Transcript: Cimzia Roundtable Event, April 8, 2026, Medicare Drug Price Negotiation Program Public Engagement Events

This transcript was lightly edited for readability.

Introductory Remarks

Moderator, RTI international

Hi everyone, good to see you all. My name is **[Moderator]**, and I'm here from RTI International. I also want to introduce a colleague with me today, **[Secondary Moderator]**. You may hear from **[Secondary Moderator]** throughout our discussion today as well. The Centers for Medicare & Medicaid Services, which I'll call by their acronym, CMS , is convening this patient-focused roundtable event and others as part of the Medicare Drug Price Negotiation Program. The information shared during these roundtables will help CMS understand patients' experiences with the conditions and diseases treated by the selected drugs, patients' experiences with the selected drugs themselves, and patients' experiences with other drugs that are used to treat the same conditions as the selected drug. The information shared during these events will also help CMS identify other medications used to treat the conditions treated by the selected drug, what matters most to patients in managing their conditions, and other important factors CMS may consider in negotiating Medicare pricing with the manufacturers of these selected drugs.

The purpose of our event today is to hear from you all, a group that includes patients, caregivers, and patient advocates, about your experiences with the conditions and diseases treated by Cimzia, including ankylosing spondylitis, Crohn's disease, non-radiographic axial spondyloarthritis, plaque psoriasis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, and rheumatoid arthritis, with Cimzia itself, and other medications for the same conditions. I want to emphasize that our focus today will be on the patient experience. If you wish to share input on other topics related to the Drug Price Negotiation Program that are not directly related to the patient experience, we ask that you put those into the email box, which you should have received earlier in the package, which is at IRARebateAndNegotiation@cms.hhs.gov, instead of sharing it in today's discussion.

Your experience and perspectives are very important to us, and we genuinely appreciate your time today. Along those lines, let's watch a brief video from CMS leadership so that you can hear from them about how much they value your time and input today.

CMS Remarks

00:02:19

Dr. Mehmet Oz, Administrator for the Centers for Medicare & Medicaid Services

Hi, everyone. I'm Dr. Mehmet Oz.

I'm the Administrator for the Centers for Medicare & Medicaid Services, also known as CMS. CMS is the Federal agency that oversees Medicare, which provides health care coverage for more than 69 million older Americans and people with disabilities. We also oversee the Medicaid program and the Health Insurance Marketplaces.

I wish I could join you today in person, but I want you to know I am eager to hear your feedback and am deeply grateful for your participation in today's discussion.

It is a crucial conversation.

No one in America should have to choose between buying groceries or paying for their medications. But many are forced to make this choice. It's a choice that comes with a personal cost in addition to a financial cost. I started my health care career as a cardiothoracic surgeon. So I know firsthand what happens when people can't get their medicine, like the ones that lower their cholesterol or blood pressure. Left unmanaged, these conditions can be dangerous.

CMS is doing incredible work reigning in the skyrocketing cost of prescription medications, and we need all of you to help us make real, lasting change.

Right now, we're working on the latest cycle of Medicare drug price negotiation.

We announced the drugs selected for this round earlier this year. Some of them are covered under Medicare Part D, and others are payable under Medicare Part B. For every drug, our priority is to reach an agreement with the manufacturer on a fair price for Medicare.

We are committed to being fair and transparent throughout the negotiation process. And that's where you all come in.

It's my goal to get input from people across the health care ecosystem. We want to hear your perspective about the drugs selected for the current cycle of negotiation and renegotiation.

Your input makes a difference – a big one. Thank you for taking the time to join us today. I'll turn it over now to our event moderator.

00:04:11

Moderator, RTI international

I also want to make you aware that staff from CMS will be sitting in on the event so that they can hear your experiences and opinions directly from you. Let me hand it over to them for a moment so that they can say hello.

00:04:22

CMS Staff

Good afternoon and welcome, everyone. I'm **[CMS Staff]**, I'm with the CMS Drug Price Negotiation Team, and we also have some other CMS staff on the call today as well. We work on the policies for getting public input, as well as negotiations and Medicare drug pricing. I just want to take a moment to say on behalf of CMS thank you for participating today. We are really looking forward to hearing about your experiences during this roundtable discussion. And I will just note that we are going to go off-camera now, so that you all can focus on the discussion. I just want to thank you, and can now turn it back over to you, **[Moderator]**.

Housekeeping

00:05:04

Moderator, RTI international

Great, thank you, **[CMS Staff]**. Before we begin, I just want to go over a few housekeeping items, and then we'll start our discussion.

First, technical assistance. **[Tech Support]** helpfully provided you all an email address if you get disconnected, you can reach out to that email address for technical support. That email address again is IRADAPStechsupport@telligen.com.

This discussion is not open to the press or the public, and we will use first names only during the discussion to protect your privacy. Please do not share any unnecessary protected health information, such as your doctor's name or name of a medical facility where you receive care, or personally identifying information, such as your employer's name, the city you live in, or the names of schools you attended during the discussion. Following the event, CMS will prepare transcripts that have participant names and identifying information removed, and these transcripts will be made available to the public.

Video recording. On a related note, we are recording today's event. These recordings will not be shared publicly. Recordings will only be used for internal program documentation, and to produce the redacted transcripts for public release, consistent with Federal privacy guidelines. By participating, you consent to being recorded for these purposes.

For participation, we hope that you will contribute your perspectives throughout the session. However, if questions arise that you do not want to answer, that is totally okay. You don't have to answer any questions you don't want to.

For background, please try to minimize background noise by silencing your cell phones and other devices if you haven't done so already, and please also mute yourself when you're not speaking.

Thank you in advance for keeping your video on during the discussion.

And just to let you know, we've scheduled up to two hours for this session. However, it's possible that we may not need the full two hours to discuss all the planned topics. If that happens, we can let everyone go a little bit early. I do have a discussion guide in front of me to help me keep track, and we do have a lot of topics to cover, so I may need to redirect our conversation, or cut a conversation short at times just to make sure we're able to cover everything and that participants have ample opportunities to share their perspectives.

If you need to take a break, or step away briefly during our discussion, that is totally okay. Just turn off your camera and microphone and rejoin when you are able to. You don't need to tell me that you're going to be stepping away from your computer, just return to discussion when you're able to.

I'm also just going to ask folks to speak one at a time. I may occasionally need to interrupt you if more than two people are speaking at a time, just to make sure that we can hear from everyone, and that everyone's comments are recorded accurately. Please use the raise hand feature in Zoom to indicate that you would like to speak, and this will help us know when someone would like to add to the discussion, take a moment to find that feature, although I think **[Tech Support]** showed you all when you were checking in where that feature is.

Finally, chat. While we are hoping everyone will focus on our oral discussions today, you can also add comments to the chat window if you don't get a chance to share them orally. This may be the case, for instance, if we don't get to hear from you before we need to move on to the next question or if you think of something later that you want to add, just be sure to note in the question or topic that you're responding to in any chat comments.

Does anybody have any questions before we begin? Okay, let's go ahead and get started.

I want to first just take a moment to get to know all of you all today and who you are, and I want to go around the room today and ask each of you to tell me your first name, tell me also if you'll be sharing your perspective as a patient, caregiver, or as a patient advocate, and some of you may be wearing multiple hats, and that's totally okay. And also, the conditions or conditions that Cimzia treats that you have experience with. And I'm going to put those in the chat window just for everyone's reference, but those, again, are ankylosing spondylitis, Crohn's disease, non-radiographic axial spondyloarthritis, plaque psoriasis, polyarticular juvenile idiopathic arthritis - which if you all are okay with, I might just say "poly-JIA" - psoriatic arthritis and rheumatoid arthritis. So again, your first name, the perspective you're sharing as a patient, caregiver, or advocate, or many, and then what condition or conditions you have experience with. **[Participant 1]**, if that's okay, I'm going to start with you.

Discussion

00:10:02

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

Absolutely! Hi, everyone! My name is **[Participant 1]**. I'm here as a patient who has taken Cimzia, also as a patient advocate, and I personally am diagnosed with non-radiographic axial spondyloarthritis, and I have experience in all of those diseases.

00:10:20

Moderator, RTI international

When you say experience, experience as a patient advocate?

00:10:24

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

As a patient advocate.

00:10:25

Moderator, RTI international

Okay, but personally non-radiographic axial spondyloarthritis. Okay, got it. Thank you. **[Participant 2]**?

00:10:36

Participant 2 (registered as a patient)

I'm **[Participant 2]**, I have Crohn's disease, and I'm here as a patient, and a patient advocate as well.

00:10:44

Moderator, RTI international

Wonderful. Thank you for coming today, **[Participant 2]**. **[Participant 3]**?

00:10:49

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

Yes, hi, good afternoon. I'm **[Participant 3]**. I have experience with Cimzia with psoriatic arthritis as a patient, and I'm also a patient advocate and patient researcher.

00:11:02

Moderator, RTI international

Wonderful. Thank you for coming today, **[Participant 3]**. And **[Participant 4]**.

00:11:09

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

Hi everybody, I'm **[Participant 4]**. I'm here as a patient advocate, and at my organization we advocate for all the arthritis symptoms and conditions.

00:11:19

Moderator, RTI international

Awesome. Thank you, **[Participant 4]**. **[Participant 5]**?

00:11:24

Participant 5 (registered as a patient)

Hi there, I'm **[Participant 5]**, and I am a patient who has taken Cimzia for rheumatoid arthritis, and I also run a group for parents with chronic illness, which would cover basically everything else on that list.

00:11:36

Moderator, RTI international

Wonderful. Thanks, **[Participant 5]**. And you yourself, you said rheumatoid arthritis?

00:11:40

Participant 5 (registered as a patient)

Yes, RA [rheumatoid arthritis].

00:11:42

Moderator, RTI international

All right, great, thank you so much, **[Participant 5]**. And finally, **[Participant 6]**.

00:11:46

Participant 6 (registered as a patient)

Hi, I'm **[Participant 6]**, and I'm a patient, and I have rheumatoid arthritis.

00:11:51

Moderator, RTI international

Wonderful. Thank you for coming today, **[Participant 6]**. Thanks for introducing yourselves and telling us about your experiences you'll be drawing from today. As you've heard, we have participants here to talk about, I think people have personal experiences of four conditions that I heard today. Crohn's disease, psoriatic arthritis, rheumatoid arthritis, and non-radiographic axial spondyloarthritis. One thing I want to ask today is that, experiences will differ by condition, and when you speak, one thing that will be helpful for me is that if you could remind the group which condition you were discussing, for instance, you might say, when I was considering a treatment for psoriatic arthritis, I thought about XYZ. That would help me understand a little bit more about the perspective you're coming from. Does that make sense? Okay, great.

We're going to talk about Cimzia and some pharmaceutical treatments in a moment, but to start with, I really just want to focus on these conditions by themselves and how they affect people. I want to open up with a question, which is, thinking about the different ways that the conditions treated by Cimzia affects people's lives, what would you say are the most important aspects of the conditions to have managed or treated? And these could be short-term things or long-term things. Again, thinking about these conditions treated by Cimzia, what would you say are the most important aspects of the conditions to have managed or treated? **[Participant 1]**.

