# Transcript: Otezla Roundtable Event, April 23, 2025, Medicare Drug Price Negotiation Program Public Engagement Events

*This transcript was lightly edited for readability.*

## Introductory Remarks

### Moderator, RTI International

Thank you so much for coming today. Hi, I'm **[MODERATOR]** from RTI International, and my colleague, **[SECONDARY MODERATOR]**, is joining me today, and she'll probably hop in here and there throughout our conversation today to ask questions.

So today, the Centers for Medicare & Medicaid Services, or CMS, is convening this patient-focused roundtable event as part of the Medicare Drug Price Negotiation Program. And the purpose of today's event is to hear from y'all, a group that may include patients, caregivers, patient advocates, about your experience with the conditions and diseases treated by Otezla, as well as other similar drugs.

Today, we do welcome input on other topics related to the Drug Negotiation Program. But we would ask that you send those through the mailbox, the IRARebateAndNegotiation@cms.hhs.gov, and we'll have that up at the end of the meeting. But today we really want to hear patient voices, caregiver voices, or if you're representing a patient advocacy organization, hear from the people that you serve. So, it's a dedicated time for hearing voices that may go unheard.

The information shared during these events will help CMS understand patient experiences with these conditions and diseases, as well as you all's experience with different drugs and Otezla.

CMS may also use this information to negotiate Medicare pricing with manufacturers of the selected drugs, so that makes your experience and perspective just extra important to us. And we genuinely appreciate your time today. So, we have a brief video from CMS leadership just to reiterate the value that is placed on your time and perspective. So, I'm going to hand it to our Telligen colleagues to share that video from CMS leadership.

## CMS Remarks

00:02:02

### Steph Carlton, Deputy Administrator and Chief of Staff, Centers for Medicare & Medicaid Services

Greetings, everyone. I'm Steph Carlton, the Deputy Administrator and Chief of Staff 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. Lowering the cost of prescription drugs for Americans is a top priority of President Trump and his administration. As the second cycle of negotiations begins under the Trump administration, CMS is committed to engaging with stakeholders for ideas to improve the Negotiation Program.

In January 2025, CMS announced the 15 Medicare Part D drugs selected for the second cycle of price negotiations. Medicare's ability to negotiate directly with drug companies will improve access to some of the costliest drugs while fostering market competition and continuing 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 Medicare Drug Price Negotiation Program. And that is why the process for negotiation engages you, the public.

This event is part of our effort to hear directly from a range of stakeholders and receive input that's relevant to the drugs selected for the second cycle of negotiations. Thank you again for joining us. Your input matters. And next, stay tuned to hear from the event moderator to give you more details on what to expect during this event.

00:03:58

**Moderator, RTI International**

Thank you so much. So, in addition to the video, I wanted to make you all aware that staff from CMS will be sitting in on this roundtable event today so that they can hear directly from you about your experiences. So let me hand it over to **[CMS STAFF]** for a moment, so that she can say hello.

00:04:17

**CMS Staff**

Yes, good morning, everyone, and welcome. We have staff here today from our Medicare Drug Price Negotiations team, as **[MODERATOR]** mentioned. And we just want to thank you all for being here today and participating. We're really looking forward to hearing what you all have to say. We are going to be off camera during the discussion, mostly so you guys can focus on discussion. But I do want to let you know that we are here and listening, so thank you.

## Housekeeping

00:04:44

**Moderator, RTI International**

Thank you so much, **[CMS STAFF]**. All right. So, before we begin, there's always housekeeping and administrative items, just so that everyone knows what to expect. So, I'll go over these quickly so that we can dive into the conversation. So participation, first, we hope that you will contribute your perspectives throughout the call today. However, if questions arise that you don't want to answer, you don't have to. It's no problem.

Background noise, so if possible, turn off your cell phone or turn the ringer down if you can, and please mute yourself when you're not speaking.

Privacy, this discussion is not open to the press. It's not open to the public. As you saw when you came in, we're going to use first name and last initials only through the discussion to protect your privacy.

We also ask that you don't share any unnecessary personally identifiable information or unnecessary personal health information during the discussion. As you can see, we are audio and video recording today. But these recordings will not be shared publicly, and following this event, CMS will produce transcripts. But your identifying information will be removed from the transcript. Those transcripts will be made available publicly.

Okay, a few other items and related to housekeeping. Video, thanks in advance for keeping your video on throughout the discussion so that we can see each other's faces.

Timing, we have about one hour and 30 minutes, and you probably have seen me hold up my paper a few times. I have this discussion guide in front of me. We have a lot of questions to cover in this hour and 30 minutes. So, now and then throughout the conversation, I might have to say, oh, we need to move along, or I might need to interrupt. It's not that I'm trying to be rude. It's more of an artifact of keeping to time.

And then technical assistance. If you get disconnected, please attempt to rejoin. If you cannot rejoin, please use the mailbox there on the screen, the IRADAPStechsupport@telligen.com.

And if you need a break, step away for a moment. You don't have to tell me, hey, I'm going to the bathroom. Just turn off your camera, turn off your microphone, step away and come back as soon as you can.

Speaking, just nice, kind rules to please try to speak one at a time. Again, I might need to interrupt if things start going a little long. I might say, thank you for this, we need to keep moving. Again, not trying to be rude, just trying to make sure everyone's heard and trying to keep us moving, or if two people speak at the same time, I might say, oh, hey, **[Participant 7]**, you go first, and then we'll get to **[Participant 3]**.

And then honest opinions, your opinions and experiences will differ. And that's perfectly fine. We just want to know what each of you honestly thinks and what your life experiences are.

Okay, so that's all my housekeeping items. I'll open the floor and see if folks have questions about process before we begin.

All right, hearing none, I'll start with introductions. I'd like to begin our discussion today by having everyone take about 30 seconds to introduce yourself. So if you would say your first name, the condition or conditions that you use Otezla or the folks you know use Otezla to treat, so oral ulcers and Behçet's disease, plaque psoriasis, psoriatic arthritis. Please indicate that.

And then, please share what perspective you'll be sharing, whether it's a personal experience as a patient, as a caregiver, or if you're speaking for the voices of many patients in a role as a patient advocate. So, I'll go ahead and just call on folks by order on my screen. No favoritism today, just by virtue of chance. So, **[Participant 1]**, it looks like you're first today. Good to see you.

## Discussion

00:08:55

### Participant 1 (registered as a representative of a patient advocacy organization)

Good to see you. Wasn't ready for that. Thank you very much, and you did a wonderful introduction, and I want to thank everyone, my fellow panelists, speakers, and thank you to CMS staff for listening and letting us know that you're there, because it's a breath of fresh air from last year's sessions, where I was on these similar hearings, and it was a little more than barking into the wind. So, it's nice to know there are humans in the loop here, and there'll be feedback back and forth, and so but thank you for listening to patient voices. My story is, my name is **[Participant 1]**.

My entire life, I've had chronic disease, MS, in my case, so I know with Otezla, I see the importance and value of basic [inaudible] with a pill? So, wow, what a breath of fresh air it is to have that innovation. Now again, I can't wait to hear from real users of this, but I know in my case I went from living in a world where there were no treatments to having many. So that was that [inaudible] innovation pipeline, I really, really want to help preserve this. Thank you very much.

00:10:20

**Moderator, RTI International**

Thank you for your passion, **[Participant 1]**. Let's see, who's next on my screen. **[Participant 2]**?

00:10:28

**Participant 2 (registered as a patient)**

Good morning. My name's **[Participant 2]**. I have psoriatic arthritis. I've lived with it for 20 and a half years.

Otezla has been the medication that's worked the longest for me. At eight, eight and a half years I've been on it. I've kind of lost track of exactly how long. I have tried many medications. I have multiple comorbidities with the psoriatic arthritis, autoimmune diseases, and it's varied from being completely bedridden, wheelchair-bound, almost on my deathbed at one point, to not needing my wheelchair, not needing a walker, not even needing a cane most days right now, being able to get around and manage my disease with the Otezla.

The medications I've been on and tried over the years have run the gamut and Otezla's been the one that's worked and worked the longest for me.

00:11:46

**Moderator, RTI International**

Thank you, **[Participant 2]**, and we'll be definitely following up. That sounds like a very rich experience to share today. **[Participant 3]**, you're next on my screen.

