

This transcript was lightly edited for readability.

Introductory Remarks

Moderator, RTI International

Thanks for coming today. I'm **[Moderator]**, and I'm from RTI International, and I also want to introduce my colleague, **[Secondary Moderator]**, who you may also hear from during today's discussion. The Centers for Medicare & Medicaid Services, which we will refer to throughout today's event using the acronym of CMS, is convening this patient-focused roundtable event, and others, as part of the Medicare Drug Price Negotiation Program.

The information shared during these roundtable events 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 that CMS may consider in negotiating Medicare pricing with the manufacturers of selected drugs.

The purpose of today's event is to hear from you all, a group that may include patients, caregivers, and patient advocates, about your experiences with the conditions and diseases treated by Xeljanz and Xeljanz XR, including rheumatoid arthritis [RA], psoriatic arthritis [PsA], polyarticular juvenile idiopathic arthritis, ankylosing spondylitis, and ulcerative colitis. We also want to hear about experiences with Xeljanz itself and with 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 Negotiation Program that are not directly focused on the patient experience, we would ask that you send that input to the mailbox at IRARebateAndNegotiation@cms.hhs.gov instead of sharing it in today's discussion. And we'll be providing that email address later on as well.

I do want to clarify that when I say Xeljanz during today's discussion, I'm referring to both Xeljanz and Xeljanz XR. You may refer to this drug however you prefer. Also, I want to give you a heads up that I'll be using some other acronyms today, in addition to CMS. Specifically, I plan to refer to polyarticular juvenile idiopathic arthritis as poly JIA, since this is a bit of a tongue twister, and ankylosing spondylitis as AS. Your experience and perspectives are very important to us, and we genuinely appreciate your time today. Along those lines, let's watch a brief welcome video from CMS leadership, so that you can hear from them about how much they value your time and input.

CMS Remarks

00:03:08

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.

00:04:58

Moderator, RTI International

Great. I also want to make you aware that staff from CMS will be sitting in on this 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. **[CMS Staff]**?

00:05:12

CMS Staff

Thanks, **[Moderator]**. Welcome, everyone. My name is **[CMS Staff]**, and I'm from the CMS Drug Price Negotiation team. There are other CMS staff members on the call today, and we work on policy of getting input from the public to negotiate Medicare drug pricing. I want to thank you all for participating today. We're going to be in this session, but we're going to be off-camera behind the scenes, so that we can focus on the discussion and take our notes. Thank you.

Housekeeping

00:05:35

Moderator, RTI International

Awesome. Thanks, **[CMS Staff]**. Before we begin, I want to review some housekeeping items and ground rules so that everyone knows what to expect. First off, technical assistance. If you get disconnected, please attempt to rejoin. If you cannot connect, please reach out to IRADAPStechsupport@telligen.com.

In terms of privacy, this discussion is not open to the press or public. 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, the name of a medical facility where you received care, or personally identifying information, such as your employer's name, the city you live in, or names of schools you attended, during the discussion today. Following the event, CMS will prepare transcripts that have participant names and identifying information removed, and those will be 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.

Participation. First, we hope that you will contribute your perspectives throughout the session today. However, if questions arise that you do not want to answer, that's totally okay. In terms of background, we ask that you please minimize any background noise by silencing your cell phone and any other devices in your area if you haven't already done so. Also, please mute yourself when you're not speaking.

Video. Thank you very much in advance for keeping your video on throughout the discussion, I really appreciate it.

In terms of timing, we have reserved up to two hours for this session. However, it's possible that we may not need the full two hours to discuss all of the planned topics. If that happens, we can let everybody go a bit early. I do have a discussion guide in front of me, and that's to help me stay on track and make sure that I cover all of the topics. We do have a lot of topics to cover, so I may need to redirect our conversation, or cut a conversation short at times, to make sure that we're able to cover everything and that everybody has ample opportunities to share their perspective.

In terms of breaks, if you need to step away briefly during our discussion, that's okay. Turn off your camera and your microphone and rejoin as soon as you're able. You don't need to let me know that you're going to be stepping away from your computer. Please return to the discussion when you're able to. Please speak one at a time. I may occasionally interrupt you if more than one person is talking at the same time, just to make sure that everybody can be heard, and that everyone's comments are accurately recorded. Please use the raise hand feature in Zoom, if you'd like to indicate when you would like to speak. This will help me know when someone would like to add to the conversation. Take a moment to find this feature if you haven't already and see how it works.

And chat. While I'm hoping that folks will focus on our oral discussion, you can add comments into the chat if you don't get a chance to share them orally. This could be the case, for instance, if we don't get to hear from you before I need to move to the next question, or if you think of something else to add later on in the conversation. Please be sure to note what question or topic you're

responding to in chat comments, so that we know. Unless you have any questions, we'll go ahead and get started.

Discussion

00:09:23

Moderator, RTI International

I'd like to start off today by asking each of you to introduce yourself briefly and take a moment to tell me your first name; whether you are sharing experience as a patient, caregiver, or from the perspective of a patient advocate; and the conditions or condition that Xeljanz treats that you have experience with. I'll start with you, **[Participant 1]**.

00:09:54

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

Hi, everybody. My name is **[Participant 1]**. I am representing a patient advocacy organization in the arthritis space, so any of the autoimmune arthritis conditions for which Xeljanz has indicated are ones that I can speak to.

00:10:09

Moderator, RTI International

Great, thank you, **[Participant 1]**. And **[Participant 2]**?

00:10:14

Participant 2 (registered as a patient)

Good morning, my name is **[Participant 2]** and I am a patient. I have rheumatoid arthritis, and I've had it since 2005.

00:10:34

Moderator, RTI International

Great. All right, thank you so much for introducing yourselves and letting me know what experience you'll be drawing from today. And I do want to give you a heads up, since you all do have experience with multiple different conditions related to Xeljanz, I do know that experiences may differ by condition. When you're speaking, this especially goes for you, **[Participant 1]**, since I know **[Participant 2]** is speaking to RA, if you could let me know which condition you're focusing on at a given time, that would be really helpful. For example, you might say, when considering treatment options for psoriatic arthritis, I hear from patients that they tend to think about X, Y, and Z. Let's go ahead and jump in.

I want to start by talking about patients' experiences with the conditions treated by Xeljanz. Thinking about the different ways that rheumatoid arthritis, psoriatic arthritis, poly JIA, and AS, because I think those are all the ones that we have represented today, affect patients' lives, what would you say are the most important aspects of the conditions to have managed or treated? These could be things that affect patients in the short term or the longer term. **[Participant 2]**?

00:12:04

Participant 2 (registered as a patient)

For me, it's pain and fatigue. Those are my two hardest aspects of having rheumatoid arthritis. Managing those two make a difference on whether I can get out of the bed or not and brush my teeth, take a shower, that type of thing. Just daily ADLs [activities of daily living].