00:13:34

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

Again, I have non-radiographic axial spondyloarthritis. I can say I was originally diagnosed with seronegative, which means no positive blood work, rheumatoid arthritis, but my diagnosis didn't exist until 2012. So that's why it changed, and actually a lot of people's diagnosis changed to that from rheumatoid arthritis, if it's seronegative. And saying that, and I guess I'll go into more of how the drug impacted that diagnosis path and helped it, but as far as the symptoms, what's the telltale sign, if you will, of spondyloarthritis is that it is of the spine. First symptoms were chest area, mid-back, and tailbone area. And so that's the same with ankylosing. Ankylosing is when there's radiographic damage. I have non-radio [non-radiographic axial spondyloarthritis], so there's no radiographic damage, but I still experience similar symptoms no matter where it is on that continuum. So in addition to that core, back, and chest pains, I think pain is one of them. It also impacts, typically one side of the body, but it impacts from my jaw, my hands, my elbows, my knee, my feet, and I also experience what's called enthesitis. Spondyloarthritis diseases typically focus on enthesitis, which is where the tendons and the bone connect more than joints. I have a lot of problems in my feet where those tendons are, and then also fatigue and brain fog are really, really important symptoms that I think impact people's lives, not only socially, but if you're trying to work or go to school.

00:15:30

Moderator, RTI international

[Participant 1], you mentioned, for instance, the pain, enthesitis, so forth. Can you talk a little bit about how this affected your day-to-day life, your quality of life, how it affected your living?

00:15:41

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

When I was originally diagnosed with undifferentiated disease, which means we don't know what's wrong with you, you've got a lot of things, and then finally the seronegative rheumatoid arthritis, I was put on a biologic for rheumatoid arthritis, and it seemed to keep me okay, but when we realized what I really had, it was because my symptoms and my quality of life got so bad because I wasn't on the right treatment. So it ended up where there were situations where I was laying in bed, and my spine was so stiff it felt like if I even shifted a half an inch, it would shatter. So I would lay there for I don't even know how long, and the only way to get out of bed was to roll off onto the floor onto my knees, and try to stretch my spine. I was getting stuck in lines at the grocery store where my feet just were frozen and in so much pain, I couldn't walk, so I'd have to call my husband to come and get me. So these were very, very real symptoms that impacted my life tremendously. That's actually when I was given Cimzia, and it changed my life, literally.

00:16:52

Moderator, RTI international

I appreciate you sharing your story, **[Participant 1]**. **[Participant 5]**, tell me about how these conditions have affected your life.

00:17:02

Participant 5 (registered as a patient)

I live with rheumatoid arthritis, and I was diagnosed when I was just 25 years old, and I went from being, at the time, a dual degree graduate student, working on a law degree and a master's, able to handle just a whole lot all at once, and I was a snowboarder, and I played water polo, to suddenly not being able to walk, not being able to type long enough to get through taking notes in a class. Certainly not being able to sit through three-hour law exams because of the pain in my wrists and my fingers, knees, toes, basically every joint I've had an experience, there. I think pain is obviously a really big factor, but so is fatigue. The lack of energy was just draining, a schedule that I had been keeping up with was suddenly completely off the table for me. It really does have a big impact on your life, and this isn't exactly a symptom, but at the time, my ability to imagine my future was really gone. I think that's one of the things that these medications provide is the opportunity to be like, okay, I can have the things I want in my life. At the beginning, for me, that was finishing law school and graduating. But later that went on to wanting to start a family, and so those are the things that I began to have hope for again once I got on a treatment that managed the other symptoms of pain and fatigue.

00:18:30

Moderator, RTI international

And **[Participant 5]**, did you experience flare-ups with your condition?

00:18:36

Participant 5 (registered as a patient)

Certainly. It took a while to get things quieted down, but there have certainly been a lot of ups and downs. For me, the biggest flare-ups were right in the postpartum period, right after my babies were born, and that was extremely challenging, because there I was with an infant, and trying to breastfeed, and trying to take care of an infant, and struggling with my hands, wondering if they were safe when I was holding them in my arms. They put those teeny tiny little snaps on every baby piece of clothing ever, and I couldn't do them. So certainly the flares during that period were probably the most challenging.

00:19:13

Moderator, RTI international

Thanks, **[Participant 5]**. I appreciate you sharing that. **[Participant 2]**.

00:19:19

Participant 2 (registered as a patient)

Thank you. For Crohn's disease, since the anti-TNF [tumor necrosis factor] category is used for moderate to severe disease, which is what I had. And, the implications for anything that's moderate to severe is obviously the depth of the mucosal inflammation. Which, for those who aren't familiar with Crohn's disease, can affect patients anywhere from the mouth all the way to the anus. And so you can have inflammation all throughout different areas of the intestine. And anti-TNFs specifically are also used for fistulizing disease, which is something that I presented with initially. And fistulas, again, if you're not familiar, are an abnormal connection, or a tunnel, between the intestines and another organ. So they can actually be within your intestines, within your smaller and large intestine, and or they can also connect out. In my case, for example, I had perianal fistulas, so I had fistulas that were in the anal area. And so fistulizing disease, as you can imagine, is something that patients don't talk about, we suffer with, and it's obviously a very humiliating, shameful disease manifestation that for me, I actually was undiagnosed for five years and lived with them in silence for five years, and it's to this day, it's been 20 years, but to this day, it is by far the worst part of my disease. I have gone through a number of surgeries, I've gone through so much since then, but fistulizing disease is horrific. It's obviously, your perianal area, you need to sit, you need to use the bathroom, you need to drive, work, anything that we do, sports, working out, anything that we do, obviously it affects our life in every possible way. From an intimacy perspective, it's not something that you feel comfortable sharing with a partner, perhaps. I have always been grateful for Cimzia, and the way it healed my fistula almost within weeks. Especially because for me, like I said, in my case, I had been undiagnosed for five years, and so I was living with these symptoms. You have drainage, you're wearing a feminine pad, you have pain. It is just a constant battle with something that you can't control. There's nothing you can do. You may have abdominal pain, so you may stop eating. In some cases, some patients may have diarrhea or constipation. There's things you can do. There's nothing you can do with a fistula until it heals. Unless a medication works properly to heal it. It certainly is something that a lot of us, again, with moderate to severe disease, have battled with, and it is by far, one of the hardest aspects of living with Crohn's disease.

00:22:08

Moderator, RTI international

I appreciate you sharing that. So it was not only the physical aspects, but also some of the social aspects as well that affected you.

00:22:16

Participant 2 (registered as a patient)

Oh, every part of my life. And I've shared this, I speak more openly about it, but it was at a time when I was in my 20s, I was in my career, dating, all the important parts of life that I was not participating in. I didn't feel comfortable socializing, going out. Having to change this pad, and even after having surgeries, having to have gauze and all this stuff, having to do that publicly, there's no comfort level in that. And I was also going through grad school, traveling, all the things that you want to try to do to live a normal life, but you're limited because of what you're experiencing with the fistulas.

00:22:52

Moderator, RTI international

Appreciate that. Thank you. And **[Participant 6]**, you mentioned you had rheumatoid arthritis as well. What are some the most important aspects to have managed or treated?

00:23:04

Participant 6 (registered as a patient)

For me, I've been a lifetime biker, and so when I would wake up in the morning just the pain in every joint, especially my hands and feet, and so I would cry at the thought of getting out of bed, just to stand up, and so when I would get ready, I would bike to work and everything, and so the first thing I would do is I would hold my hands up and see which hand I could close enough to brake. I literally couldn't close my hands, I couldn't do this. And this is what Cimzia did for me. I was lucky if I could close this much. And then the thought of going to bed at night, I would cry. Because the covers would hurt, everything would hurt. I would surround my whole body with pillows and lay with pillows wrapped completely around me. And Cimzia, it took about six months for it to kick in, and actually, I started in the clinical trials of Cimzia, so I've been on it since 2005, and it's just been amazing. Completely changed my life.

00:24:32

Moderator, RTI international

Thanks, **[Participant 6]**. And then we'll definitely, in a moment, discuss medications, but I really want to hear about how these conditions affect people's lives. **[Participant 3]**, let me turn to you. And thank you, **[Participant 6]**, for sharing that.

00:24:50

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

I was diagnosed in 2006 with psoriatic arthritis. And I say that because things have changed a lot, obviously, in terms of what people are looking for outcomes, and patients have been strong advocates for that, but psoriatic arthritis, the more we know, is a multifactorial disease. So you've heard about enthesitis already, dactylitis. There's spinal involvement in some patients, there's skin involvement, as well as the arthritic components in arthritis. And many of the drugs were originally just approved with the arthritic components. And yet, very much underappreciated the impact that enthesitis can have, or dactylitis can have on your joints as well. Talking about the impact, there was, of course, the pain. Some swelling, but not a lot. Very different than rheumatoid arthritis, but a lot of pain. Pain for me to walk, pain for me to move, stiffness of getting out of bed in the morning. But more importantly, it was the impact of all of that on top of fatigue. And you ask about what patients want, and for me, I had to work. I had a young family. I was the caregiver. I was the worker. I had to work. I had a very taxing job, I traveled all over the country and the world. I had to be able to walk, I had to make it through airports, I had to sit on uncomfortable airplanes, and I was exhausted by the end of every day. My family missed out on me. I like to call it breakfast for dinner? What's the easiest thing to make? Open a box of cereal. And that went on for years of trying to understand and manage the fatigue that came with the disease. And it wasn't like it was constant, because therapies work for fatigue, but they're often not studied for fatigue, so we often don't know those answers. So different therapies would have different responses to that aspect of the disease, but it was very life-limiting. Back to that, where I was in my point in my life, I needed to keep working, and my conversations with my physician was “let’s do what we can to treat this so that I can do what I need to do.” If you ask me that now, 20 years later, I would give you a different answer as to what the impact is, maybe, and how that impacts me. Of course, I was told I couldn’t run anymore, I couldn’t do the things that I love to do, like others, and I’ve slowly worked to get back to some of those things, but it’s it was a tradeoff for me to say if I want to work, I can’t get these other things out of my life because there is only so much that my body could do or give at any given time with the therapies. And that quality of life is really individual, and it is different for different people, and I think that that leads to a need for us to really understand the impact and quality of life, that different therapies give different patients.

00:28:12

Moderator, RTI international

Thank you, **[Participant 3]**. **[Participant 4]**.

00:28:15

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

Just to fill in the gaps as somebody who does not suffer from any of these diseases, but rather represents people with arthritis, I just wanted to share that we did a survey to figure out what are the top issues for arthritis that is not well controlled with medication. And the top five issues that corroborate what a lot of folks are saying on this call is that 52% of folks, in a study of over a thousand individuals, required additional medications for pain and depression and anxiety; 52% also developed worse joint damage; 44% unintentionally gained or lost weight; 43% required physical or occupational therapy, and then, to round it out, 28% missed work or school. So a lot of that pain, stiffness, and fatigue is encapsulating a lot of other aspects of their lives without arthritis being well managed.

