Transcript: Vraylar Roundtable Event, April 28, 2025, Medicare Drug Price Negotiation Program Public Engagement Events

This transcript was lightly edited for readability.

Introductory Remarks

Moderator, NORC

Welcome. Thank you for coming today. My name is **[MODERATOR]**, and I'm from NORC at the **[REDACTED]**. I also want to introduce my colleague, **[SECONDARY MODERATOR]**, who you will hear from at a few points in the discussion today.

The Centers for Medicare & Medicaid Services is convening this patient-focused roundtable event and others as part of the Medicare Drug Price Negotiation Program.

The purpose of today's event is to hear from you all, a group that may include patients, caregivers, and patient advocates about your experiences with the conditions and diseases treated by Vraylar, with Vraylar, and with other medications for the same conditions.

If you wish to share input on other topics that may include clinical and or policy perspectives, please do so through the mailbox at IRARebateAndNegotiation@cms.hhs.gov.

Also, I'm recovering from long-COVID, so if I cough, please, I apologize in advance. The information shared during the events will help CMS understand patients' experiences with the conditions and diseases treated by the selective drugs, which for us today is Vraylar; patients' experiences with the selected drugs themselves; and patients' experiences with other drugs that are used to treat the same conditions as the selected drugs.

CMS may use this information in negotiating Medicare pricing with the manufacturers of selected drugs. Your experience and perspectives are very important to us. We genuinely appreciate your time today. At this point, we will watch a brief welcome video from CMS leadership.

CMS Remarks

00:02:02

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

Greetings, everyone. I'm Steph Carlton, the Deputy Administrator and Chief of Staff at the Centers for Medicare & Medicaid Services, or CMS. CMS administers Medicare, our country's federal insurance program, for more than 65 million older Americans and people with disabilities.

I deeply appreciate each one of you for taking the time to join us today. Lowering the cost of prescription drugs for Americans is a top priority of President Trump and his administration. As the second cycle of negotiations begins under the Trump administration, CMS is committed to engaging with stakeholders for ideas to improve the Negotiation Program.

In January 2025, CMS announced the 15 Medicare Part D drugs selected for the second cycle of price negotiations. Medicare's ability to negotiate directly with drug companies will improve access to some of the costliest drugs while fostering market competition and continuing innovation.

Our priority in negotiating with participating drug companies is to come to an agreement on a fair price for Medicare. Promoting transparency and engagement continues to be at the core of how we are implementing the Medicare Drug Price Negotiation Program. And, that is why the process for negotiation engages you, the public.

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

00:03:58

Moderator, NORC

Okay, so I also want to make you aware that staff from CMS will be sitting on this event so they can hear your experiences and opinions directly from you. Let me hand it over to them for a moment so they can say, hello. **[CMS STAFF]**?

00:04:15

CMS Staff 1

Hi. Good morning, everyone. Welcome to the roundtable. We are very, very excited to learn from you today. I do want to let you know that we are going to be here and listening for the duration of the discussion. But we are going to be off camera to let you all focus and yeah, very much looking forward to it. Thanks.

Housekeeping

00:04:37

Moderator, NORC

Now we will go over some housekeeping items. Some of you may have already seen this, but please be patient. We appreciate your patience. Participation. Please contribute your perspectives. Please feel free to skip questions you do not want to answer. Please minimize background noise by silencing your cell phone or other devices. Please mute yourself when not speaking.

Privacy. This discussion is not open to press or public. Please use first names only to protect your privacy, and we will do the same. Do not share any identifying information, address, last name, patient health-related information. We will record and create transcripts.

Video. We appreciate you keeping your camera on during the discussion.

Timing. This session will last one hour and 30 minutes. The moderator, me, **[MODERATOR]**, may redirect a conversation or cut it short at times to make sure we cover everything.

Technical assistance. In the chat, you should see the IRADAPSTechSupport@telligen.com. If you get disconnected, if you have issues with technology, if you're attempting to rejoin, please feel free to reach out to them directly. Break. If you need to step away briefly, just turn off your camera and microphone and rejoin when you're able to. You don't need to let us know that you need to step away.

Speaking. Please try to speak one at a time. We've checked for your hand raise option, and we will look for those features when we get to the discussion portion to make sure everybody gets their fair share of time to speak.

Honest opinions. Your opinions and experiences will differ, and we want to know what each of you honestly thinks about the topics we discuss.