00:12:28

Moderator, RTI International

Could you talk a little bit more about those daily ADLs and the impacts you face?

00:12:33

Participant 2 (registered as a patient)

Sure. I've had times where I've had a flare, and I have not been able to do much for myself, like I said, the brushing of my teeth, washing my face, taking a shower, because it was too painful in my hands to grip and hold a toothbrush or soap or something like that. Sometimes the pain in my feet will be a lot to even bear any kind of weight on them, so that makes it difficult to make it to the restroom, to do regular stuff, everyday activities. So that's my hardest part, when I have those days.

00:13:29

Moderator, RTI International

Thanks, [Participant 2]. And would you mind talking a little bit more about the fatigue?

00:13:33

Participant 2 (registered as a patient)

Oh, yes. The fatigue is something that comes in waves. Most days, I'm good, but then there are times where, no matter how much I've slept, I feel like I can't get going. It feels like when you have the flu, and you can't stir and muster up enough energy for much.

00:14:05

Moderator, RTI International

And would you mind talking about, if they have, how these symptoms have changed over time, how your experience has changed over time?

00:14:15

Participant 2 (registered as a patient)

My flares are less than in the beginning because I've had to do some lifestyle modification, like asking for help is one of the major things. Also, getting the right dosage and that sort of thing for my body to calm down, for the RA to calm down some.

00:14:47

Moderator, RTI International

Thanks, **[Participant 2]**. What about you, **[Participant 1]**? Would you mind talking about the different aspects of the conditions that you can speak to that are important to have managed or treated?

00:14:58

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

Sure, and for those who were on the one the other day that I was also on, some of this is going to be repetitive, but I will have some more specific Xeljanz data as well. First and foremost, we're very connected to our patient population. We do surveys and focus groups and panels quite a bit to understand the patient experience and make sure that everything that we do is rooted in that. I had mentioned the other day that we do a survey every year where we benchmark some questions, asking "What are your top arthritis-related challenges?" which helps us to get at what you're asking. And this is disease-agnostic, so I can't necessarily tease out whether it's psoriatic arthritis versus RA versus osteoarthritis, even patients seeing these things, but pain comes up as number one every time, every year, since we've been doing this survey, since 2017. And I think that's corroborated across other surveys that we've done throughout the organization. And then fatigue. It's very familiar points. And then mobility issues and managing multiple chronic conditions round out the top four.

From anecdotes that I've heard over the years, in the short term, it's, "I want to get my life back." I hear that sentence so often that sometimes I wonder if it's a coordinated response across people who don't even know each other. But, I want to get my life back. Oftentimes people are very active, and then all of a sudden they get this diagnosis, and while they're going on their treatment journey to try to find one that's going to work for them, they feel like they're in a really dark place. So those are some of the words and phrases that we often hear. And then I think once you get onto a treatment that does work, and you have some sense of control back in your life, especially if you're diagnosed young, we often hear patients talk about, what are the long-term impacts of treatment? It's a chronic disease that I'm going to have, even if I'm in medicated remission. It's not a cure. I still have this disease for the rest of my life. What does it mean if I'm on a, say, biologic therapy for 40 or 50 years? What does that do long-term to my body? How does it interact with certain biological changes I might experience? If you're a woman of reproductive age, for example, and you want to start a family, or you're going through menopause and you're having hormonal changes, are there going to be impacts there? Those are some of the questions that we hear a lot from patients in terms of short- and long-term goals.

00:17:44

Moderator, RTI International

Thank you, **[Participant 1]**. And I believe you said that those findings apply across the spectrum of those different conditions. Are there any specific things you hear tied to rheumatoid arthritis versus psoriatic arthritis versus poly JIA or AS that you want to share?

00:18:04

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

In the autoimmune family, we do have specific anecdotes and different things and can slice and dice the data by disease area. However, I think that some of those core issues around fatigue, pain management in particular, apply pretty much across the board. I hear those things pretty universally, regardless of which autoimmune disease it is. The difference would be the pathway in which somebody got diagnosed. Ankylosing spondylitis, for example, often presents first as back pain, and delays in diagnosis can happen depending on your pathway in. Rheumatoid arthritis can be easier to diagnose, not always. Juvenile arthritis can be really tricky as well. Some people are lucky, and it can get spotted, and somebody can get referred quickly, but oftentimes that diagnostic journey can be quite lengthy if it's something that's not common, not easily spotted by, say, a primary care physician or a pediatrician. And then, of course, that changes your whole trajectory in terms of treatment, in terms of joint or other systemic damage done, and that kind of thing. So that would be where a lot of the differences happen.

00:19:18

Moderator, RTI International

Thank you, **[Participant 1]**. I appreciate you teasing that apart. I hear you. It sounds like some of the core experiences are similar across them, but in terms of that diagnostic and treatment pathway at the beginning, they can certainly look different. And as a heads up, I probably will be asking you, throughout our discussion today, to tease those different conditions apart when you're able to, but I understand that there's certainly a lot of similarities in both the experiences with the conditions, as well as with the different medications that are used for them. Thank you all for sharing those thoughts.

Now I want to turn our attention to patients' experiences with medications for the different conditions treated by Xeljanz. What medications, if any, have you or the patients that you advocate for taken, whether currently or in the past, for RA, psoriatic arthritis, poly JIA, and AS? I'm going to ask that you take a moment to enter your responses in the chat. **[Participant 1]**, for you, I realize that may be quite a lot of medications across the people you speak with, so if there are certain ones that you hear about much more frequently, or that you feel like you can speak to in more detail, maybe those would be the best ones to focus on. And if it is easier, having heard about some of the experiences you've had, **[Participant 2]**, if it is easier to verbalize them, I also understand that, too. Okay, **[Participant 2]**, Enbrel, Orencia, Humira, methotrexate, Plaquenil. It's quite a list. You have a lot of experiences with medications. We'll definitely be diving into some of those. And then, **[Participant 1]**, you have patient experiences to draw from with respect to a number of different medications as well. Thank you all for doing that. Then I can reference that throughout our discussion. I appreciate it. Thank you for sharing those medication names.

For the next few questions, we want to hear about any experiences that you or the patients that you advocate for have had with Xeljanz or other medications used for conditions treated by Xeljanz. Any of these different medications are in the realm that I'd be interested in hearing about. Please make sure that you specify which medication you're talking about at a given time as you're sharing your thoughts. Okay, so what benefits have you or the patients you advocate for experienced with medications used for these different conditions treated by Xeljanz? As a reminder, it would be great if you could tell me which medication you're discussing at a given time.

