Transcript: Rexulti 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

Thank you, everyone, for coming today. I'm **[Moderator]**, and I'm from RTI International. I also want to introduce my colleague, **[Secondary Moderator]**, and you may hear from her during the course of the conversation today. The Centers for Medicare & Medicaid Services, which we'll refer to by their acronym CMS throughout the event, is convening this patient-focused roundtable event, as well as others, as part of the Medicare Drug Price Negotiation Program. The information shared during these roundtable events will help CMS understand patients' experiences with the conditions and diseases treated by the selected drugs, patients' experiences with the selected drugs themselves, and patients' experiences with other drugs that are used to treat the same conditions as the selected drug. The information shared during these events will also help CMS to 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 the conversation today is to hear from you all, a group that may include patients, caregivers, and patient advocates. And we want to hear about your experiences with the conditions and diseases treated by Rexulti, and that will include major depressive disorder, schizophrenia, and agitation associated with dementia. We'll also talk about Rexulti itself, and other medications used for the same conditions. I really want to emphasize that our focus today will be on the patient experience. If you have input that you want to share on other topics related to the Drug Negotiation Program that are not directly focused on the patient experience, we ask that you send that input to the mailbox IRARebateAndNegotiation@cms.hhs.gov instead of using the time today in our discussion.

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

CMS Remarks

00:02:31

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.

00:04:23

Moderator, RTI international

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

00:04:38

CMS Staff

Hi everyone, good afternoon and welcome. My name is **[CMS Staff]**, I'm with the CMS Drug Price Negotiation Team, and we also have some other CMS staff on the call today as well, and we 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 for participating today. We are really looking forward to hearing more about your experiences during this discussion, and I will note that we are going to go off camera now, so that you all can focus on discussion, but wanted to say thank you first, so thank you.

Housekeeping

00:05:17

Moderator, RTI international

Thank you, **[CMS Staff]**. Before we begin, I have a few more housekeeping items and some ground rules so that everyone knows what to expect.

Technical assistance. If you get disconnected, please attempt to rejoin. If you cannot connect, please reach out to IRADAPStechsupport@telligen.com, which is on the screen.

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

Video recording. As you saw, we are recording today's event. These recordings will not be shared publicly. These recordings will only be used for internal program documentation and to produce redacted transcripts for public release, consistent with Federal privacy guidelines. By participating today, you are consenting to be recorded for these purposes.

We hope that you will contribute your perspectives throughout the conversation today. However, if there are questions you don't feel comfortable answering, you don't have to answer.

Background. Please minimize any background noise by silencing your cell phone or other devices if you haven't done so already. Also, we ask that folks mute themselves when you are not speaking.

And video. Thank you in advance for keeping your video on throughout the conversation.

We have reserved two hours for the discussion today, so it's a marathon. However, it's possible we may not need the full two hours to discuss all the planned topics. If that happens, we can let you go a little bit early. I do have a discussion guide in front of me to help keep me and keep all of us on track. We do have a lot of topics to cover, so I may need to redirect the conversation, or cut a conversation short at times to make sure that we're able to cover everything, and to ensure that all participants have ample opportunities to share their perspectives.

If you need to step away during the course of the discussion, that's totally fine. Just turn off your camera, turn off your microphone, and rejoin as soon as you're able. You don't need to tell me you'll be walking away from your computer, return the discussion when you can.

And then, speaking. Please try to speak one at a time. I may occasionally interrupt folks if two or more people are trying to talk at the same time, so we want to be sure everyone can be heard and that everyone's comments are documented accurately. Please use the raise hand feature in Zoom to indicate you would like to speak. That'll help us know you'd like to add to the conversation.

And finally, the chat function. We're hoping that everyone will focus on the oral discussion, but you can also add 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 before we need to move on to the next question, or if you think of something that you want to add later on. If that's the case, be sure to note what question or topic you're sharing about.

Unless there are any burning questions, I'd like to get us underway with the conversation and with some introductions.

Hearing no burning questions at the moment, I'd like to go around the virtual room and ask each of you to introduce yourselves briefly. As part of that introduction, I'd like for you to share your first name, and share whether you'll be sharing experience as a patient, a caregiver, or from the experience of a patient advocate, and the condition that Rexulti treats that you have experience with.

[Participant 1], you are first on my screen, so I'd like to get started.

Discussion

00:09:42

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

Hi, everyone. My name is **[Participant 1]**. I am speaking from an advocacy perspective, and I work with an advocacy that is dedicated to advancing mental health research, reducing stigma, and improving access to effective treatments for individuals living with serious mental illness. I am here to represent the people living with schizophrenia, specifically, because our headquarters are uniquely located in a community-based day treatment center that serves approximately 150 individuals living with schizophrenia, and this gives us daily direct exposure to the realities of living with serious mental illness, not in the abstract, but in the lives of real people who are working every day to maintain stability, independence, and dignity. Is that good?

00:10:37

Moderator, RTI international

That's excellent, **[Participant 1]**. Thank you. I'm going to ask about the patient experiences, so I'm very glad that you can share the lives of patients with us today. I'll go ahead and go on to **[Participant 2]**, your name, your experience as a patient, caregiver, or patient advocate, and what condition or conditions you'll be speaking about.

00:10:57

Participant 2 (registered as a representative of a patient advocacy organization)

Good afternoon, my name is **[Participant 2]**, and I represent a perspective related to schizophrenia and related spectrum disorders, including psychosis. From an advocacy perspective, one of the overarching goals that I have to share throughout this session is the unmet needs and the barriers that stand in the way to treatment, survival, and recovery for persons and families impacted by schizophrenia and related disorders.

00:11:32

Moderator, RTI international

Thank you, **[Participant 2]**. We definitely have questions on those unmet needs to talk about today. **[Participant 3]**, you are next on my screen, so would you mind taking the next introduction?

00:11:53

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

I'm **[Participant 3]**. I represent an organization that deals with advocacy on behalf of mental health, particularly focused in rural areas. Schizophrenia and major depression disorder are two things that are of huge concern, and we approach it from not only reducing stigma, but also access to appropriate therapies.

00:12:26

Moderator, RTI international

Thank you, **[Participant 3]**, for the introduction. **[Participant 4]**, you are next on my screen, so do you mind doing your intro?

00:12:33

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

Hi, I'm **[Participant 4]**, and I'm also representing a patient advocacy organization. I'll be focused on depression uses for Rexulti, and I would say ditto to everything that's been shared so far.

00:12:55

Moderator, RTI international

Appreciate everyone being willing to bring forward the patient voices today. And I think, **[Participant 5]**, you may be my last person on my screen, but not the least.

00:13:07

Participant 5 (registered as a caregiver)

I'm **[Participant 5]**. I am here as a former care partner and a current advocate. I lead a small patient advocacy organization called Voices of Alzheimer's. And I'm here to speak about the needs of the Alzheimer's community.

00:13:28

Moderator, RTI international

Thank you, **[Participant 5]**, for being here today. As you heard from the introductions, we have people with experience related to all three conditions that are treated by Rexulti. We realize that patient experiences may vary by condition, so as we go through the conversation today, if you wouldn't mind reminding us throughout what health condition you're speaking to, to reorient the group. As we get into our first question, I know we're here to talk about Rexulti, I first want to really focus on the patient experience here. Thinking about the different ways that major depressive disorder, schizophrenia, or agitation associated with Alzheimer's and dementia affects patients' lives, what would you say are the most important aspects of the condition to have managed or treated? And they can be short-term things or long-term things. **[Participant 2]**, why don't you kick us off?