00:29:18

Moderator, RTI international

That’s helpful, **[Participant 4]**, and I’d like to hear from folks about the mental health aspect that you mentioned. Did folks feel that it affected your mental health? Did you have anxiety because of the disease? And one of you mentioned, I think **[Participant 5]**, that was hard to imagine your future was one thing you said, but I just wanted to hear about the emotional and the mental health toll. **[Participant 3]**?

00:29:46

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

For me, it was devastating to get the diagnosis. A, it took a while. And B, it was devastating. And then having a very, very active lifestyle, and being so limited as to what you could actually do, was really difficult for me. I’m a Type A kind of person. I didn’t want to be limited. I hated the fact that there were days I couldn’t walk down the stairs to get coffee, thinking about, did I have to move to a one-story house? Could I survive? Could I continue to ride my bike in fundraisers? Could I walk the dog? So that has its own aspect. Am I going to have to change my job or my career? I didn’t. I forged through that. One could say I was stubborn, for many a time, because that was what I personally chose to do. Many others may not have chosen to do that. And then there’s a treatment effect, and so that’s initial diagnosis. But we talked a little bit about flares, or you asked the question, so I think once you have a successful treatment and it no longer works for you, and you experience your first flare. That, to me, was devastating, because I was so grateful that I had been treated, and that I was doing really well, and I could get back to the things I wanted to do when I had my first flare, it was worse than the initial diagnosis, because now I could see my life as a series of ups and downs and ups and downs, and that uncertainty led to a lot of dark days of not knowing what was going to happen. And then every time I would try a new therapy, that fear, what if it doesn't work? What if I get worse? What if? Made me skeptical, and that changes your outlook on life. Do you want to commit to long-term things? Do you want to commit to go on a trip two years from now? When you have no idea what two years is going to be.

00:32:09

Moderator, RTI international

Appreciate that, **[Participant 3]**, thank you. Now, **[Participant 2]**, from the Crohn's disease perspective.

00:32:14

Participant 2 (registered as a patient)

I think **[Participant 3]** touched on a lot of, I saw a lot of head nods, I was nodding myself, because a lot of a lot of what she said is a lot of what we have all experienced, and I will say, even when I spoke earlier, fistulizing disease was, and still is, a very emotional part of my disease journey. I can talk about it more openly now, but there was never a time that tears did not come from how horrific living with fistulas was. And, unfortunately, there are patients who are on the wrong treatment, and their fistulas don't heal, they live with recurring fistulas. I'm fortunate, and I'm grateful for Cimzia for having healed mine. But, again, it's happening at a time, at least for me, when you're looking at your future. I'd mentioned I was going to grad school, or I was about to start grad school. I wanted to travel, I wanted to get married, have kids, all the future that you plan on, and you don't know if any of those are realistic with the disease. And again, some of the more physical, logistical aspects, would I be able to get pregnant and have children and give birth just because of where the disease is located? Would I be able to, again, like I had mentioned earlier with intimacy, can you have a partner? There's things that, again, I talk about more openly because those are often under-discussed. Yes, there's anxiety, there's depression, there's all the uncertainty of, can I find a bathroom to be able to change my pad? Wearing the proper clothing, that was something that I realized that I was very cognizant of what I did, but I would wear dark clothing. I never wanted to wear anything lighter in case there was any drainage or anything that came through. You don't feel comfortable being on a beach or being in a water situation, beach or pool, whatever, because you have to be in a bathing suit, which doesn't allow for the same type of having a pad, or having any type of coverage. It's all those things that you think about, you have to think about, in many ways, because you don't know the situation that you're going to be in. Unfortunately, that leads to, at least for me, and again, in a very challenging time, is I was home a lot, and what does that lead to? Loneliness, losing friendships, the depression keeps building, and so I think as the years go on, and again, I'm fortunate that mine healed, but if you continue to live with them, it's like it only progressively gets worse. If your fistulas aren't healing, and your disease is progressing or not improving, then it's like the emotional toll, mental health toll is tremendous. And for many of the diseases, for everyone who's on here, they're invisible. People don't see what we're living with, because on the appearance, you can wear makeup and do your hair and look like we're healthy, but they are invisible illnesses, and it's unfortunate, I say that, I don't want to compare to other disease states, but it's unfortunate that because they're invisible, they're not given as much attention, because the visibility isn't there. If someone's losing their hair because of cancer, chemo, then that's very apparent. But when someone is living with a disease, you'd never know if I had fistulas today, or if I had them 20 years ago. And that's, I think, the hardest part for us to process mentally is we live with something indefinitely at this point, until there's a cure, and that uncertainty of our futures is hard.

00:35:48

Moderator, RTI international

And I saw a lot of heads nod when you mentioned about it being an invisible disease, and it seems like this is an experience that many people face. **[Participant 1]**, talk about, from the perspective of non-radiographic axial spondyloarthritis.

00:36:01

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

Yeah, you can just say "NRAS," but it's fine. And you're going to see, too, that we all have different diagnoses, but we share these commonalities. I checked off, looks good, invisible disease, because I wanted to make sure to hit on that. It's so true. Even my husband, who knows what I go through, will often say, "I'm so sorry, I just forgot." I'll say "I can't do the dishes tonight," whatever. "Well, why?" "You're going to ask me why, really? You know why I can't." He's like, "I'm sorry, I just forget." But that's a real thing, because it affects your mental health. A lot of people talk, and I'll speak that from the organization lead hat, you hear that all the time, too, from patients, scared to admit it at work. They're worried about, people don't understand, they're going to think I'm lazy. Things like that. And that comes with invisible disease. But also, I think it's important to also just think about this I call it, who am I now? Because it depends on when the onset is. You hear a lot of kids with JIA [juvenile idiopathic arthritis] talk about, I was born with that, I don't know anything else. This is my normal, but you hear other people, where you're like, I was an athlete, too, like we've heard before, and it's like, who am I? Because I swear, I still, to this day, believe I throw or threw the best football of any female I had ever seen. And then I was the football girl, and then all of a sudden, I wasn't the football girl. Who am I? And it's just those kinds of things, your identity, things that make you. Having to rethink what in the world that is. I just think that that is a huge, huge, huge portion of this, that I won't reiterate what everyone else said, but just completely valid. It's a huge part of this that we have to deal with is figuring out our new normal.

00:38:02

Moderator, RTI international

Thank you. We'll hear from two more people, then we'll talk about treatments, but **[Participant 5]**, go ahead.

00:38:09

Participant 5 (registered as a patient)

I definitely nodded my head at all of you, and I basically agree with what everybody has said so far, but I also wanted to quickly point out that the impact is not just on the patient, it's on their partner, it's on their children, it's on their family, it's on their friends, it spreads out from there. And in the case of my children, for example, it had legitimate impacts on their lives. My first two pregnancies were untreated. I was only able to breastfeed those boys for three months before I needed stronger medication. My third pregnancy, I was on Cimzia, I didn't have a postpartum flare. My daughter got breastfed more. So it has both real and emotional impacts on the lives of the people around you as well.

00:38:52

Moderator, RTI international

Thanks, **[Participant 5]**. And finally, **[Participant 6]**.

00:38:55

Participant 6 (registered as a patient)

Yes, I think there are different kinds of mental health impacts from the disease. For me, [I] ended up working for my doctor. She offered me a job, and so that made a really big difference because she understood everything. But what had the biggest mental health impact was trying to get access to the meds. And, once it was time to go on Medicare, I was panicked because Medicare has such bad coverage, and it's like the Hunger Games of trying to get foundation assistance for Medicare, and it's still that way today.

00:40:00

Moderator, RTI international

Great, thank you, **[Participant 6]**. For our next part, I appreciate you getting into sharing those. I want to turn our attention to some of the medications that are used to treat these conditions. Again, ankylosing spondylitis, Crohn's disease, non-radiographic axial spondyloarthritis, plaque psoriasis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, and rheumatoid arthritis. If you could use the chat window and type in, what are some medications, if any, that you, your loved ones, or patients you advocate for currently or in the past have taken for one of these seven conditions. And you can just put those in the chat. Again, what medications have you currently or in the past used for treatment for any of these seven conditions. I am seeing Orencia, Enbrel, Rinvoq, Xeljanz, Cosentyx, Cimzia, Humira, prednisone, methotrexate, Remicade, Orencia, Rituxan, and some others. Is that everyone's list there? Okay, and it is Cipro. I see Xeljanz, again, Humira, again, another TNF blocker, Otezla, Zepbound, and meds for anxiety and depression. Okay. Thank you for sharing those medications.

For the next questions, I want to note that we want to hear about your experiences that you or your loved ones have had with Cimzia, and also other medications used to treat these seven conditions. And when you're talking about these different medications, if you could tell me you're talking about Cimzia or talking about another medication, that would be helpful just so I know what medication you're talking about. What benefits have you, your loved ones, or people you advocate for experienced with medications used to treat these conditions that Cimzia treats? And as a reminder, again, let me know what medication you're talking about. Again, what are some of the benefits that you, your loved ones, or people you advocate for have experienced with these different medications? And I'll open it up. Go ahead, **[Participant 2]**.

00:42:45

Participant 2 (registered as a patient)

Quick question, just to clarify, you're saying benefits, but what if there's negative?

00:42:49

Moderator, RTI international

Oh, we'll come to that, don't worry.

00:42:52

Participant 2 (registered as a patient)

Okay, so only bring up benefits of the other medications?

00:42:55

Moderator, RTI international

Yeah, we'll talk about benefits of both Cimzia and other medications to treat these conditions and then we will certainly go talk about drawbacks in a moment.

00:43:04

Participant 2 (registered as a patient)

Okay. And the reason I ask is because all of the other ones were negatively impactful for me. I can obviously talk from a Cimzia perspective, but I don't have anything positive to say about the others.

00:43:16

Moderator, RTI international

Okay.

00:43:17

Participant 2 (registered as a patient)

I just didn't know if now was the right time to do that.

00:43:19

Moderator, RTI international

If you want to talk, if you have benefits you want to talk about, like Cimzia, feel free to mention those.

00:43:24

Participant 2 (registered as a patient)

For Crohn's disease, again, for Cimzia. I began using after trying other medications, and, for me, I was at a time when I mentioned traveling, school, and, working, it's because it was an injection, it was an option for me to use at home. So just for the ease of being able to time it based on my availability and my schedule. And then, the fact that I was able to do it, and not really have any side effects from it. So I typically will do it on a weekend, and then, maybe I might feel a little more fatigued. But other than that, I've had no side effects from using Cimzia, and I think that by far exceeds my expectations, especially for any treatments, for anything really, but just not feeling like it's a burden on me. I do the medication usually in the evenings, and then, like I said, I might be a little more fatigued the next morning, and then within maybe 12 to 18 hours, that fatigue level has worn off, and then otherwise, I literally have had no side effects. And so that especially, again, when you're going through chronic disease, it's like you try so many medications, you have side effects, you have adverse reactions, and so when you finally have a medication that not only works, like I said, in my case, healed my fistulas, and then maintained my disease from progressing. And then not having side effects, it's a win-win.