So that ends our initial welcome. And now what we'll do is, we'll get into the actual discussion and the roundtable.

Okay. So, the first thing I would like you to do is if you would like to take 30 seconds to introduce yourself. Your name. What Vraylar indications are you going to be speaking to today? And what Vraylar conditions do you have experience with? And whether you'll be sharing personal experiences or those of a loved one, or whether you're sharing patient experiences from the perspective of a patient advocate. If you would like to start, and I'll just call on **[Participant 1]** since I see her in my Zoom box, the first person, and then we'll sort of go, **[Participant 1]**, **[Participant 2]**, and then, **[Participant 3]**, because that's how I see you.

Discussion

00:07:36

Participant 1 (registered as a patient)

Thank you. I'm **[Participant 1]** And I'm not sure I understand some of the questions, but I'll answer what I do understand. So, I take Vraylar. I have a condition bipolar type 2, and the other medication I take handles a lot of symptoms, but for the breakthrough symptoms like, for instance, compulsive picking is what I took it for, what I take it for. It helps with the breakthrough symptoms in a way that the other older medications just don't address, so thank you.

00:08:16

Moderator, NORC

That was perfect, **[Participant 1]**. Thank you. **[Participant 2]**?

00:08:20

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

Good morning. Excuse me. I'm **[Participant 2].** I am a health advocate. I have worked with brain health issues for a number of years and have family friends and colleagues all coping with them. So, I'm here to represent the advocates' position on these things.

00:08:41

Moderator, NORC

Thank you, **[Participant 2]**. **[Participant 3]**?

00:08:44

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

Hi, I'm **[Participant 3]**. And like **[Participant 2]**, I'm an advocate representing older patients in particular. And we work on a lot of Medicare issues. So, thanks for this convening.

00:08:57

Moderator, NORC

Thanks, **[Participant 3]**. So, for the next question we will ask you to put the answer in the chat function. Have you, or your loved one taken Vraylar, and whether you're doing so currently or in the past? Please enter your responses in the chat.

We are short on time. So, **[Participant 1]**, if you want to enter, or we can just sort of…

Okay. No worries. Well, so your answer will be, yes, because you talked about taking it for bipolar type 2. So, you did answer that question. Thank you.

Okay, so then, now, we're moving into the discussion. And I will just say again, preface it by saying that we have four different indications for Vraylar. We have a lot of questions. So, if I move you along, if I sort of turn to another speaker, it's just to make sure we get to all the questions, because we really, we and CMS would like to hear your responses for all of them.

So, for the first set we're going to address, we're asking you all to address experiences living with conditions treated by Vraylar and its therapeutic alternatives. And thank you for introducing yourself. And so, now we're going to sort of get into the first question and I'm going to separate these questions out by the indication. So, you will hear the same question four times in a row, just so that you know. And **[Participant 1]**, for you, just refer to whichever question is appropriate for your condition and for the patient advocates, you can sort of give a global answer for all of the questions instead of repeating the same thing four times. Okay.

So, the first question is for bipolar 1 with manic or mixed episodes. In general, how does bipolar 1 with manic or mixed episodes affect your or your loved ones or patients in general, their day-to-day life? So basically, what we're asking is, how does it impact your family, work life, relationships, activities? **[Participant 1]**, would you? All of you would, do you want to say? I will start with **[Participant 1]** and then go to **[Participant 2]**, and then **[Participant 3]**, because that's how I see on the Zoom box.

00:11:44

Participant 1 (registered as a patient)

Well, I know with bipolar 1, the difference between bipolar 1 and bipolar 2 is that bipolar 2 has one more than the other, depression more. For me, it's more depression than mania. With bipolar 1, I've known people with it that when they rapid cycle, they have more hospitalizations, they have more absenteeism. Many more are debilitated to the point where they cannot work as much, and so bipolar 1 and bipolar 2, while they're both stigmatized by society as a whole right now, there are differences, as far as symptoms go.

00:12:30

Moderator, NORC

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

00:12:33

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

Well, I would, of course, I don't have the personal experience that **[Participant 1]** does, but I would absolutely agree that it affects every aspect of life because you're cycling. You don't know when you're cycling. Having medication that can control that process and allow you to stay out of the

hospital to go on and work, live your life, pick up your children, do whatever the day-to-day things that are important, is just critical.

00:13:07

Moderator, NORC

[Participant 3]?