00:14:46

Participant 2 (registered as a representative of a patient advocacy organization)

From the perspective of schizophrenia, there is no one-size-fits-all treatment. Patients typically cycle through multiple medications before actually finding one that works for them in particular. The risk-benefit-reward options that are considered are typically multifaceted in terms of what can be tolerated, what overall profile of side effects can be managed, and typically, there are not straight trade-offs. There's a conversation that needs to occur between the provider, the individual, and also the loved ones in that person's community. This is, typically, the difference between access and coverage overall, the benefits need to outweigh what those alternative impacts might be in order to get the actual adherence that could lead to effective treatment, and ultimately toward recovery.

00:16:02

Moderator, RTI international

And **[Participant 2]**, before we move on to others, you mentioned a few things that were important for patients. You mentioned tolerability, side effects, and effectiveness. Could you comment on any of those, about the importance to the patients you serve and advocate for?

00:16:18

Participant 2 (registered as a representative of a patient advocacy organization)

The overall patient population is varied, and many different treatments work differently for different individuals impacted. The important consideration is that there needs to be a distinct tolerability profile, such as lower sedation, reduced metabolic risks, overall profile in order to ensure that the desired impacts and efficacy are actually achieved. There needs to be a constant conversation in order to ensure that those are occurring, and this is a very vulnerable patient population and typically treatment-resistant, and finding a medication that works provides unbelievable opportunities to reconnect, to remove isolation, to remove all kinds of potentially negative and harmful health impacts. Once the treatment is actually identified, ensuring adherence and ensuring access are tantamount to any type of recovery that is the ultimate goal.

00:17:37

Moderator, RTI international

Thank you, **[Participant 2]**. And I'd like to stay with schizophrenia, although, **[Participant 5]**, I saw your hand go up first. **[Participant 1]**, I know you are representing schizophrenia today, as well as **[Participant 3]**. I'll start with **[Participant 1]** and then go to **[Participant 3]**, if that's all right?

00:17:52

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

What I wanted to say about Rexulti, and what makes it important compared to the other options, is that it serves a pretty specific and important role in the treatment landscape. In clinical studies, it demonstrated a 71% reduction in relapse risk, which is huge because relapse is one of the biggest problems, of course, with schizophrenia, because first of all, it might take someone five to ten years trying all different medications for schizophrenia before they land on one that's actually going to work for them. And if it's working, as **[Participant 2]** said, it doesn't have any side effects that are adverse the person wants to stop taking it for, if they stay on it, then they stand a much better chance of maintaining stability. But, the thing about Rexulti is this 71% reduction in relapse risk is huge as far as schizophrenia medication goes. Although people have tried numerous different medications, this one seems to be working for 71% of the people in the trial, so that's pretty big. Also, the patient-reported data shows that a lot of the individuals value Rexulti for providing symptom relief with less sedation and the emotional blunting that comes with a lot of the other antipsychotics. And as **[Participant 2]** said, again, that the things that we're trying to treat are the positive symptoms in schizophrenia, as well as the negative. The positives are, obviously, psychosis, and hallucinations, and all of those, and it does have an effect on them, but it also has less, or according to some of the individual responses, patient-reported data, it's less sedation and less of the negative symptoms and the emotional blunting compared to some of the older antipsychotics. Which obviously matters enormously for the daily functioning and quality of life for people. But the most important thing is that these people have gone through multiple different medications, and without success. And Rexulti may be the treatment that they finally land on that finally works. So, any barriers or hurdles to Rexulti is going to be harmful and potentially devastating for those that have been able to find stability.

00:20:49

Moderator, RTI international

I heard you say that, like **[Participant 2]**, it's an effective medication, avoiding relapsing, and treating the symptoms. I'll go ahead and go to **[Participant 3]** to see, what are the most important things from the people you serve to have treated or managed?

00:21:05

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

This is a combination of a lot of what **[Participant 2]** said, as well as what **[Participant 1]** was talking about specifically to Rexulti. We deal with mental illness in a rural setting, where everything is accentuated, all the challenges are accentuated in that you don't have access to a lot of therapists, and having a therapy that is relatively accessible, particularly as a small molecule, rather than anything else, makes a huge difference for people who often have to travel two hours to get to a physician, and much less so merely to be able to go to a pharmacy. And that it is a relatively successful drug for this very challenging set of diseases is extremely important.

00:22:12

Moderator, RTI international

All right, before we move to **[Participant 5]** and move to agitation, are there any other things that are important to have treated and managed related to schizophrenia, whether it's certain symptoms, impact on quality of life, flare-ups, worsening over time, those sorts of things?

00:22:31

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

I'll say, one thing of note that I really want to make clear to CMS is that if a person is on Rexulti, and stable, and if they, for whatever reason, lose their access—which is a high possibility, if the price is negotiated—if they lose that access, it's not an easy thing to just go back to the medication. Once they go off it, coming back onto it is not the same, because, I don't know, maybe **[Participant 3]** can speak about that science, but it's different, you can't just go back. It doesn't work as well. It's not as effective, and we've seen this in many of the people that we work with.

00:23:29

Moderator, RTI international

So, the importance of stability in their lives and maintaining stability.

00:23:32

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

Again, ensure that once they find the medicine that works, that they keep access to that medicine.

00:23:40

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

Yeah, non-interruptability.

00:23:43

Moderator, RTI international

Great. **[Participant 4]**, I see your hand, but I promised **[Participant 5]** the next comment here, and so **[Participant 5]**, I believe you're talking about agitation associated with dementia and Alzheimer's disease.

00:23:58

Participant 5 (registered as a caregiver)

I hope to. First of all, **[Moderator]**, I'd like to say that I'm honored to be in the company of such articulate spokespersons for their community. The agitation and psychosis related to Alzheimer's is a much smaller marketplace for Rexulti than other conditions. You may know that for a century, Alzheimer's has really not had effective treatment, and we are very blessed to have recently had three drugs approved by the FDA [Food and Drug Administration] which slow cognitive decline for the early stage of the patient. My wife was diagnosed in 2014, so I've had a 12-year journey with the disease and now lead this patient advocacy organization. Of course, the primary need for patients with Alzheimer's is help with their memory, and we're working, we have a wonderful pipeline of drugs in place, and we have these three early-stage drugs approved for treatments, but they only slow. We do not yet have any treatment that can stop, reverse, or prevent the disease. And my wife was actually in the very first clinical trial, this stage [phase] one trial of the first drug to be approved. I don't know if we can say drug names or not.

00:25:35

Moderator, RTI international

I have a whole series of questions on specific drugs, so you're welcome to say drug names.

00:25:41

Participant 5 (registered as a caregiver)

She was in the Phase 1 clinical trial for aducanumab, which was the first anti-amyloid drug to be approved for slowing cognitive decline in the early stage, so I know from personal experience the transformative power of treatment. I had hoped to keep **[Redacted]** at home for her entire journey with the disease, but in the late stage, like probably half of people with Alzheimer's, her agitation and psychosis became so severe that I could not continue to care for her. It was a danger for us both for her to be at home. Having access to treatment that would mitigate the severity of her agitation, of her psychosis, would have helped me to keep her at home. And that was probably the most difficult day of my life, beyond her day of death, was putting her against her will in a memory care unit. And that was solely because of psychosis and agitation. I think to have effective alternatives of treatment would be a tremendous benefit to us. And the thing I want to emphasize, and I know this is a combination, **[Moderator]**, of both FDA decisions and CMS decisions, but you're very involved in access, is that when we're diagnosed with a fatal terminal disease, it's a terminal condition, even though it's a long stage, we might make other choices than a non-terminal condition. But even though that choice might be a drug that might be somewhat more risky than would normally be available, we would like that choice. We would like for you to have confidence that, in consultation with our physicians, we will make a good choice. So, thank you. I think that's all I have to say right now. Did I cover all your...

