certainly exist for Stelara, but they will exist for all medications that have both self-administered and provider-administered formulations. The Medicare drug price negotiation program does not yet apply to Part B, but the rising prevalence of so-called white bagging has the effect of making provider-administered Part B drugs appear as Part D drugs because they're filled via specialty pharmacy rather than provider-acquired. Simply put, white bagging puts Part B drugs in Part D clothing. For reasons I'll explain in a moment, I think it's important to separate out Part B drugs filled via specialty pharmacy from your traditional pharmacy counter self-administered Part D drugs. I have two suggestions for how to accomplish that. First, the prescription drug event PDE data could be merged with Part B claims data, which will allow CMS to tell when a drug was filled via pharmacy but administered via Part B. A mechanism exists to do this since the agency is already using PDE data combined with Part B claims data to implement the low spend Medicare drug exclusion. Alternatively, CMS could revise its PDE collection tool to capture the information needed to determine that white bagging occurred. Now, why is this important? If CMS does not exclude white bag drugs from the Part D side for the purposes of the negotiation program, then PBMs, specialty pharmacies will be able to access maximum fair prices, potentially leading to an increased prevalence of white bagging, which has an entire list of problems associated with it that are bad for beneficiaries and program stewardship. I'd be remiss not to mention the self-administered drug exclusion lists or SAD list. If a drug is acquired through Part D more than half the time, the Medicare administrative contractors can move it to the SAD list, which means it becomes excluded from coverage via Part B and with white bagging falsely elevating Part D usage this could result in the loss of coverage for Part B medications for many more folks who can't administer due to disability. Essentially, if specialty pharmacies can access MFPS on these dual administration drugs, it could increase white bagging, making it appear as though these medications are self-administered more than half the time when they are not, merely filled by specialty pharmacy. Finally, I realize this is a brand-new complex program, but I wanted to at least highlight that the inclusion of provider-administered drugs filled via specialty pharmacy on the Part D side of the negotiation program could have unintended consequences, ultimately reducing patient access to much needed, provider administered medications. Thank you so much for this opportunity.

00:11:18

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

Thank you, Madelaine. 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]**.

00:11:34

### Speaker 2

Hello. For those who don't know me by now, I'm **[INFORMATION HAS BEEN REDACTED]** Survivors for Solutions and advocate for all patients no matter what their illness. I would like to thank CMS for allowing me to contribute at nine out of the ten of these public hearing meetings. I hope that the decision makers at CMS learn as much as I did that all patients shared one thing in common. Everyone during these sessions spoke to how vital their medication was to their well-being. Every single one. Yet this very negotiation program is already slowing innovation, and it only gets worse. To live with my disease, I, like millions of other patients, require a flowing pipeline of new treatments. While none of the drugs discussed are prescribed for multiple sclerosis, all are part of the same medical discovery ecosystem. I want to be a part of these sessions because ultimately, discovery for all is effective. In fact, when you interfere with one *[inaudible]* everyone. Saying you're targeting one drug is like saying you want cream in only half of your cup of coffee. Isn't that a nice thought? But in the real world, it's impossible. This drug on your hit list is a mechanism of interest to many researchers, including those fighting my disease. This, the *[inaudible]* on one drug will harm countless others. So, if you think you can isolate the damage you're doing think again. Innovations come out of wide-ranging scientific investigation. This current action is also having a wide-ranging impact, widely harming the hope of all patients. CMS has been given an impossible task to enforce a law that will help, that will hurt the very patients they are supposed to help. I do hope that you're listening carefully, listening to how vital innovative treatments are to how lives are saved by their discovery, and how you're destroying the medical research with regulatory overreach that is already choking future breakthroughs. Now I ask CMS, what will be done with these patient-focused hearings? It's been clearly established how vital these medical innovations are. Are you going to continue to steam-roll how medicines like Stelara are discovered at all? On behalf of patients everywhere, I implore you to protect patients' hope. Please consider the cost that this is already putting on those lives. Patients' hope for a future of better health is in your hands. Thank you.

00:14:25

### Kristi Martin, Senior Advisor, Center for Medicare

Thank you, **[INFORMATION HAS BEEN REDACTED]**. Please welcome our next 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]**.