00:23:32

Participant 2 (registered as a patient)

With me, I know I forgot a couple of drugs in there, but I've had nine overall, and I've gone into, like **[Participant 1]** said, medical remission with all of them. They've worked until they stopped. Right now, for me, my drug that worked well was Xeljanz, but I had to stop because I had a blood clot, so now I'm up to Rituxan infusions to manage my RA.

00:24:17

Moderator, RTI International

So the Xeljanz initially worked well for you.

00:24:22

Participant 2 (registered as a patient)

Yes. And I liked [it], because it was in pill form, everything else pretty much was an injection, except for the Plaquenil. I loved having just a daily pill, but you have to do what you have to do.

00:24:40

Moderator, RTI International

When you say that Xeljanz worked, could you tell me a little bit more about what that means to you? For a medication to work.

00:24:47

Participant 2 (registered as a patient)

Yes, sure. For a medication to work, less pain and joint stiffness. Fatigue is something that is part of the disease, so I don't really think that helped with fatigue because it's part of the disease. But for me, mobility and joint pain lessened. And I'm able to, like I said, drive and cook, stand to cook, wash a dish, those sort of things, so that makes a difference.

00:25:27

Moderator, RTI International

It sounds like it not only helped with your pain and mobility but also increased your ability to do certain things on a daily basis.

00:25:40

Participant 2 (registered as a patient)

Exactly, yep. And one other thing I wanted to harp on that **[Participant 1]** said is the mental aspect of having the diseases because I think so many people forget that it does come with a sense of grief of what you used to be able to do versus what you can do, so it takes some modification with how you see your progress. Everybody has a different measure of what progress is to them. The drugs make a difference with, like I said, ADLs, all those things, but I can't say, "I used to be a marathon runner, and now I can..." The everyday experiences for me, were good for maintaining a quality of life to be able to be as independent as possible.

00:26:33

Moderator, RTI International

Thanks, [Participant 2], for sharing that. And can I ask, since you do have experience with multiple medications, how does that mental health aspect and the way it impacts quality of life differ across the medications, if at all?

00:26:50

Participant 2 (registered as a patient)

For me, the thing that was hard, like I said, was the needles versus taking a pill, because I have an extreme needle phobia, which is hilarious that I need them now to survive. The Xeljanz was great because I could just swallow a pill, and that felt so much better than doing self-injections, and that made a difference with how I felt. As far as mentally, I had to prepare myself to be able to inject myself. In the beginning, I couldn't, but then when I got to a point that I could, it's like, "Okay, I can do this." I got brave. And for the taking of the Xeljanz, it was, like I said, a pill daily, so that was good. And the other thing, for me, Xeljanz didn't deplete my immune system as bad as some of my [medications]. Rituxan, for example, is really tough on the immune system.

00:27:58

Moderator, RTI International

Thank you for sharing all of that. In addition to the mental health aspects that you had talked about earlier, the grief of not necessarily being able to do things that you used to do, it sounds like there's also the mental health angle of this fear of needles and having to deal with that all the time. Thank you for sharing that. Can you tell me a little bit more about your switch to Rituxan? What prompted that switch? You mentioned that the Xeljanz wasn't working anymore?

00:28:26

Participant 2 (registered as a patient)

It was working. I had a hysterectomy in 2019, and after that surgery, I had a pulmonary embolism. So, I had to stop Xeljanz and figure out another thing because of that clotting.

00:28:53

Moderator, RTI International

Thank you for sharing that. And I'm sorry to hear it. Any other big benefits of these medications? You've already covered a lot. It sounds like the way that they're taken is important to you, their impacts on your quality of life, and your mental health, and those symptoms that you mentioned earlier. Any other big benefits?

00:29:19

Participant 2 (registered as a patient)

That's all I can think of at the moment.

00:29:24

Moderator, RTI International

Okay, and I forgot, you had also mentioned not depleting your immune system.

00:29:30

Participant 2 (registered as a patient)

Yeah, I did not have as many infections. [laughs]

00:29:35

Moderator, RTI International

Less infections. Okay, thank you for sharing that. **[Participant 1]**, I'm going to turn to you. Big benefits that the patients you advocate for experience from medications, including Xeljanz and others, for these conditions.

00:29:50

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

Yeah, I think all the things that **[Participant 2]** said, for sure. And a couple things I want to return to, piggybacking off of what she said around the mental health component, in particular, I feel like there are a few different things—and this might be drug-specific because it impacts patient choice—being able to have an oral administration of a drug can be a big deal to folks, and particularly for children. For our JA [juvenile arthritis] population, I think needles can be really traumatic. Formulations, like if a medication's citrate-free or not. If it's not, that can be really traumatic to patients. And then, it's funny, my organization does a podcast, and our episode yesterday was on guilt and grief. And there were some patients on talking about grief for why you might never quite be the same, or you might always have to have some sort of management of this disease, and then guilt for having to consistently lean on caregivers for support, and that kind of thing. And those are things that I think being controlled on medication, the benefits are huge, for sure. It's those quality-of-life components, ability to be a productive member of the workforce, things like that. We have a good amount of data on what happens physically and mentally when your arthritis is not well controlled, which unfortunately is a reality for many people. And the flip side of that would be the benefits. If a treatment is working for you, it allows you to live a full life, and certainly the goal, I think, is medicated remission, which is not achievable by everyone, but I think that's the overarching goal and continuing to be an emphasis across the patient community and the clinical and scientific community as well, at this point.

00:31:51

Moderator, RTI International

Thanks, **[Participant 1]**. I heard a lot of different things in there in terms of quality of life, and the way that being on the right treatment can affect those symptoms which affect quality of life. And you mentioned how the administration issue is different across the drugs. From your experience, are there other benefits that differ across the different medications?

00:32:18

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

Yeah, I think it depends on personal preference and treatment, your clinical profile. Your environmental factors may dictate whether, for example, an infused drug may be appropriate for you. Do you have either a provider, office, or infusion clinic close by that you can access easily? Some people prefer infusions because it's completely clinician-controlled, and people feel maybe a sense of comfort around having that monitoring. It may also be that that particular drug or

molecule works better for you somehow. And self-administered, similarly, there could be reasons. If you're needle-phobic, for example, that is not a preference for you, and unfortunately, there are not many [oral options], I think Xeljanz might be the only oral-administered disease modifier for arthritis. Don't quote me on that, but I feel like that may be accurate. And so your options are fairly limited there, so that could be part of it. We already talked about whether a formulation is citrate-free or not. There are some that have lower or higher risk for infection, so if you're managing multiple chronic conditions, or you are immunosuppressed for other reasons, all of those variables factor into why you might try one treatment over another.