00:27:58

Moderator, RTI international

You sure did, **[Participant 5]**. Thank you for opening and sharing your story today. I'll go ahead and go to **[Participant 4]**, I believe, speaking on behalf of major depressive disorder?

00:28:12

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

I will open by saying the majority of what I'm going to share is based on our Transforming the Definition of Wellness campaign, which is a ten-year initiative that we are now in year 11 or 12. We were waylaid a little by the pandemic, but we were inspired by the 21st Century Cures Act, and our goal is to develop a new adjunctive clinical outcome assessment that has patient-preferred outcomes for depression. Some of the things that that we've done along the way, in 2018, we conducted a survey, and got over 6,400 responses, and the survey was created by people living with depression to make sure we were asking the right questions, and some of the things that we learned from that is 49% of our survey respondents whose doctor had told them that their depression was in remission did not personally identify as being in remission. Speaking to what **[Participant 1]** was saying about anhedonia and emotional blunting. And to what everyone has been saying, 51% of the respondents said that their physical health was a reason for not taking their medication as prescribed, and that all too often they're told, "Well, do you want to feel better or don't you? These are the side effects. You have to accept them." I cannot tell you which side effects are acceptable and unacceptable, because that is individual to the person. Somebody who works with their hands or is an artist, movement disorders are right off the table for them. They may be willing to put on 30 extra pounds, whereas somebody else may not. I have a personal friend who has told me that sexual side effects are a non-starter for treating depression. And one quote from that survey, actually, this we hosted that same year, an externally led patient-focused drug development meeting at FDA, and I believe that's where this quote came from, but, "It took me four years to find a set of medications that got me to a baseline where I feel okay, so that I don't feel like stepping in front of the train every time it pulls into the station." So that, again, drives home the point that **[Participant 1]** was making about how long it can take people to find stability, and this isn't even addressing that anhedonia. This is a baseline. Other points from that survey that I'd like to pull out is that 91% of our respondents told us that their goal was to function as well as possible. And that 83% of them said that they define function as their ability to work, play, and connect with others. Pursuing hobbies and having community, in addition to being able to find meaning and purpose through their employment. And then, we asked them about 16 elements of wellness, and I'm going to call out four of them that rose to the top. The top being ability to be independent or act according to my own will. So meaning, I don't get an idea, but then the depression stops me from doing it [the idea]. Having purpose in life came second, so there's that work piece that we were talking about. The ability to get through the day, so there's that function piece that we were talking about, and then self-acceptance. So that was 2018, and in the time since then, we've been doing systematic literature review, expert interviews, and qualitative interviews with people living with depression, and, this is my last piece, the three domains that have risen to the top and are in the proposed measure that we have a draft of are resilience, understanding and control—so that being, I understand that I'm depressed, and I'm able to work with that depression—and having a positive focus, and then the fourth being, of course, that function, and being able to do what I want to do. Thank you.

00:33:19

Moderator, RTI international

Thank you, **[Participant 4]**, for bringing in a whole array of aspects that people with depression want to have managed or treated. Before we move on to delving into specific medications, does anyone else have an additional thought or comment related to what are the most important aspects of these conditions we're discussing today to have managed or treated? I'm going to go ahead and move on. The next question, we're going to use the chat, so get your typing fingers ready to go. Let's turn our attention to patients' experiences with the medications for major depressive disorder, schizophrenia, and agitation associated with dementia and Alzheimer's disease. Here's the question for the chat. What medications, if any, have you, your loved ones, or patients you advocate for taken? What medications, if any, have you, your loved ones, or patients you advocate for taken, whether currently or in the past, for these conditions that we're discussing today? Take a moment and put them in the chat. And if you wouldn't mind tagging which condition you are discussing. And I'll give everyone a couple moments to do that. Okay, Vraylar, clozapine. All the antipsychotics, thank you. Cobenfy. Vraylar, these are very unsurprising to see. And **[Participant 5]**, I think you mentioned, there you go, I knew you had a few, because you had mentioned some. I think **[Participant 1]**, if you have any, and **[Participant 3]**, if you want to add any in. It looks like, **[Participant 3]**, you added Rexulti and Vraylar. Aduhelm. One more. **[Participant 1]**, I'm going to give you another moment or two, I see you typing vigorously. Thank you, **[Participant 1]**. Thanks, everyone, for taking the time to share these medications.

For the next few questions, I want to note we want to hear about, again, experiences your loved ones or patients you advocate for had with Rexulti, as well as the medications that you listed here on the screen. And as we're going through, again, please reference which medication that you're speaking to. We're going to start off with what benefits have you, your loved ones, or patients you advocate for experienced with the medications used for major depressive disorder, schizophrenia, or agitation associated with dementia and Alzheimer's disease? Benefits of any of these medications. **[Participant 5]**, go ahead and get us started for agitation associated with Alzheimer's.

00:37:02

Participant 5 (registered as a caregiver)

Even though I'm this small segment here, I'll get it started. Clearly, aducanumab, Kisunla, and Leqembi are anti-amyloid drugs. They remove the protein amyloid from the brain, reduce it dramatically, and this has extended the early-stage life of thousands of people now by two or three years, so that's dramatic. That does have some serious side effects called ARIA [amyloid–related imaging abnormalities], which, as the amyloid is removed, it sometimes creates small breaks in the capillaries, the veins in the brain, and results in bleeding. But it is segmented to specific subgroups, and three or four MRIs [magnetic resonance imagings] during the first six or eight months, which is when this side effect occurs, really prevents or monitors it extremely well. While my wife was not on Rexulti, I spoke with many patients over the weekend at a conference I was speaking at, and two of the couples I spoke with were on Rexulti, a caregiver and patient, and they were extremely laudatory of the benefits, and both of them said they would not be able to have attended today, either because of the condition of the patient, or because of the fear that the patient would have an episode. I thought that was pretty significant and that I should share that.

00:38:53

Moderator, RTI international

Thank you. When you said they were laudatory, the benefits, you noted that they were even able to attend and not have an episode. Are there any other benefits that they shared with you during that conversation?

00:39:05

Participant 5 (registered as a caregiver)

I think the ability to continue to care for the individual at home was a very significant advantage. But given my history, you could understand how important that was to me.

00:39:20

Moderator, RTI international

Yeah. That is a very important aspect.

00:39:23

Participant 5 (registered as a caregiver)

Once my wife was in memory care, it was during the period that Rexulti had been approved for individuals living with Alzheimer’s, and I requested the drug for my wife, and they refused. So that was a major disappointment.

00:39:44

Moderator, RTI international

Thank you for sharing that, **[Participant 5]**, and opening up with us today. Others want to talk about the benefits, whether it’s Rexulti or any of the other medications that are listed here? **[Participant 1]**, go ahead.