00:44:53

Moderator, RTI international

Okay. And also, how effective was Cimzia for you?

00:44:58

Participant 2 (registered as a patient)

Very effective, as I mentioned with fistulas, they healed after living with them for five years. They literally healed within weeks, which was a shock to not only my physician, but myself. I didn't realize how quickly it would work, the effectiveness. And then, I have been able to be on it for a number of years, so for example, there was a surgery that I would have needed to have, and it didn't have to happen until 2020, and so I've gone years without disease progression. And so I consider that, just from a maintenance perspective, it's allowed me to live my life with the disease, yes, but in a way that has not been as limiting as sometimes when you fluctuate medications.

00:45:45

Moderator, RTI international

Okay, great, thank you, **[Participant 2]**. And **[Participant 1]**, benefits you've experienced with Cimzia and also other drugs?

00:45:50

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

Personally, Cimzia was my miracle drug. As a patient organization lead, you'll hear patients often say that was my miracle drug. And that was mine. I was very successful. When I said I couldn't get out of bed and rolling, I was prescribed Cimzia at that time. That was the worst I have ever been in my life, was during that phase. And within three weeks, I was feeling almost back to myself again. It was an incredible impact on my life. And in saying that, I was successful on it for six years. In addition in conjunction with my experience and speaking as an organization lead, you'll also hear patients say it worked until it didn't. And so that's not uncommon. I have never found another treatment that works for me as well. Hopefully I will, but I have had good success with Cosentyx for many years. It just never was quite as good, but I want to make it really clear that what works best for me isn't going to necessarily work best for somebody else. I do find that difficult to give parallel of the other benefits from the other drugs, because I can guarantee you Cosentyx is somebody's miracle drug. In saying that, I also just want to make it clear, too, that with Cimzia being a TNF inhibitor, and then you've got Cosentyx, which is an IL-17A [Interleukin-17] blocker. These are two different mechanisms of action. So you'd think, in theory, isn't that strange? She did really well on two different [medications], but that's important to note, too, because it does make Cimzia very different. It also, you've heard people, RA and Crohn's, there are many dual diagnoses here. It's not uncommon to say somebody with spondyloarthritis has something else as well. So I think it's important, too, to look at what Cimzia treats as well, because if somebody doesn't just have my diagnosis, that is an indicator that this treatment may be their miracle, or may work better for others. I think subgroups and understanding that, because in reality, I know that in insurance, therapeutic alternatives is a thing, but in the patient world, it's not.

00:48:14

Moderator, RTI international

Great, thanks, **[Participant 1]**. **[Participant 5]**.

00:48:19

Participant 5 (registered as a patient)

I want to piggyback off of that point. First, I'll say that a number of these medications have been successful for me for a time, and as far as taking away pain and fatigue and making my life possible, these medications are life-changing when they work. Cimzia, for me, is particularly important because it is the only molecule, the only pregnancy-safe, the best pregnancy-safe drug. The molecule is missing the Fc [fragment crystallizable] portion, which is what allows the medication to cross the placenta and impact the fetus. When you're thinking about planning a pregnancy, there is a real reason to pick Cimzia over some of these other medications. Some of the other medications are also safe during pregnancy, but there's a real reason that patients might want to be choosing this one, which is what makes me concerned when and there's an insurance issue, or a step therapy issue, and patients are being shunted off to other medications whether Cimzia is going to work for them remains to be seen, but if it's something that they'd want to try, I would want them to have access to it if they were considering pregnancy, because it is believed to have the least placental transfer. And for me, the pregnancies where I was basically untreated, because that's what the data showed at the time, was basically stop everything and good luck to you. Those went really badly. They were really difficult. During my second pregnancy, I flared so badly that eventually they were like, the inflammation is more of a risk to your baby than restarting Enbrel. So I went back on Enbrel during that pregnancy, but I still had a really bad postpartum flare. It was really difficult. Night and day, with my pregnancy on Cimzia, and so I just want to really emphasize the specific point that Cimzia gives patients who are considering starting families, which is not only me, but lots of people in the group that I represent, it gives them peace of mind because there's a lot of stigma about using medication at all during pregnancy, and so at least if you can say, this is the one with the least placental transfer, and you can choose that, it makes you feel a lot better.

00:50:25

Moderator, RTI international

Great, thanks, **[Participant 5]**. And actually, I'm going to go first to **[Participant 6]**, who also has rheumatoid arthritis, just to pair the two together, and then I'll come to you, **[Participant 3]**. **[Participant 6]**?

00:50:35

Participant 6 (registered as a patient)

Yes, I agree completely with **[Participant 1]**. Cimzia has been a miracle drug for me, and it has completely changed my life, and luckily, I've been on it 21 years, and it still works. And if an insurance company, they say, we don't cover it anymore. And if a drug works for you, you don't change. Period. You don't change, and so when insurance companies try to tell you, that's just insane.

00:51:19

Moderator, RTI international

And **[Participant 6]**, you said that you've had it for 21 years, and it still works. Can you tell me a little bit about how it benefits you, and how it makes life better for you?

00:51:30

Participant 6 (registered as a patient)

I can do everything that I did before Cimzia. It's just completely changed my life. I can bike 20 miles a day. I can walk five miles a day. I can do everything. Yes, I have had a couple joint replacements, and I've also had more joint damage, but that's not because of Cimzia, that's because one rheumatologist I had lowered the dose and then when I finally got back to my original rheumatologist, she took the x-rays and went over every one and pointed out the damage that had happened because he lowered the dose of it.

00:52:25

Moderator, RTI international

All right, thank you, **[Participant 6]**. **[Participant 3]**.

00:52:30

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

My story is maybe a little bit different, but, 20 years ago there were only TNF inhibitors for psoriatic arthritis. They were the only ones that were being used at the time. And I had a fabulous response to my first TNF inhibitor, sub-Q [subcutaneous] administered, it was fabulous. But like many others, the efficacy started to wane after a couple of years, we increased the dose, we increased the frequency, it wasn't worth it at that point to keep paying for it, the symptoms were coming back. I couldn't walk, I had pain, I was fatigued, etc.

00:53:12

Moderator, RTI international

What was that drug, **[Participant 3]**?

00:53:15

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

Which drug was that? I started on Enbrel. I then switched to another TNF inhibitor, again, limited choices. Is another TNF inhibitor going to work or not? And modest impact, but I was burned with a lot of side effects that I had never had before that were quite scary because I had been diagnosed with asthma in the past, and I developed severe respiratory infections. With minimal efficacy. But not with these bad side effects, the decision was to go on the next TNF inhibitor. So now you would say, that's crazy. Why go on three? There were very limited choices, but there was also a lot of data emerging that the TNF inhibitors are not all the same. Just because they have the same target doesn't mean they all work the same way. And as we know, in PsA [psoriatic arthritis] and in rheumatoid arthritis, efficacy's not 100% like it is with some of the newer therapies, let's say, in psoriasis. Different people respond to different medications and need access to different medications, and I'm a scientist by training. I worked with my physician, and we decided I would go on Remicade as an infusion. That was limiting. I had to give up half a day, or almost a whole day, once a month just to get to an infusion center and get the infusion, and I was exhausted afterwards, and the red tape, etc. But it worked. So that was great. But it started wearing off over time, too. These diseases can change in different people. They're multifactorial. There's many different presentations of my disease. And I am treatment-resistant to most of them. After several years of Remicade and increasing the dose, it became so expensive for me to pay for it at the dose we were at and the frequency that I asked my doctor to change. The IL-17 inhibitors were not approved yet for PsA, so we knew that my insurance company wouldn't give it to me, so I tried Cimzia. And I have to say, I was really surprised. I, as a scientist, thought there was no way that I was going to get a benefit from Cimzia. And it proved me wrong. And it changed my whole perspective as a patient advocate and a patient research partner to say that just because I had limited access, or just because it's the same class, means that they all work the same. They don't. My side effects were different across all of them, my efficacy was different. And at the time, they had put the effort into, I don't know what they have right now, if it's an auto-injector, but they had this really cool syringe system that was really easy to use, it had an OXO grip, it was easy to handle. It's a viscous solution, so it took a little bit to push the self-injection in, but it wasn't difficult at all, and it gave me back the freedom of not having to go to an infusion center. Which is what a lot of the Medicaid patients have had to do in the past. And I didn't have to go to a doctor's office to get them to give me the shot, just so I could get access. It had great impact on my fatigue, my aura, my mental health, that sort of brain fog went away when I went on it, and I had all the signs and symptoms relieved. So I loved the actual process of it, and it gave me flexibility, so with my doctor, I could have done two shots once a month, or one shot every two months, or one shot twice a month, which is what I chose. And I had great efficacy. So I loved when I was able to go on Cimzia, and it proved everyone wrong. How can you fail three TNF inhibitors and have success with a third one? They weren't primary failures, they were all what we call secondary failures. You have an impact, and then it starts to wear off. I since moved on to the IL-17 blockades, and I could say the same thing about them. Failing one doesn't mean you're not going to respond to the other, because I had that benefit as well. But treatment-resistant disease happens in a small percentage of patients, but it could be up to 30% of patients who become treatment-resistant over time. And a lot of the organizations are coming up with guidelines right now on how physicians should be handling patients that are treatment-resistant. How to sequence through therapies. And being open-minded and using shared decision-making is really important for patients and physicians to choose those next therapies. And for me, it's that open-mindedness, because I wasn't expecting to have such a great response.

00:58:24

Moderator, RTI international

[Participant 3], one thing I wanted to ask about is, when you have experience with more than one medication for the condition, how do the benefits of the medication differ? And one thing I heard from you is that the initial TNF inhibitors, I got Enbrel, Remicade, was there one more?

00:58:40

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

Humira.

00:58:45

Moderator, RTI international

From what you're saying, it sounds like one benefit that you experienced was that the treatment did not wear off over time, like the other three.

00:58:58

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

Eventually, it wore off. I had to move on to an IL-17 inhibitor. My doctor would see me limping down the hallway, and I'd say, "I'm fine," and he'd say, "Really? Are you?" And would do a joint count, and realize that I wasn't doing fine. This was all in addition to being on DMARDs [disease-modifying antirheumatic drugs] and prednisone and other therapies as well, with additional background therapy. I did try some of the new oral therapies. One, I had some terrible, weird side effects, and one, I had absolutely no response to. I do know what it's like to be on therapies where you get nothing but I've also been on therapies where because this disease is multifactorial, something will pop up, the enthesitis will be worse, or randomly develop dactylitis in your toes, that's really painful, where I'd never experienced that for 15 years, and 15 years later, I'm on a therapy. Or where the psoriasis may get worse on one and it may get better on another, so patients and physicians are making trade-offs all the time in psoriatic arthritis. Are you treating the pain, the inflammation? Are you treating the enthesial joints? Are you looking at the joint damage, are you having joint damage progression? Is your spine worse? Is your scalp or your skin good, better, or is it getting worse? Which on some therapies that's been an experience of mine as well. Patients then make trade-offs. What is the most important thing that you want to have treated at that time, and how can you get there?