We've done some survey work here, and I think there's some external literature, too, that backs this up, that it's not terribly common for you to respond to the first medication that you try. There are not really effective biomarkers yet in arthritis. I think there's one at the moment that will tell you with a pretty decent degree of accuracy whether a TNF [tumor necrosis factor] inhibitor will work for you or not, but that's pretty much it, and so it's really still an art form. Xeljanz is not typically prescribed as a first-line therapy, and we certainly see that. We did a data poll for all of the major biologics a few years ago, and Xeljanz was only taken as a first medication 4% of the time, which is the lowest percent, next to Actemra, of all of the medications that we looked at. For most people, it was either second, third, or the biggest chunk was actually fourth. For 47% of people who had taken Xeljanz, it was the fourth medication that they tried. And in terms of, like, having to change treatment early in the course of their disease, Xeljanz, 93%, and this is for people with RA I should specify, had to change early on in the course of treatment within one to two years. They had to switch off of Xeljanz, and only about 7% were on it for three to four-plus years.

00:35:21

Moderator, RTI International

Can I follow up on that really quick, **[Participant 1]**? Did you all assess the major reasons that people switched off of Xeljanz?

00:35:29

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

Yeah, we did ask. Most often, it was said that the drug didn't work as well, so for Xeljanz specifically, 38% of respondents said the drug didn't work; 26% said they had a bad reaction or side effects, 7% had insurance requirements or some insurance-related reason, and then there were 30% who said other, and I'm not totally sure what the other is, I'm sure we have those data points somewhere lying around.

00:36:00

Moderator, RTI International

Thank you for sharing those data points. That's helpful information. And I wanted to zoom in a little bit more on safety and tolerability. I know we've talked about that a little bit. **[Participant 2]**, I know you mentioned some other conditions that you've had come into play, and how that impacted what you can and can't take, but would you all mind talking about how different medications differ in terms of safety and how easy they are to tolerate, side effect-wise, et cetera?

00:36:40

Participant 2 (registered as a patient)

For me, the most that I've gotten from was Actemra. When she mentioned it, I was like, "I knew I was forgetting one." For me, the tolerance more or less has been my stomach, gastrointestinal things for all of them, except for one. Plaquenil gave me skin issues and rashes, and that one I can no longer tolerate because of that. But as far as everything else, it's gastro for the most part for me, and maybe a headache a time or two from infusions, but nothing major. I guess the blood clot. But nothing major outside of that for me for tolerance.

00:37:53

Moderator, RTI International

Thanks, **[Participant 2]**. I wanted to make sure that we covered that, and we'll talk more about drawbacks in a minute, but I wanted to zoom in a little bit more on that safety and tolerability aspect. Anything to add, **[Participant 1]**, in terms of the benefits of different medications on the safety and tolerability front?

00:38:14

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

Yeah, in some of the data that we've looked at in the past, side effects come up quite a bit, or "I don't like the way it makes me feel" for reasons or difficulty in taking medication. We had asked a question in a survey around what leads to difficulties in taking medications as prescribed, and next to insurance challenges, side effects was the next answer choice. When a patient is thinking about a drug to take, especially if they're not biologic naive and they've been through the rigmarole already, efficacy and then side effects is a huge question that people want to know about.

00:39:03

Moderator, RTI International

Thanks, **[Participant 1]**. It does sound like how easy it is to tolerate is indeed important to folks when they're thinking about the benefits of these different medications. Let's move on and talk in more depth on drawbacks and challenges that you or the patients you advocate for, **[Participant 1]**, have experienced with medications used for the conditions treated by Xeljanz. And as a reminder, to the extent that you can, it's really helpful if you can let me know what medications you're discussing at a given time. What are the key drawbacks or challenges that patients experience with these medications?

00:39:57

Participant 2 (registered as a patient)

Drawback for me, a few different things. In the beginning, I did not have insurance when I was first diagnosed, so I could not afford anything but prednisone. Cost would be huge, and thankfully, I have had insurance to cover for the most part of my health journey, but the insurance company also has dictated what I can and cannot take sometimes through my health journey. That's one of the things that's frustrating because if you do find something that works for a time, and then they say, "We're no longer going to cover that," that's hard. That's one of the huge drawbacks for me, has been cost and accessibility. The health insurance, medical coverage insurance, has told me what I can and cannot do.

00:41:10

Moderator, RTI International

Thanks, [Participant 2]. A huge drawback associated with cost and whether you can even access a given medication. What about other big drawbacks that we haven't already talked about to the different medications you have experience with?

00:41:31

Participant 2 (registered as a patient)

I did not like having one work, and then on year three, it's like, this isn't working, and you have to switch to something else, because then you have a whole new sense of side effects for something else. And I know many people have said to me, "You don't want that one because it causes cancer." And then you have to weigh, do I have a quality of life and be able to get out of the bed, or have risk for cancer? I try not to think about all the side effects that come up because I would drive myself nuts if I did, so I focus on the quality of life and what's working for that quality of life.

00:42:30

Moderator, RTI International

In terms of thinking about what's working and that efficacy aspect, I know you've mentioned now a couple of times, things don't necessarily work for a long time. Would you mind elaborating a little bit on your experiences across the different medications in terms of how long they worked?

00:42:52

Participant 2 (registered as a patient)

Sure, I wish I could remember exactly. Some were longer. Enbrel worked for me for, like, five years, and then all of a sudden, it didn't work anymore. Orencia never did catch on for me. Humira was for a short period of time. Kevzara never caught on for me. Methotrexate never did much for me. My longest stint was Xeljanz and Rituxan.

00:43:29

Moderator, RTI International

Thanks for sharing that. There was quite a range, and some never worked.

00:43:33

Participant 2 (registered as a patient)

Yeah, exactly.

00:43:38

Moderator, RTI International

All right, thanks for that. [Participant 1], any major drawbacks or challenges that you wanted to add that your patients that you advocate for have experienced?

00:43:49

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

Sure, to piggyback on that last point, in a survey that we did with specifically RA patients, we had found, on average, between two and three medications that a patient had to try before finding one that worked for them. And then the need to change early in treatment as you're going through that journey, I already mentioned for Xeljanz, it was 93%, it worked for maybe one to two years, that kind of thing, but I'm looking across Xeljanz, Actemra, Orencia, Rituxan, Remicade, Simponi, Cimzia, Enbrel, and Humira. Of those, I don't see any on my list where less than 50% didn't have to change after one to two years. It's a pretty high churn. And many within that three- to four-year mark, in some cases, five years plus, and if you're lucky, you can go a decade plus and still be stable on your medication. And there's no rhyme or reason for why a medication might stop working, it's the tricky nature of autoimmune disease. I think that's a really important component to overall thinking about the long-term treatment journey.