00:39:58

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

It’s very difficult to talk about a specific antipsychotic drug in the schizophrenia world, because every brain is so different, and every person responds to a medication so differently. What works for one person may not work at all for another person. But in general, it’s funny because it’s only been recently that—and I want **[Participant 2]** to address this as well. We have historically, for schizophrenia, looked to help people’s positive symptoms. Their psychosis and their hallucinations, whether it’s audio, visual, whatever. And it’s only been within the past ten years maybe, not even, that we’ve been really trying to look at different mechanisms that can have an impact on the negative aspects, anhedonia and their blunting, and so I think that that now, people who are living with schizophrenia, yes, they want to get rid of their psychosis if they’re aware of that psychosis at all, but I think more important, they want to be able to go outside, you know what I mean? Be in public, and not be embarrassed, or not be scared. And that is a big deal. That is a really big deal, that they can go out into public and talk to people. These medications not only take away some of the hallucinations and those kind of things that might be very frightening for people, but it helps their entire life, as far as going from staying in one room and completely self-isolating, or not being able to get up or get a shower or get dressed for days or weeks, even. Being able to get up and get dressed and go outside and talk to people, go to the store, get a job. These things are such huge steps, and without those medications, so many people living with schizophrenia can't do that. It's absolutely life-changing. And, **[Participant 5]**, your story's such a big impact, and thank God for the work that you're doing there. I feel like with schizophrenia, one of the saddest things is that it's affecting young people, its onset is their teens and early 20s. To be able to get out in front of that and get that medication in place before they decline and have enough cognitive deterioration that they can't completely come back, although that's arguable. It's a big deal, and these symptoms, you can't just mark them down in a list, because it's not that simple at all.

00:43:28

Moderator, RTI international

I'm going to ask you a clarifying question that may be overly simplistic, so bear with me, **[Participant 1]**. In your response, you said these medications help take away the positive symptoms, just help people live. Are there particular ones that fall into these medications' buckets that you want to highlight or note?

00:43:45

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

All of the antipsychotics, whether it's the newer antipsychotics, whether it's combinations of all of the antipsychotics. I started thinking, the reason it was taking me so long is because I'm like, am I going to go all the way back… how far back should I go? First of all, you can't talk about one antipsychotic, because it's not that simple. As much as I can give you these data on Rexulti, the relapse rate and that kind of thing, really, you can't talk about just one. You have to look at the body. And many times, you have to look at a combination of more than one.

00:44:40

Moderator, RTI international

Thank you, **[Participant 1]**. And I'm going to go to **[Participant 3]** next, and **[Participant 3]**, I see you also put some notes in the chat about Zyprexa, and that it's well-tolerated and good stabilization. Do you want to comment a little bit more on the benefits of the sundry medications?

00:44:54

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

I think what **[Participant 1]** just said is absolutely key. It's not just one, although Rexulti certainly seems to have shown itself to be relatively effective. But I also wanted to add on, again, we deal with mostly mental illness in a rural population. And stigma is absolutely huge. The notion, it's an undergirding of, pull yourself up by your bootstraps, do it on your own, and we know that that's not always possible. The idea of the success of many of these drugs and being able to allow people to go out and feel normal, because if you don't feel and act normal, everybody in your community is going to know immediately, and it reinforces the stigma. I don't pick one over any of them. I think having the armamentarium is the most important thing, Rexulti being one of them.

00:46:06

Moderator, RTI international

Thank you, **[Participant 3]**, for weighing in. And **[Participant 2]**, I know you also can comment on schizophrenia, so I'm going to hand off to you.

00:46:13

Participant 2 (registered as a representative of a patient advocacy organization)

Thank you. Couple framing comments. Finding a doctor, once a family or an individual impacted recognizes symptoms that are of concern, is especially hard, as **[Participant 3]** mentioned, in rural communities, but also in urban communities. There aren't enough providers that exist in the United States. Then, once you actually find a doctor and you actually get a proper diagnosis—and there are many, many switching of diagnoses that takes place—then you have to find a therapy. And when any therapy is subject to utilization management, you are essentially going through, as **[Participant 1]** mentioned earlier, cycles of impact on your brain, starting, stopping, switching, starting, stopping, switching. CMS itself designated antipsychotics as a protected class, recognizing that this is a unique, vulnerable patient population, that anytime you disrupt access to a medication that works, there are potentially grave consequences that could occur. Any price negotiation process should not undercut those protections that are already guaranteed by law. Specifically, to the challenges with existing treatments and desired attributes of treatments. What we hear from our community is that weight gain, movement effects, such as tardive dyskinesia, feeling flat, no effect, are identified as being really high potential side effects with schizophrenia. And their loved ones have told us that the most frequent reasons for quitting medications relate to weight gain, sexual dysfunction, lethargy, lack of affect. Preventing delusions was the top priority that our community has shared with us for choosing a treatment, overcoming the other obstacles that I've shared earlier, and the weight gain in particular. So those are some framing considerations that I would offer for consideration.

00:48:32

Moderator, RTI international

Thank you, **[Participant 2]**, for context, providing this context and contextualizing these benefits. I think, **[Participant 4]**, we have not talked about major depressive disorder, and you wrote all antidepressants. So, if you want to comment on the benefits of all antidepressants.

00:48:50

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

And I should also say many of the antipsychotics, as well, are also used to treat depression. And I'm going to try to keep this very brief, because I want to acknowledge what you said at the beginning of the call, but, one note, and this is more for the individual and their provider. But, talking about that stigma, even the language of antipsychotics, people will say, "Well, I'm not psychotic." Especially if they haven't had experience of psychosis, but we know that we use these to treat depression as well and so we can't change the legal language because, as it was mentioned earlier, it's in the six protected classes, but we encourage providers to have that conversation with their patient and make the decision together, and explain, yes, this is what the class is called, but that's not what we're using it for here. And again, all of that is based on a relationship, and the ability, the trust that is formed in that relationship. I don't want to be ditto to everything that's been said, but when you put drug utilization review into the mix, then that undermines that relationship, undermines that decision that was made. And so, I ask you to consider that as well.

00:50:41

Moderator, RTI international

Thank you, **[Participant 4]**, and did you want to also share about anything related to the benefits, whether it's efficacy, dosage, administration, that you've heard of through your patient advocacy work?

00:50:53

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

I don't have any specifics there that I can share, no.

00:50:56

Moderator, RTI international

Okay, thank you. Before I move on to the next question, anyone else have things that they want to raise related to benefits of any of these medications, whether efficacy, dosage, safety, administration? The world is your oyster. Then we'll do a little compare and contrast, and I'll open this to all conditions. For those who have knowledge or experience with more than one medication for these conditions, how would the benefits of the medications compare or contrast? How do they differ? **[Participant 1]**, go ahead and kick us off for schizophrenia.

00:51:48

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

I can only reiterate that the different medications, you can't possibly compare and contrast the different medications, because every single brain is different, and every single person is going to respond differently, whereas, I think it was **[Participant 4]**, I don't know. Anyway, someone said that somebody might be okay gaining 30 pounds, whereas another person might be like, absolutely not, that's a deal stopper right there. So this whole class, antipsychotics for schizophrenia specifically, how can you compare one to another, because I have heard people say, "I've been on clozapine, and that's the gold standard," and that's not true, because then I've heard another person, a person living with schizophrenia, say, "I didn't want that, and it didn't work for me, and I am on this drug, and this is the drug that worked." And another person, when you ask a person with schizophrenia what drug they're using, they would hesitate to tell you sometimes, because they don't want you to think that that's the right drug. There is no one antipsychotic. You can't say that Rexulti is the best one, or you can't say that Cobenfy is the best one, or any of them. Or Abilify, any of them, or Risperidone. There is no best one because you need to have all of them, because every time, like I said, maybe somebody tried five different antipsychotics and combinations of antipsychotics, and they finally found that right combination that works, but if they get pulled off that for whatever reason, they're back at the beginning, and now they have to start all over again to see what's going to work. If there's anything that I could beg you to consider in in making any kind of decision about Rexulti, it's that this drug, and all antipsychotics, are protected for a very good reason, and to put any other hurdles in front of people who so desperately need these drugs. It's a lot more than just a pricing issue.