01:00:46

Moderator, RTI international

Thank you. I'll ask this question of others who can chime in. That is, if you have experience with more than one medication for this condition, how do the benefits of the medications differ, if at all? Again, if you have experience with more than one medication for this condition, how do the benefits differ, if at all? **[Participant 5]**?

01:01:11

Participant 5 (registered as a patient)

I think several of us have touched on that already, but I started on Remicade, it worked a little bit, but not very much. For many years, Enbrel was my miracle drug, and it worked really well for me, and then it stopped. So I think the benefits change based on how the drug works for that person. I don't think you can say that Enbrel is better than Rituxan is better than whatever. And where you are in your life and in your disease changes it as well. The best I ever felt was the first time I was on Rituxan. It was like a miracle drug for me, but then that one wasn't, it depends on what you want in your life as well. That one wasn't pregnancy safe, so I had to get on a different one for that. I know you're sensing a theme in what I care about, but I think, comparing the benefits, it's just a matter of it's so individual, which drug is going to work for which person, is my point.

01:02:13

Moderator, RTI international

And **[Participant 1]**, you had mentioned the individual differences as well.

01:02:16

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

Yeah, it's so hard to answer a question about what was more beneficial of one or the other, because it's just going to depend on who you talk to. We're all heterogeneous diseases, we all have various comorbidities. That's why it's great that we have so many therapies, and to **[Participant 6]**'s point, don't rock the boat. Enbrel did nothing for me. I failed it right out of the gate, but hey, that's a TNF inhibitor. Why was Cimzia the best I ever had? I don't know. But I do want to add, because I threw it in the chat and I was encouraged to mention it, I forgot to say before, for me, one of the big things was the administration. Cimzia had such a thin needle, I didn't even hardly feel it go in. And that's a huge deal, because when I took Taltz, and I forgot to put that in my original list. The first time I took it, I had a softball-sized welt on my leg, so big, because you do it in your upper thigh, I couldn't wear pants for two weeks. I had to literally go shopping, because I had to go to a conference, and I had to buy a pair of pants too big for me, because it was so painful for the fabric to hit my legs. Those are all types of things, too, that matter. I'm sure Taltz is a miracle drug and doesn't cause a softball-sized welt on lots of people, but it did for me. It's just really hard, I guess, is my point, to say what are the benefits of other drugs because it just depends on the person, really.

01:03:53

Moderator, RTI international

Thanks, **[Participant 1]**. **[Participant 4]**.

01:03:56

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

To piggyback on that, we did another survey with 1,700 participants over nine rheumatoid arthritis drugs. And without fail, within one to two years, for every single drug, more than 50% of people were off the drug and trying a second drug, and then eventually trying a third or fourth drug. So we usually always talk to our advocates that a lot of times, specifically with RA, it's almost like an art in diagnosing and really feeling out the patient and what their preferences are and what they want in their treatment is very, very important. And to reflect on **[Participant 5]**'s comment in there, that having access to these choices is really important for our patients.

01:04:37

Moderator, RTI international

Great, thank you, **[Participant 4]**. So we've talked about the benefits.

01:04:40

Participant 5 (registered as a patient)

Can I quickly add something to that? It is scary to be diagnosed with something that you know you're going to have for the rest of your life. And here, there are six biologics to treat this, and you've been through three of them already. There's also limited pool of options, and so the bigger the pool gets, the easier it is to say, okay, I can live with this for the rest of my life, and the less mental impact there is of what am I going to do if this one stops working?

01:05:10

Moderator, RTI international

That makes sense. Thanks, thanks, **[Participant 5]**. So we've talked a bit about the benefits. I want to talk about the other the flip side, the drawbacks. What are some drawbacks or challenges that you, your loved ones, or patients that you advocate for have experienced with medications used to treat the conditions that Cimzia treats? As a reminder, let me know about the medication you're talking about when we're discussing. Again, the drawbacks and challenges of medications that you've used, or people that you know have used, and then also just remind me which medication you're talking about. **[Participant 2]**.

01:05:50

Participant 2 (registered as a patient)

So like I mentioned, I'd had issues with all the other medications I'd been on. So I'd say for 6-MP [6-Mercaptopurine], first, none of them actually healed my fistulas, and so obviously there was no benefit from actually managing my disease. But 6-MP, which is used for chemotherapy as well, is an extremely difficult pill, and extreme nausea, hair loss, a lot of the similar chemo type of side effects. Not only are you experiencing all those, but then you're also not getting any benefit from the disease. For Humira, which is an injection, I had adverse reactions, so I developed immediate adverse reactions, and so we, with my physician, decided to immediately take me off of that. Prednisone and budesonide were the steroids I mentioned on there, and steroids, as many of us know, again, there's a lot of risk to being on steroids, either short-term or long-term, as well as side effects, and they're not a maintenance medication. But in the case of needing to treat the disease in the immediate moment, they're used. And Cipro and Flagyl, I had forgotten, but they were in my initial treatment, so they're the super basic way to try to treat fistulizing disease, and they did absolutely nothing, but I have actually allergic reactions to both. Cipro caused issues with my nervous system, and Flagyl was extreme nausea and vomiting. Again, options that I don't have, even if I needed to take them for any other reason, they're now on my allergy list, and so they're not even an option for me for any other disease state. In my case, the medications that I have tried, I've had adverse reactions to, and that's actually a big part of my decision-making, even when I decided on Cimzia, was because I unfortunately tend to be that patient that has issues with even vaccine, all kinds of things. I have issues, from a reaction perspective, it's that much more worry if you're trying a new medication. Like I had mentioned earlier, not having side effects from Cimzia just alleviates the stress that you're already undergoing by living with the disease, it's like, okay, I don't even have to worry if I'm doing my medication tonight, I'll be fine. I can do, I can live my life tomorrow. It doesn't mean something's going to happen, because I already know that I'm confident in how Cimzia has worked.

01:08:21

Moderator, RTI international

Thank you. And **[Participant 6]**, what drawbacks have you experienced with medications designed to treat rheumatoid arthritis?

01:08:28

Participant 6 (registered as a patient)

The drawback with methotrexate is it didn't work. But I have to take it as a background medicine for Cimzia. And the drawback with Cimzia is the cost, and trying to access it, and I applaud CMS for putting this on the list of negotiated prices. That being said, that's ludicrous. To go from $80,000 a year to $30,000 or $40,000 a year, even if it went to $10,000 or $5,000 a year, that's insane for most of us. What's the point?

01:09:18

Moderator, RTI international

Thank you, **[Participant 6]**. **[Participant 3]**.

01:09:23

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

[Participant 6] mentioned the dreaded methotrexate, which many treatment algorithms still put as a first-line therapy. I wish all the doctors who prescribed it had to take it and live with it, personally, is my response to them. That is a difficult, difficult drug, and to get a good effect and get to a high dose, I would give up a whole day of my week, and because I worked, it had to be Saturday, so I'd take it on Friday night and I'd ride through the weekend. My Saturdays were pretty much forgotten. It made me sleepy, it gave me brain fog, it made me incredibly tired, on top of already having this disease, a very different feeling than the disease feeling. It was horrible. I could hardly wait till I could get off methotrexate and be on a therapy where I didn't have to take methotrexate with it, to get that benefit. And so I seriously question and wish that all the companies would study their drugs without the combination of methotrexate, and that we could learn to find ways to treat the arthritic components without methotrexate, and not have to make it a first line, just because it's cheap, and it's not actually that cheap. Make that an option. The second one for me was infusions. I loved to hate going to infusions when I was young and active. Being tied to an infusion chair and the whole process of the infusion was really challenging. It was quite sad and depressing to be in an infusion suite with other patients who had much more serious illnesses than me. And you couldn't help but overhear stuff that you just didn't want to have to hear. And it took time away from work, and I had to explain that to people when I didn't really want to talk to my employer about my disease state. I'm a pretty private person, and I didn't want them to know that I was potentially disabled, because I was afraid they would treat me differently, and some bosses did. And then lastly, prednisone. Prednisone's a horrible drug. It's a necessary drug, but it is horrible. And, again, it's showing its head in treatment guidelines. It is not, as was said before, something for long-term treatment. It shouldn't be. Even short-term, high-dose infusions are horrid. For anyone who's had to have them, it's terrible, and yet people think that they take that, for example. So I would say, if I was to compare methotrexate and high-dose prednisone infusions over three days to any of the other drugs I've been on, I could live with the other ones. Those were much worse. That being said, I was on a TNF inhibitor that gave me terrible side effects. And I've been on other drugs where different aspects of my disease have presented themselves, where I'd never experienced that part of the disease before, which makes me think it's not working the same way as maybe the other drug was, which again gets back to many different patients need different options. And not everyone will respond the same way to every therapy and just because CMS puts one class of therapy on their formulary and negotiates a price, I think that that's really short-sighted from a patient impact perspective because each of these therapies have some unique aspect, and each patient's going to respond differently.

01:13:08

Moderator, RTI international

[Participant 3], one follow-up question for you. You mentioned that with the prednisone, that was horrible. Can you tell me specifically how it was bad and horrible?

01:13:16

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

I made shared decision-making, it was a poor choice. But I was very sick, and I went on high-dose prednisone infusions. A gram a day for three days. They had to give me potassium infusions because of the side effects of it altering your potassium. The potassium infusion got extravasated into my arm. I had a terrible burn. I couldn't sleep for a week. I was nutty. I warned my family I was going to be crazy, and then I put on 40 pounds. And there was nothing I could do about it. I sat there and knew that, I just I was on high-dose steroids. I'm a pharmacist. I knew what was going to happen, and I could not stop. I just watched that Cushingoid effect take place. It took me a whole year to lose the weight, and it's been a battle, but I couldn't do anything about it. And in the long run, it was a temporary fix. It helped me get through maybe a month or two, and then I was back to square one. And I had terrible spinal disease and crippling back pain, and I couldn't walk for months, six months, and the steroids were just temporary. I don't know if that helps or not.

01:14:53

Moderator, RTI international

It does help, yeah.

01:14:54

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

It was miserable. For me.

01:14:58

Moderator, RTI international

Great, thank you for sharing that, **[Participant 3]**. **[Participant 5]**.

01:15:03

Participant 5 (registered as a patient)

I will fully agree with the methotrexate and prednisone reviews that we've heard already. One side effect or downside that I don't think anybody's mentioned yet is, a lot of these medications are immune suppressants, and they're supposed to be suppressing our immune system to make them stop attacking ourselves, but that also, of course, makes you more susceptible to lots of other infections, which was particularly scary during the pandemic to be having to worry about being more susceptible. The past couple of years, I've been in a loop of sinus infections, where I've had two sinus surgeries, and I can't get the infections to stop, and so now I'm also on IVIG [intravenous immunoglobulin] infusions to go to combat to push my immune system back up, where for me, right now, it's biosimilar Rituxan. I think it's called Ruxience? But I think, what I'm experiencing with increased problems with infection could happen on almost any of these drugs, so that's just a side effect that I don't think anyone had brought up yet.