00:13:16

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

Sorry about that. Yeah, I think, I mean mostly what everybody else said. [J]ust a lot of times, older adults have greater functional impairment than younger adults might have. So, if you're experiencing mixed symptoms and people with higher, severe depression, they might have more functional impairment. So being able to have medications that can help some of those mixed symptoms, I think, can really make a big difference if function is a particular challenge.

00:13:55

Moderator, NORC

Thank you. So, now we're going to move on to bipolar 1 with depressive episodes. Same question, how does it affect your, your loved ones', patients' day-to-day? And for that I'm going to start with **[Participant 1]** again.

00:14:10

Participant 1 (registered as a patient)

My initial diagnosis when I went on this journey was a major depression, and it wasn't until actually, I was in my twenties when I realized that I couldn't sleep. And so, when depression debilitated me for a long time, and mania only came after changing my diet, after changing some lifestyle changes, and so depression really interferes with everything. It's almost like pushing a boulder up a hill, and it's constantly afraid that it's going to run over you and make you go all the way back downhill. It is, although able to function, able to get degrees, able to work full time, I was definitely running the same race everyone else was, just backwards.

00:15:14

Moderator, NORC

And now I'll turn to **[Participant 2]** and **[Participant 3]** if they have anything to add to what they've already said. And **[Participant 2]** first and then **[Participant 3]**.

00:15:21

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

Yeah, I don't think I do. I think that was beautifully said.

00:15:27

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

I mean, the only thing I think it's complex. People who experience mixed episodes, it's not uncommon in older adults to have mixed episodes with both manic and depressive symptoms. It's usually in people where it showed up prior to their being in the Medicare program. It's less common to have your first manic episode at an older age, but it's not impossible. And sometimes it can be

associated with some other type of experience that you've had. If you've had a stroke, or something else going on. But that's why I think it's so important to have different treatment options available so that you and your clinician can decide what's best for you.

00:16:22

Moderator, NORC

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

Next indication, major depressive disorder. In general, how does major depressive disorder affect you, your loved ones, or patients' day-to-day life. And again, we're looking for how it affects your family life, your work life, your relationships, your activities? And we'll go round robin again, starting with **[Participant 1]**, if you have anything to add.

00:16:50

Participant 1 (registered as a patient)

Well again, major depression was my initial diagnosis, and I need to add that my day-to-day life is very different as a medicated person with mental illness as opposed to what it was pre-medication. Without medication, and one of the symptoms of mental illness, certainly schizophrenia, but also bipolar, is that you think you're better, so you get off it. And it's [inaudible]. It's a cycle. So, when I'm off it, which I haven't been a long time, it's almost like you're laying down the ground, and you're waiting for someone to pull you up. It's such dead weight that it's really, it's hard to get up by yourself. So, the person who's pulling you up really, unfortunately, is the chemical. But fortunately, the chemicals are available.

00:17:49

Moderator, NORC

Thank you, **[Participant 1]**. **[Participant 2]**?

00:17:52

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

Yeah, I would, guess **[Participant 3]** sort of touched on that, and I think that's important to note that it's this medication that's bringing you out and allowing you to function, and not every medication is going to work the same way for every person, because their health issue affects them differently and manifests differently. So, having a variety of options that they and their physician or providers can work through and find something that functions well for them and minimizes these drastic events is very important and want to see that continue.

00:18:39

Moderator, NORC

Thank you, **[Participant 2]**. **[Participant 3]**?

00:18:41

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

Yeah, I mean depression, it affects a significant portion of people over the age of 65. Treatment-resistant depression has been on the increase, whether it's because of increases in diagnosis or in actual incidence. I think it's not completely clear yet by the data. But it has a significant impact on quality of life, and it's associated with higher mortality rates, rates of suicide are highest in the old,

over 85, primarily among men. So, most of the time there needs to be a combination of pharmacotherapy as well as psychotherapy to address other types of factors, and then also if you have an underlying medical condition as well. Depression as with all mental illness, is highly stigmatized. A lot of people have comorbid anxiety in old age. It's just important to have as many tools in the toolbox as the doctor can.

00:20:06

Moderator, NORC

Thank you. So now, moving on to schizophrenia. In general, how does schizophrenia affect you, your loved ones' or patients' day-to-day life, and please feel free to say I've said what I've said. I have one thing to add or I have nothing to add. So, we'll start again, the round robin with **[Participant 1]**.