00:54:28

Moderator, RTI international

Thank you, **[Participant 1]**. I hear you say the answer is, it depends on the person for those benefits.

00:54:34

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

Oh, don't say that. See? Now, **[Moderator]**, you can't just simplify it and make it like that, because there's so much more.

00:54:45

Moderator, RTI international

I want to acknowledge that I'm hearing you say it depends on the person and what they need and in their life at any given time, so **[Participant 3]**, I'll go ahead and go to you.

00:54:57

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

Again, I'm a Johnny-one-note. My audience is a very rural audience, and the challenges are already above that of many places, particularly in terms of access, and I want to hammer home what **[Participant 1]** has said about, every brain is different. Once you're on something that seems to be working, you cannot create more barriers for access to that. It's way too delicate a situation, and again, in the rural community, the less visible impact you have, the more likely people are going to stay on their medicine, whatever the trade-offs are for it.

00:55:45

Moderator, RTI international

Important benefit is maintaining adherence through access. I'll move to **[Participant 5]**.

00:55:58

Participant 5 (registered as a caregiver)

To my knowledge, there are no other antipsychotics approved for individuals living with Alzheimer's to address their psychosis and agitation. Rexulti is by far the best choice we have. It's more of a choice of, do we venture into an antipsychotic drug or not, because of the historical side effects. But how wonderful, I know these are really difficult, and I feel it's a wonderful opportunity to learn about your disease, or the one the rest of the audience is addressing, and I hear some common problems and some very unique problems, stigma being one of the most common, but you have a choice. I know these aren't easy choices, and continuity is a major issue. We don't have a choice, and that's the day we look forward to. I'm glad to hear you have that choice. I'm glad to hear that some folks find a good option.

00:57:06

Moderator, RTI international

Thank you, **[Participant 5]**. I know we've said it all depends on the person, but I have one additional question in this line of discussion. We talked about benefits. Are there drawbacks or challenges that you know about that people have experienced with these medications used for schizophrenia, major depression depressive disorder, or agitation associated with Alzheimer's. Drawbacks or challenges that you think are important to raise? Go ahead, **[Participant 2]**, get us started.

00:57:41

Participant 2 (registered as a representative of a patient advocacy organization)

I would frame it as the challenges related to not providing access to a medication that someone finds that actually works for them. What that could lead to is partial adherence, or even worse, non-adherence. What will that lead to? Higher rates of relapse, rehospitalization, suicide attempts, potentially death, and other unwanted side effects. Those are all from the human perspective. When we talk about a societal perspective, the downstream negative impacts to society, interactions with the criminal justice system, family disconnection, and on and on and on, really are traumatic, an overwhelmingly expensive economic burden to the United States, to society, to the loved ones involved with that individual. Whether it's any of our conditions that we're talking about, when you remove access, you must replace it with another option, many of which won't work for the person. That could lead to the partial adherence or the non-adherence that leads to the negative downstream societal impacts.

00:58:56

Moderator, RTI international

[Participant 2], I know we talked a lot about access. You mentioned the ability to adhere to the medication. Are there medications that you're aware of that enable people to better adhere or make them less able to adhere, for whatever reason?

00:59:10

Participant 2 (registered as a representative of a patient advocacy organization)

It is a bit of a broken record, as someone else said, that everyone's brain chemistry and metabolic chemistry, so to speak, is unique, and the tolerability of one option versus another option is what the provider and the family and the person diagnosed need to weigh. Each has a unique profile and impact on an individual once you find it, which is why the disruption that could be caused by removing access to a drug like Rexulti could lead to all these negative outcomes.

00:59:46

Moderator, RTI international

And **[Participant 2]**, you mentioned tolerability. Have you heard, through your work, some drugs are more or less tolerable than others? On the average, again, recognizing that everyone's brain chemistry is different. I don't want to be dismissive of that point, but if you have stories or insights onto the tolerability side.

01:00:06

Participant 2 (registered as a representative of a patient advocacy organization)

The metabolic tolerabilities are well documented. There are, again, different reactions to different chemical agents, but it wouldn't be fair to characterize any one medication as having more or less, other than what is published in the research. But the balancing act and monitoring from the provider perspective is going to be key to make sure that everything is in proper balance.

01:00:35

Moderator, RTI international

Thank you, **[Participant 2]**. I'm going to go to **[Participant 1]** next to stay with schizophrenia, and then **[Participant 5]**, I'll be sure to get to you.

01:00:43

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

The only thing I wanted to say is beautifully spoken, **[Participant 2]**. That was beautifully put, and it's so important to recognize that you're asking us to do something that it's not fair at all for us to have to do that. You're asking us, "Do you want to cut off your right arm or your left arm?" [laughs]. What **[Participant 2]** said, I want to reiterate everything that he just said. It's mainly access to all of them, and you hear stories, sure, of people gaining weight, or people having issues. But you can't single one out, because they are all affecting people so differently.

01:01:41

Moderator, RTI international

All are effective, it depends on who.

01:01:46

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

A short, brief comment. I think **[Participant 1]** had it a little bit wrong. It's not a trade-off of your right arm or your left arm. It's a trade-off of, do you want to remove your ears and have no hearing, or your eyes and not be able to see? It's that severe.

01:02:11

Moderator, RTI international

[Participant 5], we'll go ahead and give it to you. Drawbacks of, I know you said it's the only one, are there other drawbacks that you want to say across the medications that you've encountered?

01:02:25

Participant 5 (registered as a caregiver)

I think it's not the topic and not what you were asking for, but my wife pushed another resident in the care facility she was in, and was removed and sent to a psychotic hospital, whatever you call them, for two weeks, was incarcerated, essentially, for observation. This is after I had requested Rexulti and been denied. And why would that happen in an institution with a high medical expertise, and it's the star rating system? And this really was tremendously impactful on my life, and to be denied that choice, not for price, but for different reasons of access for something that really does need to be modernized and rethought, was pretty damaging.

01:03:27

Moderator, RTI international

So, the non-treatment was the drawback.

01:03:29

Participant 5 (registered as a caregiver)

Right.

01:03:31

Moderator, RTI international

All right. **[Participant 4]**, did you want to comment on any drawbacks that patients that you advocate for have shared with their experience with medications?

01:03:42

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

Yes, not specifically to Rexulti or any of the alternatives, but I wanted to speak more to what **[Participant 1]** had shared earlier about the cocktail of drugs that many people find themselves having to deal with. And I was actually a co-investigator on a study looking at youth in the 85th percentile for weight, who are prescribed second-generation antipsychotics, which we know can cause weight gain. And the part that I want to drill down on is, we asked the youth, the parents, and their prescribers about their attitudes toward intervening to prevent undue weight gain. And the youth all said, “I want to get ahead of this thing. I want to take whatever I have to in order to not gain any more weight,” whereas the parents and the prescribers were both more cautious, and they were concerned about over-medicating. And wanted to wait and see, is this child going to gain even more weight, and is this going to be problematic? And then we’ll look at interventions. It’s the full ecosystem. We have to ask the individual, “What do you want out of your life,” have to talk to their caregivers as well as to their providers, and I know I was talking about youth, we’re mostly focused on adults here, but again, to reiterate what everyone else has been saying, it’s the individual and their preference, and how do they define their quality of life?