01:16:10

Moderator, RTI international

Thanks, **[Participant 5]**. **[Participant 2]**.

01:16:13

Participant 2 (registered as a patient)

I just wanted to add a little bit on the prednisone, and **[Participant 5]** just touched on this a little bit, which was that risk of immunosuppression, and by far, steroids or prednisone is riskier in the IBD [inflammatory bowel disease] space for Crohn's disease and ulcerative colitis. And especially during the pandemic, and thereafter, there's been a lot of research, and most of our drugs were actually, safe to continue, despite initial fears, whereas prednisone put patients at a higher risk. And unfortunately, with prednisone comes, obviously, the side effects that were already mentioned, but also osteoporosis, and cataracts, early cataracts. High blood pressure, and a lot of other things that can be prevented if not putting someone on prednisone. And because it's a cheap, inexpensive drug, it's used, again, for a short-term basis, but all you're doing is causing more problems for the patient in the long term and putting them at risk by trying to use an inexpensive solution, which, again, is not to be used for maintenance for our diseases.

01:17:18

Moderator, RTI international

Great, thank you. For those, I think this is true for many of you, if you have experience with more than one medication to treat your respective condition, how do the drawbacks of the medications differ that you've experienced? How do the drawbacks between different medications differ? Yeah, **[Participant 2]**?

01:17:41

Participant 2 (registered as a patient)

I'd say one of the easiest ways to answer this is just being able to have quality of life. Like I mentioned with Cimzia, I really am not affected. I might be a little more tired the morning after, but it's like I can sleep a little bit more, another hour or two, and I feel okay. With the other ones, I was completely limited. With 6-MP, like I mentioned, I had extreme nausea, hair loss. I literally could not eat. I lost a significant amount of weight. I couldn't socialize, do anything like normal life, because I was literally living with nausea 24/7, which obviously is not fun, and then we were trying to use it for about six months, so it was miserable. It was a very challenging six months. And so I think that aspect of just being able to have quality of life with Cimzia and really not having any effects. That is a huge difference, where whatever our lives are, work, have a family, have kids, travel, there's no limitations, whereas with other drugs there have been.

01:18:44

Moderator, RTI international

And **[Participant 3]**?

01:18:49

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

I agree, it's a quality of life issue, really. You can look at all the side effects, or a doctor can say your joints are this much better, but if you're still not able to get back to what you need to be able to do, then is that the right therapy? And so I think, with Cimzia, it gave me back my life at the time, and what I needed to do, and allowed me to continue to be able to do that. How do patients make choices now if they've failed multiple drugs? And a lot of times, based on that disease, you're looking at clinical trial data, which is inherently flawed in a way that it doesn't always look at the aspects of life and things that patients want, because they're not quantifiable, or there hasn't been an outcome measure that's been approved to go into a clinical study that's really patient-oriented and patient-based. You're looking across in a disease like psoriatic arthritis, six, seven, eight domains, and saying, okay, today I have more of these three and less of these three, so I want to look for a drug that seems to have a better response across these three than these three. And each time you're making a change in therapy, you're having to say what's most important to me and what does this product in a clinical trial say it's going to deliver. I'm a strong advocate for outcome measures and research, and including the patient voice, so that the things that are most important to a patient are actually studied so we can look at the data and say, I don't care if it gives me a 20% response in my joint pain, 20% is nothing. I want, 80% response. But I also want to know that I can bike, like **[Participant 6]**, and take care of my kids, and do all these other things as well.

01:20:52

Moderator, RTI international

[Participant 5].

01:20:55

Participant 5 (registered as a patient)

What I thought when you asked this question is that you don't know what the drawbacks are going to be until you try the med yourself. And we've been talking about how everyone has an individual response, and I think it's also important, to keep in mind the investment time for patients who are trying these medications. We're not talking, try it for a week and decide if it's working or not. It's usually, a month or two or three, and then you see if maybe it's working and maybe it's not, so it's not a simple decision, and it's not a simple process. But we need to have access to as many different options as possible, because you don't know what the drawbacks are going to be until you try it and see what the drawbacks are for you, and whether you can live with that.

01:21:41

Moderator, RTI international

Excellent. Great. So one question, wrapping this up, is overall, when considering a potential medication for these conditions that Cimzia treats, what factors matter most to a patient? So again, when considering a potential medication for the conditions that Cimzia treats, what factors matter most to a patient? It could be, how effective it is, it could be how safe it is, it could be side effects, how easy it is to use, or so forth. But what do you think is the most important thing to patients? **[Participant 6]**?

01:22:19

Participant 6 (registered as a patient)

I think efficacy is the first, and then accessibility to the drug.

01:22:27

Moderator, RTI international

Okay. **[Participant 2]**?

01:22:31

Participant 2 (registered as a patient)

I think you mentioned all the things that a lot of us probably think is, not only efficacy, and **[Participant 3]** was just saying this, you want the drug not to work at 20%, you want it to work at 80%, or, like in my case, like I've shared with my fistula, it healed them 100%, so it is very much telling that the drug worked for me.

01:23:02

Moderator, RTI international

[Participant 1].

01:23:07

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

Without repeating anything that I've already said, I think to summarize it, the most important thing is, am I going to have the quality of life that I need to be able to live the life that I choose for myself, which is going to be a little different from everyone else, but that's an efficacy. And to **[Participant 3]**'s point, I'm looking at what is working better in enthesitis versus the joints because that matters to me, personally, where I know that wouldn't matter to somebody else, especially if a drug like Cimzia treats different diseases. There's going to be different value for different people, but, **[Participant 6]**'s point is just so right on, too. You've got to be able to access it. And the same as don't disrupt my access. I am constantly living in fear every year, that the insurance company is going to take away my drug that's working, and I'm going to have to start all over because they think there's a substitute. And that's, to me, what matters the most, that nobody disrupts my continuity of care and quality of life.

01:24:18

Moderator, RTI international

Great. **[Participant 3]**, I'm going to go to **[Participant 2]** first, so she can finish her thought. Go ahead, **[Participant 2]**.

01:24:23

Participant 2 (registered as a patient)

What I was going to say was, and actually it was just brought up, that long-term consideration. We want the drug to work for us, obviously, in the short term, but then until we know X number of drugs are going to be available to us for the rest of our lives, and so that's the thing, is how long is this drug going to work right now and heal our disease or whatnot? But then how long can I stay on this, stay on Cimzia without having to consider another drug? Because, again, with chronic diseases, we don't have a cure, we don't know when we will have one, and so we want to be able to have that trust in the medication so that we can continue to stay on it for as long as possible in our ideal world. And, to that point, with our providers and ourselves being the decision makers, not insurance and no one else deciding on that, we need to be able to continue the drug that is working for us indefinitely, until perhaps it doesn't, or there's another reason to change. But there should be no other decision, no other decision maker in that in that conversation. It should be us and our physicians.

01:25:33

Moderator, RTI international

Thanks, **[Participant 2]**. **[Participant 3]**?

01:25:36

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

One of the things that I think every patient would say is hey, I'd like you to cure my disease. But what's being used now is talking about remission, and **[Participant 2]**, that was mentioned a little bit about not having certain aspects of the disease recur. So remission is really important. The problem is, you look at a clinical trial and you don't know across the six of us which three of us are going to go into remission and which ones aren't, unless we have a chance to try that therapy and see if we're the ones who are going to go into remission or have that 80%-90% response that we're looking for. And I think in terms of access, why when I turn 65 do I have to change my therapy and potentially change my whole quality of life just because I turned 65? And the amount of time and investment that I would have to go through if I can't stay on my current therapy and I have to switch to something else. We've all invested so much time and energy to get to a point of good well-being and quality of life, and then to be forced into that because we can't afford the drug because it's not covered just because we turn 65, is horrific to think about, that that is the turning point. And knowing that you may lose that response and never get it back, because you're having to cycle back through drugs for someone like me, that I've already proven that I've failed on multiple occasions. And that is concerning.

01:27:23

Moderator, RTI international

So access is very important. **[Participant 6]**.

01:27:26

Participant 6 (registered as a patient)

And to follow up on what **[Participant 3]** said that when I went on Medicare, I chose the Part D plan that covered Cimzia, and the next year they dropped it and there is no plan in my area that covers Cimzia. But fortunately, I fought for a non-formulary exception so that now I have to stay on that plan, even though last year, the new drug laws say, oh, you can't raise it more than 6%, you can't raise the premiums more than 6%. Mine went from $50 to $95. But there are little loopholes, oh well. I have to stay on that plan no matter what they charge me, because I have a non-formulary exception and that is insane. I think Medicare really, really sucks.

01:28:35

Moderator, RTI international

Right. Thank you all for that feedback so far. I have just a handful more questions here for you all. Let's talk about how well Cimzia and other treatments for these conditions meet patient needs. At the beginning of our discussion, I asked you all to reflect on the most important aspects of the conditions that Cimzia treats to have managed or treated. What was most important to be managed or treated? Aside from the aspects you've already shared, what other medical needs related to these conditions are important to you, or people you advocate for? **[Participant 1]**?

01:29:18

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

I just put this in the chat, but this is a perfect segue, as I talked about comorbidities earlier, but it's not just dual or triple diagnosis. I was referring to somebody having maybe Crohn's disease and something else, but the uncontrolled inflammation, these are associated with these diseases, well documented, that if not controlled, lead to comorbidities, like Alzheimer's, like cancer. We're talking about these very real situations that are often not talked about, and that all stems back to being on the right treatment for the right person at the right time is vital. To thinking about things, and I think that particularly with Alzheimer's and knowing that that's a risk, you're four times more likely to get Alzheimer's with our diseases, and CMS should certainly care about that for the population they serve. I do think that those are other things that need to be considered when we're thinking about the value of a treatment. And making sure that we're controlled, that we're on the drug that controls our diseases.

01:30:26

Moderator, RTI international

[Participant 2]?

01:30:28

Participant 2 (registered as a patient)

Exactly. I was going to agree with that point I had seen in the chat, but with IBD, with Crohn's disease, it can lead to colon cancer, especially if a patient has been living with a disease longer than eight to ten years. Untreated disease obviously leads directly to colorectal cancer. Not only, obviously, is the cost implication for cancer, but also surgery. For many of us with untreated disease, it can lead to a number of different types of surgeries. I've had fistulotomies prior to being on Cimzia, which has now changed the anatomy of my perianal area, unfortunately, because I was, like I said, I was undiagnosed, so I was untreated properly, and I went through surgery instead of treatment. And now that has affected me for the rest of my life. That said, just in general, Cimzia being used as a treatment for Crohn's disease, in my case, it prevented me from having a lot of other complications for a long period of time, but patients with IBD can have surgeries leading to resections when you're removing a part of the intestine, removing your entire large colon, which then leads to an ostomy. It can completely change our lives in such a way that the surgical nature is not just like a quick in-and-out surgery. You completely can change your life and your anatomy, lose literally parts of your colon, because of untreated disease or not being able to be on the medication.

