Transcript: Orencia Roundtable Event, April 14, 2026, Medicare Drug Price Negotiation Program Public Engagement Events

This transcript was lightly edited for readability.

Introductory Remarks

Moderator, RTI International

Hey everyone. My name is **[Moderator]**, and I'm going to be the moderator today, and I work for RTI International. I also have a colleague of mine, **[Secondary Moderator]**, who you can see as well. She'll be helping me today, with a few questions here and there, so you may be hearing from her today. The Centers for Medicare & Medicaid Services, or 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 about 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 the selected drugs. The purpose of today's event is to hear from you all, which is a group that may include patients, caregivers, and patient advocates about your experiences with the conditions and diseases treated by Orencia, including rheumatoid arthritis [RA], psoriatic arthritis, polyarticular juvenile idiopathic arthritis [poly JIA], and the prevention of acute graft versus host disease with Orencia, 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 related to the patient experience, we ask that you send that input to the mailbox at IRARebateAndNegotiation@cms.hhs.gov, instead of sharing it in today's discussion. And that email address should have also been in the welcome packet, so you don't have to remember that email address. 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.

CMS Remarks

00:02:30

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.

00:04:22

Moderator, RTI International

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

00:04:34

CMS Staff

Yes, good morning, everyone, and welcome. My name is **[CMS Staff]**, I'm with the CMS Drug Price Negotiation team, and I'll note that we've got some other CMS staff on the call today as well, and we all work on the policies for getting public input, as well as negotiations for Medicare drug pricing. I want to take a moment on behalf of CMS to thank you all so much for participating today. We are really looking forward to hearing about your experiences during today's roundtable discussion. And I will note that we are going to go off camera now so that you can focus on the discussion, but wanted to say thank you, and I'll go ahead and turn it back over to you, **[Moderator]**.

Housekeeping

00:05:15

Moderator, RTI International

Thank you, **[CMS Staff]** and team. Before we begin, I do also want to go over some housekeeping items and some ground rules, just so that everyone knows what to expect today. First, if you get disconnected, please attempt to rejoin, and if you can't, if you have trouble rejoining, please reach out to IRADAPStechsupport@telligen.com, which is an email address that should have been sent to you earlier, and someone will be able to help you get back online.

This discussion is not open to the press or to the public. We will use first names only during our 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 any personally identifying information, such as your employer's name, or the city you live in, or schools you attended during our discussion. Following the event, CMS will prepare a transcript and will have participant names and identifying information removed, and those will be made available to the public. 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, first we hope that you all contribute your perspectives throughout this session. However, if a question arises, and you do not want to answer the question, that is totally okay. For background, please minimize background noises by silencing your cell phone and other devices if you have not done so already. Also, be sure to mute yourself when you're not talking, just to prevent distractions. Thanks in advance for everyone having your video on throughout the discussion.

And to let you know about timing, we have reserved up to two hours for our session. However, it is possible that we may not need to go the full two hours to cover all the planned topics, and if that happens, we can let everyone go a bit early. I do have a discussion guide in front of me to help me keep track of what we need to discuss, and we do have a lot of topics to cover, so I may need to redirect our conversation, or cut short a conversation at times, to make sure that we can cover all the questions that we have, and that everyone has a chance to speak today.

If you need to take a break or step away during our discussion, that is totally okay. Just turn off your camera and your microphone and rejoin when you're able to. You don't need to tell me that you're leaving, just turn off your camera and your microphone and return as soon as you're able to. Also, try to speak one at a time. I might occasionally interrupt you if more than two people are speaking, just so I can make sure that I can hear everyone. Please use the raise hand feature in Zoom to indicate that you would like to speak, and this will help me know when you would like to add to the discussion. Finally, while we are hoping that you will focus on our oral discussion, you can also add any comments into the chat 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, or we need to move on to another question, or if you think of something later that you want to add. Be sure to note what question or topic you're responding to in the chat, so we understand the context. First, I want to pause for a second and see if anyone has any questions. So unless anyone has any questions, let's go ahead and get started.

Discussion

00:08:57

Moderator, RTI International

I first want to get to know everyone and a little bit about you. I'm going to go around the table here and ask everyone to tell me your first name. Tell me if you're joining as a patient, as a caregiver, or sharing your perspective as a patient advocate. And then also the condition or conditions that Orencia treats that you have experience with, either personally as a patient, or maybe as an advocate or caregiver. So again, your first name, whether you're a patient, caregiver, or advocate, and then the condition or conditions that Orencia treats that you have experience with. I am going to start first on my list here, which is **[Participant 1]**.

00:09:45

Participant 1 (registered as a caregiver)

My name's **[Participant 1]**, I'm a rheumatologist, so I'm joining as a caregiver. I use Orencia to treat rheumatoid arthritis, psoriatic arthritis, juvenile arthritis, and I've actually used it in some of the conditions that are being actively studied in Phase III trials for Orencia.

00:10:05

Moderator, RTI International

Wonderful. Thank you so much for joining, **[Participant 1]**. And next is **[Participant 2]**.

00:10:13

Participant 2 (registered as a patient)

Hi, I'm **[Participant 2]**. I am a patient who has used Orencia and other medications like it to treat my rheumatoid arthritis, which is a systemic inflammatory disease.

00:10:30

Moderator, RTI International

Wonderful. **[Participant 2]**, thank you so much for coming today. And next is **[Participant 3]**.

00:10:40

Participant 3 (registered as a patient)

I'm a patient, for rheumatoid arthritis, and I've used a variety of drugs for it. Currently, I'm taking Orencia, since 2013 actually, and I'm currently in clinical remission due to Orencia.

00:11:10

Moderator, RTI International

Wonderful. Thank you, **[Participant 3]**. We're happy to have you here today. Next is **[Participant 4]**.

00:11:16

Participant 4 (registered as a patient)

Good morning, my name is **[Participant 4]**. I'm a patient living with rheumatoid arthritis, and I'm currently using Orencia, but I've used several other medications in the past.

00:11:26

Moderator, RTI International

Thank you, **[Participant 4]**. Next is **[Participant 5]**.

00:11:30

Participant 5 (registered as a representative of a patient advocacy organization)

Hi everybody, I'm **[Participant 5]**. I am an advocate for the Arthritis Foundation, and we represent all patients with arthritis, so all of the forms of arthritis indicated for Orencia.

00:11:42

Moderator, RTI International

Wonderful. Thanks, **[Participant 5]**. And last but not least is **[Participant 6]**.

00:11:47

Participant 6 (registered as a representative of a patient advocacy organization)

Hi, my name is **[Participant 6]**. I am a patient advocate representing autoimmune diseases, so that would be the psoriatic, rheumatoid, and juvenile arthritis in this case.

00:11:57

Moderator, RTI International

Thanks so much, **[Participant 6]**. One thing I'll make sure I understand, so no one, at least for today, is here to speak for the prevention of acute graft versus host disease, just the poly JIA, psoriatic, and rheumatoid arthritis, is that right? I see heads nodding. Okay, I want to make sure I understand everyone's perspective today.

One thing I'm going to add today is, we have three different conditions we'll be discussing, and when you're talking about your experience, about the condition, or about the drug, it would be helpful for me to know what conditions specifically you're talking about. That helps me know, for instance, if you're talking about psoriatic arthritis, or rheumatoid arthritis, or polyarticular juvenile idiopathic arthritis, which I'm going to say today poly JIA, to make things a little easier on myself.

I know we're here to talk about Orencia, but I want us to talk about the condition itself before we talk about the treatments. So again, for now, we're going to talk about the condition itself. Thinking about the different ways that rheumatoid arthritis, psoriatic arthritis, and poly JIA affects patients' lives, what would you say are the most important aspects of this condition to have managed or treated? And it could be things that need to be managed in the short term or in the long term. Who wants to go first? **[Participant 3]**, go ahead.

00:13:28

Participant 3 (registered as a patient)

For me, it's pain, number one, excruciating pain. Fatigue, those are the two main things, and not being able to do basic things, whether it's exercising or everything that you do, when it's at its peak, it's painful. You can't keep it off of your mind, or I find it very hard.

00:14:06

Moderator, RTI International

[Participant 3], you mentioned you can't keep it off your mind. Tell me how that affects you.