00:14:39

### Speaker 3

Thank you and good afternoon. My name is **[INFORMATION HAS BEEN REDACTED]**. I'm an advocate and a patient living with chronic conditions. **[INFORMATION HAS BEEN REDACTED]** Chronic Care Policy Alliance. The CCPA is a network of state and regional advocacy organizations working on public policy that improves the lives of those living with chronic conditions and diseases. I became a health advocate because of my

own struggle to get access to a medical condition, and to find treatments that allowed me to resume my daily activities. What I learned through that struggle, and what I want you to take 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. One medication may eliminate symptoms for one patient, but not for another. As the negotiation progresses, we urge CMS to make sure the price negotiated protects patients who use the product while also preserving access to alternatives for those who need other alternatives. Stelara is an example of a medication that can be used to help people with a number of medical conditions. Ulcerative colitis is an inflammatory bowel disease that causes inflammation and ulcers or sores in your digestive tract. People who have this disease are often in pain and unable to be too far from a bathroom when the disease is active. It absolutely inhibits the ability to live a normal life. There is no cure. Crohn's disease causes abdominal pain, diarrhea, weight loss, anemia, and fatigue. Some people can have severe chronic symptoms that never go away. It leaves them in pain and unable to function normally. Crohn's disease cannot be cured. Psoriasis is a dysfunction of the immune system that causes inflammation in the body. Psoriasis plaques itch, burn, and sting. It can impact other organs and tissues in the body. People with psoriasis may also experience other health conditions. For instance, one in three people with psoriasis may develop psoriatic arthritis, which is swelling, stiffness, and pain in the joints and areas surrounding the joints, which become permanent. Neither of these diseases are curable. With these diseases, people deal with physical symptoms as well as emotional ones. They must hope that treatments available to them will be available so they can continue to enjoy and work and have a normal life. Patients need medications to be improved. They need new users found and cures discovered. We asked that CMS ensure that both the negotiation process and the other policies within the IRA support ongoing research into both new treatments and new indications for existing cures. Additionally, CMS should take great care to protect patients using the product off label or in a different dose from being penalized or their care interrupted due to the negotiation process. This is especially important for people with chronic conditions and rare diseases. Interruptions can progress, can cause progression of the disease, more pain and damage, and potentially increased use of the healthcare system. Thank you so much for this opportunity to present these comments.

00:18:01

[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 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]**.

00:18:17

[Speaker 4](#)

Hello. I am a resident of **[INFORMATION HAS BEEN REDACTED]**, Colorado and I'm here on behalf of the Global Healthy Living Foundation and the people who use Stelara, to share my personal experience with this treatment. 56 years ago, I was diagnosed with Crohn's disease, a type of inflammatory bowel disease that's caused by an overactive immune system. The condition's chronic and incredibly life changing without

a treatment to help manage the symptoms. Because of this condition, I experienced multiple bowel resections leaving me with nine feet of intestines. I tried many biologics over the years, hoping one would lessen the anxiety of finding the nearest restroom and needing spare clothes with me in case of an unexpected accident, as well as relief from the painful cramping and bloating that limited my activities. Unfortunately, one after another of those treatments failed. When my medical provider prescribed Stelara, I was hopeful. My insurance covered a huge portion of the cost with a \$75 copay. Which gave me one less burden to worry about and allowed me to focus on what matters the most to me and that's my health. I long to lead an active life with hiking and biking and walking in my neighborhood, taking car and boat rides and such without the worry of having enough time to reach a restroom in close proximity. Even entering shops, restaurants and businesses meant having to scope out where the restrooms were before I could relax and take part in anything. Many times, though, the painful cramping and the bloating kept me at home. Almost two months into being on Stelara, the symptoms were manageable, and they have remained that way for the two years or more that I've been on it. I can even eat certain foods again that would have normally caused issues. I can enjoy the activities that I love now. I feel the best I have in a very long time at 77 years old, I am finally living an amazing quality of life and I am thankful for having access to Stelara, which has made the difference for me. Thank you for listening to my story.

00:20:40

[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 Jaime, who registered in the category of other. Jaime reported no conflicts of interest. Welcome, Jaime.