01:31:58

Moderator, RTI international

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

01:32:02

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

Not sure if this fits with what you were asking, but in terms of helping manage the disease, we talked about mental health, we talked about quality of life, we talked about stiffness, joints, etc. Things like yoga, lifestyle management, meditation, other things that cost money for patients to go and take part in. Exercise programs, working on cardiovascular health, healthy eating. Those are all things that we know these inflammatory diseases, it's really important for patients to have access to that as well. And that's part of overall good management of these disease states, in addition to having access to the drugs. Drug negotiation, obviously, is number one. But being able to incorporate, being able to help manage and fit that into some of the plans and some of the access for people over 65, I think is really important to encourage because that, for many patients with inflammatory conditions, is also a game changer on top of taking new therapies.

01:33:14

Moderator, RTI international

Great. Thank you, **[Participant 3]**. So for the next couple of questions, I'd like for you to reflect on your experiences with treatments for these seven conditions. Focus on the treatments for these conditions. And treatments can be Cimzia, can be other medications, but it can be other things beyond pharmacological treatments. **[Participant 3]** was touching on that just a moment ago. First question for you all is, which important aspects or needs of these conditions are currently being addressed, or at least partially addressed, by existing treatment options? I'll talk in a moment about what's not being addressed, but first, what important aspects or needs of this condition are being addressed, or at least partially addressed, by existing treatment options? So I guess, maybe I'll reframe the question. I see some confused faces. What are the treatments now doing for you today? What needs are they meeting for you today? That they are helping you with. And I heard **[Participant 2]** say they're helping with quality of life, is one thing I heard about as an example. **[Participant 2]**.

01:34:35

Participant 2 (registered as a patient)

I'd say, yeah, quality of life is obviously, importantly, where I can live my life, but then I think in my case with Crohn's disease progression, these diseases can progress, so it has prevented that progression. And I'd say also prevention to a degree. I had fistulizing disease, I no longer have fistulas. It has prevented me from developing fistulas throughout all these years since the initial ones were healed. I think progression and prevention are the biggest ones for me, because that really is telling of what my future looks like with Crohn's disease.

01:35:18

Moderator, RTI international

Thanks, and **[Participant 5]**?

01:35:20

Participant 5 (registered as a patient)

I think that really makes a lot of sense, and it's the same for an arthritis condition, it's preventing my joints from becoming more damaged down the road, because once joint damage is irreversible once it's there, maybe that's going to help me avoid surgeries if I'm on the right treatment. I've certainly had been in situations where my treatment wasn't working, where I've had to wear double knee braces and double wrist braces and use the wheelchair at the zoo with my kids. But being on a working treatment allows me to, live the life that I want to live, be a person, and I think that's the key thing to me.

01:36:04

Moderator, RTI international

Again, how medications and treatments, and treatments can be beyond medications like physical therapy or so forth, how they are meeting patient needs today, at least fully or partially. I think we may have answered that fully I guess, to tell by [your] faces. So let me ask for the flip side, which is what important aspects of these conditions are not being addressed today by current treatment options? What's missing? What's been unmet? **[Participant 2]**?

01:36:45

Participant 2 (registered as a patient)

This was brought up at the beginning, was fatigue. A lot of us live with fatigue as part of our disease, or because of medication, and that is not a commonly used term, patient-reported outcome. It's not one of the things that's being measured, and it's one of the things that, again, limits our life to a degree, or we have to base our life based on the fatigue levels, and it's not a consideration. So I'd say that by far is the biggest one that's not addressed from a treatment perspective.

01:37:24

Moderator, RTI international

[Participant 6]?

01:37:26

Participant 6 (registered as a patient)

Lack of specialists in many areas of the country, and for where I live, which is a fairly large area, there are no longer rheumatologists at all within 50 miles of me, and they're becoming fewer and fewer and fewer. And then if you live in a rural area, the lack of access to doctors and specialists.

01:37:59

Moderator, RTI international

[Participant 3]?

01:38:02

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

I just want to say I love that answer, the lack of specialists, because I think that, and not every specialist is going to be your fit with every patient. I have fired specialists before. It's a very hard thing to do, but sometimes they don't always meet your needs, so choice is important. I didn't mention physical therapy, but you had. And the limits on physical therapy, how many times you can go, how many times you can access it. I don't think we as patients with joint disease really want to be in physical therapy, but when we need it, we really need it. And being limited to only once a week or twice"a week, the benefits of being there in person far outweigh what we can do at home alone by ourselves to improve our disease and so, many health plans have a lot of limitations on that. I have two more things. One is radiographs. X-rays, advanced technology for looking at joints, joint damage, etc. The limitations that are put on some of the access to those so that our doctors can't actually look at it that often, and they're just looking at radiographs when that means nothing sometimes, and it's better to have an ultrasound, or better to have an MRI [magnetic resonance imaging] on something, so that's really important when you have joint disease, spinal disease, other things. And then lastly, I mentioned it before. The fatigue and the PROs [patient-reported outcomes], and there are some good PROs that are being developed and being used for fatigue, but there's a lack of appreciation of the need to study fatigue by physician and the physician community. And I see a lack of industry members wanting to include it, and the only way they're going to have to include it is if someone in the government forces them to put it into their study and forces them to use a tool. And we know there's many that are out there, the PROMIS [Patient-Reported Outcomes Measurement Information System] tool works really well, etc. Even though it's recommended as a primary outcome measurement and a core outcome set by the psoriatic arthritis community, it's still not showing up in all the clinical trials and that's really disappointing to me, that we can go to all this work as advocates and highlight what these elements are, and it's not being taken seriously, and it's not being adopted the way it should be.

01:40:26

Moderator, RTI international

And by PRO, you mean patient reported outcomes? Let me make sure I understand the acronym you gave. Okay, just wanted to double check. **[Participant 5]**.

01:40:35

Participant 5 (registered as a patient)

Just to expand slightly on what **[Participant 3]** and **[Participant 6]** said, we talked a little bit about how yoga, or healthy eating, or access to exercise classes are very useful in managing and living a healthy life with these diseases. They're not always accessible to people, particularly if those people are having trouble just affording the treatment, or even just health care in general in the first place. The more money of your budget that gets eaten up by paying for your treatment, the less you have to invest in things like that. And so if more of those things would be covered, I think it would make a really big difference in people's lives. And, **[Participant 6]** also mentioned the problem with finding specialists. I would also add to that, that in addition to having trouble finding specialists, sometimes it's really difficult to get your specialists to talk to each other. For example, the sinus issue that I've been having, I'm seeing an immunologist, I have my rheumatologist, I have an ENT, they all I have a primary care doctor, they all kick me around, and it's not really clear whose responsibility dealing with this sinus infection issue is, and luckily, I've been able to get to a point where my team is working pretty well together and talking to each other, but that can be another really big burden on a patient when the specialists are not communicating with each other, and you're forced to be the go-between, and sometimes you'll get conflicting information from different specialists, and a patient is trying to figure out what to do with it themselves. So I think that's another aspect of that.

01:42:03

Moderator, RTI international

The coordination of care. Yeah, **[Participant 1]**?

01:42:07

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

I just want to add, this one is from an advocate organization perspective, but, health equity. We just can't get past this conversation without saying not everybody is at the table, whether it's here in this conversation, in clinical trials, a lot of people of color are never even offered Cimzia, or similar. They're often offered methotrexate, or some of the other the prednisone, things that we've just said were not good for all of us, and that's a real situation, and I think that what needs to really be looked at when we're talking about prescription drugs, affordability, access. We don't have the full picture unless we understand what it's doing systemically to all people. So I just wanted to throw that in there.

01:42:57

Moderator, RTI international

And then, **[Participant 6]**, then I have just one more question to ask. Go ahead, **[Participant 6]**.

01:43:02

Participant 6 (registered as a patient)

Absolutely, **[Participant 1]**, I completely agree. And plus, the hoops we have to jump through. For example, the prior authorizations, and my doctors don't keep up with it, and I send them reminders. It's time to apply for prior authorizations, and then they fail to do it, and then I don't get the meds. And I can be three months without access to my meds because of the prior authorizations, when they know I've been on this drug for 21 years, and still, I have to fight for it.

Follow-up Questions

01:43:50

Moderator, RTI international

Thank you. Earlier, **[Participant 1]** was talking about the small gauge needle, syringe, and then also **[Participant 3]** was talking about the infusion clinic, and that made me realize there was a question I wanted to ask about the administration of the drugs. For those of you who have experience with self-injection, can you provide your perspective on the different delivery devices, such as a pen, which is like a pre-filled cartridge, versus a syringe, and how that's maybe influenced your decisions about therapies that you use? Does everyone know what I mean by a pen? I just want to make sure I'm being clear. **[Participant 2]**.

01:44:38

Participant 2 (registered as a patient)

I'd say having tried Humira, which I know it's changed now, but it is painful, and if I were to have been asked at that point in time when I had tried it, and had also been on Cimzia, I would 100% not recommend Humira, just solely because of how painful it was. Aside from whether it worked or not, and it didn't for me, and I had adverse reactions, but that is an aspect that it affects your decision to do your treatment on time. There is an avoidance factor for some patients who ignore the timing of when they need to do their injections. I think that, at least for me, has been a big part of the ease of the administration of the syringe as compared to a pen. And then I didn't touch on infusions, but again it's limiting to be able to have to schedule at an infusion center during their hours, based on their availability, as compared to being able to inject my own syringe at my own leisure, at my own time. Even if I'm traveling, I can travel with the medication versus being tied to someone else's schedule.

01:45:44

Moderator, RTI international

And actually, just a follow-up question. Imagine that there were two drugs that worked exactly the same and worked exactly as well as the other. They were fully equivalent. Would you make a choice based on if one was an injectable pen versus a syringe? Would you prefer one over another?

01:46:02

Participant 2 (registered as a patient)

Yes, 100%. Like I said, with Humira if I was given both of those choices right now, I would 100% say the syringe that is less painful than the pen that is 100% painful.

01:46:13

Moderator, RTI international

Okay, thank you. **[Participant 5]**.

01:46:17

Participant 5 (registered as a patient)

I've tried basically all the administration techniques, and I was surprised when the syringe was less painful. There's a fear factor to get over, it felt like a really big deal to stab myself with a needle, and so the auto-injector is appealing at first, because that's easy, you just press a button, but the syringes were definitely less painful. Also, if I had the option, as someone who's about to spend 900 hours in the infusion center this month, because my Rituxan and my IVIG collide, I would love to be able to choose whether to have an infusion or an injection, but that isn't really always a choice that's offered to patients because sometimes doctors are making the recommendation of the next drug based on what has worked so far, what hasn't worked so far, and sometimes you get a choice, and sometimes it's like, the next one that I think you should try is an infusion, and there you are. So if there were more choice, that would be great, but I don't think patients always get that choice or know that they might have that choice.

01:47:20

Moderator, RTI international

[Participant 3]?