01:05:37

Moderator, RTI international

Thank you, **[Participant 4]**. Okay, you’ve all really driven home access, the individual and their preference. When considering a potential medication for schizophrenia, major depressive disorder, or agitation associated with dementia, what factors matter to patients most? What matters most to patients in picking a medication?

01:06:10

Participant 5 (registered as a caregiver)

I’ll make Alzheimer’s first. I think it’s efficacy.

01:06:16

Moderator, RTI international

And what does efficacy mean to you, **[Participant 5]**?

01:06:26

Participant 5 (registered as a caregiver)

That, given certain risks that are known and shared at the time the decision is made to accept the medication, that they are outweighed by the benefits of treatment.

01:06:45

Moderator, RTI international

Thank you, **[Participant 5]**. Shall we move to schizophrenia? **[Participant 3]** you can go first.

01:07:03

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

I think what **[Participant 5]** said is absolutely true about just about anything. It's efficacy. Is it dealing with the condition that you're looking to ameliorate? But I think a close second is side effects, the importance of, once you've identified a drug that works for you, staying on it, being consistent. I think **[Participant 2]** said there was lack of compliance and then semi-compliance. I put those both about equal, semi-compliance with schizophrenia, or major depressive disorder, you have to be either all the way in, or you're not.

01:07:55

Moderator, RTI international

Thank you, **[Participant 3]**. **[Participant 1]**, do you want to add to **[Participant 3]**'s comment?

01:08:00

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

I wanted to reiterate that, first of all, it could be the whole cocktail is going to be the perfection of what is going to take someone who is saying, I want the efficacy, of course I want the efficacy, but if they are going to be gaining weight, or having sexual dysfunction side effects, or maybe it's efficacious in keeping their hallucinations at bay, or keeping them from being psychotic, or floridly psychotic, but they're still not able to get out of bed and get a shower or clean their apartment. You're balancing some different scales. Again, it goes back to access to the whole realm, because it might be effective in one area, but you might need something else to help you in another area that's going to balance that scale to give you the stability that it's going to take to get you out of the house and back in the world.

01:09:21

Moderator, RTI international

Thank you, **[Participant 1]**. And **[Participant 2]**, do you want to weigh in as well?

01:09:24

Participant 2 (registered as a representative of a patient advocacy organization)

Real briefly, to put an exclamation point on that, it's really about improved cognition. That if you find a medication that allows you to participate in activities of daily living, being able to interact with friends and your family, being able to cook dinner, even just sit down at dinner, being able to go on a date, being able to fall in love, being able to go to your job. When you don't find a medication that works, none of those things typically work the way that they should, so you become isolated, you become socially disconnected, that leads to despair, that leads to the other negative impacts that were described earlier.

01:10:11

Moderator, RTI international

Disease of disconnection. And, before we move on, I don't know, **[Participant 4]**, if you want to weigh in about what you've heard about what matters most to patients when considering a medication. What is part of that patient preference that you've heard about?

01:10:25

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

I front-loaded my comments, but everything that I shared from our work around the Transforming the Definition of Wellness campaign. Being able to understand and interact with the depression and know what is happening to you, having that positive focus, but most of all that function and that ability to do all of the things that **[Participant 2]** just said.

01:10:56

Moderator, RTI international

Thank you. Things that people take for granted. I'm going to move into the next section. You've all provided very helpful input so far, so I thank you for that. I'd like to talk about how well Rexulti and other treatments for the conditions we're talking about today meet patients' medical needs. Earlier we asked you to reflect on the most important aspects of the conditions treated by Rexulti, to be managed or treated. Aside from those aspects that you've already shared, what other medical needs related to these conditions are important to you, loved ones, or patients you advocate for? Go ahead, **[Participant 1]**, get us started.

01:11:53

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

We've covered pretty much all of the symptom domain, so I want to raise a point that you may not typically hear in the discussions, and that is that evidence shows that when access to antipsychotic medications is restricted through, whether it's formulary barriers [or other barriers], [it] doesn't affect just the health care outcomes, it affects the criminal justice system. And there's plenty of research that found that patients with schizophrenia in states where there are any kind of prior authorizations for antipsychotics or any access barriers. This one study from USC [the University of Southern California] found a 22% increase in the likelihood of imprisonment, and that restrictive formulary policy added an estimated $362 million in incarceration costs nationwide. That's real people whose symptoms destabilized because they couldn't access their medication and ended up in jail cells instead of in treatment programs. When CMS evaluates the cost of a medication like Rexulti, I would urge them to consider the full cost of restricted access, including the costs that would fall outside of Medicare's budget, but squarely on our community's shoulders.

01:13:18

Moderator, RTI international

Thank you for bringing up some social needs, too, **[Participant 1]**, I appreciate it. Other medical needs that we haven't discussed related to these conditions that you wanted to address? **[Participant 5]**.

01:13:35

Participant 5 (registered as a caregiver)

As I mentioned before, I don't know that schizophrenia or other conditions will ever be preventable, but we certainly hope that one day Alzheimer's will be preventable, but until that day, we certainly do need drugs that stop the cognitive decline, and that's where the major emphasis is now.

01:13:59

Moderator, RTI international

So, cure. It's an important medical need. How about **[Participant 4]**?

01:14:12

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

I wasn't quick enough on the draw to be able to give you statistics and percentages, like I did earlier, but, we conducted a smaller scale survey in 2022 for older adults living with depression and chronic physical health conditions, and we learned a lot of things, and we hosted a convening, to talk about the results of that survey with people with lived experience, as well as other patient advocacy organizations and researchers. But some of the main things that we learned was, A, that living with a health condition is depressing. So you will find that comorbidity over and over and over again. But one thing that we were very surprised by, or not very, was that there was a greater effect of depression on the ability to manage whatever chronic health condition than the health condition on the ability to manage depression. When you're depressed, we've been talking about adherence, we've been talking about adherence in terms of people living with schizophrenia, or people living with depression. But you're not going to manage your chronic health condition, you're going to see more decline and more deterioration there because you're depressed. And that was very eye-opening for me, personally.

01:16:05

Moderator, RTI international

The ability to manage your other health conditions is an important unmet medical need. Anyone else have an unmet medical need that are important to patients? Whether it's related to symptoms, side effects, quality of life, anything else?

01:16:26

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

There's that higher risk of suicide in individuals living with schizophrenia. They're adjusted, and **[Participant 2]** could speak to this more eloquently than I could, but their life expectancy is significantly decreased if a person is living with schizophrenia, and obviously with depression, and obviously with Alzheimer's as well, so there's many of the other social aspects that are taking place.

01:16:57

Moderator, RTI international

[Participant 2], you've raised your hand about those unmet medical needs, and then I'll go to **[Participant 5]**.

01:17:02

Participant 2 (registered as a representative of a patient advocacy organization)

I know some of the voices on this panel represent loved ones, care partners, but I think the impacts on the caregiver are extreme and multifaceted, including not being able to work, including higher rates of anxiety, stress, other physical and emotional dysfunction, suicide, loss of employment completely, family disconnection. We're thinking about the patient perspective, but let's think about the broader family perspective, and how it impacts negatively all of the things that would be the connective tissue for the family when access to a medication that's actually worked, including having to go through two prior steps to get to one that works to actually be restricted with a barrier, to me, seems flatly ridiculous.