For psoriatic arthritis, we actually did a survey last year trying to understand the relationship between psoriasis and psoriatic arthritis, and 35% of our psoriatic arthritis patients told us they used five or more medications for the treatment of their PsA, and then for those who had to make a switch, more than half had indicated that the reason was, it was no longer effective. I think that's pretty common across all of the autoimmune areas. The other thing is that I've heard a number of patients say that they feel like they collect autoimmune diseases. They don't always live in isolation, and I'm thinking about our pediatric population and some of the interviews we've done with those patients. Sometimes, you start with juvenile arthritis, and then you get uveitis, and then maybe psoriatic arthritis comes along as well, and that changes the efficacy, sometimes, of a treatment, or having to add on different treatments and things like that, so that's one bucket.

Insurance issues and cost is huge. That contributes both to issues around being able to be compliant with medication, but also delays in access, which, of course, these diseases can be degenerative. You can't reverse the damage done in many cases. And then there's a mental health anxiety component that is a really huge correlation with having to deal with the administrative rigmarole that patients often go through. A couple of other areas that we haven't touched on yet are logistical and environmental factors that can be drawbacks that you wouldn't necessarily think about all the time. We've heard people say, people who have mail order delivery of their medications, "it was delivered at the wrong address," or "it was delivered when I wasn't home, it was delivered at the wrong time, and now it's been sitting not at the temperature it's supposed to be at, is it still safe to take?" Those kinds of things can add general anxiety and the environmental factors that contribute to, particularly, self-administered medications. If you're traveling internationally, for example, our pediatric population, we've had parents say, "My kid is going to study abroad for six months, how am I supposed to make sure they can access their medication?" Those kind of components you have to factor in because it's a chronic disease.

And then the last piece is, these drugs are heavy-duty oftentimes, and so the issues around being immunocompromised and higher infection risk, that has a domino effect because that impacts herd immunity with vaccines, for example, and things like that. There are other impacts that you can draw circles around, drawbacks that get outside of the general space of your disease, but matter very much to your overall health.

00:48:06

Moderator, RTI International



Thank you, **[Participant 1]**. I really appreciate all of that input. Thank you for echoing **[Participant 2]**'s thoughts regarding cost and access. I certainly heard about more on the efficacy front and how long things last. Those environmental and logistical issues seem major for sure, as well as those immune ones that you mentioned. You got at this a little bit with how long they're efficacious, but any other differences to tease out across the different conditions that you have experience with, **[Participant 1]**, in terms of those drawbacks?

00:48:53

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

I can't think of any more that I haven't already covered, but if I do, I'll put it in the chat later on.

00:49:00

Moderator, RTI International

Thank you, I appreciate it. And I know we've talked a little bit about risks and side effects already, but to go back to that, since we are talking about drawbacks and challenges, **[Participant 2]**, I know you had mentioned the risk of cancer, and balancing that with benefits and stuff, and I know you've already talked about side effects a little, but would you mind talking a little bit more about which side effects are most important to you when you're making decisions about going from one therapy to another one?

00:49:39

Participant 2 (registered as a patient)

The risk of infection has been my hardest thing. I basically hid out from 2020 to 2023 because, like **[Participant 1]** said, being in crowds and trying not to catch COVID [coronavirus disease-19]. Unfortunately, I did, and because of the Rituxan, my immune system was really low, and that left me in the hospital for three months fighting for my life, and it left me on oxygen 24/7, and my whole life has changed with being in a new space, having to rely on oxygen, and going to different therapies, so my quality of life changed because of my drug choice, so that's been quite an adjustment for me. As far as the other risk factors, it seems small compared to fighting for your life with a disease. But I've had pretty good experiences for the most part with other things, maybe gastrointestinal that are hard with taking my kids to school, and not feeling well, and feeling sick, and being pregnant with RA and not being able to take medication during that nine-month period was really hard. I don't have experience as far as getting pregnant while on RA drugs. I didn't stop, and some people stop, and then they're worried about their fertility, but I didn't have that experience. But I also did not go into remission, as a lot of times people do with pregnancy. And my doctor kept saying, you're going to remission any day now, and it never happened. I was ready for my daughter to come out so I could get back on some kind of biologic.

00:52:21

Moderator, RTI International

I hear you, being able to be on medications, definitely a critical factor for things, and I also hear you that those side effects of the GI [gastrointestinal] issues and a skin rash here and there, it doesn't necessarily compare to your experience with getting infections. Thank you for sharing all of that, I appreciate it. Let's move on to the next question. In terms of considerations, when you're considering a potential medication for a condition treated by Xeljanz, what matters most? What matters most to patients when they're considering a potential medication for these conditions?

How effective it is, how safe it is, how easy it is to use? I know we've already talked about this to some degree.

00:53:26

Participant 2 (registered as a patient)

I would say if it's covered. You're a slave to the health care company to say whether it's covered or not. And I've had times where something wasn't covered, and I had to seek out a pay assistance program to get whatever medication. Coverage is huge, because it's like \$2,000 a month for some things, and you can't afford that. Affordability is huge for most people, I think that'll probably be number one, and then number two, probably, if it works and how long it's going to work for them.

00:54:15

Moderator, RTI International

Okay, so cost at the front and foremost, and then those efficacy issues come next in your experience?

00:54:24

Participant 2 (registered as a patient)

And I would say the accessibility. As **[Participant 1]** talked, some of the things, I'm like, "Oh my gosh, that's right, I have experienced that." You don't realize when you're going through life, making it work. But, what she spoke about, the coverage, the accessibility with the drugs coming through mail order and not being at the right temperature, or the package being damaged, I know exactly what she's saying, because you're scared, oh my god, this costs so much. And can I still use it? Because it sat on that person's truck, or it was at my neighbor's, and it was supposed to be here? So those kinds of things are important as well because that makes you feel like, oh, gee, is this still safe? And then the other thing, for me, I always felt bad when I had to change drugs, and then I still had some left over. And knowing that there are people that can't afford it, and you're supposed to trash it, and it's the waste for me, that guilt felt like someone could be using this. But you can't give it to someone else.

00:55:35

Moderator, RTI International

I hear it. And thanks for expanding on those, logistical and environmental issues, that storage and stability and sitting on somebody's porch, et cetera. That's helpful to hear. What about the degree to which a medication was recommended by a health care provider? How much does that factor in when you're considering a medication, whether it's the one that your health care provider recommends?

00:56:11

Participant 2 (registered as a patient)

Not as much for me. The only thing that my rheumatologist has recommended, let's try a JAK [janus kinase] inhibitor versus a TNF blocker, so the way that the chemistry of the drugs, that's about the only thing that he's come and said, "I recommend a JAK inhibitor now because blah blah blah didn't work." Usually, it's that reason, but, like I said, he can recommend all day, but final say is that

insurance company. And a lot of times, they want to see something fail first and then you can go for something else, which is really hard, but that's kind of the system.

00:57:01

Moderator, RTI International

Okay, so health care provider's recommendations come into play. But then also, it sounds like they weren't recommending specific medications, they were recommending medication types or classes more broadly. **[Participant 1]**, anything to add here about important considerations when choosing a medication for these conditions?