00:14:12

Participant 3 (registered as a patient)

I would imagine, and I probably should have said, it's depressing because you wonder if there's any hope. You go from a person who never has experienced anything like that, to it's just with you every moment, including when you're trying to sleep, or during the day. One of the other things is, if you're not moving, then it's even worse trying to unfreeze whatever's frozen there to try to get moving. I didn't find a way to escape all of those symptoms or conditions.

00:15:09

Moderator, RTI International

Okay, **[Participant 3]**, so rheumatoid arthritis has both a physical and also a mental health component to it.

00:15:14

Participant 3 (registered as a patient)

Absolutely.

00:15:15

Moderator, RTI International

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

00:15:23

Participant 2 (registered as a patient)

Yes, I second all of that. Also, I would say that brain fog is something that I have struggled with a lot. That's one of the things that kept me from really being able to pivot when the physical symptoms disabled my body. I had a background in science, and I think if I had had less fatigue and brain fog, I could have used my mental capabilities more. Also, those physical symptoms, the debilitating nature of rheumatoid arthritis as it breaks down your joints over time, I've been really impacted by that. I had a hip replacement in my early forties, and I've got many other joints that need replacing, which feels a little ridiculous when your body's still attacking them because you haven't gotten good symptom control. I think overall, there are a lot of different things that add up to disability for me, and for many others I know.

00:16:30

Moderator, RTI International

I'm going to go to **[Participant 4]**, then I'll go to **[Participant 1]**.

00:16:36

Participant 4 (registered as a patient)

Thank you. I agree with everyone else. I would say the fatigue, loss of joint function, pain, the brain fog, which for me leads to a lot of frustration, and sometimes not even being able to get out simple words, word-finding difficulties, loss of independence. It's very frustrating not to be able to do simple things that people take for granted, and having to ask for help is challenging. And it's very anxiety-provoking, and it's also very unpredictable, so it makes it hard to make plans because you don't know how you're going to be feeling that day, or if you do something, how it's going to impact you for several days or weeks afterwards.

00:17:25

Moderator, RTI International

Can you tell me a little bit more about the anxiety, **[Participant 4]**?

00:17:28

Participant 4 (registered as a patient)

It's a lot of things. It's making plans and wondering if you're going to be able to do them. It's anxiety when you're having an unfamiliar pain or an exacerbation, how long it's going to last, or if things are going to get worse. When you're trying a new medication, anxiety whether that's going to work and what the side effects are going to be from that new medication. So those are some of the things.

00:17:53

Moderator, RTI International

Great, thank you, **[Participant 4]**. **[Participant 1]**, go ahead.

00:17:56

Participant 1 (registered as a caregiver)

I want to take an approach to this from having taken care of thousands of patients with rheumatoid arthritis. I think we need to remember that prior to 1998, there weren't very good treatments for rheumatoid arthritis. The goals as a physician were to get people to the end of the day, and maybe to the end of the week, but really your goals were very short-term, and you knew that this disease was going to severely affect someone's life and ultimately would end their life quickly. And then in 1998, when Enbrel came out, we had a massive shift in the ability to take care of patients and shift our treatment goals from tomorrow, or the end of the week, to how are you going to look over the next few years? And then Remicade came out a year later, and that helped us get more options.

But it wasn't really until 2005 when Orencia came out that we had a whole other treatment class for taking care of patients with rheumatoid arthritis. And so this, again, expanded our ability to take care of patients, and it prolonged their life, and it helped prevent a lot of the other things that we aren't even talking about right now because we've sort of forgotten about them. Rheumatoid arthritis is not a disease just of the joints. Rheumatoid arthritis has massive, what we would say, extra-articular manifestations. You can see people develop interstitial lung disease [ILD]. You can see people develop accelerated atherosclerosis. It's an independent risk factor for coronary artery disease. In fact, some of my patients I've seen, their initial presentation was early myocardial infarction or heart attack. It can affect your eyes in the form of scleritis and episcleritis. It can lead to something called Felty syndrome. Patients with uncontrolled rheumatoid arthritis are at risk for two to three times the increased risk for malignancies in the form of diffuse large B-cell lymphoma and other blood malignancies. It can lead to neurologic problems because patients can develop cervical spine instability that then can paralyze them. And a lot of these things we don't see anymore, and we don't appreciate them as much anymore because we have medicines like Orencia that can halt the disease, prevent damage to joints, can prevent destruction of joints leading to disability, and it can prevent the progression of disease to affecting all these other organ systems that are really deadly for people. And so I think that's an important thing to remember, is that the history of being able to get this medicine has changed our perspective of, this is a really bad disease to, it's predominantly a joint disease, and like patients have said, it leads to some mental health side effects, but there are a lot of other things that are associated with rheumatoid arthritis we're forgetting about because we have such good treatments now.

00:20:45

Moderator, RTI International

Thank you, **[Participant 1]**. And again, we'll definitely talk about the treatments in a moment. Just for a moment, I want to talk about the patients' experiences with the conditions themselves, and **[Participant 5]**, I see you have your hand up.

00:20:57

Participant 5 (registered as a representative of a patient advocacy organization)

I'm really grateful that there are patients here to tell their specific stories. I maybe see my role in this conversation to supplement with patient data that we've gathered over the years, and one that's very relevant to this question is, we do a survey every year, now every two years, where we benchmark questions. One of them is, what are your top arthritis-related challenges? And pain comes up number one every single year. And the top three in the most recent survey we did were pain, fatigue, and then managing multiple chronic conditions, to back up what everyone has already said here.

00:21:35

Moderator, RTI International

That's helpful. Thank you, **[Participant 5]**. How do these conditions impact someone's ability to stay independent? **[Participant 1]**.

00:21:48

Participant 1 (registered as a caregiver)

Tremendously. When disease is uncontrolled, a lot of times we spend time trying to get patients at-home care so that they can get dressed and use the toilet, and I'm writing patients out on disability intermittently. There are a lot of ways that this can affect people's independence.

00:22:15

Moderator, RTI International

Yeah, **[Participant 1]**. **[Participant 2]**?

00:22:19

Participant 2 (registered as a patient)

It's a huge impact on independence. In my early thirties, I worked a job or two, most of the time I was taking care of an active family. I hiked, swam, kayaked, all of the things. I am an extremely independent person by nature. Ten years later, I didn't drive myself. I was relying on a walker for a while until I got on Orencia and it really started working for me. It really wipes out your independence. I've had to learn to ask for help, which is so hard as somebody who was raised to tackle it myself and handle everything. It's been one of the biggest mental blocks and physical challenges for me to get used to that lack of independence.

00:23:20

Moderator, RTI International

I'm going to finish with **[Participant 6]**, then I'm going to move to another topic.

00:23:25

Participant 6 (registered as a representative of a patient advocacy organization)

As you know, I'm also here to speak on congregate for the patient population I represent, but our patients report difficulty with daily tasks, so they usually need a caregiver, roommate, friend, partner to assist them with many of the daily tasks they have. I'd also like to highlight that 20% of all autoimmune patients have more than one autoimmune disease, so if one autoimmune disease is not managed, it can exacerbate symptoms in the other, leading to further complications with daily activities.

00:23:59

Moderator, RTI International

Thank you. I said I was going to stop by **[Participant 6]**, but **[Participant 4]**, let me let you get the last word, and then we'll talk about treatments. Go ahead.

00:24:06

Participant 4 (registered as a patient)

Yes, like **[Participant 2]**, I'm extremely independent, but unfortunately, with this being so unpredictable and that I retired early because I wasn't able to consistently do my job roles, so that was very frustrating.

00:24:22

Moderator, RTI International

I really appreciate you all sharing your perspectives about these conditions. Now I want to turn a little bit towards the medications that are used to treat rheumatoid arthritis, psoriatic arthritis, and poly JIA. In the chat window, it would be helpful for you all to put down some of the medications that you're using today, or some of the medications that you used in the past for your condition. And for **[Participant 1]**, for yourself, you could put in medications you prescribe that might be helpful from your perspective. And from our patient advocates, if you know of medications that you've heard about from your patients that they use, you can put those in there as well, as best as you can, it might be hard, and that's totally fine, so again, putting into the chat window medications that maybe that your loved ones, patients you advocate for, or that you care for have taken for rheumatoid arthritis, psoriatic arthritis, or poly JIA. And take a moment to put those into the chat, and then we'll look at those. I see Orencia, Enbrel, methotrexate, Rinvoq, and Xeljanz. I see rituximab was in there earlier. Also see some other new ones, like Humira, Remicade, Cimzia. It's moving really fast. SSZ [sulfasalazine], HTQ [hydroxychloroquine], Rinvoq. This is very helpful. I wanted to see some of the medications that you all are familiar with. Thank you for sharing those medications' names.