00:20:56

[Speaker 5](#)

Thank you for having me. Good morning. I'm Jaime H. I'm a board member for IBDMoms, and I'm also a patient. I'm here today to share my experience with Stelara for Crohn's disease, psoriasis, and psoriatic arthritis. To summarize my disease impact, I was a sick kid who grew into a sick adult. I had not known a life without some form of body pain or fear of eating food because of painful consequences until my first dose of Stelara. I have lived with these diseases for more than 30 years. I just turned 42. Despite being chronically ill, I've always been driven. I was the youngest in my high school graduating class, but I was the oldest in my college graduating class. At age 28, I built my first house. I had a career and a life I loved. By 31, it was gone. I began a Crohn's flare in 2012 that has left me disabled. In a matter of a few months, I could no longer bend fingers into a fist or wear shoes due to inflammation and swelling. I cycled through five treatments before Stelara became available for Crohn's disease. Each led to severe allergic reactions. If you haven't experienced anaphylactic shock or pancreatitis, I don't recommend them. A little over a year on my last anti-TNF biologic, another severe allergy developed. It was early 2016, I feared hospitalization or surgery as my doctors felt we ran out of options until Stelara became available for Crohn's. Crohn's and psoriatic disease indications have different dosing. Insurance would not approve Crohn's dosing until it became approved by the FDA. My symptoms intensified by the day. I wasn't holding nutrition. Steroids were keeping me alive. Despite that, I accepted an invite to speak in DC. During that trip, I collapsed in pain while trying to walk half a block from my hotel. I felt like I was dying. Seven years ago today, my life changed. On November

14th, 2016, I received the Stelara loading dose. Two days later, I flew back to DC to speak at a congressional briefing about the ACA. I walked five miles that day unassisted, and for the first time since childhood, I ate a pain-free meal. Not every day since that infusion was like that, but it showed me that there's a treatment that can work and work well. It still took over three years to achieve remission for my conditions. I got married. I can walk unassisted most days, and I made a whole person who just turned two years old. It's not just my miracle, it's also one for many people I know and love. Quite a few of them can no longer affordably obtain Stelara due to the donut hole or their Medicare plan removing it from formulary. I fear for them, and I fear for me. At the time of writing this, Stelara locally priced is \$26,000 to \$29,000. My PBM marks it up to \$54,000. Something needs to be done and I hope you can help my communities and thank you for your time.

00:23:51

Kristi Martin, Senior Advisor, Center for Medicare

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

00:24:06

Speaker 6

Thank you so much. Hi, my name is **[INFORMATION HAS BEEN REDACTED]**, and I'm here today as a Crohn's patient. I'm also a former Army officer, Afghanistan veteran, and unfortunately, one of the many vets who suffers from multiple illnesses due to burn pits. Just one of those illnesses happens to be my Crohn's disease, which also happens to be the illness that has been most effective on my on my life. Ten years ago, after suffering some pretty horrific GI issues as most Crohn's patients have, I was finally diagnosed with Crohn's disease. It certainly took an entire toll on everything in my life. I lost my career. My disease was so severe that I couldn't get to work. I couldn't leave the house. I couldn't leave my bathroom most days and over about six years, we continually tried to find the right medication for me and continued to fail. We finally settled on Humira, which seemed to at least get me not symptom free, but I was able to get out of the house again. Unfortunately, starting in February of 2020, over a period of about 19 months, I started getting severe symptoms such as muscle myalgia. I had been training for IRONMAN Chattanooga. I suddenly couldn't exercise at all; I went from being a lifelong runner to not being able to run across the street. I had rashes, I had severe joint pain and eventually started having tremors as well, which is what brought me to the neurologist. At that 19-month mark, as I had developed the tremors, I'd also lost my ability to walk. And that's when I found out that I was experiencing a severe reaction to Humira. It had caused drug-induced lupus and a neurological condition that we still don't know if it's permanent yet or not. So, I may have a new condition on top of the ones I already have. After I came off the Humira, of course my symptoms came back and once again I became homebound, unable to move, unable to do anything, in severe pain. That's when they finally put me on Stelara. Stelara, after the first eight weeks, I really reached remission and after six months I was in symptom-free remission for the first time in ten years. This is my first opportunity to really feel like I'm getting my life back and able to do the things that I once loved. It's difficult to get your life back, but it certainly does present a much better life to have that opportunity rather than not having it at all. And I refuse to use the "L" word because I don't think anybody who deals with this is a lucky person at all. But I

am fortunate in that being a veteran, I have care by the VA hospital and my Stelara is delivered to my front door free of charge. As much as this has impacted my life, I went from a very independent Army Officer to a person who worked in consulting and was very independent to being completely dependent upon my VA benefits, my husband, and the business I was able to start in my spare time. So, I would really hope that everybody could get that opportunity like I have to get the medication that can bring their life back, but without going broke.