00:57:31

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

Yeah, everything **[Participant 2]** said is backed up by all of our data. Certainly efficacy, side effects, things like that, but then it's those hoops that you have to jump through because that takes up so much time for so many of our patients dealing with prior authorizations or cost issues, step therapy. She mentioned, how many hoops am I going to have to jump through? We hear that quite a bit, especially those who've been through the rigmarole, like I said before, they know what that journey could look like, and so they want to know up front what is involved, which drug requires the least hoops? And that's where they want to start.

00:58:14

Moderator, RTI International

Okay, easiest in terms of ability to access and the administrative burdens associated with getting them. That's really helpful to hear. Thank you. You all have provided a lot of helpful input so far, and I really appreciate it.

I want to switch gears a little bit and talk about how well Xeljanz and other treatments for these conditions meet patients' needs. At the beginning of our discussion, I'd asked you to reflect on the most important aspects of rheumatoid arthritis, psoriatic arthritis, poly JIA, and AS to have managed or treated. Aside from the aspects that you have already shared, what other medical needs related to these conditions are important to you and the patients you advocate for? Any that we haven't talked about, or that you want to reemphasize?

00:59:21

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

What we hear about a lot, based on the inquiries we get in from our helpline, most widely used search terms on our website, and most widely attended webinars, are anything having to do with the lifestyle aspects of managing disease. So that's everything from diet, inflammatory food—foods really matter to overall disease impact—supplements, [questions] like, “does turmeric really work?” Things like that that don't necessarily have a strong evidence base behind them, alternative therapies, whether it's acupuncture, access to physical therapy, exercise. There are a whole suite of evidence-based programs specific for arthritis management, and being able to move, and what's safe, and what's not, and if I'm in pain, is it safe to exercise? It feels counterintuitive, but yes, it is an important component of disease management. Things like that, we get a ton of inquiries about, and I think that matters a lot in the aggregate to how well-controlled your disease is.

01:00:43

Moderator, RTI International

Thank you for raising some of those. I don't think we had talked about a number of those, so diet and nutrition, those type things, as well as exercise, physical rehabilitation, those do seem like some really important medical needs here that we haven't discussed yet. **[Participant 2]**, did that raise any other thoughts for you of things that you haven't discussed yet?

01:01:12

Participant 2 (registered as a patient)

No, but I agree with the exercise. I've heard that over and over. As far as inflammatory foods, for me, I don't have triggers. Some people do, and it's real. That's definitely something that happens to some people. But no, not that I can think of. I've never had physical therapy for RA. I've had it for getting back to normal from the other stuff.

01:01:51

Moderator, RTI International

What about important medical needs related to specific symptoms? I know we've talked about your pain and fatigue and such. Are there important needs that you have related to those?

01:02:09

Participant 2 (registered as a patient)

I go and get monthly infusions to help my immune system some. I do IVIG [intravenous immunoglobulin] infusions every month, so that helps somewhat with my fatigue, I try to take iron and those sorts of things, but not anything that I can think of that's specific.

01:02:44

Moderator, RTI International

Ok. What about managing other conditions? Managing those comorbid conditions? Could you talk a little bit about that, and the medical needs associated with that?

01:02:56

Participant 2 (registered as a patient)

Oh, yeah. For me, my other conditions now are lung-related, so I go to a pulmonologist, and I have done pulmonary rehab [rehabilitation] to try to get my lungs improved. I've done nutrition on my own because I want to drop some weight, and that will help with my joints, having less stress on them. I forgot to mention that I also had prednisone. Because I was on it for so long, I suffer from avascular necrosis in my right hip, so I will need a replacement, and that was because of taking steroids for so many years. That's a whole different thing that I've gotten from the RA fun in my life, so [inaudible].

01:04:00

Moderator, RTI International

Sorry to hear it. In addition to comorbid conditions, also some complications associated with the medication and the disease. Thank you for sharing that. **[Participant 1]**, I'm going to come back to

you. In terms of medical needs, as I've asked you a few different times, are there big differences in terms of the medical needs across the different conditions? Are the medical needs pretty much the same between rheumatoid arthritis, psoriatic arthritis, poly JIA?

01:04:42

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

I think so. Each of those has comorbidities that are more prevalent or common than others. Off the top of my head, I couldn't tell you exactly what, but there are some differences. With autoimmune arthritis in general, there are certain comorbid conditions that are directly linked to the arthritis, including certain types of heart disease. We've already talked about lung disease, or lung issues, eye issues, uveitis, and some others. There are some that are like that, but there are also other comorbid conditions that are more common among people with arthritis. Diabetes and heart disease are chief among them. What's interesting about that is that, while medications may be different to treat those, those other lifestyle or self-management factors that we talked about before are the same, diet, exercise, things like that. That's an interesting component. One of the medical needs that patients often have, because most people with arthritis have multiple providers that they see regularly to manage either their arthritis or their arthritis and comorbid conditions, is access to the suite of providers that you need and coordination among those providers so the emphasis is really on your whole-person care. And unfortunately, that is not how it works for most of our patients unless you're in an integrated health system. Even then, you may not have that quarterbacking that patients talk about really needing. My rheumatologist and my endocrinologist really needing to be able to talk to each other, that kind of thing. Medication management is certainly part of this as well. I think those are the big ones.

There's more and more research coming out all the time about the impact of—I feel like eventually, these are going to be indicated for everything—GLP-1s [glucagon-like peptide-1] and [their] relationship specifically to rheumatoid arthritis, potentially, and a pathway for GLP-1s to be potentially helpful for managing RA. There already is some research around leaky gut and joint health, which is interesting across any joint-related condition, which would include autoimmune disease but also osteoarthritis. There's some interesting little scientific nuggets there that may be useful in the future for medical management of arthritis.

01:07:24

Moderator, RTI International

Thank you for sharing that. It sounds like, depending on which condition a patient is dealing with, the constellation of other comorbid conditions may differ, but the basic medical needs associated with a lot of those sound like they're relatively similar overall.

01:07:41

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

Yeah, and this is probably only true for psoriatic arthritis, but oftentimes, the pathway is starting with psoriasis, and then psoriasis to psoriatic arthritis, so that's one unique pathway in that space.

01:08:00

Moderator, RTI International

Thank you, **[Participant 1]**. Okay. And to follow up on your point about care coordination and access to different providers for the different comorbid conditions, and getting those providers to coordinate among each other can be tough. **[Participant 2]**, anything to add about that? Care coordination and working with different providers?