00:11:58

**Participant 3 (registered as a representative of a patient advocacy organization)**

All right. Can you hear me?

00:12:00

**Moderator, RTI International**

Yes.

00:12:02

**Participant 3 (registered as a representative of a patient advocacy organization)**

Great. My name is **[Participant 3]**. I'm a **[REDACTED]** by training. I'm here representing Haystack Project. I'm **[REDACTED]**. We are an umbrella organization of over 140 rare and ultra rare disease patient advocacy organizations. Of note, Otezla is a treatment for several rare diseases, including Behçet's, as well as pediatric, moderate, and severe plaque psoriasis. I'm also the mom of a child with a rare condition. So just here, speaking on behalf of our community today. Thank you.

00:12:44

**Moderator, RTI International**

Thank you, **[Participant 3]**, so we may ping you for a couple of the conditions throughout. All right. So, **[Participant 4]**, you're next on my screen.

00:12:54

**Participant 4 (registered as a patient and representative of a patient advocacy organization)**

Hi! My name is **[Participant 4]**. I have multiple chronic illness diseases. I have rheumatoid arthritis. That was what I was first diagnosed with. Upon working with my rheumatologist and going through all the skin conditions I have, I also was diagnosed with psoriatic arthritis and a specific piece of psoriatic arthritis, hidradenitis suppurativa, which, of course, Otezla treats, but I am no longer, unfortunately, on Otezla, because I'm a hard-to-treat patient, but I wanted to bring my experience with it to here.

00:13:36

**Moderator, RTI International**

Thank you, **[Participant 4]**. Yeah, that is absolutely one of the critical components of the discussion today. So, thank you for being here. **[Participant 5]**, you're next.

00:13:47

**Participant 5 (registered as a patient)**

Hi, everyone. My name is **[Participant 5]**. I'm a disabled **[REDACTED]**. I'm a stage 3 cancer survivor, and I live with psoriatic arthritis, fibromyalgia, and axial arthritis. I've been managing chronic illness since I was **[REDACTED]** and went out of remission when I was **[REDACTED]** due to cancer. I live with a pain level of about 8 and 9 on a daily baseline and use several mobility aids to get around. I'm giving you a patient perspective. I also want to warn that I do have a service dog, and she might alert during the call. Why I'm here with Otezla is, I have failed three biologicals so far. I'm currently on Otezla as a Band-Aid between finding the next best solution.

At first it helped with my skin, but it's no longer doing much. It's a temporary fix while we wait for an infusion approval, hopefully, that it's starting in **[REDACTED]**.

Biologicals are extra risky for me. They are a trigger to reoccurrence for my cancer. So, every treatment choice is very high stakes between relief versus risks, and it's not a decision that I can take very easily.

I'm on disability and extremely grateful for the use of Medicare. It's made a huge difference in my ability of care. But at the same time, it's very limiting, because many manufacturer coupons and patient assistance programs don't work together very well with Medicare, so it makes treatment harder and longer to actually get to and afford even. I don't do this alone, so I have a caregiver and a service dog, and it takes a lot to manage my conditions, which I consider almost having a full-time job just for my health.

I'm here for more, also because people like me deserve to be heard, and a lot of the times we don't have the energy sometimes to advocate for ourselves. So, I'm trying to be here for others. I'm also trying to find a way where, without financial punishment of being sick, we can find a better solution for medications. So, thank you.

00:15:54

**Moderator, RTI International**

Thank you, **[Participant 5]**, for being here and through your challenges and speaking up and having voices heard. **[Participant 6]**, you're next on my screen.

00:16:04

### Participant 6 (registered as a patient, representative of a patient advocacy organization, and as other)

Thank you so much for the opportunity. My name is **[Participant 6]**. I am here representing a couple groups, so patient organization, which is Arthritis International Foundation for Autoimmune and Autoinflammatory Arthritis. We actually cover all of the diseases and conditions that are treated by Otezla. So Behçet's, psoriatic arthritis, also plaque psoriasis falls under our comorbidities, and also I am a patient living with axial spondyloarthritis. Although I have not personally used Otezla, I have used similar treatments as well, and then I'm also representing a coalition, the EACH [Ensuring Access through Collaborative Health] and PIC [Patient Inclusion Council] Coalition that focuses on patient inclusion council, which is all about the patient voice and listening to stories and experiences on Otezla and other diseases and treatments.

00:16:56

### Moderator, RTI International

Thank you, **[Participant 6]**, so we'll hear your voice multiple times as we talk about each condition. Thank you. And **[Participant 7]**, you're next.

00:17:04

### Participant 7 (registered as a patient)

Hi! I'm **[Participant 7]**. I am a patient living with psoriasis and psoriatic arthritis, as well as a couple other comorbid conditions. I have run the gamut of many of the treatment options, including Otezla, which I am not currently taking. But it was an important step in my journey to finding my right treatment.

00:17:34

### Moderator, RTI International

Thank you, **[Participant 7]**, and again, I'll call on you a couple of times throughout for each condition. And, **[Participant 8]**, why don't you wrap us up?

00:17:42

### Participant 8 (registered as a representative of a patient advocacy organization)

Maybe we'll wrap things up, and maybe my perspective is going to be a little different because decades ago I went through the process of trying to find out what was my condition. I went to a PCP [primary care physician], had no ideas, sent me to a rheumatologist who had no ideas. Luckily, my daughter, my young daughter at the time, had a chemical peel need, went to a dermatologist who was brand new, talked about it a little bit. I said, well, what's this stuff on my kneecap? And he said, you've got psoriatic arthritis. Go see a rheumatologist. So over a period of five years, I struggled with trying to find out what was going on.

But unfortunately, there was no real success in treating. They put me on Vioxx, which had to be pulled from the shelves because it was so bad. And then they put me on Celebrex, which really didn't do that much for anything, pain or otherwise. So, I basically said, I'm just gonna live with PSA [psoriatic arthritis] and stopped taking medication. I'm now with an advocacy group, the Nevada Chronic Care Collaborative. And I work with people who have been on Otezla and dealt with what I dealt with, but they're getting relief that I didn't get relief from.

00:19:02

**Moderator, RTI International**

Thank you, **[Participant 8]**. Sounds like we have a whole depth of experience here today. One more thing in the introduction section before we dive in, and some of y'all had spoken on this already. Put this in the chat, if you would, and it can be a yes or no. Have you or your loved one taken Otezla, whether currently in or in the past? And just enter yes or no. Let's make sure everyone is all set for the chat as we get underway. Perfect, fantastic.

Okay, so again, thank you very much y'all, for introducing yourselves and telling us what perspective and experiences you'll be bringing today. I want to start talking about y'all's experience with the conditions treated by Otezla as well as other drugs. And so, there's a lot to talk about with this question. So, if you see somebody talking and you want, again, please feel free to raise your hand. I'll try to make sure to moderate and make sure folks are all heard.

Given that in the introductions folks had said psoriatic arthritis the most, I'm going to start with that condition. But we'll also go through plaque psoriasis and Behçet's disease. So, starting with psoriatic arthritis, how does psoriatic arthritis affect your life or the ones you know, how does it affect their day-to-day lives? What is your life like with this disease?

00:20:27

**Participant 2 (registered as a patient)**

I'll be happy to start. At the time of my onset, I was an **[REDACTED]**, so I taught **[REDACTED]**. I went from being able to work a lot of days, 14 hours. That was my day as an **[REDACTED]**.

And it started in my knees, and someone who's had multiple knee surgeries before my onset and things, I thought, oh, great, what did I do with my knee again? And it progressed from there. In less than a month, I was in a wheelchair and my orthopedic surgeon is going, this looks rheumatological, you need to get into a rheumatologist. I've been through five rheumatologists. First one looked at me, says, no clue, you need to find someone else. Went to **[REDACTED]**. He kind of got us on the right path, started, kind of gave a tentative diagnosis of adult-onset Still's disease. Then we started what is called step therapy at that time, and it didn't work. I'm going to forget the name of the medication. It's an anti-malaria drug that was often used to be the first step in treatment, and it didn't work. I went back and I was like, this is not working. He basically told me he didn't care, and to keep taking the medicine, and he'd seen me in three months, and I was like, no, you won't. I'm going to find somebody else that actually cares about my treatment. Then I went to the **[REDACTED]**. There is where I met a gal who just started her fellowship in rheumatology. and she said, I don't know for sure what you have, but I will stay with you, and we're going to work to find something that works.