00:20:25

Participant 1 (registered as a patient)

Well, I personally don't have schizophrenia. My mother does, and as a result of it, unmedicated, she was unable to function, she was able to work, and that's it. At home it was apparent that she was like a body in motion stays in motion, a body at rest stays at rest. So, she would work the whole day, then come home, and just basically fell free to paralysis, emotional paralysis. So once she became medicated, I'm not sure if she ever took Vraylar, but I do know that she was able to function to the point where it was an equitable exchange, where suddenly she was able to get the same chance as other people her age to function, and as you get older, the functionality unfortunately diminishes with age, but definitely in her social circle with older people, in her skilled nursing facility, she's able to function just a little bit better, closer to what they call normal. The GAF [Global Assessment of Functioning] is definitely remarkably better than it was before.

00:21:44

Moderator, NORC

Thank you, **[Participant 1]**. **[Participant 3]**, I mean **[Participant 2]**?

00:21:48

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

So actually, I have a cousin with this diagnosis, and she's been with that diagnosis since I was a child. And, she's never found a medication that really allowed her to function and work and those types of things. So, she's always needed care. It has involved her whole family, her mother particularly, but her siblings. Everyone was affected and involved in her care, especially her mother, who has passed now, so her siblings have picked this up. So having and continuing to have new and evolving medications to help with these devastating brain health issues is critical. So, we want to make sure that everything we do, while we want to lower costs, also keeps this momentum going so that there's something new, so other people don't have to, or can, I guess it's a better way to phrase it, can function and have some normal and thriving life.

00:23:08

Moderator, NORC

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

00:23:11

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

I just want to point out that a number of years ago we used to say that people with serious mental illness live on average 25 years less than someone without serious mental illness, and that's changed over time. It's still a lower average lifespan. But depending on if you're a man or a woman and depending on how well-resourced you are, that's changed somewhat. And in part it's changed because there have been newer second-line antipsychotic medications that have been introduced, thank goodness.

And so, it has a very significant effect on people's lives. My brother-in-law has atypical schizophrenia and also has concurrent bipolar, which is not uncommon. And he's been helped quite a bit with ECT [electroconvulsive therapy] primarily for depressive symptoms. But people need the options that are out there.

And, I think part of the reason why this drug was chosen is it's estimated that about 25% of people with schizophrenia in [these] next few years are going to be over the age of 65. And thank goodness, right? Because they lived long enough where they didn't typically live that long. And it looks like from the fact sheet from CMS, about 116,000 individuals were taking Vraylar last year. So just want to make sure that that medication stays available and is not subject to increases in utilization management or any of the other things that we've seen from selected drugs.

00:25:06

Moderator, NORC

Thank you. Just a quick reminder, this was a great point. But today, it would be great if you focus on the patient experience. And we have another set town hall coming up for the more policy, clinical aspects. But we do appreciate the point you made, so we will...

00:25:24

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

[MODERATOR], I just want to point out that dealing with utilization management is a patient experience issue. I mean, it's being delayed from being able to take the medication that your doctor prescribes you. That is a patient experience. And to say that it's just a policy issue, because maybe the agency doesn't want to talk about it or hear about it, I get it. But it's a patient experience issue.

00:25:52

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

I absolutely agree with that particularly in this instance, where someone may be having an episode. And so, anything that makes it harder to get into a get their medications and become functional again is exponentially worse than just having the cycle. So, yeah. I agree, it's completely a patient issue.

00:26:26

Moderator, NORC

There are follow-up questions where you can address that from the patient's access and clinical perspective. But for now, we'll move on to question three, which is what aspects of bipolar 1 with manic or mixed episodes are most important to you, your loved one, or patients to have managed or treated? So these things could be, how you feel, how you function in your daily life, how long you

live, and then we'll have this for every indication. So, what aspects of bipolar 1 with manic or mixed episodes are most important to you, your loved one, patients to have managed or treated?

00:27:12

Participant 1 (registered as a patient)

For me, I think the ability to work is number one. Truth be told, I don't work right now, because I take care of a husband with dementia, with frontotemporal dementia. However, the fear of quitting my job, the fear of not having insurance, to not be able to pay for my medication was a major concern of mine. As a result, keeping my medication going was definitely detrimental to my functionality as a person. I think, with bipolar, in general, it's not what you see on TV, things like Sally Field in *ER* or *Silver Linings Playbook*, whatever. It's not as debilitating as people foresee on the outside. But people don't realize that on the inside it is debilitating and not to be dramatic, because I don't suffer as much as other people, because I've had the advantage of having good therapists and good medication. But I do recognize that it definitely interferes with life. It definitely makes me feel like I'm swimming upstream with medication. I'm not swimming upstream against a current, however, I'm still swimming upstream with my mental health issues.