00:27:29

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 representative of a patient advocacy organization. **[INFORMATION HAS BEEN REDACTED]** reported a conflict of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

00:24:44

Speaker 7

Thank you very much. My name is **[INFORMATION HAS BEEN REDACTED]**. I'm **[INFORMATION HAS BEEN REDACTED]** the International Foundation for Autoimmune & Autoinflammatory Arthritis, also known as AiArthritis. We're the only organization in the world that narrows over 100 auto disease to a couple dozen that also include inflammatory arthritis as a major clinical component. Also unique to AiArthritis, our leadership consists of people living with our disease and their care partner. As such, our slogan is: we don't represent the patient voice, we are the patient voice. Our mission includes listening to our peers who identify missing gaps in education, awareness, advocacy, public policy, and research. And then we work to design innovative, peer-led resources, guidance, and solutions. We know that Stelara has shown positive impacts in the treatment of moderate to severe Crohn's disease by providing an effective medical management approach, especially in patients who have not respond to anti-TNF agents. It also offers potential alternative for those who may not have had success with other treatment options, contributing to the improved disease management and quality of life for many individuals. The reported miracles of treatment with Stelara from patients include various positive experiences, with many describing as a miracle drug. For instance, we have heard other users mention that in their first shot of Stelara for psoriatic arthritis, their scaling was 99.9% gone within the first 30 days. Another patient with Crohn's disease expressed gratitude for Stelara, stating it kept them from remission for almost five years. It was easier to administer and did not burn like other previous medications. This is just an example of how important potential side effects are to consider as well. As a biologic burning is too cumbersome, for some, adherence would become an issue and as a result, could worsen desired outcomes. Additionally, a patient who have joined a clinical trial for Stelara to treat Crohn's disease reported the achievement of remission for the first time in a decade after more than 20 surgeries. The point is, when Stelara works, it works. It may not work for everyone, but when it does, it's a miracle drug. We also know that it's an efficacy in treating multiple conditions. Stelara has been proven for treatment for moderate to severe plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis. Its versatile efficacy is many of the reasons that we know how Stelara has been improving lives. It is also improving quality of life, dosage, convenience, positive safety profile, alternative for non-responders, easy of administration, and research-backed results. The



effectiveness of Stelara has been supported by a range of clinical studies demonstrating its ability to achieve and maintain remission in patients with conditions like Crohn's disease to effectively reduce the severity of Crohn's and psoriasis symptoms. I appreciate your time and we thank CMS for taking the time to listen so many patients and patient advocacy organizations, thank you.

00:30:19

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 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]**.

00:30:34

Speaker 8

Thank you for having me. My name is **[INFORMATION HAS BEEN REDACTED]**, I'm a person living with psoriasis and psoriatic arthritis. I've had psoriatic disease for 30 years. For the first 16 years, my treatments were limited to phototherapy, creams, and anti-inflammatories, none of which were effective for my arthritis. In high school, when my arthritis became prevalent, I had trouble sleeping, exercising, I had to quit soccer and replace all my recreational activities with physical therapy. After school, I would go right to bed because of the fatigue, and sometimes I wouldn't even make it to school because I couldn't sleep or had trouble walking due to my hip pain and morning stiffness. In college, I learned about biologics. I tried Humira first, which actually made my psoriasis worse. I did research and learned that a new biologic called Stelara had hit the market. It had only been FDA approved for a few years, which is scary but what was scarier was the alienation by my peers due to the look of my skin and the inability to participate in activities. While Stelara did not get me 100%, it got me pretty close. I was able to play recreational sports again, participate in all the college activities, and even complete an archeological dig. Most importantly, I was able to establish myself as a working professional without the stigma of my disease. I had seven years of relatively normal life with only occasional flares. Unfortunately, after seven years Stelara started losing effectiveness. If I knew what I knew now, I would never have stopped taking it. I spent the last six years trying new treatments, basically every biologic on the market and then some, and none have been as effective as Stelara. Without an effective treatment, I had to wear braces to do normal activities like cutting my food, yard work, walking the dogs, use kitchen aids to open cans and stir. I can't even write the statement I'm sharing today without pain or type throughout a day's work. Seven years is a long time to feel normal with a chronic disease, and without affordable access to medication like Stelara, there's no way would be where I am today with my education or my career. Access to medications like Stelara are imperative for people with a chronic disease like mine to live a good quality of life and urge you to make that available to them. Thank you.