It was through her I started on Rituxan infusions. Helped a little. Not a lot. At this time I have no skin plaques or involvement. So, psoriasis or psoriatic arthritis was not even really on our radar as a possible diagnosis. When she finished her fellowship, I was not allowed to follow her because of the insurance I had at the time. Because she is out of state. I live on a border between two states, and she happened to be on the other side of the state line. And that is a problem, especially for people that live on borders. And the guy that had been the supervisor of her fellowship took over my care, and he was convinced I had Mediterranean fever disease, or something like that. And I'm like, I'm not Mediterranean descent. And we did genetic testing. It wasn't the case. He quit my treatment. This is where I almost ended up dying. I got so bad. I couldn't do anything for myself. And then my parents, I was still fighting for disability at this time. My family said, we'll find a way of paying for my treatment if I could go back to my doctor, that had been working with me, trying to figure out what was wrong. And during that time my parents were cleaning up, trying to make the house more handicap accessible, happened to find a slip of paper from a dermatologist I seen when I was a kid where I've been diagnosed with psoriasis. And when we found that paper, I was like, oh, yeah, I kind of remember that. I had these things on my knees and elbows for like three months. And they went away with steroid cream treatment, and they never came back, so I never thought about them again.

And when I went back to my current rheumatologist, and she's like... I mean I couldn't fight anymore, my body is starting to give up. And she said, all right, I got a crazy idea. Let's try treating you for psoriatic arthritis. At that point in time, I was like, I will try anything. And so, she started me on Humira. And it took about three months, but it actually worked.

It was a roller coaster ride. I'd get the shot, and I'd have this high, and then, two weeks later, right before I was due for my shot again, I crashed. And it was this constant up and down motion. I don't like that, but I liked the fact that right after my shot, I was pretty good compared to where I had been. I could do some things for myself again, and I was in my late twenties by this time. That's important for someone that age. And she said, okay, well, Enbrel is a simpler biologic, but it's only a week. Let's try it. So, we went to Enbrel. It did not work at all. I got worse. We went back to Humira, and Humira worked for me for five and a half years. When it failed, I developed multiple comorbidities. I developed autoimmune inner ear disease, Sjögren's, I have Raynaud's.

So, these are all things that came about, and when we tried Remicade, I had a major reaction within two, three infusions. And then Otezla had been recently approved for psoriatic arthritis, and that is when I went on Otezla. And the thing I absolutely love with Otezla is it's a pill I take twice a day, and if I get sick, I can stay on it. I don't know how many times I get a cold, and I have to postpone my biologic and then I'd flare. And it was this never-ending cycle. And with Otezla, it kind of stops that cycle for me.

00:27:42

### Moderator, RTI International

Thank you, **[Participant 2]**. I've heard so many things. Difficulty getting diagnosed, difficulty fighting to get treatment, and just the general cycle of trying to get the right medication. **[Participant 7]** and **[Participant 5]**, I see that you all have posted something in the chat. Do you mind if we hear a little bit from you about your experience with psoriatic arthritis? **[Participant 5]**, looks like you have your hand up. Please go ahead.

00:28:08

### Participant 5 (registered as a patient)

So, mine is a little bit different. I am now **[REDACTED]**. I started this journey, again, I was a juvenile arthritis warrior at **[REDACTED]**, stopped, regained again at **[REDACTED]**. I can't work anymore. The pain is so daily and severe, and it feeds off the other chronic conditions that I manage. My joints have deteriorated so much. My fingers are the size of little sausages half the time, and very hard to fold, very hard to grip. I have what my family calls butter hands, because they're so swollen.

If it weren't for PT or physical therapy, I wouldn't be able to move. I rely on a cane, a walker, or a wheelchair depending on how I'm functional that day, and I used to work 16 to 18 hours a day in the medical field. So going from something like that to not being able to move at all is very deteriorating also for your mental health.

And now, even getting out of bed, I feel like it's a battle. The fatigue that comes with everything deteriorating, plus the medications you take, is very crushing. It's not like tired, like you could take a nap and get up. It's like bone deep exhaustion that doesn't feel like it's going to lift or get any rest. And it's on top of everything, with the fact that some of the psoriatic arthritis and other issues that I have affect the bones in my neck, my migraines have also gotten worse. So, all of that combined. And then for years I was told that I just had anxiety or fear of surviving cancer, and that my pain was something that I was experiencing from being depressed, and it was brushed off. And it wasn't until I had a stroke and spent weeks in the hospital, and my inflammation, didn't matter what they did, never went down. When they put me on potassium, it skyrocketed my blood pressure, like different things that they give me at the hospital, and one nurse, she had rheumatoid arthritis herself, and she's like, I think you have a form of arthritis. Obviously, I'm not a doctor. I can't diagnose you. I'm going to speak to the on-call doctor, and they tried an anti-inflammatory. And all of a sudden, everything reduced, and they put me on steroids in the hospital. And that's when I was finally acknowledged.

It has taken me three denials to actually be approved for disability. I actually had to go in person and have a hearing, and I could barely hold my own weight at my hearing back in the day because I had gained so much weight from being bedridden, and I was finally approved. So, I'm trying to keep being functional, but barely being functional. So, I'm trying to find a new avenue of work where I can work from home.

So, a lot of adjusting has happened, and that adjustment has also affected my family. It affected my mom, who was my caregiver until she passed away, and then my husband took over. It has affected us financially, so like they say that being sick also affects your pocket, and I agree with that detrimentally, because people don't realize that mobility aid is not always covered by your insurance. Adjustments to your home and things that you need to get done to your home for you to have a livable life, are not covered by insurance, and then add the cost of medication to that, you have to kind of pick what you can pay for, and where you have a survivability to be able to just live. But, that's my perspective.

00:31:57

**Moderator, RTI International**

Thank you, **[Participant 5]**. It's a lot of calculation just to manage and survive.

I'm going to ask one more question related to psoriatic arthritis, and I'm going to jump to another condition in this section. So, what aspects of psoriatic arthritis are most important to you, or those that other patients that you work with to have managed or treated? So, what aspects of psoriatic arthritis are most important for you to have managed or treated? **[Participant 7]**, thank you for hopping in, because I know you had some items in the chat.

00:32:29

**Participant 7 (registered as a patient)**

Yeah, so for me, psoriatic arthritis is complicated. I am one of the ones who also has the psoriasis. So, finding the right balance of treating both, the arthritis symptoms as well as the skin symptoms, is one of my biggest challenges. When I start on medications, sometimes they work better for one than the other, and finding that right medication that will control both has been a really difficult journey.

And I think a lot of what we've heard from **[Participant 5]** and from **[Participant 2]** so far, it's the same thing. I was diagnosed fairly young. I was in my twenties. I had symptoms starting for several years beforehand, but didn't really know what was going on. I also have a couple other comorbid conditions, and so one of them is a rare collagen-based disorder that impacts my joints. And so, I wrote off a lot of those arthritis symptoms at first to that other condition, which has no treatments, and it took a long time for me to actually realize that what was happening was bigger than what I was just used to dealing with my whole life with that other disorder.

And getting doctors to listen, the first rheumatologist I saw, because I wasn't actively, similar to what **[Participant 2]** said, I didn't have active psoriasis at the time. I was pretty much in remission from the skin part of my condition, and so the first rheumatologist I saw said, well, if you don't have any psoriasis, it can't be psoriatic arthritis.

And I also am one of those patients who doesn't have the labs. I was negative for the rheumatoid factor, so it couldn't be rheumatoid arthritis. I don't have elevated blood markers for inflammation, so it couldn't be, according to that first doctor, and then finding other doctors who were more willing to listen to the actual patient experience. The second rheumatologist I saw, I was very lucky, looked at me. Wasn't even close enough to physically examine me at the time, but looked across the room and was like, oh, well, your fingers are visibly sausage-like. So, we're going to go ahead and we're going to start treating you for psoriatic arthritis given that you had, I was diagnosed with psoriasis when I was a toddler and was in and out of dermatology my entire life. So, even though it wasn't an active condition, absolutely, it existed in my chart, and so we should take that seriously.