01:17:58

Moderator, RTI international

Thank you, **[Participant 2]**. **[Participant 5]**, if you wouldn't mind, taking the next turn.

Participant 5 (registered as a caregiver)

There are a hundred different types of dementia. Alzheimer's is one, although by far the most prevalent. Many patients with dementia have multiple dementias. For years, decades, the diagnostic tool for Alzheimer's was autopsy, which most patients preferred to prevent. But now, today, because of the investments that have been made over the last 10, 20 years, we have a blood test. This is a huge advance for us. We've really been effective the last year or two. But it is only we, in the Alzheimer's community, who have that. We do not yet have any biomarkers that can yet identify the other three most common: vascular FTD [frontotemporal dementia], Lewy body [dementia], and so that would be a huge advance, because if someone just had Alzheimer's, would they have the same result to Rexulti as someone who had Alzheimer's and FTD? Or would that be different from FTD? The combination here is very challenging, and to understand the true drug benefit on the condition when the condition remains partially unknown is difficult.

01:19:39

Moderator, RTI international

Thank you, **[Participant 5]**, that's very important. Now, reflecting on your experience and knowledge of the treatments for these conditions, to what extent are those medical needs being addressed by the currently available treatments and medications? Go ahead, **[Participant 3]**.

01:20:16

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

I'll stick my neck out a little bit and say I think relatively well. There's always room for improvement, that's why pharmaceutical companies study these things over and over and over again. But, I think we're miles ahead of where we were maybe ten years ago. And again, to both **[Participant 2]** and **[Participant 1]**'s points early on, because it may take so long to find the right therapy or combination of therapies in order to get there. I think we're in a much better place. But again, it gets to, can we have a consistent access to these therapies? And if there's an interruption, I agree with **[Participant 2]**. It's ridiculous, but it's also cruel.

01:21:25

Moderator, RTI international

Thank you, **[Participant 3]**, for sharing that. **[Participant 1]**, to what extent would you say that current treatments address the medical needs of people with schizophrenia?

01:21:38

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

First of all, **[Participant 3]**, yes, I agree that we have made enormous progress, and that today schizophrenia is not essentially a death sentence. However, I don't know how many people today have been diagnosed with schizophrenia and told, "You will be on disability for the rest of your life, you will have to struggle with this for the rest of your life. You won't get married, you won't have kids, you won't have a family, you won't have a job." That is the reality. And that is unacceptable, and so yes, we have come a long way, and if we can catch it, and if somebody can find the right treatment, then they can have a life. But we're not at the point yet where somebody who is newly diagnosed is told, "But don't worry, we got you. There are effective treatments, and you can go on and have a healthy, happy life." We're not there yet, we're not even close, and our perspective at the organization I'm with is grounded in what we witness every day, and that is that individuals are doing everything that they can to manage this serious illness and to live with dignity. And even if they are stable 28 days of the month, there's going to be a few days that they struggle. It might be half the month that they struggle, and the other half the month they're good, but they might go six months. But then you'll see them looking disheveled, and you know that they're having a tough time, and this is it. Access to effective treatment is the foundation of what makes it all possible. And I can't say strongly enough, I urge you to consider very carefully the consequences of any action that could put access at risk.

01:23:47

Moderator, RTI international

[Participant 1], before we move on, I wanted to ask, you said, "We've come a long way, but we're not there yet." That made me think that there might be some gaps in treatment that remain despite the currently available set of tools that are available to us. Could you comment on any gaps that you've seen, or gaps that remain in terms of treatment?

01:24:08

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

Sure, the cognitive issues are still not adequately addressed. We're getting better. We still have a ways to go, and I think that we can find a cure. I think that we can find a cure, and ultimately, we will. But we need continued investment in in research, and to put any barriers up in that, I keep thinking the psychiatric drug development already faces the lowest success rate of any therapeutic area. Psychiatric drugs are absolutely the lowest. They're the longest trials to run, they're the most difficult trials to run, and they've got the highest failure rates. It's like 6% of them make it through. Six percent! I mean, that's billions of dollars that's being invested, and only 6% of that is making it on to be accepted, so there's so much uncertainty in this space, so any uncertainty that you add, it's going to risk further investment needed to develop these next generation of therapies and treatments, and a cure eventually, which we're not there yet. We need that. And the fact that today, people are still being diagnosed and told, "You will be on disability for the rest of your life." And I hear it all the time, that people are still being told that. And that goes back to the stigma of when a person is diagnosed with schizophrenia, and then they are devastated. It's a devastating diagnosis. And it doesn't have to be. So, yes, **[Participant 3]**, there's been remarkable progress, but man, we're not there yet.

01:26:07

Moderator, RTI international

Thank you, **[Participant 1]**. **[Participant 5]**, I see you put your hand up. Gaps in treatment, again. No, not a cure, but what are some of the other gaps in treatment that you are aware of?

01:26:18

Participant 5 (registered as a caregiver)

In the Alzheimer's community, we have a bit of a different situation. We've just broken ground in treatment. We've got a huge way to go, and I hear both **[Participant 3]** and **[Participant 1]** citing similar situations. We have a tremendous pipeline. We're all very, very hopeful now. For decades, there was very little hope in our community, and one of our advocacy jobs is to share the hope and let people know that, hey, we've made such progress, and there's a great deal more to come. One of the major issues for us is integrating this dramatic change in the availability of any treatment into clinical practice. We've got a very disjointed—GPs [general practitioners] don't like to deal with any cognitive issues because they're not trained or supported, and they haven't been able to help patients, so they pushed it off. And we don't have nearly enough neurologists and other specialists to treat the disease once it is diagnosed. But, getting the blood test, you'd think the blood test, it's a few hundred dollars, it would be integrated very quickly. No, it's a real chore. And the general lack of awareness that we now have disease-modifying treatment is a big, big challenge for us.

01:27:36

Moderator, RTI international

Thank you, **[Participant 5]**. Before we move on, **[Participant 4]**, do you want to comment on any major gaps in treatment or concerns that remain despite available treatment options?

01:27:48

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

Absolutely. My understanding of our audience is that about one-third of people living with depression are able to find relief, if not in the first round, relatively quickly. And about one-third of them go through at least four treatments before they're able to find relief. We've been talking on this call about how long that is to go, to wait months to see if it's even working or not. And then another third aren't able to find relief with what's out there, with what is available right now, and so that's why DBSA [the Depression and Bipolar Support Alliance] is an advocate for novel treatments and innovation and new treatments, and that's also the reason for us developing a new clinical outcome assessment, are we asking the right questions? Are we structuring these trials correctly in order to find relief? But I do not believe that we will find the one treatment that then we can let all of the others go, because this one is the magic bullet. Our goal is to try to find relief for those, that third of the population, but for those who were fortunate to find it right away, and for those who struggled to find it, we need to preserve their access in order to maintain their wellness for all of the reasons that everyone else has already cited.

01:29:41

Moderator, RTI international

What I think I'm hearing across major depressive disorder and schizophrenia is there are many options that are available help many people, but there are there are some folks for whom none of these treatments work. Is that a fair summary of what I heard, **[Participant 1]**, **[Participant 4]**, **[Participant 2]**, or **[Participant 3]**? Do you have an additional thought or insight?