00:32:47

Kristi Martin, Senior Advisor, Center for Medicare

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

00:33:06

### Speaker 9

Thank you. My name is **[INFORMATION HAS BEEN REDACTED]**. I am 60 years old and from **[INFORMATION HAS BEEN REDACTED]**, Utah. For more than half of my life, I spent my professional career **[INFORMATION HAS BEEN REDACTED]**. But today, I am fully retired at no easy choice of mine. I retired in 2018 due to my diagnosis with Crohn's disease and diabetes. For context, in 2010 an emergency room visit changed my life forever. I ended up in the ER for a bowel obstruction and was finally diagnosed correctly with Crohn's disease, after being either undiagnosed or misdiagnosed with IBS for about 15 to 20 years. Four months after the ER visit, I underwent colo-rectal surgery where 3.5ft of my small intestine and half a foot of my colon were removed. Over the span of 13 years since my surgery, I have been put on a range of biologics to manage my Crohn's disease, including Humira, then Entyvio, and Renflexis to help me adjust to my new normal. I have been on Stelara since January of 2023, where every eight weeks I take an injection listed at \$26,517, with the copay listed as \$2,641.09. I am thankful to receive copay assistance, but it won't last long as copay assistance only works with private insurance. In a couple of years, I will be an enrollee of Medicare. And as things stand now, there will not be any financial assistance programs available to me. I must note that between my wife, who is on Medicare now, and I, we are on five of the ten drugs up for Medicare price negotiation through CMS. The total price charged to our biopharmacy of the other four drugs Entresto, Jardiance, Eliquis and Farxiga is \$3,805.52 a month with a total monthly copay of \$417.98. This is in addition to the cost of Stelara. This is why I believe negotiating for lower prices is crucial. I am already on a fixed income and have been hit financially hard with medical expenses between my wife and I, which means lower drug prices will ultimately let us enjoy some savings and give us more breathing room that we desperately need. Drugs don't work if people can't afford them, and we must put the innovation talking points aside when most drugs on the market are funded by the American taxpayer. Thank you, CMS, for allowing me to speak and thank you to everyone else for listening.

00:36:17

### Kristi Martin, Senior Advisor, Center for Medicare

Thank you for your comments, **[INFORMATION HAS BEEN REDACTED]**. Please welcome our next speaker, **[INFORMATION HAS BEEN REDACTED]**. **[INFORMATION HAS BEEN REDACTED]** registered as a representative of a patient advocacy organization. **[INFORMATION HAS BEEN REDACTED]** reported a conflict of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

00:36:32

### Speaker 10

Hi, I'm **[INFORMATION HAS BEEN REDACTED]**, **[INFORMATION HAS BEEN REDACTED]** the Partnership to Fight Chronic Disease. Thank you so much for hosting these sessions. Stelara has FDA approval for several autoimmune conditions: plaque psoriasis, psoriatic arthritis, Crohn's disease, and Ulcerative colitis or UC. UC and Crohn's are chronic progressive inflammatory diseases that involve recurrent flares associated with substantial abdominal pain, diarrhea, weight loss, fatigue, and bowel injury. Without a cure, remission is the