For the next part, we want to hear about experiences that you, your loved ones, or patients you advocate for have had with Orencia, and also these other medications that are used for rheumatoid arthritis, psoriatic arthritis, and poly JIA. When you're talking about medications for the next couple questions, let me know what medication you're talking about, so I understand more about the context. If you're talking about Orencia, let me know that. If you're talking about Humira, let me know that. My first question is, I want to talk a bit about the benefits. What benefits have you, your loved ones, or people you advocate for experienced with medications that are used to treat these conditions? And as a reminder, let me know which medication you're talking about. Again, the benefits that you, your loved ones, or people you advocate for have experienced with the different medications. **[Participant 3]**, go ahead.

00:27:35

Participant 3 (registered as a patient)

For Orencia, it's alleviated the pain, the fatigue, I'd attribute my CRP [C-reactive protein] levels as being normal, no joint aches, no soreness, just plenty of energy, just everything. Some of the others, like methotrexate, I experienced excessive fatigue and nausea, so that doesn't work. And, Enbrel, it was always the pain was always present in some of the symptoms. And then, Humira, unfortunately, I got some kind of sepsis infection from it, so I had to stop that, which, I guess that can happen with anyone. And Arava, I sometimes get a rash. But I've discontinued that.

00:28:47

Moderator, RTI International

We'll put some benefits, we'll definitely talk about some of the challenges people have with the drugs as well. **[Participant 2]**.

00:28:57

Participant 2 (registered as a patient)

Orencia is honestly, I call that my miracle drug. It was the one that really turned it around for me. I tried a bunch before that that really didn't help or gave me different symptoms. But I had much less fatigue and brain fog. I was able to start exercising more, and I made a lot of gains while I was on it. Unfortunately, in time, it stopped being as effective for me, and I've had to go to something else, but there are only so many of these medications, so it wouldn't surprise me if I need to circle back to it at some point.

00:29:47

Moderator, RTI International

What others, some of the benefits that you've experienced with Orencia, and also some of the other medications. **[Participant 1]**?

00:29:55

Participant 1 (registered as a caregiver)

I don't want to answer questions that are not currently being asked, but can I tell you what makes it a core differentiator, and why it tends to make people feel, so one of the big things we see with Orencia is that it's a different mechanism of action for patients. A lot of these things, patients are starting on anti-TNF [tumor necrosis factor] therapies, your Humiras, Cimzias, Remicade, Simponi, Simponi Aria. You're starting there, and they can work well, but if you fail that drug class, then you really only have to fail two of those medicines, and then you're trying to look for something different. Orencia offers a mechanistically distinct option where TNF fails, and so one thing that we see that patients have experienced with this is that one, they get lower rates of serious infections than they did when they were on anti-TNF, which is huge for our patients, especially the older population. And there's not that signal for increased tuberculosis reactivation, which for some of my patient population, that's kind of a problem. And then you get less risk for herpes zoster. So we see people having less trouble with infections.

The other thing is that we see it reduce the risk of RA-associated interstitial lung disease, and that's one of the big things that makes Orencia so favored for us as rheumatologists and for our patients, is that sometimes when they have concomitant interstitial lung disease, the mechanism of Orencia is very special and important for us to be able to slow that down. When they see the ability of their rheumatoid-associated interstitial lung disease improving and slow down and become stable, then they can become more functional, which might not have been as true on other therapies. And then also, it's got a really good steroid-sparing effect. One thing that we observe in our patients, a lot of times when they're on Humira or Enbrel or something, then you're hitting them with a lot of steroids over time to try to bridge them through some flares. Patients who get on Orencia tend to experience less flares, and they have reduced steroid burden, and so they have less side effects from steroids. So those are some of the things I want to touch on.

00:32:11

Moderator, RTI International

Great, thank you, **[Participant 1]**. **[Participant 4]**, go ahead.

00:32:15

Participant 4 (registered as a patient)

Yes, Orencia has been good for me. I would say I'm about 85% to 90% of what I call the real me, the pre-RA me, so I definitely have a lot less brain fog, and I'm able to be more active, I'm able to go to the gym and ride an e-bike [electric bike] now, and I've actually been able to plan to go on a vacation, which is something that I definitely would have been hesitant to do in the past because of not being able to do all the fun things you want to do on a vacation.

00:32:48

Moderator, RTI International

Very cool. I also want to hear about benefits around Orencia or other medications to treat these conditions, like the dosage and also how it's taken and administered, an infusion versus an at-home therapy. **[Participant 1]**, go ahead.

00:33:11

Participant 1 (registered as a caregiver)

Massively beneficial, and so something I actually didn't share earlier is I actually am a patient as well, so maybe that's what gets me involved in this group. There are certainly advantages to oral therapies, there are advantages to injectable therapies, there are advantages to infusible therapies, and there are drawbacks to all of them as well. But I think one of the really nice things about Orencia is that you have dosing variability, the infusions, when they're required, are short in duration. Remicade initially was about a five-hour infusion, then got shortened through some studies to two to three hours, but the time in the chair for patients who are on Orencia, 30 minutes if you're efficient, and so you're in and out, so not as burdensome on your life as other infusion therapies. And then there's always that option of being able to switch to injection if you can. You have two benefits there. The other thing is that it's monthly, which sometimes feels a little burdensome, but actually can be helpful, even from a psychological standpoint. Sometimes when you space medicines out too far, for example, Skyrizi, which is used for psoriatic arthritis, it's four injections a year, so they're every three months. But what we see is patients, when they get closer to that dose, they're feeling like they're not getting enough medicine. A lot of times when you're getting either the weekly dose of Orencia or the monthly dose, it's comforting to know, okay, I'm getting my medicine now, so you're not feeling that psychological weight of, god, I have another thing, it's not due yet, am I flaring now? The dosing is, honestly, very good for Orencia. And it's very unique as well.

00:35:10

Moderator, RTI International

Thanks, **[Participant 1]**. **[Participant 2]**.

00:35:16

Participant 2 (registered as a patient)

I also would say that for a patient who struggles with brain fog and memory, I found the monthly infusion of Orencia was easy for me to remember, easy to show up for. Also, they did my blood work right there, so I didn't have to remember to have a separate appointment to do my blood work and keep up with all of that. I think overall, it gave me a lot more confidence that I was going to be able to keep up with things. Also, as a patient, taking medications that have a long list of potential side effects, knowing that I had those nurses there when I was taking something that could be dangerous really made it feel like a much safer experience as a patient.

00:36:10

Moderator, RTI International

That's helpful. Thank you, **[Participant 2]**. **[Participant 4]**.

00:36:13

Participant 4 (registered as a patient)

I'd have to say I do the injections, and I like that because I have my autonomy to do this when I'm on my own schedule, but I have my autonomy, which with this disease process and its unpredictability, you don't have that in many aspects in it, so at least having the autonomy to treat it at home rather than going to the infusion center is one thing that I like. One reason I wanted to be here today is because I'm not on Medicare yet, but I know sometimes Medicare dictates that you can only get the infusion versus an injection. And I really would want to advocate that it's up to my rheumatologist to decide, which means I get the medication and not the insurance dictating the mode of administration.

00:37:01

Moderator, RTI International

Thank you, **[Participant 4]**. I also want to talk about tolerability, how easy it is to tolerate, either Orencia or other medications. Can you tell me about whether these medications are easy to tolerate?

00:37:35

Participant 2 (registered as a patient)

Orencia was the one that I have tolerated the best, honestly. I had a bit of a headache and some fatigue the following day, but other than that, I could hardly tell I was taking a medication other than the positives that it gave me. A lot of the other ones have given me side effects you just can't live with. Methotrexate made me sick for five out of seven days. The Plaquenil turned me into a sobbing mess. A lot of the others had no change. I have some nerve damage in my big toe from leflunomide, which is Arava. So overall, I would say the one that worked the best was, luckily, the one that also gave me the lowest side effects.