01:08:25

Participant 2 (registered as a patient)

I'm lucky enough to have all of my specialists in my primary under the same umbrella, so they're under the same health care system, which is huge because I can't imagine if they weren't. They're not in the same location, but at least they're all on that same system, so if I go to MyChart, this person knows you saw so-and-so, this is what you discussed. I can't imagine navigating without them being in the same system. It's already a lot on your everyday time with different things, so I can't imagine if they weren't.

01:09:09

Moderator, RTI International

It sounds like it would be a big barrier to overcome if that were happening for sure. Thank you for sharing that that's one issue you haven't had quite as much experience having to deal with. I appreciate it.

For the next couple of questions, I'd like for you to reflect on your experiences with treatments for conditions treated by Xeljanz. This could include Xeljanz as well as other medications for the same conditions, as well as other types of available treatments that aren't medications, necessarily. Opening it up to all different sorts of treatments here. We've talked about a lot of different important aspects and medical needs that that patients need to have addressed for these conditions. Of those important aspects or needs, which ones are being addressed, at least partially, by the existing treatments that are out there? Which of your medical needs or the patients you advocate for do you feel are being addressed by existing treatment options?

01:10:35

Participant 2 (registered as a patient)

Pain management and the disease management. As **[Participant 1]** said, it's a progressive disease, so trying to slow down some of the damage that RA can cause, you're trying to modify and slow down the process. For me, that's major with my rheumatologist. Eye health is another huge one with a few different drugs. You have to really make sure that you do your eye exams, and they're actually looking out for the health of your eyes.

01:11:23

Moderator, RTI International

And when you said that that's something with a few different drugs, do you feel like some medications are addressing those needs that you mentioned, slowing disease progression and the eye, better or worse than others?

01:11:45

Participant 2 (registered as a patient)

That's hard to say because, like I said, DMARDs [disease-modifying antirheumatic drugs] have worked for me as far as not having any physical turning of my hands or nodules and knots. But prednisone, like I said, is on the other end of the spectrum, so I haven't really had any major things outside of what I mentioned.

01:12:22

Moderator, RTI International

What about others? Aside from slowing disease progression and the impact on the eyes, what other, if any, important needs are being addressed, at least partially, by existing treatment options? This could relate to some of the symptoms we've talked about, quality of life needs that we've talked about.

01:12:48

Participant 2 (registered as a patient)

Allowing such things as quality of life, the difference between me taking medication and not taking medication literally is if I'm able to get out of the bed or not. That's a literal thing. Medication definitely is something that I'll have to take for years, and because my list that I listed in the chat is so vast, I'm on my ninth med. Because I'm at the end of the line, I'm hoping that this one will hold for many years to come.

01:13:30

Moderator, RTI International

In terms of quality of life, even being able to get out of bed, and it sounds like, overall, the medications have done that for you, at least briefly. Thank you. That's a pretty important medical need to have met for sure.

01:13:46

Participant 2 (registered as a patient)

Oh, yeah.

01:13:49

Moderator, RTI International

[Participant 1], I'm going to turn to you. Medical needs that are being addressed, at least partially, by existing options?

01:13:57

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

Going to the ten-thousand-foot level, the advent of biologic therapy to treat autoimmune arthritis, the impact of that cannot be overstated. The ability for it to manage disease activity and even put people into medicated remission was unheard of forty years ago. Because they're so recent, you still have a lot of visible signs of disease among older people who were diagnosed and initially managed before. We've been doing juvenile arthritis conferences since the early eighties, and if you

look at pictures of those, it's a sea of wheelchairs, and now you hardly see any. You see kids doing yoga and all these different things. Doesn't mean that they're not in pain, that they don't have difficulty, for sure they do, but it's much less visible, and that is a direct result of DMARDs. In the aggregate, being able to have that comparison in mind is super important. There is a real issue, though, with people who either don't respond to any medication, or who have cycled through, like where **[Participant 2]** is, maybe you're towards the end of the line, and what happens there. I think there's a lot of science looking at that, and then hopefully there will be new classes of medication in the future. It sits in this funny place where these drugs are game changers for so many people, yet they don't work for everyone, they're not perfect, and in some cases, it may appear that your disease is controlled well, but you may still be in a lot of pain, or vice versa.

01:15:40

Moderator, RTI International

Thank you for mentioning the visible cues of whether the treatments are working or not. And I know you also got at some medical needs that are not really being addressed yet, and I want to dive into those more in a minute. In terms of the medical needs that are being addressed, at least partially, I'm sorry, I'm doing this to you again, **[Participant 1]**, are there differences across the different conditions in terms of which medical needs are being addressed by existing treatment options?

01:16:18

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

Oh, goodness. Probably. I don't know offhand. I don't know if any of the specific data points I have could lend to that, but if I think of anything, I'll throw it in the chat.

01:16:33

Moderator, RTI International

Okay. And what about different medications? Are there medications that are meeting those needs to a greater or lesser degree, from what you understand from the patients you advocate for?

01:16:46

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

I think it's very person-specific in your disease profile. Most providers still start, if you're going to go up to a biologic, with a TNF inhibitor as a first line because they were the first to come about, and still the most prevalent, and then from there, you're going to go from one to another. There may be a reason why a physician might start you on a different class for one reason or another. It really is still a bit of an art form.

01:17:18

Moderator, RTI International

Okay, varies highly by the patient. I hear you. Okay, you already started to go in this direction, [let's talk about] important aspects or needs that are not being addressed by existing treatment options. **[Participant 1]**, I heard you saying that the medications that are available don't necessarily work for everyone, and that they're not perfect, and that you can get to a certain point in terms of line of therapy where there may not be other good options available. **[Participant 2]**, I'm going to turn to

you on that one. Do you mind commenting a little bit about that, as well as any other needs that you feel like aren't being addressed by what's out there?

01:18:04

Participant 2 (registered as a patient)

What [Participant 1] was saying, that when you or someone like me does cycle through many of the available drugs, what happens to people like me? I would love to know what's on the horizon for new developments with biologics. And she's exactly right, they have been a game changer, and they're not the first line of defense for doctors to prescribe. It would be nice if they had more options for people that are out of options.

01:18:45

Moderator, RTI International

Okay, so more options when you do reach that point where you've tried an awful lot of different stuff. What about other needs? Can you think of other needs that are not being addressed right now by existing treatment options? Any big gaps in treatment or concerns that you have despite the treatment options available?

01:19:07

Participant 2 (registered as a patient)

What happens when a person, especially now in this job market, if they get laid off? If my husband was laid off tomorrow, how would I afford Rituxan infusions? The drug has a drug card as far as getting it discounted on the drug, but you have to have it administered at—I have to be at the hospital because of all my other stuff, so I don't go to an infusion center, one of those independents. The cost of that is \$150,000 every single treatment that I go to, and I go to two different sessions every three months. If I were to lose that benefit, what would I do? How do you solve that? I know I can't be the only one thinking of that. That's a huge thing, cost.