goal and not only provides symptom relief, but importantly, also allows the bowel to heal. Remission can last for months or years, depending on the person, and Stelara enables remission for many. Few of us can imagine being unable to leave our homes without fear of bowel incontinence or anal bleeding, needing ready access to a restroom at any time, and risking the embarrassment and stigma associated with bowel urgency and incontinence. Nighttime bowel incontinence is also an issue, adding to the burden of illness for patients and caregivers. The higher the symptom burden, the greater the anxiety and overall mental health toll of living with these conditions. Also, with each flare, people face more inflammation that increases the hazard of permanent injury and need for major abdominal surgery. Per the Crohn's and Colitis Foundation, up to 45% of people with UC and as many as 75% of people with Crohn's will eventually require surgery. Multiple surgeries for Crohn's can lead to too-short of small intestine, creating malnutrition and high morbidity. For people who respond well, Stelara's use reduces the need for surgery by enabling remission and allowing the bowels to heal. Treatment is nuanced for autoimmune conditions, and what works well for one person may not work at all for another. Treatments can also lose effectiveness over time, and comorbidities are common. Both may require treatment changes, can lead to treatment stoppages, and a higher burden of illness. These unmet needs and the need for choices are essential for patients. Once diagnosed, people face multiple hurdles to gain and maintain drug access, having to requalify for treatment or health plan changes that restart step therapy are common. A study by Let My Doctors Decide showed that most Medicare plans scored poorly on patient access to medicines across the four conditions that Stelara treats, because of the significant access barriers that plans impose. Today's unanswered question is how much will CMS value the achievement of additional indications that address unmet needs? Stelara received FDA approval for treating Crohn's and UC seven and ten years, respectively, after its first FDA approval. Those efforts add tremendous value in providing new treatment options, enhancing remission, and reducing the heavy toll of illness. We should encourage these efforts by valuing them. Thank you again for this opportunity.

00:39:35

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

Thank you, **[INFORMATION HAS BEEN REDACTED]**. Now we'll move on to our final speaker for today's session. Please welcome **[INFORMATION HAS BEEN REDACTED]**. **[INFORMATION HAS BEEN REDACTED]** registered as a representative of a patient advocacy organization. **[INFORMATION HAS BEEN REDACTED]** reported no conflicts of interest. Welcome, **[INFORMATION HAS BEEN REDACTED]**.

00:40:07

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

**[INFORMATION HAS BEEN REDACTED]**. Can you, can you restart? I think you were muted. You're still muted **[INFORMATION HAS BEEN REDACTED]**.

00:40:17

[Zoom Technical Lead](#)

If you are muted, try star six on your phone.

00:40:20

Kristi Martin, Senior Advisor, Center for Medicare

Try star six on your phone **[INFORMATION HAS BEEN REDACTED]** to see if that can unmute you.

00:40:26

Speaker 11

Okay. I'm unmuted.

00:40:28

Kristi Martin, Senior Advisor, Center for Medicare

We can hear you. Go ahead, **[INFORMATION HAS BEEN REDACTED]**. Okay.

00:40:30

Speaker 11

Okay. All right. Great. Thank you. Hello and thank you for this opportunity. I **[INFORMATION HAS BEEN REDACTED]** AiArthritis, which stands for the International Foundation for Autoimmune & Autoinflammatory Arthritis. And I'm here to represent the millions of patients nationwide who have improved quality of life because of their access to Stelara. As the Centers for Medicaid and Medicare Services begin to implement this negotiation process, we just want to really take an opportunity also to express our gratitude for the efforts to include patients in the conversation as an organization, as an organization whose tagline is we don't represent the patient voice, we are the patient voice. We will continue communicating with CMS representatives to ensure that the agency places patient welfare in the forefront of the process, and that patient input is considered every step of the way. An autoimmune and auto inflammatory arthritis diseases, we need to understand if they are heterogeneous, which means they can be unique to individuals even within the same diagnosis. They are caused by issues when the body's immune system, which is complex and requires regulation and overactivity caused by this uncontrolled inflammation. Well, there are many biologics and biosimilars on the market, the mechanism of action and how it responds to that individual is important to understand. In this case, an interleukin 12 and 23 antagonist may sound like a bunch of mumble to a lot of people, but for people that it works, it's important to note. Also, recent guidelines Stelara was recommended as one of the medications to use in people with moderate to severe disease, which is a subgroup, and if they have failed, a TNF inhibitor, which is often first prescribed. Other things to consider about these diseases, Stelara is to indicate includes the high prevalence of comorbidities, and that, that must be considered when and through the doctor patient decision-making process. Given the average age of onset for these diseases is 20 to 40 in adults in any age in children and uncontrolled inflammation leads to these types of inflammation, it is vital that the person has access to the treatment that works well for them. Regarding alternative therapies, AiArthritis would like to stress there is no such thing as an alternative therapy when a biologic like Stelara is working. If any other drug targets the same mechanism of action, that's fine, but never disrupt the continuity of care because it may not work the same if you put the patient back on it again. As you've heard of all of these many stories, it gives people's life back. It allows them to go to school, have jobs, hold their children. Please don't ever lose health. Have patients lose access to the one miracle drug that makes a difference in their lives. Thank you so much.

00:43:08

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 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](#).