00:38:27

Moderator, RTI International

Okay. **[Participant 1]**.

00:38:30

Participant 1 (registered as a caregiver)

It's actually one of the best-tolerated biologic options you can get in rheumatoid arthritis. You're looking at a handful of drug classes here. Generally, I think I mentioned this before, with anti-TNF therapies, you're experiencing a little bit more infection risk. The other thing is that there's some cardiovascular toxicity with anti-TNFs that you don't get with Orencia, and you have a higher risk of reaction to some of the medicines. Remicade's got some mouse protein in there, so we see a lot more trouble with infusion-related reactions to anti-TNFs than to Orencia. The newest drug class that came out, JAK [Janus kinase] inhibitors, we love them. They're oral medicines, but they have black box warnings for major adverse cardiovascular events and blood clots.

From a physician's perspective, Orencia is one of the safest, cleanest biologic options we have for people, and we see that they do really well when they get the medicine. And one of our other cohorts speaking just said, maybe get a little headache after the first infusion, but generally, when they're comparing it against things like methotrexate, which give you oral ulcers, hair loss, fatigue, worse brain fog, or the neuropathy associated with Arava, they are ecstatic when they get put on Orencia, because they're going, "This isn't giving me nearly the stuff that anything else has given me so far." It's very well tolerated.

00:40:07

Moderator, RTI International

Thank you, **[Participant 1]**. I saw a lot of heads nodding as well. A question which **[Participant 1]** about five minutes ago touched on, and this is a question for everyone, if you have experience with more than one medication for these conditions, how do the benefits of the medications differ from each other, if at all? Again, if you have experience with more than one medication, how do the benefits of the different drugs differ for you? **[Participant 3]**?

00:40:50

Participant 3 (registered as a patient)

I think it's sort of hard to compare, since the Orencia, I hesitate to say is almost the perfect drug as far as all my symptoms. Methotrexate, frankly, for me, the pain and everything that went along with rheumatoid arthritis was better than the side effects of methotrexate. Enbrel helped some. I wasn't in excruciating pain, and I was in constant pain 24 hours, but I could walk without feeling too bad. And then Arava, it has those side effects of rash and whatever.

00:41:56

Participant 1 (registered as a caregiver)

Could you clarify that question a little bit? Because you're asking what the difference is in using Orencia compared to experience in using other medicines?

00:42:06

Moderator, RTI International

It could be comparing Orencia to other medications, but it could also be comparing different medications to each other as well, like Humira versus Enbrel, for instance. Just want to understand how do the benefits of the different drugs differ from each other.

00:42:23

Participant 1 (registered as a caregiver)

That's a nuanced question, because I had mentioned a little bit of this earlier, and they all have benefits and drawbacks, but essentially, when I'm discussing options with patients, you're talking about efficacy, the durability of the medicine, the safety, and how well people tolerate durability, meaning how long it works for patients. People get different effects. **[Participant 2]** is a patient who, I have this experience with a lot of patients, who feels the comfort of being taken care of in an infusion setting because of all the reasons she listed, the litany of side effects and being close to providers, and that's markedly different than somebody using it at home. But **[Participant 4]** prefers the idea of being able to use the injection at home. And so that conversation comes down to shared decision-making with your patient. What does your life look like? What works better for you? When you're talking about other therapies, Enbrel compared to Humira, and I've used both of those therapies, it's just what would you prefer? Do you prefer one that's going to burn when you inject it? Because one of them is based in citrate. Humira used to be based in citrate, and that burned like crazy. It used to be, take it out of the fridge, set it on the counter, pace back and forth with a cup of coffee in your hand before you got the gall to inject yourself. But one's once weekly, one's twice weekly, Simponi injection's once a month. Simponi infusion's once every eight weeks for 30 minutes. Orencia is once weekly injected, or it's once a month for 30 minutes. Remicade, do you want to sit for longer? Do you want to have the ability to increase the dose from 5 mg [milligrams] per kg [kilogram] to 7 to 10, closing that interval from 8 down to 4? There are a lot of considerations that go into how do these medicines compare to one another and how well they work, but I think it has a really special niche. And that's why I'm so passionate and made a strong effort to cancel some patients today to talk about this because it is essential that we preserve this medication. It's helpful for older patients, people with infectious risk, cardiovascular risk, ILD prior malignancy that failed other therapies, it's got great durability. It's a very niche medicine.

00:44:48

Moderator, RTI International

I'm glad you were able to come today, **[Participant 1]**. **[Participant 5]**, and then after we're going to talk about the challenges that people have had.

00:44:58

Participant 5 (registered as a representative of a patient advocacy organization)

I want to follow up on what **[Participant 1]** said, and with special attention to the pediatric population, because we hear so often from families, because with juvenile arthritis, it's a whole family disease. It affects the siblings, the parents, you're taking time off of school, you're taking time off of work, it really has such an impact that way. The frequency and route of administration matters there, and then also, when he said the citrate piece, I know that's maybe a little bit different than Orencia, but to shine a light on how the sensitivities of those kinds of impacts really affect children more, that was such a huge issue with Humira, and when we polled a bunch of pediatric families about some of the things that matter most to them with medication, citrate-free came up number one every single time. So that seems like maybe a small detail, but to them, it is so impactful, so I want to emphasize that.

00:46:03

Moderator, RTI International

That's helpful, thanks so much, **[Participant 5]**. We talked a little bit about the benefits, and I want to now talk about some of the drawbacks or challenges that you or people that you love or treat have experienced with the medications for these conditions. What kind of drawbacks or challenges have people experienced, either with Orencia or with other medications? **[Participant 1]**.

00:46:33

Participant 1 (registered as a caregiver)

I don't want to speak for everybody. I think a lot of our patients have touched on this already here, is that Arava, people have mentioned the side effects of neuropathy. People have mentioned a lot of the side effects from methotrexate, I think one we haven't really touched on is the slower onset of action. If we were going to say one drawback, maybe, to Orencia is that it has a little bit of a slower onset of action compared to maybe a TNF, or especially a JAK inhibitor. So that's a little bit of a tough thing, but as soon as it works, the durability's very good. So those first eight weeks of getting somebody on Orencia are a little tough, but after that, it's great. I think most of the side effects are like you said. I remember the burning of Humira very closely. I have patients that now suffer from neuropathy because of the Arava. The other thing that's interesting is I remember getting a call from my insurance company before I started Remicade. And I was told, "Hey, we wanted to let you know your infusion's tomorrow, and we want you to know that you may die from hepatosplenic T-cell lymphoma." And so now, every time I prescribe an anti-TNF, I have to talk to them about the risk of hepatosplenic T-cell lymphoma, which was uniformly fatal at the time. I don't have to talk about that with Orencia, that's not a problem with Orencia, but you do have to mention it to patients when you're starting them on anti-TNFs. There's nothing that's universally effective for people. The infection risk is still there. Infusion logistics can be hard for people, cost and access is complex, and that's the thing I'm most worried about here. There's a lot of different things that lead to negative effects with biologics.

00:48:38

Moderator, RTI International

[Participant 2], you're next, I believe.

00:48:41

Participant 2 (registered as a patient)

I was going to mention the amount of time that it takes to figure out that some of these medications do not work, and then to have to follow those up with other medications in the same class. It really slows patient access to the medication that's going to work, I think.

00:49:04

Moderator, RTI International

How long does that take, **[Participant 2]**?

00:49:06

Participant 2 (registered as a patient)

For some of them, Humira, I was asked to be on for six to nine months, and then again with Enbrel after that, and that's a really long time when you've got that clock ticking, and you know that it's destroying parts of your body.

00:49:25

Moderator, RTI International

Okay, thank you. **[Participant 4]**.

00:49:30

Participant 4 (registered as a patient)

As far as side effects, some of them, because it lowers your immune system, then getting infections. I know the one year I was sick for four months, because I'd get over one thing and then I would get sick with something else, so then you've got antibiotics and things like that. Fatigue was awful with methotrexate. I think I was only good maybe one day of the week after that. I've had really bad acne from Rinvoq, and I've never had acne in my life, and I get put on this medication, and I'm getting strange acne all over the place. I've gained 12 pounds on one medication. And it was definitely medication-based, my cholesterol went up and things like that, so you're trying to help one thing, and then you have all these other conditions you've never had in your life before.