00:28:40

Moderator, NORC

Thank you, **[Participant 1]**. **[Participant 2]**?

00:28:44

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

Yeah, I don't think I have anything to share here.

00:28:49

Moderator, NORC

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

00:28:52

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

I would just say, because we're focused on the Medicare population, and I know there are people in Medicare who continue to work. I mean my brother-in-law was diagnosed in his late teens, and so he's been on disability for quite some time. But I think, broader than the work issue, it's sort of a broader experience of feeling like you can contribute, whether it's in your relationships with people, in volunteer work, in just being able to be active in society, and not feel like your condition dictates how your day is going to go, and even with medication it doesn't necessarily cure, but feeling like you can go out and just function in the world. Go grocery shopping, clean your place, have sort of basic needs met, and not feel as much, maybe, as a burden to other people in your family or your friends, and everybody wants a feeling of belonging.

So, I think all of those things are what I've experienced on a personal level, and then, of folks that we interact with, with serious mental health issues when we've had conversations about them, especially with older age. That's what resonates.

00:30:28

Moderator, NORC

Thank you. So, moving on to the next indication, which is bipolar 1 with depressive episodes, what aspects of bipolar 1 with depressive episodes are most important to you, your loved one, patients to have managed or treated? So, it's going to be the same question, just a different indication. So again, I'll turn to **[Participant 1]**.

00:30:53

Participant 1 (registered as a patient)

As **[Participant 3]** was saying, there is a sense of to love and to work are parts of actualization, and there is a sense of productivity that goes along with working, and I think that when unable to work, it just adds to the depression. It adds to, even, an idle mind is the devil's workshop, I think, since I resigned from my job, I did not want my identity to be my illnesses or my husband's illnesses. I wanted to contribute. As a result, I set up boards. I volunteer at different nonprofits, things like that. And does that mean that I'm able to work because I can set aside this time, not really because I'm still a little, my functionality is definitely impaired. However, my depression will dictate that I don't have anything to contribute. And when you hear about high suicidality with depression and with bipolar type 1, it's because they feel like they don't contribute to the world. So as a result of it is a catch-22 with mental illness that medication allows the person to function enough, maybe not to work full-time, but at least to contribute whether it's through activism or philanthropy, or even gardening, or whatever someone could do. I think that it does definitely impact that the ability to contribute is my number one aspect as far as my disability, my mental illness, is concerned.

00:32:39

Moderator, NORC

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

00:32:42

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

Yeah. And I would say that there's some amount of fear of going out if you don't have a well-maintained medication that keeps you balanced and because you're afraid if you go out, you're going to suddenly display some of these characteristics of the illness. And so, that sort of limits your world, and doesn't allow for you going out and making that contribution. So, it's very important to find a medication that creates that safety zone.

00:33:27

Moderator, NORC

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

00:33:30

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

I mean, I would say, from just a family perspective, safety, both in terms of suicide, and then also in terms of just not getting hurt by the police. If you've ever had a loved one who has been in a manic state, or my brother-in-law is a very big guy. He's six and a half feet tall, and was outside in his underwear one evening, and police were called, his girlfriend called the police, and he was not a

danger to other people. We were afraid he was going to be a danger to himself, but a six and a half foot guy and [I]t's worse if you're black or from other disadvantaged communities.

And it's terrifying that that can happen. So, you know that the importance of having good care can't be underestimated. So, I think just feeling like you have a will to live. Yeah, it is pretty basic. And if medication can provide that, then that should be available.

00:34:47

Moderator, NORC

Thank you. So, moving on to major depressive disorder, what aspects of major depressive disorder are most important to you, your loved one, or patients to have managed or treated? And some of the themes that we have heard is productivity, personal safety of the patient, we have heard about not being idle, feeling self-worth and value. So, if you all wanted to add anything to those themes that would be great, and I'm just summarizing, because we will have many more questions coming up. So, with that, **[Participant 1]**?