But that to me, one of the biggest hurdles, even though I've been very lucky, I've only had three rheumatologists, and two of them have been very active and very believing me, and determined to treat, but it's been a very difficult ride, nonetheless. And then just actually getting coverage for the medications, like the constant fight of step therapy or insurance formularies, getting on one, changing jobs and having a new insurance, and having to then appeal to keep the same medication and not lose it. All of that kind of factors into the management of it. Like we've heard before, I've had to step back from a career that I had for 15 years, and I loved because of the ongoing joint damage in my hands. And so, trading out something and finding something new to keep me going was… it's all really difficult to balance.

00:36:04

**Moderator, RTI International**

Thank you, **[Participant 7]**. **[Participant 8]**, I would like to hear from you. And then, **[Participant 3]**, if you could also then take us out of psoriatic arthritis, and into either plaque psoriasis or Behçet's. I will hand it after **[Participant 8]** says his experience.

00:36:19

**Participant 8 (registered as a representative of a patient advocacy organization)**

Yeah, as I said earlier, I'm kind of the older version, because there was really no understanding. And even today, and you've heard that from some of the other panelists, I don't think the medical profession is fully aware of what we're talking about. This is a double autoimmune activity, and they focus on one or the other, and not the two. But I did want to bring up that one of the things that I found very interesting is, I go to a new doctor or a new clinic and I'm doing the intake. They never have anything that says psoriatic arthritis, it'll say rheumatoid or osteo, but it doesn't. I'm always writing that in, and then I'll talk to the doctor, and I'll say, do you know anything about it? Well, I've read something about it, but I don't really understand. So, I think there's a lot of education that's still needed in the medical profession about this particular condition, and therefore any medication applied to it may not be connected in the way it should be.

00:37:30

**Moderator, RTI International**

Thank you, **[Participant 8]**.

All right, so I'll go ahead and hop to **[Participant 3]**. And **[Participant 3]**, if you want to close out the psoriatic arthritis and bring in, you can pick, take your choice of Behçet's or plaque psoriasis. I know you can speak to both.

00:37:43

**Participant 3 (registered as a representative of a patient advocacy organization)**

So I think that in hearing that other folks have had this since adolescence, since toddlerhood like **[Participant 7]** mentioned, I think it's really important, at least from our perspective, what I've heard from our families is not only the negative effect that has on the patient themselves, but on the family unit as a whole, the caregiver as a whole. Pediatric psoriasis, that can greatly decrease health-related quality of life not only for the patient but the family. We had feedback that self-image, relationships, physical activity can be affected. Patients diagnosed at a young age have a greater likelihood of psychiatric disorder, sleep problems, social discrimination. Those are things, speaking as a mom of a child with a rare disease, that doesn't only affect the patient. It can affect parents and others that care for that individual.

Also, I think it's really important to note that Otezla has no black box warning. Like it was mentioned, it's a pill, and it doesn't require needles. There's no injection. And I think that even though most people think kids at baseline can't take pills, it's miraculous what they can do when they're faced between a pill and a needle. And so, that's something that I don't think can be emphasized enough.

Also from a Behçet's perspective, it's extremely rare in the U.S. It significantly impacts quality of life. And the most important thing about Otezla here, not only is it a pill, but it is the only FDA-approved treatment for the painful oral ulcers that are very, very common in Behçet's. And so it's one of those things where there is no other option, there is no other choice. So Otezla is the only FDA-approved treatment for that specific indication with Behçet's. That's all I had. Thank you.

00:39:57

**Moderator, RTI International**

Before you go off mute. So, you said you've talked with patients who have Behçet's. Could you say a little bit about what their life experience is like without having medication, how they manage that condition?

00:40:09

**Participant 3 (registered as a representative of a patient advocacy organization)**

I think that has been mentioned, I think in many diseases and rare diseases especially, the experience is very different. The disease is very heterogeneous, so each individual experiences the disease very differently. So, for some people with Behçet's, they don't actually experience very severe oral ulcers, so maybe they don't need Otezla. But for those who do take it, they notice a decreased incidence of oral ulcers, they recover faster when they do have the oral ulcers, and also notice that they're less painful when they do have them. So, that's really the feedback we've received from that community.

00:40:58

### Moderator, RTI International

Thank you, **[Participant 3]**, for sharing about Behçet's, people who have Behçet's, their experience. **[Participant 1]**, can you comment on Behçet's and what life is like? I know you said earlier you had MS [multiple sclerosis]. But I don't know if you are aware of folks with Behçet's and their experience that you could pass along.

00:41:15

### Participant 1 (registered as a representative of a patient advocacy organization)

Not specifically. I do want to note that while everyone here has a different experience, different stories, disease and comorbidities that affect them differently, there's so much commonality that we share. Share this frustration with medical system with doctors who try, either not equipped or don't know enough about our personal situation. And then the frustration, we have the lack of options we have. But then, at the same time, the commonality we have is, man, you guys are all so freaking smart. You guys are all PhD-level understanding of your condition. And how you guys, we all have to become experts in our disease and take ownership over our solution. And so, and just lastly, I'll say the importance of having, I think several of you have said over and over again, how you have to try on various medications with a lot of frustration, a [inaudible] until you find the right one. Sometimes it fits like a slipper, sometimes not so much. But the fact that you have the option to cascade through that, the hope that brings to say, look, I got a plan. I go through plan A, B, C, D, and get you the one that works for me. And that's so, while we all have to deal with the burden of that suffering depression, whatever it is, at least they hope to try again, that good that another drug in the pipeline can provide us, and what I really want to say is, I really hope that we keep this pipeline going, that we need not more, not fewer options, but more so at the rate until we get the right fit.

00:43:12

### Moderator, RTI International

Thank you, **[Participant 1]**. I appreciate your passion. **[Participant 6]**, do you want to round us out with anything you want to say about the folks who have Behçet's and their experiences?

00:43:19

### Participant 6 (registered as a patient, representative of a patient advocacy organization, and as other)

Yeah, actually, I failed to mention when we started, I also have a diagnosis of Behçet's disease, and saying that, we don't believe it actually is Behçet's. We believe it's Sjögren's disease, but I can speak very, very well on what it's like to live with Behçet's disease because of thinking I had it for several years. I have been in many support groups. I'm actually part of the OMERACT [Outcome Measures in Rheumatoid Arthritis Clinical Trials], which is outcome measures in rheumatology working group to design the outcome measures for Behçet's disease, which is based on what patients say are the most important domains to be studied. So, what I'd like to say about Behçet's, first of all, it is such a systemic disease. One of the most reported issues are the mouth sores. That's why I have the diagnosis. I can tell you what it feels like to have these kind of sores in your mouth, even though they are what I believe is related to Sjögren's disease. I have been at conferences, when you have to talk for a long period of time, it starts to trigger the inflammation in your tongue. So I have had to be at conferences where I'm trying to speak, but because of the canker sores and the sores in my mouth, my tongue swells, and I've actually had to sit there with painkillers. I can't even swallow. My friends have to trickle them down my throat in order to swallow. Plus the sores are very painful if they open. So, you have to worry about food, eating with a straw, things of that nature are very common. So that tells you the severity of these, and why something like Otezla to treat those. But I also want to just make sure that it's clear. Behçet's also involves systemic vasculitis that can impact your veins. It can impact your skin. It can impact your brain. It can impact your gastrointestinal. It has so many different organ systems that are involved. It is an exceptionally complex disease.

00:45:19

### Moderator, RTI International

Thank you, **[Participant 6]**, and I think there was only one other person who mentioned, I think, **[Participant 7]**, you mentioned plaque psoriasis. Did you want to add anything to your experience related to plaque psoriasis? Otherwise, we'll move to the next section.

00:45:33

### Participant 7 (registered as a patient)

I have both plaque psoriasis and pustular psoriasis. And I think that's one of the things that has been one of the most difficult things for me is that all of the approved treatments for psoriasis are for plaque psoriasis.

And so, while some of them do work on the pustular psoriasis just by the nature of working on the immune system and it's all related. The pustular psoriasis is actually worse for me, and I spent a huge chunk of my life with that being misdiagnosed as acne and being on tons of acne treatments that did absolutely nothing, and in some cases actually made it worse, because they would dry out my skin, and then it would cause an immune reaction, and then I would end up with plaques from overtreating with the wrong kind of treatment and all of that kind of disruption.