00:50:28

Participant 1 (registered as a caregiver)

And the acne should not be understated, actually. The acne should absolutely not be understated, especially when we're considering diseases that include pediatrics. The acne can be severe to the point where dermatologists are talking to patients about doing things like, what's the retinol one? Extreme medicines to try to reverse acne. It's not like a zit here or there, so it's like cystic acne.

00:50:57

Moderator, RTI International

Others want to talk about drawbacks of Orencia, or some of the other drugs that are used to treat these conditions? We've been talking a lot about the different drugs, the benefits and challenges, and I want to talk now about when considering the different medications for these conditions, what factors matter most to patients? Again, when considering a potential medication for these conditions, what factors matter the most to the patients? **[Participant 2]**.

00:51:47

Participant 2 (registered as a patient)

For me, the very first one is always going to be how long it's been out, and how well it's been tested, kind of as a pairing. I want to know that these medications are well researched and that we know what the long-term effects are going to be on a human being. The second is taking a broad look at the potential side effects and cross-referencing with things I already know about my own health history and the history of my family. I try to skip over anything that has a side effect that is linked closely with a family health history, or my own personal health history. I recently had to skip a biologic because it could lead to a bowel tear if you have diverticulosis, which I do, so things like that. And then, of course, the cost. Am I actually going to be able to pay the copay? Am I going to be able to find something to cover that gap, if that gap is too big? Those would probably be my biggest considerations for any medication.

00:52:59

Moderator, RTI International

Thank you, **[Participant 2]**. **[Participant 6]**?

00:53:03

Participant 6 (registered as a representative of a patient advocacy organization)

Adding on to what **[Participant 2]** said, we often hear from our patients there's a lot to do with how they access the medication and what administrative burden is associated with it. So that's prior authorization, where it is on the formulary, if there's additional utilization management with step therapy. I know, **[Participant 1]** has mentioned, **[Participant 2]**'s mentioned, we want the patients to be able to decide with their doctor, and making that shared decision-making model is really important. And then **[Participant 2]** also mentioned the copay, so I'm not I'm going to get on my soapbox here and mention that copay accumulators and maximizers are really hurting patients, particularly with Orencia. We've heard that a lot from a recent campaign that we've run.

00:53:51

Moderator, RTI International

Others, what really matters to patients, the factors that matter most to patients when considering a medication? **[Participant 5]**.

00:53:59

Participant 5 (registered as a representative of a patient advocacy organization)

A lot of the survey work that we do, the things that come up most, number one is efficacy and then side effects, but then closely following, and in fact, this is top of mind for many patients, is what quote, "hoops" they'll have to jump through, so piggybacking on some of the conversation that's already happened around either formulary placement issues, prior authorization that they'll have to go through, cost, things like that. So that certainly is top of mind, particularly for those who are not biologic naive and have been through the rigmarole before. Side effects, and efficacy, and then, what we've already talked quite a bit about is route of administration and those kinds of things that matter a lot. Do you have an infusion center close by? If not, then maybe an infused drug is not going to be a good option for you. Do you have mobility issues in your hands, or some other challenges that are going to make self-administration difficult? I think those things matter quite a bit as well.

00:54:57

Participant 1 (registered as a caregiver)

People want to feel good. They want to feel good fast. And they want it to last, and they don't want it to be interrupted. And they want to be able to function day to day. Anytime I've ever talked about starting a biologic, the question is how long is this going to take to work for me, and how long is it going to last before I fail and have to go to something else? I failed Remicade after three years, failed Humira after two. You're looking for duration of response in these things. But again, the other thing is cost. It doesn't matter how great the medicine is, if you can't get it in a financially feasible fashion, it doesn't matter. And that's it.

00:55:47

Moderator, RTI International

[Participant 3], did you have a moment to also chime in on this, about what's important to you, what matters most when choosing a medication?

00:56:00

Participant 3 (registered as a patient)

I think, obviously, the first thing is well, any medicine that they [tell me about], I'll really delve into the possible side effects. And then I try to ascertain whether it's something that they have to list, or what the percentage is of people that actually experience some of those more serious side effects. That would be the first thing. As far as the time it takes, it's funny because Orencia, for me, took six months. We were just getting ready to maybe try something else, and then it clicked after six months. Then, of course, the third thing, and I've been fortunate as far as insurance goes, when I first started, I was on private insurance, which there's a lot more options, I think, or at least there were for me. But the cost, and for instance, Orencia this year, when I was changing to the Medicare Part D provider, no one in my area would agree to cover Orencia. And I realized that I could drive a hundred miles round trip to get the infusion, but frankly, I'd rather be able to give myself an injection at home. Fortunately, I have an incredible rheumatologist who was able to show my Part D provider that I chose that I had to have Orencia, and she did that without me even asking. She saw that it was turned down when I filled it out. Cost is really important. The $2,100, if you're on Medicare, out of pocket is still very hard, especially when you're on a limited income. Those are the main things I look at.

00:58:28

Moderator, RTI International

Thanks, **[Participant 3]**. **[Participant 4]**, I saw your head nodding when she mentioned the six months. What came to mind when you heard her say that?

00:58:36

Participant 4 (registered as a patient)

It took me six months as well before I really started to appreciate a good benefit from it. But then once it started to work, it really worked well.

00:58:45

Moderator, RTI International

It took a little while, okay. You've all provided a lot of helpful information so far. Next, let's talk about how well Orencia and other treatments for these conditions meet patients' needs. At the very beginning of our discussion, I asked you all to reflect on the most important aspects of rheumatoid arthritis, psoriatic arthritis, and poly JIA to have managed and to have treated. Aside from the aspects that you already shared, what other medical needs related to these conditions are important to you, your loved ones, or patients you advocate for? Again, thinking about the different aspects of these diseases to have treated or managed, aside from what you've already mentioned, what other medical needs related to these conditions are important to you, your loved ones, or patients you advocate for? **[Participant 5]**.

00:59:52

Participant 5 (registered as a representative of a patient advocacy organization)

I'm not sure if this is directly relevant to your question, or maybe a little tangential, but I'm going to shoot for it. A thing that we haven't talked about yet that we hear so often, and we've done a lot of survey work and focus group work and patient interviews around this, is the need for care coordination, because most patients with autoimmune arthritis have either multiple providers to help manage that condition alone, and/or multiple providers to manage comorbid conditions. So the need to have not just streamlined actual administration of care coordinated, which of course is important, but also what I would call quarterbacking. We've heard that a lot from patients, that if I'm seeing my endocrinologist and then I go see my rheumatologist, and my rheumatologist asks, "Oh, I see there's this treatment change from your endocrinologist, why did they do that?" Well, I don't know, I'm not a doctor. We hear that a lot, and the need for better actual medical care coordination across all of the comorbidities, in a word, whole-person health.

01:00:57

Moderator, RTI International

That makes sense. So help managing all these other conditions that the patients have as well.

01:01:04

Participant 5 (registered as a representative of a patient advocacy organization)

And making sure they all work together. The medications, the treatment plan, that they're all aligned.

01:01:16

Participant 1 (registered as a caregiver)

I don't necessarily know if access would fall into play here. I'm trying to think about your question, and I think it's been mentioned before. I think it was **[Participant 3]** who actually mentioned this a second ago, is access a lot of things people need. I'm in a part of the country where access is a major thing for people's health care, and when you have rheumatoid arthritis, you're dealing with an underserved field of medicine as is, there are not a ton of rheumatologists, so access is a big thing with patients' health care that they're looking for. They don't want to have to drive a hundred miles to and from to try to get a single medicine.