01:20:17

Moderator, RTI International

This access and affordability issue is something that's not really being addressed by the current situation.

01:20:26

Participant 2 (registered as a patient)

Right.

01:20:27

Moderator, RTI International

What about in terms of symptoms? Any symptoms that are not being addressed by currently available treatments?

01:20:41

Participant 2 (registered as a patient)

Not for me. Like I said, I've been tolerating this pretty well. I do have my flares here and there, and some of them are weather-related, stress-related, but that's nothing someone can really help with.

01:21:04

Moderator, RTI International

Okay. **[Participant 1]**, any other unmet needs come to mind while we were talking? Any things that aren't addressed in the patients you advocate for?

01:21:15

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

Yeah, I think there are certainly a subset of patients who still deal with chronic pain and then fatigue, like **[Participant 2]**'s talked about, and there aren't necessarily magic bullet treatments there, and I think that causes a problem. I don't know if you've experienced this, **[Participant 2]**, but the number of patients that I've spoken to who have gone through the rigmarole of trying to get to some sort of effective pain management strategy and have tried a number of things and, if you're lucky enough to have access to a pain management specialist, even then, oftentimes, they experience issues of not being believed. That is so, so very common, and fatigue as well, so people often look for life hacks or support groups or things like that, which can be helpful for sure.

In terms of treatment of rheumatoid arthritis, psoriatic arthritis, and even with juvenile arthritis now, "treat-to-target" is a major emphasis. We're at a point now where you can have a goal of low disease activity or even remission, and "treat-to-target" really focuses on that. There's enough research about that now to show that disease activity is lower and meeting [their] goal is higher among patients who are in those cohorts. Of course, that requires access to a sophisticated medical system where you can have that opportunity with a rheumatologist or other providers, true shared decision-making ability to react quickly if a medication's not changing, which of course is dependent on the insurance system being able to keep up with the "treat-to-target" approach. I guess my answer is that, yes, there are still some true unmet needs in terms of symptom management, disease activity, but also there's the clinical delivery and being able to experiment to find the right sort of treatment, and sometimes it's a dose of a medication that is outside the FDA [Food and Drug Administration] label and [being] able to access that, or whatever it may be. It's a combination of those things.

01:23:31

Moderator, RTI International

Bringing it back to the medications, and Xeljanz specifically, as well as some of the other medications that are commonly used for these conditions, you all have talked about a number of different medical needs. Any contrasting or comparing across the different medications in terms of how well they meet those needs, specifically in terms of symptom relief? I know, **[Participant 1]**, you said there are still some things to be handled on the symptom relief front and disease progression front. Any differences that you hear about between medications? No. Okay.

Before we part ways, because the event is nearly over, I wanted to give you an opportunity to summarize your thoughts on the importance of Xeljanz for patients, or to raise any topics that you

feel we did not adequately cover today in our discussion. Do you all have any final thoughts about Xeljanz, the conditions treated by Xeljanz, or other medications that treat the same conditions that you feel are important to share with CMS?

01:24:55

Participant 2 (registered as a patient)

I was going to say that Xeljanz, when **[Participant 1]** brought up the traveling aspect, that is so true because at least you can travel with a bottle versus needles that are harder to explain. I went on a family vacation in 2017, and thank God I was on Xeljanz because we were going abroad. And trying to explain having needles to TSA [Transportation Security Administration] would have been hard, so that's at least a positive thing that I can think of that comes from Xeljanz in that it's a pill.

01:25:36

Moderator, RTI International

The way it's administered can make a big difference, and traveling with different types of medications can certainly be a different experience. Thank you for sharing that, **[Participant 2]**. **[Participant 1]**, any, any final thoughts about Xeljanz or these conditions or other medications for them?

01:25:58

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

Going back to a common theme of the conversation, it's so individualized, the treatment needs, and that could be a result of your particular disease profile, comorbid conditions, all those things. Some of it, like I said, is an art form, and it's hard to know what's going to work best for you until you get there. But then also, these other factors, whether it's being able to travel if you travel a lot, or you live in a rural area, you don't have access to an infusion center, or whatever it is, those factors matter a lot in terms of your ability to be compliant to a medication. And each of the medications has different profiles in terms of side effects, infection risk, other things like that. All of those really should be taken into account in an ideal world. The patient and the provider would be able to look at all of those variables and then identify what is the best treatment for you. I think being able to have pretty broad access to the entire suite of molecules is best as you're going through this rigmarole of trying to find what's going to work for you.

01:27:10

Moderator, RTI International

Okay, so there's the importance of having a range of different options because what's helpful or what works for people can really vary quite a lot, it sounds like.

01:27:20

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

Yep.

01:27:21

Moderator, RTI International

Thank you. Any other final thoughts from you all before we part ways today? You've provided an awful lot of helpful input. All right.

01:27:32

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

Thank you for the opportunity.

Closing Remarks

01:27:33

Moderator, RTI International

Thank you. We really appreciate you participating in today's event. I appreciate you taking the time to talk with me and us today. Your experiences and input were extremely valuable and will help inform CMS' negotiations for Medicare pricing for Xeljanz. CMS staff, as we mentioned at the beginning, have been listening to the roundtable and will be able to bring your perspective back to their teams. **[CMS Staff]**?

01:28:05

CMS Staff

Yeah, I'd like to echo what **[Moderator]** said. We have really appreciated hearing your experiences in this roundtable, so thank you all for showing up, and we appreciate you. Thank you.

01:28:22

Moderator, RTI International

Great. Thanks, **[CMS Staff]**. And if you all find that you have any questions following today's session, you can submit them to the mailbox. The address is here, but I'll also say it out loud, IRARebateAndNegotiation@cms.hhs.gov, and you would use the subject line of "Public Engagement Events." Thank you again so much for your time today, I really appreciate it.

===== 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 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 companies with direct/indirect interest in the Negotiation Program (e.g., drug companies, health plans) 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 companies or related associations with direct or indirect interest in the Negotiation Program (e.g., drug companies, health plans).
Yes	Any other personal or professional relationships or interactions with companies or related associations with direct or indirect interest in the Negotiation Program (e.g., drug companies, health plans) that may be considered a financial COI.

Participant 2: Registered as a patient who has experience with the selected drug or the conditions treated by the selected drug

Declared Conflicts of Interest	
No	Receipt of financial payments (e.g., gifts, funding, research support, honoraria, travel, or other expenses) from companies with direct/indirect interest in the Negotiation Program (e.g., drug companies, health plans) 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 companies or related associations with direct or indirect interest in the Negotiation Program (e.g., drug companies, health plans).
No	Any other personal or professional relationships or interactions with companies or related associations with direct or indirect interest in the Negotiation Program (e.g., drug companies, health plans) that may be considered a financial COI.