And that's actually one of the things that Otezla was best at for me was, Otezla actually treated the pustular psoriasis better than anything else I've taken until my current treatment, which is a Remicade biosimilar infusion. But even from childhood, the plaques would come and go, but the pustular psoriasis never went away until I was put onto a systemic medication.

Plaques are the thing that we talk about the most, and they're itchy, and they're painful, and if you scratch them, then they get bloody, and they're awful. And people think that you have something wrong with you. And what if it's contagious? And what is this rash all over you? It's really hard. We talked about, I think **[Participant 3]** brought it up specifically, I was a toddler when the plaque started. Luckily both of my parents also have psoriasis, and so they immediately took me to a dermatologist, and I immediately started on steroid creams and things like that.

But as a teenager, I could get the plaques under control, but not the pustulars under control, and I was bullied heavily, like your parents don't love you enough to take you to a dermatologist and things like that. And it was like, little do you know, I see a dermatologist weekly. Little do you know that I've been on birth control since the minute I got my period because they thought maybe that was impacting it. And the amount of treatments that I was on over the years, and so I think that we sort of slough off, especially as someone who deals with the arthritis side, too, I slough off my skin condition a lot as the lesser of my problems, mostly because, as an adult, knowing what it is, I don't really care if I get sideways glances from other people. I'm sort of over it.

And so, the arthritis impacts my day-to-day functioning more, but as a teenager, oh, absolutely not as a teenager, the skin condition was absolutely the worst thing that I was handed. I could handle needing to use crutches sometimes, because my joints were so bad. I could handle that. That was fine. People felt bad for you, like you show up to school with a crutch. People feel bad for you. They help you open your locker. You show up to school covered in sores, and people keep their distance from you. It's a very isolating thing to grow up with.

00:48:55

**Moderator, RTI International**

Thank you, **[Participant 7]**, for sharing that. All right, so thanks everyone. These were very profound experiences, and I thank you for your openness.

I think we've started talking a little bit about what your medication journey was like. What it's like with Otezla. How did you, the different drugs you've tried. So, I'm going to delve more deeply into that medication experience again. I'm going to start with arthritis again, the psoriatic arthritis again, because that's the bulk of representation here today. Considering the medications for psoriatic arthritis, what matters to you most? Considering medications for psoriatic arthritis, what matters to you or the patients you work with most? And, **[Participant 4]**, I haven't had a chance to hear from you. Would you mind kicking us off?

00:49:43

**Participant 4 (registered as a patient and representative of a patient advocacy organization)**

Sure. For me it was the dactylitis, and especially in my toes. I work **[REDACTED]**, and so I am on my feet eight to ten hours a day. And so for me, a drug that works is going to make the swelling go down, and I'll be able to use my hands to put clothes on hangers and fold clothes, things like that. And I think for me, that's the biggest thing I need from a psoriatic arthritis drug.

00:50:19

**Moderator, RTI International**

And I know some other folks had mentioned the pill versus the needle. Is that a consideration for you?

00:50:26

**Participant 4 (registered as a patient and representative of a patient advocacy organization)**

No, because of my diabetes, I'm kind of used to the needle. So, pill is easier, definitely. But that doesn't matter to me more than something else. I just need it to help the symptoms go away.

00:50:47

**Moderator, RTI International**

Okay, getting rid of the symptoms to do your life. All right, **[Participant 5]**, I see you nodding. Chime in there.

00:50:58

### Participant 5 (registered as a patient)

I had to resort for Otezla, because biologicals can make you more autoimmune compromised, and they put you on them, the first precursor that they asked was, have you had cancer before? I had to get five different clearances from all the oncologists that saw me, anybody that was on my team, to even consider the biological.

Unfortunately, when they started to fail, Otezla was a great option for me to be on, but now we're starting to see that it is starting to fail as well, which means that I need to find a different solution. But I am diabetic as well, so the needles don't scare me. I'm with **[Participant 4]** on that. What Otezla was also good for is that I have a condition that, and we don't know where it's coming from, that my throat would close up when I was younger, and I couldn't swallow things, and so pills back in the day used to scare me. Now they don't as much because I have to resort to them.

But yeah, that's the reason I went with Otezla, and for me, my hair was falling. I needed something to tackle the areas where it was very visible. I had to cut my curly hair in such a way that I had to cover this. Coworkers would come up from behind me sometimes and brush off, and they're like, oh, my God, your dandruff is so bad. Did you not wash your hair today? And, the commentary was unnecessary, but it was very embarrassing. So, a lot of that has helped with the Otezla, I do see a lot of that has reduced, but it is coming back unfortunately.

00:52:52

### Moderator, RTI International

Thank you, **[Participant 5]**, for that. And so comorbidities and managing other conditions is one of the pieces of the puzzle for y'all. **[Participant 2]**, I see you have your hand up. Did you want to comment on what's most important for you when considering other medications?

00:53:09

### Participant 2 (registered as a patient)

Yes, joint pain was probably my first indicator to onset and then losing my energy level. And I also, someone mentioned brain fog. I was like, yeah, I used to have horrible brain fog.

Now, in addition to Otezla, which was amazing. It would get me to having the best day, where I can get my pain level to a four, and that was my best day, and that was the best I've been in years. With managing my disease and me. I was like, oh, it's a four. **[REDACTED]**.

And then, this was about three and a half years ago, we had tried different diets. I went gluten free. I went dairy free. I did the inflammatory diet changes to see if they would help. Well, three and a half years ago, my rheumatologist recommended I try ketogenic diet and that has been wonderful. I am down to only being on Otezla on a regular basis. I still have to take an allergy med, I'll take if it's a bad day.

But I am no longer on opioids, and my best day will be a two pain level. I have a little more energy provided that I don't overdo the day before, which was yesterday for me. And so, today I woke up going I have no energy. But diet and Otezla's made a world of difference. I'm off all my depression meds. I'm off all my anxiety meds. I don't have panic attacks like I used to. These are all things that we don't think about, and then also I don't have the brain fog I once did. But I don't know if I'd ever gotten [inaudible] my disease at least managed with the Otezla. And then we added the diet component, and it's made a huge difference in my day-to-day life.

Now, yeah, I still have joint pain, and I still have bad days. I have days where getting out of bed is a struggle. But then I have really good days. I feel like I'm actually getting something accomplished on those good days, and I can take care of myself. I can cook for myself. And that's a hard thing with ketogenic diet. You can't just go grab something prepackaged out of the pantry or out of the fridge. You have to cook, and so you have to be getting better in order to do that diet. That's the struggle. So, if I'm sick, I struggle to eat because I don't have the energy to go prepare food. But it makes such a difference in my pain level that I make myself do it even when I don't feel like doing it.

00:56:31

### Moderator, RTI International

So, I heard pain management, getting good energy, getting your brain back and your mental health back were really important considerations for you, **[Participant 2]**. **[Participant 7]**, you put your hand back up. Do you mind if I hop over to you?

00:56:44

### Participant 7 (registered as a patient)

It's about finding something that, and I think I said this a little bit before, it's about finding something that's going to work on both my joints and my skin, and finding something that does both is really hard. I spent a lot of time on one medication that was working really well for my joints. And so, we were seeing a lot of progress. As my joints get bad, my weight goes up, and that introduces other complications. And so, managing weight, especially with steroids being the important sometimes bridging of that gap, right? How do we get the inflammation down quick while we go on steroids? Steroids then mess with our metabolics, make us hungry, and we end up gaining weight often, and so finding something that works enough on my joints that I can get outside, and I can work out, and, like **[Participant 2]** said, just to cook.

My primary joints affected are in my hands and in my feet, and so standing over the stove is difficult, but also just holding tools or washing dishes when my arthritis is the most out of control. And because I've had it for so long, I'm starting to develop some neuropathy in my fingers, and especially when I'm heavily inflamed, that is worse. And so things like washing dishes can be really difficult, because I'll drop them because I don't feel the ends of my fingers very well.

But the other thing for me also is I've traded that off where I've been on medications that have worked really well for my joints, but they've left my skin a mess. And so, for example, I was on Simponi for years, and I had about three years where it was good for my joints, but I was covered in psoriasis, like head to toe covered, and it was some of my most uncomfortable time as an adult was on that particular medication.