01:47:23

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

I agree with what's being said, and contrary to popular belief that an auto-injector is really great, I will choose a pre-filled syringe anytime that I have that option. So the question is why? Sometimes it's the force by which you have to push the device into your belly, your thigh, your arm, in order to be able to depress and inject, and that leaves marks, and that hurts. Sometimes it's just the speed at which it's being delivered. That it's going in so fast, you want to pull back, it's this automatic reaction. You have to force yourself to hold the auto-injector against your skin. Some of those are faster, some of those aren't. And sometimes it's because the drug really burns and hurts. I didn't do my homework, I should have. And I took, I think it was Taltz as an auto-injector, and it just about kicked my butt. I almost threw the auto-injector across the room. I was so surprised, and I've tried them all, and I had no idea, so but now I'm stuck with three more of those devices that I have to go through until I can call up the pharmacy and say, "Hey, the next time, I really want that syringe." And the syringes, they're usually a little more surprised, like, "Really?" And so they don't tend to have as much stock sometimes. But I know it's counter to what someone who isn't using these devices would feel, but in my experience, obviously, it seems like with many others. It's you can control the pain, and you can control the speed, and it becomes less painful when you have control yourself.

01:49:06

Moderator, RTI international

[Participant 3], one follow-up question. When you say control the speed, do you mean the speed of the needle entering the skin, or the actual injection of the medicine?

01:49:14

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

The injection of the medicine.

01:49:16

Moderator, RTI international

That's what I thought, I just wanted to double check. Okay, thank you. **[Participant 1]**.

01:49:21

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

I'll piggyback on some, and then add a couple. That moment when you have to stick the auto-injector in, and you it goes [buzzing sound] and you're waiting for it to end because it burns, and I experience that. You want to just pull it out, and then with Cosentyx, there's two. You have to do one in one leg, and then one in the other, so you do it twice. And so that that also can be problematic for a lot of people. I've already talked about how I thought Cimzia had by far the easiest, it didn't hurt. There is needle phobia, that's a real thing. But pain is a real thing. I think we hear too often as a patient organization is adherence to treatments. That's a big problem, is if it hurts to go in, they're not going to do it. I also just want to throw out there, too, when you're talking about juvenile patients, they're really, really not going to be adherent if they're not happy with the pain tolerance, getting even past the needle therapy, that's always an issue that we hear in the juvenile community. And lastly, I just want to throw out that while there are some pill forms, maybe not true therapeutic alternatives per se, to one I'm on right now, Rinvoq, for example, is a pill form. While some people will choose a drug based on that, and you do tend to see more teenagers going that direction preferred. You'll also hear from a lot of patients who have been on these treatments before say I don't want to go on a pill because, we talk about emotional and mental, they tie the injection or the infusion to being something that's treating it more aggressively. And it doesn't mean that it does or it doesn't. It doesn't mean the pill form isn't as effective as something else, but there is a mental, real component that several patients who have been on these treatments for a long time have said I don't trust the pills, because if I'm on an infusion, I know that's serious, so that's a real thing.

01:51:32

Moderator, RTI international

Thanks for that, **[Participant 1]**. I also just want to pick up on one thing that **[Participant 3]** was talking about, the infusion centers, and I want to pick up on that just for a moment, which is, how much did location of therapy, a clinic, or infusion clinic versus being able to do something at home factor into your willingness to try a therapy. **[Participant 2]**?

01:52:02

Participant 2 (registered as a patient)

At the time of my decision-making for Cimzia itself, actually, that was the biggest decision. My physician and I decided because I was traveling a significant amount of time for work, and so we knew that in order for me to adhere to the schedule of an infusion it would just be very unlikely. So our decision-making was exclusively because of the ability to be able to do it at home.

01:52:25

Moderator, RTI international

Okay. **[Participant 1]**?

01:52:32

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

I'm speaking on behalf of others in particular, so a couple different factors to consider with the infusion. Many people have, in addition, can they travel? So now I don't even know if you have the ability to get to there, but these are not quick. You're scheduling half a day. Most people have to take off work, and I can tell you, some people get exceptional fatigue and feeling really worn down afterwards. Some don't. Some people feel energized, but I know, one of our staff members who has lupus, she has to take off a day and a half every single month, because she's got to take off half a day to get the infusion, and then she has to take off the next day to recover from the infusion. So that's a real thing as well.

01:53:22

Moderator, RTI international

[Participant 6]?

01:53:24

Participant 6 (registered as a patient)

I wanted to mention when I started on Cimzia, I was lucky that I was in the clinical trials because I would not have been able to inject it myself, because my hands couldn't do it. In the clinical trials, I went every two weeks and the nurse injected me. And then, when the trials asked for volunteers of the patients to learn how to self-inject, I was the first one to volunteer because I knew that eventually I would be able to take it home and inject at home.

01:54:07

Moderator, RTI international

[Participant 6], what's easiest for you to do at home? A cartridge or a syringe? What do you prefer?

01:54:14

Participant 6 (registered as a patient)

I've never had experience with anything other than Cimzia. And so the syringe is what I do.

01:54:23

Moderator, RTI international

We're almost done here, but before we part ways I wanted to give you all an opportunity to summarize your thoughts on the importance of Cimzia for patients, or raise any other topics that you feel weren't covered adequately today during our discussion. Do you all have any thoughts about Cimzia, the conditions treated by Cimzia, or other medications that treat the same conditions that you feel are important to share with CMS? **[Participant 2]**.

01:54:53

Participant 2 (registered as a patient)

I think we touched on it a little bit, but it wasn't, one of the actual topics. I think somebody used it as part of their response, but the prior authorization consideration really needs to extend to medications. I know that there's prior authorizations being considered for procedures, which, again, many of us have to undergo procedures, but our medications shouldn't have to undergo a prior authorization process if we've been on this drug for X number of years. And I think that's something that, again, we've talked about in different ways, but if we are on a medication that is working, that is effective, that our providers and ourselves have decided to be on. There should be no interruption to that, to our care with the medication, because it can affect long-term, our disease state, surgery, complications, flares, etc.

01:55:41

Moderator, RTI international

[Participant 1]?

01:55:43

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

I just wanted to focus on the value of what makes this different than others. And with keeping in mind, again, it's all individualized, but a couple of the key points, I think, that came out, not just from me, but others today, are it's indicated for pregnancy, that's huge, so that isn't comparable to any other drug that makes it exceptionally valuable. It treats diseases like juvenile idiopathic arthritis, the polyarticular. So that is important. We can't get past the method of application. All of us have talked about how that impacts adherence strongly. If you can't, if it's too painful to take, you're going to stretch or skip doses. It just is. And then what happens? You're going to have worse inflammation, worse outcomes, potential comorbidities, etc. And the fact that it's not so novel that it's indicated for many treatments, because there's several of them there, but I want CMS to not ignore what makes Cimzia valuable as far as subgroups, and that that can't compare with anyone else. So that would be what I want the takeaway to be.

01:56:52

Moderator, RTI international

Thanks, **[Participant 1]**. **[Participant 5]**?

01:56:56

Participant 5 (registered as a patient)

I agree with that, obviously. Cimzia was a really important aspect for my pregnancy, but I think also that the pregnancy idea is just an example of how patients really deserve the ability to work with their physician and choose the treatment that the doctor and patient think is right for them, that best meets their needs, medically, for whatever reason that is. In my case, it was pregnancy. In someone else's case, it might be different. And I guess the last thing I would want to say is that while I love the idea of limiting the cost of these drugs, everyone thinks they cost too much, we all want them to cost less. Cost control sounds good, but as I've seen here in **[Redacted]** with the PDAB [Prescription Drug Affordability Board], we're concerned that some of these might have the unintended consequence of harming or limiting patient access to these drugs. I just want to reemphasize how important it is, especially as we talked about, each patient is unique, and each goal is unique, and the way you're going to do on the drug, the drawbacks and the positives are unique. That means that we all need to have access to as many drugs as possible and be able to take the ones that our physicians recommend.

01:58:08

Moderator, RTI international

Thanks, **[Participant 5]**. **[Participant 3]**.

01:58:12

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

I'm going to echo that 150%. When I heard that this product was up for review by CMS, I raised my hand because I wanted CMS to understand that just because they have other TNF inhibitors on their formulary and they've negotiated with other TNF inhibitors, that there is still value in adding additional TNF inhibitors to the formulary, and additional price negotiation, because I'm an authentic lived experience of someone who this was their fourth TNF inhibitor, and I had tremendous benefit from it. And I never would have thought that was the case, and so offering patients choices, allowing physicians and patients to make those choices together, if they choose to stay within the same class. That should be allowed, because one never knows if you're going to be the responder in that trial, or if you're going to be the nonresponder in that trial. And if the company's willing to come to the table and negotiate, then the formulary should be opened, or they should be made to negotiate, and patients should have those options. And I was really fearful that some of the discussion was going to include, why do I need to have four on my formulary? And I'm here to say, you need to have them all.

01:59:28

Moderator, RTI international

Thank you, **[Participant 3]**. And **[Participant 6]**, you want to finish this off?

01:59:32

Participant 6 (registered as a patient)

Yes, another for me, another really important value of Cimzia is that it also offers a Part B formulary that if I can't survive the Hunger Games to get foundation help with Cimzia, I can go to my doctor's office and get an injection under Part B, which is covered in both places, Part D and Part B, and that is really important just to know in the back of my head, I have a place I can go to if I really need it.

Closing Remarks

02:00:15

Moderator, RTI international

Thank you, **[Participant 6]**. So again, thank you all for participating in today's event. I really appreciate you all sharing your experiences and hearing what you all had to offer, so thank you again so much for your time. Your experience and input were very valuable and will help inform CMS' negotiations for Medicare pricing for Cimzia. As I mentioned, CMS staff were listening in to you during today's roundtable and will be able to bring your perspective back to their teams. **[CMS Staff]**, I just want to see if you had anything you wanted to say before we adjourn.

02:00:49

CMS Staff

Yes, thank you so much for sharing your experiences and your knowledge with us. You've given us a lot to think about and to consider, and we're just really grateful for everybody's participation today, so thank you.

02:01:08

Moderator, RTI international

Wonderful. Thank you, **[CMS Staff]**. And if you have any questions following today's session, you can submit them to the mailbox, which is IRARebateAndNegotiation@cms.hhs.gov, that should have been in the materials that you received earlier so you don't need to memorize that, with the subject line Public Engagement Events. Thank you again for your time today and take care everyone.

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

For a list of the drugs selected for the current 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-2028.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 patient who has experience with the selected drug, the conditions treated by the selected drug, or other treatment(s) or drug(s) similar to the selected drug for those conditions; 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 health care 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
Yes	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, the conditions treated by the selected drug, or other treatment(s) or drug(s) similar to the selected drug for those conditions

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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Participant 3: Registered as a patient who has experience with the selected drug, or other treatment(s) or drug(s) similar to the selected drug for those conditions; representative of a patient advocacy organization

Declared Conflicts of Interest	
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Yes	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 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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Participant 5: Registered as a patient who has experience with the selected drug, the conditions treated by the selected drug, or other treatment(s) or drug(s) similar to the selected drug for those conditions

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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Participant 6: Registered as a patient who has experience with the selected drug, the conditions treated by the selected drug, or other treatment(s) or drug(s) similar to the selected drug for those conditions

Declared Conflicts of Interest	
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