01:02:08

Moderator, RTI International

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

01:02:13

Participant 5 (registered as a representative of a patient advocacy organization)

One other thing I was thinking about, this goes back to something I think it might have been **[Participant 3]** who mentioned this earlier, about the lifestyle factors that are so important for disease management as well. Obviously, there's the clinical management, but then self-management aspects, and how "movement is medicine," that term that we use a lot, but we find a lot of patients, and we've done survey work here, too. As you can tell, we do a lot of survey work because we want to understand what our patients are experiencing. For those who don't engage in physical activity, a lot of it is fear. I don't want to make it worse. If I'm in pain, it's intuitive to think that if you move, that it is going to make it worse. It's counterintuitive to think that if you move more, that it's going to make it better. And going back to access, to effective self-management programs that are specific for people with arthritis. Exercise programs are one of those, and certainly there are others, but I think that's a really critical wraparound piece to overall disease management. And a barrier, when people feel like they will hurt themselves if they move.

01:03:17

Moderator, RTI International

[Participant 5], I'm pretty sure I know what this is, but just so I don't make assumptions, can you unpack for me what "movement is medicine" means?

01:03:24

Participant 5 (registered as a representative of a patient advocacy organization)

I will phone a friend and ask **[Participant 1]** as the rheumatologist, but what I will say is, just from my standpoint, there are, we call them AAEBIs [Arthritis-Appropriate, Evidence-Based Interventions] for short, but they're arthritis-specific, evidence-based, self-management programs, there are ones, Walk With Ease, there are Enhance Fitness that the YMCA [Young Men's Christian Association] runs, there are aquatics programs, and specific programs that are indicated to be proven to help people with arthritis, and certainly physical therapy programs as well for that, but **[Participant 1]** can probably speak more from a clinical standpoint. Sorry to put you on the spot, **[Participant 1]**.

01:03:59

Participant 1 (registered as a caregiver)

No, it's okay. Essentially, it's exactly what it sounds like. Not to sound like I'm being hoity-toity or something, but it literally is movement is medicine. She's right, there are a lot of different programs that do this, but essentially, the idea is that patients will lose disease control with decreased activity, that leads to increased stiffness, that leads to increased steroid use or different medication use, and then it leads to increasing falls and frailty, so the idea of movement is medicine is trying to keep people going so that their muscles maintain strength, and takes pressure off joints, and then doesn't force them into a place where they're changing their therapies all the time, and lead to loss of disease control. I don't even know how you'd really describe it. It's a saying, but it's also a thing because there are types of physical therapy and things you can plug people into that help them move.

01:05:07

Moderator, RTI International

[Participant 2]?

01:05:10

Participant 2 (registered as a patient)

We've touched on this a little bit, but I want to reiterate the mental toll of living with these diseases, and how that shifts when you get control with a medication that's helping you. You can go from feeling very depressed, and rightfully so, because you don't have the symptom control, you can't do what you need to do, you're feeling terrible all of the time, you're exhausted, your thoughts don't even seem to be your own, because you can't even remember your child's name sometimes, and that feels pretty ridiculous in your mid-thirties. And when you're depressed like that, it gets really hard to do the things that you should be doing for yourself that will make you feel a bit better. If it won't conquer the symptoms, it will help. It snowballs and piles and avalanches on top of itself. And that shift, that once you see the light. I can do some things today that I couldn't do yesterday. And that starts to break through that cloud of depression and the deep anxiety that, "I'm going to need to be in a wheelchair soon if this doesn't turn around," which is something really real that people face. I don't think you can underestimate how heavy that is and how huge it is in a person's ability to live a healthy life.

01:06:44

Moderator, RTI International

Thanks, **[Participant 2]**. I saw a lot of heads nodding while you were talking. **[Participant 3]**, go ahead.

01:06:52

Participant 3 (registered as a patient)

Talking about the motion and exercise, one of the things that hit me as we were all talking is motivation, and I have I always like to say the best rheumatologist, but that's for me. All of this stuff is inner motivation, and it's a mental health thing, but there are really, to my knowledge, no programs out there really designed to keep people motivated individually. I go to physical therapy every once in a while, I'm very fortunate to do that, and they're really good. Each one, each type of thing you go to is motivating, but there's not an overall umbrella of I want to feel better today, whether you're feeling a little hopeless, or I can't even get the whatever it takes to get out and exercise, it doesn't matter what it is. To my knowledge, there's not an organized umbrella that people can go to.

01:08:18

Moderator, RTI International

Thanks, **[Participant 3]**. And **[Participant 4]**.

01:08:23

Participant 4 (registered as a patient)

And I think this goes along with what **[Participant 3]**'s saying, it's a lack of psychosocial support in general that I can say I'm fatigued, and a person that does not have an autoimmune disease thinks, "Oh, drink some more coffee." I could drink ten pots of coffee, and I'm going to be fatigued. It's a different type of fatigue. So I think having that lack of psychosocial support from other individuals that have these type of disorders can make it really challenging to have someone really appreciate what you're going through.

01:08:56

Moderator, RTI International

Thanks, **[Participant 4]**. For the next couple questions, I want us to reflect on your experiences with these conditions, with the treatments for these conditions. And that could include Orencia and other medications to treat these conditions, as well as other treatments, like physical therapy. Let's think about all the different treatments. First question for you is, what important aspects or needs of this condition are being addressed today or at least partially being addressed by the existing treatments? And we'll talk about what's not being addressed in a moment. But for now, at least, what is being addressed by the treatments that are out there, either pharmacological, like Orencia and others, or non-pharmacological, like physical therapy? What is being addressed? Does that make sense? **[Participant 4]**, go ahead.

01:10:08

Participant 4 (registered as a patient)

I think that slowing down progression of joint erosion is one thing that's being well managed.

01:10:20

Moderator, RTI International

So, slowing the disease progression. **[Participant 2]**.

01:10:24

Participant 2 (registered as a patient)

I would also add, I think there is a lot of focus on the inflammatory nature of these diseases, and rightly so, that's the easiest thing to see. I wonder, though, having had my inflammation controlled and still struggling with fatigue and brain fog, if maybe that's not the whole picture.

01:10:52

Moderator, RTI International

Others, what's being addressed, either fully or partially, by treatments available today? **[Participant 1]**.

01:11:02

Participant 1 (registered as a caregiver)

I think **[Participant 4]** is right. Structural damage is absolutely being addressed. There's going to be a population of people that, when they're gone, I'll have younger rheumatologists come to my practice, and they will never know what bad rheumatoid looks like. They'll have no clue, because it won't exist anymore, provided we still have the ability to give people these medicines. So not only is it addressing structural disease, but it's addressing functional decline, I would say. Mobility and general independence is being addressed through these medications. And then **[Participant 2]**'s right, too. We're trying really hard with these medicines to address systemic inflammation. The hard part is how well does that translate to what people experience? But she's absolutely right. You can get patients' CRP under control and go, "Wow, I'm doing a really good job as a rheumatologist." Then you walk in the room and say, "How do you feel?" And they go, "I'm tired." And **[Participant 4]**'s right. It's not a tired that you can cure with coffee. You cannot cure it with amphetamines. It's like this fatigue comes from a terrible place. And so that's maybe a little underserved right now. I have hope we're getting there.

01:12:20

Moderator, RTI International

Thank you, **[Participant 1]**. From others, [about] what treatments are addressing today? And again, they can be drug treatments, or they can be non-drug treatments. Hearing none, I'll move to the other side. We talked about what was being addressed, let's talk about the flip side. What important aspects or needs of this condition are not being addressed today by existing treatment options? **[Participant 3]**.

01:12:58

Participant 3 (registered as a patient)

One of the things that, it's been critical for me, so maybe for others it wouldn't, and it's diet. I started a rabid research of everything that might affect my RA. And in my particular case, my rheumatologist partnered with me on it when I kept pursuing it, and one of the things I had discovered, for instance, is gluten. Actually, when I gave up gluten, and who knows if it's really connected, my Orencia jump started almost immediately. I think they've sort of proven, **[Participant 1]** would know, that they are really studying the connection between the gut and RA and the brain, and so diet, to me, is a major thing that I wish they would emphasize, because I think it could have, well, for me it has had an effect.

01:14:20

Moderator, RTI International

Thanks, **[Participant 3]**. **[Participant 2]**, any important needs that are not being addressed today?