Switching off of that and coming on to Cimzia, allowed me to, like **[Participant 2]**, I started to change my diet. I also find I am better managed when I am on a lower carb diet. It just seems to work better for my body. But I had COVID and COVID caused a medication failure, and I had to switch again. And this is one of those things that we all have to deal with all the time. You never know what's going to cause a medication failure. Sometimes, for me, it's been repeatedly, it's injury and infection. And so, you have to pause the medication, and when you pause the medication and you go back to it, it doesn't work the same. And so that's one of the biggest fears for me, too. One of the nice things about Otezla is not having to pause when you get sick.

And Otezla, for me, worked on my skin amazingly. I had the least amount of psoriasis in my entire career journey with all of this, but it wasn't great for my joints, and finding that good balance is so hard. I've never been afraid, I was afraid of needles as a kid, but over the years of having so many different disorders and so many different doctors, you sort of have to, either you develop the full blown medical PTSD [post-traumatic stress disorder] around needles or you just have to get over it. And I took the get over it path. I lucked out, so I was never really afraid of the injections. I started on injections. I didn't have a problem with that, but that was also before there were any pills that were an option.

I started on sulfasalazine and methotrexate as pills but when they were insufficient, then the next step was either a self-injection or an infusion. There were no pills at that time. So you sort of have to get over it quick if you really want to get better.

01:00:41

**Moderator, RTI International**

Thank you, **[Participant 7]**. And **[Participant 5]**, it looks like you have your hand up to share.

01:00:48

**[REDACTED]**

01:00:53

**Participant 5 (registered as a patient)**

So, one of the major things that every single provider I saw, and that kept blaming was my weight, and obviously with comorbidities and everything, they kept blaming the weight. Like the weight was, as soon as the weight came off, you won't have these issues. The migraines will go away. The joint problems will go away. So, I gave in and had weight loss surgery **[REDACTED]**.

It's now officially been **[REDACTED]** and unfortunately, we had the reverse effect, and all my providers were very stunned. My joints are now hurting 10 times more than when I had more weight on me. The fatigue has become worse, and even though the diet has changed and I can have a little bit more energy, the body now no longer has the fat padding, so there's certain things that affect me more now because of it, and everything that they thought that was going to go away actually got worse, and the migraines got worse. The joint problems got worse. The vascular issues of lymphedema from cancer got worse. So a lot of the catch-all that they put on the weight, stating that the diabetes will go away with the weight. That was the only thing that happened out of everything, which was the major thing, but that was the only thing that got better. Everything else got worse. So a lot of the doctors were stunned by that.

So, I can agree with **[Participant 7]**, they keep putting the issue of the weight on us when also we're gaining weight from all the issues and medications we're on, which make us feel like a failure, almost like I'm not doing enough. So it's kind of a catch-22 with it, and it becomes very... I avoided going to my doctor because I did not want to hear one more time, you have to lose weight when I can barely move a joint to be able to do so, and it doesn't matter that I was almost starving myself regarding what I ate to not gain weight, and it made things worse. So, it was just like I said, a catch-22 on how to handle the situation.

01:03:13

**Moderator, RTI International**

Thank you, **[Participant 5]**. You're darned if you do, and you're darned if you don't.

And so, I'm going to move to Behçet's. And I think, **[Participant 3]** and **[Participant 6]**, you were able to speak to Behçet's. When considering potential medications for Behçet's, what matters to you or those you know the most?

01:03:37

### Participant 3 (registered as a representative of a patient advocacy organization)

Yeah, I can go ahead and start. I think from a practical standpoint, I agree with a lot of the other participants. They bring up similar points to those in Behçet's, but I think I might add specifically for Behçet's, this is the only FDA-approved treatment for oral ulcers. So, I kind of struggle with this question, because it seems like more a question for sleep disorders. What's more important, falling asleep or staying asleep? Because there are treatments for both of those things. But I guess I'm unclear like how exactly that relates to Behçet's or other rare diseases, because if our patients get oral ulcers, this is the only approved medicine that they can have.

And we can't lose this drug or future drugs in development for oral ulcers. So, I hope that this is something that the folks from CMS on the call can think through because I struggle with how you incorporate that perspective when you're speaking to the companies during the negotiations.

And then, just from the larger rare community, I want to mention that many medications in the rare disease space are actually used off-label. And we're very dependent on future research of these drugs. So, from our perspective, it's also very important to understand what implications these negotiations will have on rare diseases and other disease states.

I see a lot of nodding heads, so I think that others probably echo that sentiment. And I will say, I realize it's not for the discussion today maybe, but happy to provide you more examples of this, or would love to have further discussion on this topic. We want to continue to partner with CMS obviously on this, and how we can monitor for the impact that the negotiations may have on future innovation.

01:05:34

### Moderator, RTI International

Thank you, **[Participant 3]**. Yeah, and you can definitely, we'll put that mailbox up at the end. And so, I know that would be welcome. So, thank you for bringing that up and being willing to [inaudible] the floor to the patient stories today. And, **[Participant 1]**, it looks like you get the closing comment on Behçet's. What's most important in terms of what matters most?

01:05:55

### Participant 1 (registered as a representative of a patient advocacy organization)

I'm glad that this disease has the treatment aligned with it, but I also want to note that there are so many other conditions that we all experience that don't actually have names or have different names. I have a disease called multiple sclerosis, and the first name is multiple, because there are so many different versions of it. If we were all [inaudible] people [inaudible], we would have every different [inaudible]. So, the reason why I'm chiming in here is because the [inaudible] I see is so, so apparent from diet to keto. By the way, I also have trouble with my fingers. I have issues, and need to cook, but I will have a couple of string cheese and beef jerky handy to tap into, to help with that. So, I could talk about that elsewhere. But we all are choosing to treat ourselves in the best way possible.

I want to see that, and honor that and show that that instinct has to make ourselves better is great. I can't help but notice that, it's like the innovation that developed with Otezla should not be ever stymied, for example, as **[Participant 3]** said, I'm sorry, for disease off-label, secondary, those folks are gonna be left behind as we pull the ladder up, because we can't stop the innovation train unless we all move forward. My fear is that the idea we have to squeeze a drug so hard that innovation stops is detrimental beyond cost, beyond anything else. So just want to honor everyone's effort to treat themselves and take advantage of all the options out there.

01:07:58

### Moderator, RTI International

Thank you, **[Participant 1]**. And so, this closing thought on, then we're going to move to plaque psoriasis real quick. **[Participant 7]**, I think you're the representation for plaque psoriasis. I don't know if you want to add anything that you didn't share with when we talked about psoriatic arthritis. I know kind of pulling them apart is a little artificial for you, because it's both.

01:08:17

### Participant 7 (registered as a patient)

It's both, but also I spent a lot of my life before the arthritis symptoms came on. So I'm going to speak backwards a little bit here to being a teenager with psoriasis. I think it's amazing that we now actually have biologic options. We didn't have systemic options when I was young. It was steroid treatment topically. And that was pretty much it. And now we have a lot more options. We've learned a lot more about what psoriasis is. And we're not surface-level treating it anymore, which I think is really amazing and really important.

I know that I struggled a lot with the issue of overtreatment with steroids and skin thinning and flare ups after. And so, thinking about what I wish I could have had when I was younger, I wish I could have had any of these biologic options as a teenager, to have something that I could use all the time, and not just wait for it to get bad enough to feel like using the steroids was worth it.

Because the steroid cream you were limited on, how much you could use it, and how much of your body you could use it. So I had to pick and choose, like which part was the worst part. I think the better understanding in general of psoriasis now that we have compared to when I was a teenager also, not having the misdiagnosis, and not having dermatologists want to put me on Accutane, which would have done nothing to actually help my problem, but could have caused so many other issues. I think that's a huge thing to think about.

We've made so much progress, and, like **[Participant 3]** and **[Participant 1]** were saying, finding more uses for these medications to treat other disorders that don't currently have treatment. And, like I said before, I have plaque psoriasis, but I am primarily a pustular psoriasis patient, and there's nothing.

And I can treat that off-label with the things that work for plaque psoriasis, because technically, that's all they can give me and they often work, but they don't work as well as something that maybe would target that particular expression.

It would be really nice to see more research into some of the lesser common types of psoriasis. Plaque psoriasis is not the monolith, but when we hear about research, we only ever hear about plaques.