00:35:28

Participant 1 (registered as a patient)

I consider myself, I hate to say it, but a connoisseur of psych wards. Unfortunately, I've been through the gambit, I've been on separate scenarios and episodes as a result of my medication.

So anyway, as a result of my major depression, I've been in hospitals, and it was a cycle constantly. And hospitalizations in 1988 was $600 a day, when I was at **[REDACTED]** Hospital. Last time I was in a hospital was **[REDACTED]**, and it was about $1,500 a day, and that's just for the hospitalization. The amount of fees that I had to spend, and my family had to spend as a result of those hospitalizations was astronomical. And also, the disruption of a crisis was difficult as far as major depression. And I think that, I remember one time that my medication, and my medication is expensive, Vraylar I can only get …

So, one time I do get samples from my doctor for Vraylar because I can't afford it. I also take Latuda, which is $1,500 a month, which I'm able to get, I was able to get a scholarship for, and now I get it through GoodRx, by the grace of God, instead of $1,500, it's $27.

And I say this because there was one time when I went to the pharmacy to pick up my medication, and they said that my insurance had lapsed, and I was working full-time at the time, and they said it would be a thousand dollars on that day. And I remember saying to that person, that I remember calling the insurance company and saying to the utilization review person. I said, you know what either you, Cigna, could pay for this, or you could pay for hospitalization, or you, **[REDACTED]** from Cigna, could pay for it when I go on public aid.

And so, as a result of it, there is a major aspect of the financial burden that adds to the depression and adds to the quality of life, so I can vocalize that, I'm pretty articulate. However, there are a lot of people who can't, and they go without.

00:38:21

Moderator, NORC

Thank you, **[Participant 1]**. **[Participant 2]**?

00:38:25

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

I would just agree and say, price is, of course, an issue and something I think everyone wants to manage. The access is what's important. Is getting access for a reasonable amount and not causing other issues down the line. Not being able to change when you need to change and get a different one that suddenly works for you when your other one doesn't. And it's critical, because that's one of those things. It's, how do I manage that when I'm in need? How do I jump through all those utilization management hoops?

00:39:08

Moderator, NORC

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

00:39:11

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

Yeah, I agree with **[Participant 2]** and with **[Participant 1]** as well. I don't have anything to add on this one. Thank you.

00:39:19

Moderator, NORC

Thank you. Moving on to schizophrenia. What aspects of schizophrenia are most important to you, your loved one, patients to have managed or treated?

00:39:32

Participant 1 (registered as a patient)

With the experience of having a mother who has schizophrenia, I think the safety issue is number one. I think, even my brother-in-law who passed away and had schizophrenia, I remember one time he was at his home, and he had a situation. The police did not want to go in. They wanted my husband to go in instead and deal with him, because and the thing is that **[REDACTED]**, I'll say his name because he's a person, he didn't mean any harm to anyone, but when he was threatened, then he would act out. As a result of it people would perceive him as violent, even though he's more afraid of the other person than they were of him, and I think that keeping someone safe, we all have a right to safety. I think people keeping someone safe is the most important thing. And unfortunately, people with schizophrenia when they're going through an episode because they look, I don't know what it is, deviant or odd or something like that. Then the response makes it worse, and their treatment it's a lot harder to get through the outer crust of someone with schizophrenia than is with someone who doesn't suffer, with someone who suffers from diabetes or cancer, or there are things that people are used to having GoFundMe pages for.

00:41:08

Moderator, NORC

Thank you so much. **[Participant 1]**, and yes, you can use a first name as long as you're not sharing anything more and humanize people, of course. **[Participant 2]**?

00:41:18

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

I would just agree with that, and say, I think part of the issue is that they have trouble with communications. When you have that diagnosis and are having an episode, it affects your ability to communicate, which is something that would alleviate some of the problems I would imagine, with interactions with other people, but still wouldn't solve the major issues. So it's just finding something that can address those things, finding a medication that can address them.

00:41:55

Moderator, NORC

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

00:41:58

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

I mean, there's a lot of highs and lows with schizophrenia, different than what you experience with individuals experienced with bipolar. But there's highs and lows. So, I think things that just kind of help, anything that can help kind of even you out a little bit. And then I mean with the medications for these conditions and schizophrenia in particular, I think a lot of people with schizophrenia know that there can be a lot of weight gain. So, the adverse events are really, the side effect profile is really important, and having medications, the newer ones tend to be a little bit better, not having as much of an experience of TD [tardive dyskinesia] is good.