01:14:27

Participant 2 (registered as a patient)

I think, and this may be because I'm in an underserved rural community, but I don't think that the rheumatology community is offered enough complementary therapies. Diet is certainly some place we can cut inflammation. Physical therapy, we've also mentioned, that's been really helpful to me once I finally accessed it. Before I accessed it, the attitude I met was, you have rheumatoid arthritis, of course your muscles aren't feeling good, and your joints hurt. Of course they do. But through physical therapy, I was able to learn, and through occupational therapy [OT], which I know very few rheumatology patients who have had occupational therapy offered. It's huge. They can teach you how to protect your joints. There's so much that we could be getting as patients, but it seems to be we focus on the drug treatment, our time being limited, the doctor's time being limited, and we aren't often referred to those other things. I don't know if it's because I'm on Medicare. I really don't know what the problem is, but I know there's more help out there that we're not getting.

01:15:45

Moderator, RTI International

[Participant 1]?

01:15:47

Participant 1 (registered as a caregiver)

This is probably not going to help anybody, but I can tell you what that is. That is what you're observing in real time, happens when we find medicines that are really helpful. We would have done that a lot in the eighties, because that was what we had, but when we've gotten all these good medicines, you're right, a lot of those things that are really helpful. I just referred four people to OT this morning. But we have forgotten that those things are valuable and complement our medicines. And it's a testament to how well the medicines work because we're so reliant on going, "Oh man, we need to get them on these medicines." But you're right, a lot of those other complementary things need to be addressed, and there's definitely a shortcoming of that in the rheumatology community. And you can even see that at the national conference levels. I went one time to focus on what could be offered from a dietary perspective, and there's some people out in California doing some studies on that, but it's really hard to do those studies because they're poorly funded, and they wither away and die wherever they are, so some of those complementary things absolutely have fallen by the wayside because the medicines have gotten so good.

01:17:01

Moderator, RTI International

So even with the benefits to the medications that **[Participant 1]** was alluding to, are there still some major gaps in treatment or concerns that remain, even with current available treatment options? Again, some major gaps in treatment or concerns that remain even today, even with some of the treatments we have. **[Participant 2]**?

01:17:28

Participant 2 (registered as a patient)

I was diagnosed in 2014. I came into this during the time of all of these miracle medications. I'm still disabled. That's still my reality. So even though they're there, even though they are potentially something you can access, the road to get there still leaves some of us lost and disabled. And I don't think we can lose sight of the impact that that has. I'm meant to be a scientist. Not a disabled lady with rheumatoid arthritis.

01:18:12

Moderator, RTI International

[Participant 2], I don't want to put words in your mouth, but is one of the gaps that we can't reverse some of the things that happen in the body, some of the damage?

01:18:22

Participant 2 (registered as a patient)

Absolutely. That is one of the gaps. One of the things I'm waiting for is for people to get really great with hands because my hands are a wreck. I would really like to straighten them out without losing strength or dexterity. Right now, I've been given the option to have strength in one and dexterity in the other, and that is a hard thing to make a lifelong choice about in your forties. What do you want?

01:18:51

Moderator, RTI International

Thanks. **[Participant 5]**.

01:18:55

Participant 5 (registered as a representative of a patient advocacy organization)

We hear that a lot as well, and that oftentimes, even if your disease appears well-controlled from your labs and scans and things like that, you could still be in a significant amount of pain and have mobility issues that way. So that's one thing. Another is I think there's a lot of, we have this data, but I think there's probably a lot of external data as well, showing how many medications patients often have to cycle through, either when they're biologic naive because it takes sometimes two to three times to try to find something that works for you, but also, you may be on a medication for a decade, and all of a sudden it stops working for you. And we have some of those data points as well, including for Orencia from a survey that we did a few years ago. And, so that, I think, is a consideration, thinking about long-term impacts, and then thinking about the most common types of requests and calls that we get in through our helpline. A lot of the questions people have are around efficacy of some complementary medicines, supplements. You hear all these things about diet, what's separating fact from fiction is huge. CBD [cannabidiol] comes up quite a bit. We get a lot of questions about that. People are trying to find other ways to manage pain, fatigue, other things like that, so I think there's still a huge unmet need in those spaces.

01:20:21

Moderator, RTI International

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

01:20:26

Participant 1 (registered as a caregiver)

I was going to piggyback off **[Participant 2]** there, which is, she's mentioned a couple of things about being in an underserved area, and she was diagnosed in 2014, and one, we are missing the ability to reduce damage and to fix damage that's there, but also, one of the things that is really important with this disease is being quick and having access. The problem with these medications is that if I want to start somebody on them, you're wasting time and that time is not like, oh, we're wasting time. It's like MacGruber-style, the bomb's ticking, the timer's ticking on the bomb. You have to give people these medicines quickly and efficiently. And this may be branching into something different, but I think we all support CMS' goal of making or improving the affordability of these medicines under the Negotiation Program, but things like Orencia, you have to be careful about how negotiating these prices can lead to unintended consequences. Specifically, if it's not able to be done feasibly in offices, you're going to limit access to people who are in rural areas. They're not going to be able to get medicines quickly in their doctor's office. They're going to be shuttled out hundreds of miles to a big center, where ultimately they're going to pay a lot more, Medicare's going to pay a lot more money to be infused at a big center. We have to preserve access, we have to preserve affordability, and we have to limit the administrative burden of these medicines, so people can get these quickly, and so we can do as very best as we can to prevent the damage to joints that right now is irreversible.

01:22:32

Moderator, RTI International

[Participant 6].

01:22:35

Participant 6 (registered as a representative of a patient advocacy organization)

I was at an event where both Dr. Oz and Dr. [Marty] Makary [Food and Drug Administration Commissioner] were speaking, and I can't remember which one of them alluded to this, but we're going down the innovative pipeline to precision medicine, so I think, something that we are missing in the space, but we're working towards, is getting the right medications that meet the right person based on their lived experience, genes, things like that. It's exciting that things like that are coming, but they don't currently exist.

01:23:05

Moderator, RTI International

Thank you. One thing I also wanted to ask that I forgot, which is, do you feel that certain medications or treatments address medical needs to a greater or lesser extent than others? Again, are some medications or treatments addressing medical needs to a greater or lesser extent than others? **[Participant 2]**?

01:23:30

Participant 2 (registered as a patient)

I think overall, all of these disease-modifying and biologics are addressing the same sort of need. I think the really important thing to note is that the drug that meets my need might not be the one that meets **[Participant 3]**'s need. And she might take something different from what **[Participant 4]** needs. It's all so individual, and until you start on that journey and put that patient with that medication, you don't know. I'm sure **[Participant 1]** could agree with that. You don't know which patient's going to do well on which medication.

01:24:07

Participant 1 (registered as a caregiver)

No clue.

01:24:08

Participant 2 (registered as a patient)

Not that simple.

01:24:11

Moderator, RTI International

[Participant 4]?

01:24:12

Participant 4 (registered as a patient)

And going along with that is not allowing the rheumatologist and the patient to make that decision, but being dictated that you have to go through step therapy and basically starting everyone on methotrexate because it's the oldest and least expensive, and that is one of the biggest frustrations, you have to try this next because that's how it goes, and it's like, no, that's not the medical decision, that's the third-party payer decision.

01:24:44

Moderator, RTI International

One question I meant to ask earlier, and we were talking about infusion clinics versus administering the medication at your home. One question I wanted to ask you all was, how much did the location of the therapy, in a clinic, infusion site, or at home, factor into your willingness to try a therapy when you're starting initially, or maybe when you're starting, or thinking about changing a therapy? How much does the location of therapy factor into your willingness to try or change to a new therapy? **[Participant 2]**?

01:25:30

Participant 2 (registered as a patient)

I can say for me, there are two sides to that. I've already mentioned that I felt more confident getting my infusion in an infusion center because I knew there would be help if I encountered any side effects. I'm also a rural person, so my trip to infusion is four hours round trip. That is certainly a big barrier. Weighing those two things against each other, honestly, it was a bit challenging, but knowing that I'd already failed so many other medications, you have to flip that coin and give it a try also.

01:26:11

Moderator, RTI International

Others, how much did the location of therapy factor into your decision of moving to a therapy or starting a new therapy? **[Participant 1]**?