01:10:56

**Moderator, RTI International**

Thank you, **[Participant 7]**. Okay, so this has been such a rich discussion. And we're in our last 15 minutes. And I still have many questions. So, I'm going to kind of combine some questions for folks, and maybe just take one or two experiences. So, thinking about your experience with Otezla for psoriatic arthritis, what are the benefits and what are the drawbacks for Otezla, for psoriatic arthritis? So, take one or two voices here. **[Participant 7]**, you're still up.

01:11:31

**Participant 7 (registered as a patient)**

So, I actually went on Otezla, after failure on an anti-TNF [tumor necrosis factor], because I had COVID in April of 2020.

And so, there were a lot of thoughts that went into starting on Otezla for me specifically, and one of them was at the time where we had very minimal support for COVID infection and the high risk of being on the biologics and suppressing my immune system. Otezla being a selective suppressant and being safer in that regard without the black box warning on infections and everything that goes with all of the other medications, Otezla jumped up to the top of the list of potential treatment options when we were evaluating that failure. But also at the time it was being looked at in clinical trials as a way to treat that post-COVID cytokine storm. And so, my rheumatologist was very heavily involved in research, and she very much pushed that Otezla was really at the time, the only option, because of all of the other risks that were going around, pre-COVID vaccines and all of that, Otezla was the safest. It was indicated. It had all of the right boxes for it, and it had some side effects that we were a little bit concerned about for me, but we decided to move forward with it anyway.

And what I say is that Otezla was absolutely the right medication for me at that time. It was not the right medication for me long term. I did end up having the side effects were too much for me. I was unable to maintain the lower carb diet that I wanted to be on because of the GI side effects that I was experiencing, and that made it a lot worse. And it was great for my skin. I would actually love to see Otezla looked at for the pustular psoriasis. It's the first thing that actually made a huge difference there in my entire life, was Otezla, and I actually got to the point of remission for the pustular psoriasis while I was on Otezla, and I do think that I've actually maintained that since I've gone off of it, which has been fantastic.

But I do think that one of the barriers I had to Otezla was, despite the fact that it was really the best choice when I went on to, it was, we did have to fight with insurance because it was not on the formulary, and thank goodness that I was on private insurance at the time, because I was able to get the $0 copay coverage from the manufacturer because it was fully not covered by my insurance. So, the only reason that I was able to be on it for three years at all was because there was assistance, otherwise, even though it was the right decision, it wouldn't have been possible.

01:14:30

**Moderator, RTI International**

And **[Participant 7]**, since we're already speaking, and you're our representation for plaque psoriasis in Otezla, anything else you want to add in terms of benefits or drawbacks for your plaque psoriasis?

01:14:38

### Participant 7 (registered as a patient)

Yeah, for the first time in my life I had zero pustular psoriasis eruptions, which was fantastic. I never thought I would be in that place. I also didn't have any plaque psoriasis. I think, within the first month of treatment, my skin conditions in particular dropped, and that was something that I had sort of resigned that I could get the plaques under control with steroids. And then just go with moisturizers to try and keep it under control. But for the most part, I sort of figured that that was just going to be my normal, that I was always going to have the pustular psoriasis. And Otezla was the first drug that actually did anything about that.

And I think that was really fantastic. And once I got it under control, I've been able to actually maintain it with switching to a different biologic. But that was really an unexpected and really wonderful surprise for me. I was not expecting that, but I do think that it did a great job on my plaque psoriasis, too. I've had to use less topicals, and I think the idea, like I said before, about being a teenager with this before the biologics and things like Otezla were even an option. Taking a pill that could keep it at bay was a lot easier than the complicated regimen of trying to treat all of this with the right moisturizer, the right soap, the not too hot showers, the only use steroids when it's really bad, and only on the right spots, but don't let it get too bad, so that they don't work. It was just super complicated. Being able to take a pill is way easier, and when you have involvement that covers that much of your body, the topicals just don't work. They just don't work. We need something that's systemic.

01:16:29

### Moderator, RTI International

Thank you so much, **[Participant 7]**, and I know, **[Participant 3]**, you had said, for Behçet's disease, this is the only drug available. But are there other benefits or drawbacks that you or [Participant 6] would like to, say for the oral ulcers from Behçet's disease, benefits and drawbacks?

01:16:50

### Participant 3 (registered as a representative of a patient advocacy organization)

I think, from our perspective, I'm not sure that there are any patient-specific drawbacks that folks gave me. Their biggest concern, obviously, there's a lot of, they're pediatric patients, we heard from a lot of caregivers and I think they're concerned that negotiated prices in Medicare could have downstream impacts on formulary inclusion and out-of-pocket costs outside of Medicare, so I think their concern is their disease disproportionately affects children. About 50/50 are on Medicaid versus commercial, and they're not able to be on Medicare yet. So, we read over and over that the air will be allowed out somewhere, and the cost will move and increase elsewhere. Since commercial payers don't have an out-of-pocket cap like Medicare does, if this is something that is working for their children, that commercial payer, like if they're on commercial insurance, their pricing might go up. I think those are bigger concerns that they have. So, how will CMS track how the first year goes with the initial round of negotiated drugs in terms of impact outside of Medicare? And then how can those findings be used to maybe improve on the 2027 price before they come out? But they didn't necessarily say anything specific regarding their own personal experience. I think they're just worried, I need my kid to keep getting this drug.

01:18:34

### Moderator, RTI International

Thank you, **[Participant 3]**.

All right. So, I'll quickly, just one or two, voices on other medications, that you've taken benefits and drawbacks, especially compared to Otezla, and I'll open the floor. You can choose the condition you want to speak to, benefits and drawbacks of other medications you've taken. And, **[Participant 2]**, I know you mentioned, Enbrel, Humira and those kind of failing. I don't know if you want to be the representation for this question here.

01:19:05

### Participant 2 (registered as a patient)

I've tried Rituxan, Humira, Enbrel, Remicade, Kineret, those are the ones I can name off top my head. Might have a larger list. The benefit is it's a pill. Take one pill, twice a day. I can stay on it even if I get sick. I stayed on it when I had COVID. I stayed on it when I've had the flu. I stayed on it when I've gotten those illnesses that you can pick up anywhere. It's kind of hard to avoid them sometimes. That was really scary being on a biologic. And you're always afraid of, what is that illness going to do to me? And how's that going to combine with a flare that's going to happen when you have to go off that medication?

And for me, I am allergic to all corticosteroids. I cannot take any prednisone, Solu-Medrol. I can't use any corticosteroid cream. I can't do any joint injections. So, not being able to have a steroid to help me out of a flare is even a larger struggle.

Now one of the downsides to Otezla is, I did have some gastrointestinal side effects, especially early on with Otezla. I soon learned that certain foods would trigger the gastrointestinal upset and for me it was usually sugar and carb based. And now, especially since I've done ketogenic for three, three and a half years. If I eat too many carbs, yeah, I will have a lot of gastrointestinal upset, but the side effect is very minor for me when compared to how much it has improved my daily life, being on Otezla, and the fact that it works in helping me manage my disease.

01:21:35

### Moderator, RTI International

Thank you, **[Participant 2]**. **[Participant 4]**, do you mind if we move on to the next question, and you can maybe piggyback what you'd like to say, because we're in our last three minutes. Same, **[Participant 1]**, I'm going to move on to one more question, because we're in our last three minutes. But, **[Participant 4]**, I will let you start us off. So, if you had something you want to say, you can piggyback it on.

What would it be like? Imagine, if you will, that no drugs were available for psoriatic arthritis or for Behçet's and the ulcers, or for the plaque psoriasis. What would your life be like without this medication?

So, **[Participant 4]**, can I just let you start that off?

01:22:10

### Participant 4 (registered as a patient and representative of a patient advocacy organization)

Yeah, sure. So, my life, I would not be able to be working my **[REDACTED]** job. I would probably have applied for disability much sooner, and I wouldn't be, I call these the poisons that keep me walking and working. We look at the things that these drugs can do, their side effects, and we kind of weigh that with, okay, well, am I going to be able to move my hands tomorrow? Am I going to be able to stand up and walk tomorrow? So, I think for me, going forward... And now I just lost my train of thought.

I think we need these drugs. Everybody's psoriatic arthritis is different. I have the hidradenitis. And it did really well for my hidradenitis, but it did nothing for my rheumatoid arthritis. So that is why I'm no longer on that drug. But somebody else's impacts completely differently.