So, as much as treating the actual effects of your condition, making sure that it doesn't have too much, the benefit risk profile, there's risk with all of these types of medications. But just, if there's ones that are lower than others to just have those have those as options, and more, we still need more, I think, even than what exists now.

00:43:25

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

And every patient is different. I have one friend who often went off her medications, and it was because her personality, she couldn't handle the weight gain. It was just a deal breaker for her. Of course, it meant that she was often more in need of those medications. But so, every person is unique and that was just it for her.

00:43:55

Moderator, NORC

And this is great, because this segues into the next section, which is, experiences with Vraylar and therapeutic alternatives.

So, for this section, what we would like you to do is address your experiences with Vraylar, and in addition to Vraylar, any other therapeutic alternatives, and by that I mean any other drugs that treat the same conditions. So we will get started.

The first indication is bipolar 1 disorder with manic or mixed episodes. So, the question here is when considering potential medications for bipolar 1 disorder with manic or mixed episodes, what matters to you, your loved ones, or patients the most? And by this we would like you to address, how well does the medication work? How quickly it helps a patient? How frequently do you need to

take it? Once a day? Twice a day? The ease of how you take it? How safe is it? Side effects, which you all alluded to already? It's convenience? It's ease of use? Recommendation from a health provider? So, if you could sort of address all of those when you're addressing bipolar 1 disorder with manic or mixed episodes, and then we'll do that for all the other indications. And I'll start with **[Participant 1]** again. Thank you. This is great. This is great discussion.

00:45:23

Participant 1 (registered as a patient)

Well, that question is about a paragraph long. I couldn't keep track of the whole thing, but I'll try to. So, the number one issue for me is treating the symptoms. However, I've got a lot of health issues. I've got chronic leukemia and small cell lymphoma. I've got hypertrophic cardiomyopathy. I've had all sorts of things going on in my life, and so when I take medication, I have to be very careful that it intertwines with what I take for other things.

For instance, when I was taking Latuda, it caused a QT prolongation. So, with my heart condition, already I have issues with that. So, the doctor had to come in, I had to bring in a cardiologist to work with a psychiatrist to figure out if I could take it.

For instance, Rexulti is something similar to Vraylar, but I couldn't take it because of my other conditions. So, Vraylar is available as an alternative, because it just weaves into the chemicals of my body. However, there are other medications that allegedly are in that same family, but I've tried the gambit, Zyprexa. I gained 50 pounds on Seroquel. I had to sleep. I had to take it nine hours before I wanted to wake up. And so Latuda, yes, I do have to take 350 calories before I go to bed before I take it, and I have gained weight. However, it's better than the alternative. So, like I said, I'm swimming upstream, with my weight I just swim upstream as well. However, I'd rather be fat and sane than skinny and dead. So, thank you.

00:47:16

Moderator, NORC

[Participant 2]?

00:47:18

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

So, I guess I would just say, because I can't address all of these individually. I don't have that experience with them. But I would say that some of the older SSRIs [selective serotonin reuptake inhibitors] and things have had some big negatives, so I'm thrilled that there's new and improved treatments that are out there, and that at least with Vraylar, you don't gain a lot of weight with that one. So that's addressing one of those barriers and concerns. And I think it's just critical that we have these conversations with patients, and thank you so much for doing it, so that everybody comes in with an educated understanding from the patient perspective, because it is so much work and effort and fear, and it involves every aspect of your life. So, anything we can do to support the patient in seeking a treatment, that works for them is just so important, and I'm so thrilled that you are listening. And thank you, **[Participant 1]**, for talking about this.

00:48:46

Moderator, NORC

Thank you, **[Participant 2]**. **[Participant 3]**?

00:48:48

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

Agreed. Well said. I think one of the main things, I mean the second-generation antipsychotics are just, there's no way to describe how much better and different they are. My great-grandmother had dementia, and she had psychosis, and I was a teenager when she was in a nursing home and watched her get Haldol shots, and that is hard to see a loved one, and to have to go through shots, especially when you're in the middle of an episode of some kind.