01:26:25

Participant 1 (registered as a caregiver)

I think if you're looking particularly at infusion centers, I can speak about this from the perspective of multiple angles. I run an infusion center, an independent infusion center. I've had to get infusions at independent infusion centers, I've had to get infusions at hospitals, I've had to send people to hospitals. By far, independent infusion centers are the most efficient. They have the ability to offer more access to patients, which is easier, and it leads to higher compliance. And also it can be personalized. I know that sounds corny, but when you have patients who come in, offering them a bottle of water and crackers and a warm towel means a lot more than when they go into a hospital and somebody's getting plasmapheresis next to them, and they're there for their Orencia. And they feel more like a number in a cancer setting than somebody who's being thought of as the person, and how are we going to make you feel better in this setting. But then also, it improves access for people, so you think about that for patients. Right now, I'm literally trying to figure out how to get a guy, 90 miles from me, an infusion somewhere closer to him. And unfortunately, I'm probably going to have to say either we do something different, or you're going to have to drive to come get this medicine here. And that shouldn't be what governs my ability to put somebody on medicine. So we have to do things to preserve and encourage independent infusion centers to exist because it continues to give access to patients, and it continues to offer a model that functions better for the patient.

01:28:23

Moderator, RTI International

[Participant 1], the answer may be, it depends on the patient, but all things being equal, do your patients prefer at home or going to an infusion center?

01:28:35

Participant 1 (registered as a caregiver)

I think it's fifty-fifty, but if they have to get an infusion, they don't want to go to the hospital and get it. I can tell you that they do not want to go. If they say, "I'd rather get an infusion because I'll be monitored," and then I say, "Okay, well, you have to go to the hospital to get it," they'll say, "Okay, I'd rather just inject it myself."

01:28:57

Moderator, RTI International

Okay, thanks, **[Participant 1]**. **[Participant 2]**.

01:29:00

Participant 2 (registered as a patient)

I wanted to also mention that for me, the infusion center has added another coach to my health care team. Over the years, they have caught many of the balls that have been dropped as my doctors changed because we've had a lot of caregivers come and go from the practice that I'm in over the last six years, particularly. So having those nurses looking at my care every month was one of the reasons that major things did not go wrong for me, so I find them valuable there, too.

01:29:43

Moderator, RTI International

Great. But the distance was a downside, as you mentioned. You said two, four hours round trip, I believe? Any other parts about that? And then we're actually wrapping up, we're going to finish a little early, and I want to ask one final question of everyone.

We're almost done, but before we part ways, I wanted to give you all an opportunity to summarize your thoughts on the importance of Orencia for patients, or to raise any topics that you feel like we didn't adequately address today or discuss today. Do you all have any final thoughts for me about Orencia, and then the conditions that Orencia treats, and other medications that treat these conditions that you feel is important to share with CMS before we adjourn? **[Participant 6]**?

01:30:31

Participant 6 (registered as a representative of a patient advocacy organization)

Thank you for this opportunity. I haven't engaged in a roundtable before, but I felt compelled to this year, considering how many autoimmune drugs are being reviewed by CMS, and how this concerns our organization and patient populations, and how we see HHS [Department of Health and Human Services] messaging impacting drug development, like we saw earlier this year. Companies pulled out of Phase III trials for Epstein-Barr vaccinations, and Epstein-Barr is a precursor to several autoimmune diseases, so you can understand our sensitivity there. In the case of Orencia, this product has incoming biosimilar competition, and targeting drugs that have incoming competition can discourage investment in biosimilars and other generics for autoimmune diseases, which makes it more difficult for alternatives to enter the market and can cause companies to withdraw their investments into autoimmune disease treatments. I put in the chat earlier, we're really underfunded, under-researched, so any companies withdrawing their investments is really going to impact our patient population. And then biosimilars can also help cut costs by 30% for patients, which can lead to increased medication adherence and easier accessing their drugs. I wanted to share that today. Thank you.

01:31:45

Moderator, RTI International

Thanks, **[Participant 6]**. Others want to share some final thoughts? **[Participant 1]**.

01:31:54

Participant 1 (registered as a caregiver)

I agree with what you just said from the standpoint of I've never participated in a roundtable before, but again, I felt compelled from a couple of angles, I'm a sitting board member for a state rheumatology society, and I run an infusion center, and I take care of increasing numbers of patients, and this is a very worrisome negotiation that's going on for our medications. And what I mentioned earlier is that we all support lowering drug costs. I think that is huge. But the statute to implement this maximum fair price is going to create a problem downstream. If it affects our ability to obtain and administer medications under Part B, then what we're going to see is massive margin compression at infusion centers, and we're not going to be able to offer those medicines to patients. And what that's going to do is that's going to inhibit already limited access in an underserved field of medicine. And when that access is limited even further, and the care gets shifted to places like the hospital, you're going to see one of two things that happen, and we've seen this already start to happen. The first thing is that patients are going to end up, their insurance companies are going to pay more because hospitals are going to require higher facility fees. But then the other thing that's going to happen is there are going to be gaps in patients' care because they're going to have that limited access, and they're not going to be able to get there. And with limited continuity in care for our patients, all those manifestations of rheumatoid arthritis that we discussed earlier in psoriatic arthritis, these extra-articular things, you run the risk of seeing more of that, and if you get more interstitial lung disease and more blood problems, then you're going to end up with a higher burden on the health care system because people are going to be seeing hematologists, pulmonologists, they're going to be hospitalized more frequently. We have to be very careful about this reimbursement model and not cause so much margin compression that's going to force independent infusion centers that provide such good access to patients. We have to be careful that we don't lose that and force cost somewhere else. It seems up front this is great, we're going to save a bunch of money, but at the end, you're going to limit access, you're going to compress care, and it's going to force it somewhere else. The money's going to come, somebody's going to have to pay for it somewhere else, and we have to be careful about that.

01:34:53

Moderator, RTI International

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

01:34:59

Participant 2 (registered as a patient)

I wanted to speak to the overall cost of living with rheumatoid arthritis and what that looks like if the right drug for me isn't available. If the right medication isn't available, then I need a lot more joint replacements. I've already had some, the right medication not being available in time is why I'm on disability. That is a loss of an entire career. I try not to think about those numbers. They're big. It's had a huge impact on my life, on my ability to raise my family the way that I wanted to, on my ability to contribute the way that I saw myself contributing as a young person. I think that you can put a price on the drugs, but you cannot put a price on what they do for the people who they help.

01:36:02

Moderator, RTI International

Thanks, **[Participant 2]**. I wish I was there to give you a hug. Thank you for that. Anyone else?

01:36:08

Participant 1 (registered as a caregiver)

You can do even better. You can help make this policy effective for people like **[Participant 2]**. That's where you are. This is better than a hug. This is making these medicines available to be delivered to her sooner and help preserve her function. That's what your role is in this, and that's why we're all here right now.

Closing Remarks

01:36:31

Moderator, RTI International

Thank you. Does anyone else have any final thoughts before we adjourn? I want to thank you all for participating today. I learned a lot. My grandmother had rheumatoid arthritis, which is one reason why I wanted to moderate this roundtable, and I learned a lot more about her condition than I knew even before she passed away, before all these treatments came out in 1998 that **[Participant 1]** was mentioning. Appreciate you all taking time to talk with us today, and your experiences and input were very valuable, and will help inform CMS' negotiations for Medicare pricing for Orencia.

As I mentioned, CMS staff were listening in today to the roundtable and will be able to bring your perspectives back to the team. **[CMS Staff]**, I want to see if you have any final thoughts before we adjourn.

01:37:22

CMS Staff

I want to take a moment to thank everyone so much for sharing your experiences and knowledge with us today. You've given us a lot to think about and to consider, and we're really grateful for your perspectives and participation, so thank you.

01:37:39

Moderator, RTI International

Great, thanks, **[CMS Staff]**. If you have any questions following today's session, you can submit them to the mailbox, which should be in your welcome packet. That's IRARebateAndNegotiation@cms.hhs.gov with the subject line "Public Engagement Events." And again, thank you all for your time today. You all take care.

===== 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 caregiver who has experience caring for an individual who is treated by the selected drug, with the conditions treated by the selected drug, or other treatment(s) or drug(s) similar to the selected drug for those condition(s)

Declared Conflicts of Interest	
No	Receipt of financial payments (e.g., gifts, funding, research support, honoraria, travel, or other expenses) from 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.

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 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.
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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.

Participant 3: 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 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.
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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.

Participant 4: 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.
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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.

Participant 5: 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.
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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 6: 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.
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