01:30:07

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

For me, yes.

01:30:08

Moderator, RTI international

We're in the last section here, we're almost through. Before we part ways, I wanted to give everyone an opportunity to summarize any thoughts on Rexulti, or for patients, or raise any topics that you feel weren't covered adequately by our conversation today. I'll go around the virtual room. If you have no additional comments, that's totally fine. Do you have any final thoughts about Rexulti, conditions treated by Rexulti, or other medications that treat the same conditions that you feel are important to share with CMS? **[Participant 4]**, since you're large on my screen right now, I'll start with you. Any closing thoughts?

01:30:55

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

No, just thank you for the opportunity to share. Really appreciate being able to do that.

01:31:04

Moderator, RTI international

Thank you, **[Participant 4]**. **[Participant 2]**, any closing thoughts, whether it's about the condition, the medications available, or any other topics that you wanted to share with CMS today?

01:31:17

Participant 2 (registered as a representative of a patient advocacy organization)

Thank you for the opportunity to participate, and to put a number, which is not an easy thing to do, because the number is probably much bigger once you think about the family and the broader friendship circles, but about 120,000 Medicare beneficiaries rely on Rexulti. Approximately half a million rely on this broader antipsychotic class. CNS [central nervous system] drug development, as **[Participant 1]** said, takes 20% longer, with clinical trial success rates of just 6%, half the rate of non-CNS drugs. So the numbers matter. The impacts are real and potentially devastating if there's any increased barriers to access.

01:32:03

Moderator, RTI international

Thank you, **[Participant 2]**. Thank you for bringing it to people's lives and the magnitude. I'm going to stay with schizophrenia, so I'm going to go to **[Participant 3]** for your closing thoughts.

01:32:17

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

Every word that **[Participant 2]** said, I double. We have to have these things available. Rural communities are highly reliant on Medicare, and I suspect 120,000, another **[Participant 2]** mentioned, quite a few of them are in rural communities, and for all the other reasons that I've said and others have reinforced. We need to have these drugs and readily available.

01:32:50

Moderator, RTI international

Thank you, **[Participant 3]**. And **[Participant 1]**, do you have some closing thoughts? You're smiling really big, so I think you have a few extra words.

01:32:57

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

Yes, and this is something that I've been thinking about this whole entire time, is that we are talking about access, and although these are price negotiations, you're not talking about pulling a drug off the market. But, what happens? When a drug's negotiated price changes its economic profile, payers and pharmacy benefit managers may respond by adding utilization management tools, prior authorizations, and step therapy requirements, and stricter coverage criteria. It's not theoretical. In surveys of payers representing over 200 million people covered, 96% of the payers said that they plan to increase their utilization management in response to any price negotiations, and they will add step therapy, and they will add prior authorizations to any negotiated products, and some came out and said, we prefer the non-negotiated drugs with the rebates over the negotiated drug. They have the power to do that. They have the power to interrupt access. And for a population as clinically vulnerable as individuals living with schizophrenia, adding these administrative barriers between a patient and their medication keeping them stable, it's not a cost-saving measure. It's a clinical risk. And also, we know that the utilization management barriers will affect patients on antipsychotics, and there are decades of peer-reviewed evidence showing exactly what happens. Thirty-seven percent prescription abandonment rates, they go to get their medicine prescribed, and they face a barrier, and they abandon that medication. That's 37% of the people that are getting this thing that they can't get their medication, that go psychotic. They don't get better. There's 23% higher hospitalization costs, there's increased incarceration, there's treatment disruptions, so the question isn't if this happens, the question is, why would we risk that happening? I beseech you, please, please, keep this a protected class and protect it from any of these. I am all for changing the prices. But I feel like there's other ways to do it that won't have the unintended consequences of people losing their access. Thank you.

01:35:28

Moderator, RTI international

Thank you very much, **[Participant 1]**. We hear any of the social needs. We heard **[Participant 2]** talk about the family needs, we hear you all mentioning access and the importance of that. **[Participant 5]**, I'm going to give you the final closing thought, whether it's about Rexulti, conditions treated by Rexulti, or other medications that you wanted to raise that you didn't have a chance to talk about earlier, and you think is important to share with CMS.

01:35:57

Participant 5 (registered as a caregiver)

First, I want to thank RTI for what I think has been a very well-managed and very well-spoken dialogue. I'm thrilled that CMS wants to hear the patient and the advocacy voice. When my wife was diagnosed in 2012, we did not have nearly the penetration of voice represented in the regulatory environment, and that, to me, is a wonderful emotional as well as physical benefit for us. I do not endorse any product, nor does Voices of Alzheimer's endorse any product. I want to represent the Alzheimer's community, which I know is not the largest community for this drug, in imploring, as **[Participant 1]** did, in the sense that please do not limit our access to the few treatments that we have. Having a choice is so important to us. We've waited so long to have the ability to interfere with or moderate our conditions at all that it's extremely important to us to be able to have uninterrupted access. And thank you again.

Closing Remarks

01:37:23

Moderator, RTI international

Thank you to all of you. I've heard you talk with great passion and compassion for others, and so I appreciate you taking the time to participate in today's event. Your experiences and the input was very valuable and will help inform CMS' negotiations for Medicare pricing for Rexulti. CMS staff have been listening to what you have to say today and will be able to bring that perspective back to their team. With that, I'm going to hand off to CMS to provide some closing remarks. **[CMS Staff]**, if you want to come back on.

01:37:59

CMS Staff

Absolutely. Before we go, I want to thank you all very much for sharing your experiences and knowledge with us today. You really have given us a lot to think about and to consider, and I want to express gratitude for your perspectives and participation. Thank you.

01:38:18

Moderator, RTI international

Thank you, **[CMS Staff]**. And as we close out, if you have any questions following today's sessions, you can submit them through the mailbox, IRARebateAndNegotiation@cms.hhs.gov, with the subject line Public Engagement Events. If you wanted to share those statistics or the reports, you're welcome to submit those during that time, too. Thank you all for giving us the time today. I learned a lot today, too.

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

For a list of the drugs selected for the current cycle of the Medicare Drug Price Negotiation Program, click on the following link: https://www.cms.gov/files/document/factsheet-medicare-negotiation-selected-drug-list-ipay-2028.pdf

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

Appendix

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

Declared Conflicts of Interest	
No	Receipt of financial payments (e.g., gifts, funding, research support, honoraria, travel, or other expenses) from companies with direct/indirect interest in the Negotiation Program (e.g., drug companies, health plans) in excess of $10,000 by you, your spouse, or an immediate family member.
No	Direct assistance preparing your remarks from someone who is NOT a family member, caregiver, friend, or your health care provider.
No	You, your spouse, or an immediate family member is employed by or holds equity interest (stock or ownership interest) in excess of $10,000 in companies or related associations with direct or indirect interest in the Negotiation Program (e.g., drug companies, health plans).
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 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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Participant 3: Registered as a representative of a patient advocacy organization

Declared Conflicts of Interest	
No	Receipt of financial payments (e.g., gifts, funding, research support, honoraria, travel, or other expenses) from 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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Participant 4: Registered as a representative of a patient advocacy organization

Declared Conflicts of Interest	
No	Receipt of financial payments (e.g., gifts, funding, research support, honoraria, travel, or other expenses) from 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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Participant 5: Registered as a caregiver who has experience caring for an individual with the conditions treated by the selected drug; representative of a patient advocacy organization

Declared Conflicts of Interest	
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