So, that is probably all I have to say right now, because we do need these drugs, because everybody is so different in how they present with their psoriatic arthritis.

01:23:34

### Moderator, RTI International

And now **[Participant 8]**, what would life be like for you without these medications? Because you kind of lived it before, like **[Participant 6]** put in the chat.

01:23:43

### Participant 8 (registered as a representative of a patient advocacy organization)

Yes, and that's why I loved hearing from everybody on what Otezla has done for them. I dealt with pain, I dealt with fatigue. I would have to get on the floor in between my work time and just try to get some energy back so I could get up and go back to work. It was a nightmare, and I wouldn't wish it on anyone.

01:24:09

### Moderator, RTI International

Thank you, **[Participant 8]**. Okay, so my last question and we have about one to two minutes left before we close out. So just kind of thinking big picture about all the things we discussed today. How would you summarize the importance of Otezla for people with psoriatic arthritis, plaque psoriasis, or the ulcers from Behçet's?

So, thinking big picture, I know it's a big question.

01:24:43

### Participant 2 (registered as a patient)

The way everyone reacts to a medication is different. And so, options are desperately needed. For me, Otezla is a lifesaver. It's allowing me to function in daily life. I can actually care for myself, as far as cooking, cleaning, bathing, dressing, just things everyone does on daily basis and never thinks about not being able to do. I've been in that place where I couldn't do any of those things for myself, and it is such a necessity. Honestly, I don't know where my rheumatologist and I go if Otezla fails for me. It's always really scary when that happens, because you're like, I was so good. And then you go so bad in that medication adjustment, as a medication fails, and it takes two to three months to find out if another medication is going to work, and you never know what medication is going to work for you.

There's no way of taking a blood test and saying, oh, you need this medication. Now, would it be wonderful if we get there one day? Yeah. But right now, the doctors need to have options for people, because you think, oh, this is going to work. It may not. Because Humira and Enbrel are both TNF blockers, but they did not work the same for me. I think, having the options and the doctors and patients having the ultimate say. I hate that insurances can say, yeah, no, you don't qualify when you're like, but it's my only option.

01:26:54

**Moderator, RTI International**

Thank you, **[Participant 2]**, for saying it so succinctly and profoundly. So, **[Participant 1]** and **[Participant 7]**, we are at time. I want to invite you to put in the chat while we do closing, because I want to be respectful of the time y'all have given us today. So sorry to cut us short. It's been such a rich conversation this morning. So again, thank you very much for taking the time today. I think our folks from CMS wanted to reappear, and if you want to say any other closing thoughts.

01:27:29

**CMS Staff**

I'll just briefly say, thank you so much on behalf of CMS, and certainly on behalf of my colleagues that were also on the call today and listening. We just really, really appreciate the time and information that you all have shared today, your personal experiences, the experiences of your loved ones, the experiences of the communities that you all serve. You've given us a lot to think about, and we're just so deeply grateful for your time and information. So, thank you.

01:28:01

**Moderator, RTI International**

Yes, I'll just echo that. Thank you again for everyone's openness today and sharing that and taking the time. Your experience will really be helpful to inform CMS' negotiations for these drugs. And then the staff that were here today can bring these perspectives forward. So that was the beautiful thing about our time together today. So, the slide I mentioned earlier, if you have things you wanted to share or questions following today's session, please submit them at this mailbox here, the IRARebateAndNegotiation@cms.hhs.gov, and you can use the subject line, public engagement events. So, the things that we didn't have enough time to cover, or we had to rush through, you're welcome to add those in, or I know, **[Participant 3]**, you said you had some things you wanted to share. Please submit them through that. So, thank you again, everyone and I'm just very grateful for the time we had together today.

All right. Bye, everyone.

**===== END OF TRANSCRIPT =====**

For a list of the drugs selected for the second cycle of the Medicare Drug Price Negotiation Program, click on the following link: https://www.cms.gov/files/document/factsheet-medicare-negotiation-selected-drug-list-ipay-2027.pdf

For more information on the Medicare Drug Price Negotiation Program, please click on the following link: https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program

## Appendix

Participant 1: Registered as a representative of a patient advocacy organization

| **Declared Conflicts of Interest** | |
|---|---|
| No | Receipt of financial payments (e.g., gifts, funding, research support, honoraria, travel, or other expenses) from a company with direct/indirect interest in the Negotiation Program, in excess of $10,000 by you, your spouse, or an immediate family member |
| No | Direct assistance preparing your remarks from someone who is NOT a family member, caregiver, friend, or your healthcare provider |
| No | You, your spouse, or an immediate family member is employed by or holds equity interest (stock or ownership interest) in excess of $10,000 in a company or related association with direct or indirect interest in the Negotiation Program |
| No | Any other personal or professional relationship or interaction with a company or related association with direct or indirect interest in the Negotiation Program that may be considered a financial conflict of interest |

Participant 2: Registered as a patient who has experience with the selected drug; a patient who has experience with the condition(s) treated by the selected drug; a patient with experience with other treatment(s) similar to the selected drug for those condition(s)

| **Declared Conflicts of Interest** | |
|---|---|
| No | Receipt of financial payments (e.g., gifts, funding, research support, honoraria, travel, or other expenses) from a company with direct/indirect interest in the Negotiation Program, in excess of $10,000 by you, your spouse, or an immediate family member |
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| No | Any other personal or professional relationship or interaction with a company or related association with direct or indirect interest in the Negotiation Program that may be considered a financial conflict of interest |

Participant 3: Registered as a representative of a patient advocacy organization

| **Declared Conflicts of Interest** | |
|---|---|
| No | Receipt of financial payments (e.g., gifts, funding, research support, honoraria, travel, or other expenses) from a company with direct/indirect interest in the Negotiation Program, in excess of $10,000 by you, your spouse, or an immediate family member |
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| No | Any other personal or professional relationship or interaction with a company or related association with direct or indirect interest in the Negotiation Program that may be considered a financial conflict of interest |

Participant 4: Registered as a patient who has experience with the selected drug; a patient who has experience with the condition(s) treated by the selected drug; a patient with experience with other treatment(s) similar to the selected drug for those condition(s); a representative of a patient advocacy organization

| **Declared Conflicts of Interest** | |
|---|---|
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| No | Any other personal or professional relationship or interaction with a company or related association with direct or indirect interest in the Negotiation Program that may be considered a financial conflict of interest |

Participant 5: Registered as a patient who has experience with the selected drug

| Declared Conflicts of Interest | |
|---|---|
| No | Receipt of financial payments (e.g., gifts, funding, research support, honoraria, travel, or other expenses) from a company with direct/indirect interest in the Negotiation Program, in excess of $10,000 by you, your spouse, or an immediate family member |
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| No | Any other personal or professional relationship or interaction with a company or related association with direct or indirect interest in the Negotiation Program that may be considered a financial conflict of interest |

Participant 6: Registered as a patient who has experience with the selected drug; a patient who has experience with the condition(s) treated by the selected drug; a patient with experience with other treatment(s) similar to the selected drug for those condition(s); a representative of a patient advocacy organization; other

| Declared Conflicts of Interest | |
|---|---|
| Yes | Receipt of financial payments (e.g., gifts, funding, research support, honoraria, travel, or other expenses) from a company with direct/indirect interest in the Negotiation Program, in excess of $10,000 by you, your spouse, or an immediate family member |
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| No | Any other personal or professional relationship or interaction with a company or related association with direct or indirect interest in the Negotiation Program that may be considered a financial conflict of interest |

Participant 7: Registered as a patient who has experience with the selected drug; a patient who has experience with the condition(s) treated by the selected drug; a patient with experience with other treatment(s) similar to the selected drug for those condition(s)

| **Declared Conflicts of Interest** | |
|---|---|
| No | Receipt of financial payments (e.g., gifts, funding, research support, honoraria, travel, or other expenses) from a company with direct/indirect interest in the Negotiation Program, in excess of $10,000 by you, your spouse, or an immediate family member |
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| No | Any other personal or professional relationship or interaction with a company or related association with direct or indirect interest in the Negotiation Program that may be considered a financial conflict of interest |

Participant 8: Registered as a representative of a patient advocacy organization

| **Declared Conflicts of Interest** | |
|---|---|
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