So, having an oral option, once-a-day option is a great breakthrough for patients, and we work a lot as an aging-focused organization with the American Association of Geriatric Psychiatry. And so, I asked them to send me some stuff, and I just I have two studies that one person from our Research Advisory Council sent to me. One of them was published in the AJGP [American Journal of Geriatric Psychiatry] Journal, and the other one was not, but looking at Vraylar in particular, in terms of safety, and also efficacy and side effects in older populations in particular. These do have a boxed warning on them. It's an old one from 2005. They weren't tested at the time. The original drugs in people with dementia-related psychosis. So, it's still advised not to give them to folks who have that. That has set up an access block just writ large for antipsychotics for patients, but in Medicare in particular.

But in any event, this drug does seem to have a good profile by the people who actually are experts in it and prescribe it, which is nice to see, and I hope CMS takes these pieces into consideration.

00:51:09

Moderator, NORC

Thank you, **[Participant 3]**. So, now we're moving on to bipolar 1 disorder with depressive episodes. Same question. How does the medication work? How quickly does it help you? How frequently does it need to be taken? How safe is it? Its side effects, convenience, ease of use, provider recommendation? **[Participant 1]**?

00:51:31

Participant 1 (registered as a patient)

The medication, taking it once a day. How quickly does it work? Frankly, it's not a magic pill. If there was a magic pill, everyone would be taking it. So, it generally takes maybe a couple weeks. However, for me, it's a combination to treat these symptoms with, I've got EMDR [eye movement desensitization and reprocessing], I've got therapy, I've got all these things and my support system. So, the symptoms are lessened. As I mentioned before, I take it, because, as a breakthrough symptom even with my medication, I started mutilating, picking, and cutting and stuff like that. And what Vraylar did was it took away the sensation, the reaction, the positive reaction I had from my destructive behavior, so it was able to ease that. Did it stop it that night? No, no, it took a while, but it definitely did help, and without it I wasn't able to stop.

I think one of you mentioned the ECT, and I think that there are times that without that, people wouldn't be able to stop and get better. So, the medication helps me get to a point where I can at least listen to my therapist, listen to the professionals. And it definitely helped after a few nights, I'd say, that suddenly I realized that I wasn't obsessed with my behavior. However, I wouldn't say it's one-and-done. It's not like I have a headache. Let me take a couple of Advil. It goes away in half an hour. This definitely is a long-acting drug.

00:53:20

Moderator, NORC

Thank you, **[Participant 1]**. **[Participant 2]**?

00:53:24

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

I don't think I have anything to add here. Thank you for asking.

00:53:28

Moderator, NORC

[Participant 3]?

00:53:29

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

Nothing to add.

00:53:31

Moderator, NORC

Thank you. So, we are moving on to major depressive disorder. Same question. When considering the potential medications for major depressive disorder, what matters to you, your loved ones, or patients the most? And it's the same questions that I had before. How well does the medication work, how quickly it helps, how frequently it needs to be taken, how safe is it, its side effects, convenience, ease of use.

And so far, we've heard about side effects, how long you have to take it before it helps, and the fact that it helps is a good thing. So, if you'd like anything to add to what you've said so far, that would be great.

00:54:13

Participant 1 (registered as a patient)

These are getting kind of redundant, I mean, I understand...

00:54:16

Moderator, NORC

We are, so please feel free to say I've answered already, which is why I'm trying to like do a little quick, summary to sort of...

00:54:23

Participant 1 (registered as a patient)

Okay, so what you said about the different aspects, and as far as major depression, the number one thing I think that medication has to be is number one accessible, but number two, definitely ease of taking it. I think I've got a friend who takes medications, let's say, 12 times a day. That's ridiculous, and they have a phone that goes off several times during the day to tell her to take a medication. The ease of taking it is, it would probably be top of my list. I know I take Lamictal, and Lamictal is very chalky, and I have to take it separately from all my other medicine, because otherwise I choke

on it. So, Vraylar, if it's going to be available to people who already don't want to take their medicine, who already don't want to take the medicine, or don't want to admit the fact they're ill, I think you really need to make sure that it's easy to take, the dosage is reasonable. And it's not a horse pill, because I think that definitely will affect whether or not someone will take it.

00:55:34

Moderator, NORC

Thank you, **[Participant 1].** And then this section, you can also address any other drugs which you've been doing like therapeutic alternatives. And I just put it out there for **[Participant 2]** and **[Participant 3]**, if they had anything to add.

00:55:43

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

No, I just want to join **[Participant 1]** and **[Participant 3]** in saying that ease of use is very important, top of my list, because it lowers barriers to actually taking the medication, and makes it feasible in a busy life.

00:56:02

Moderator, NORC

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

00:56:04

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

I mean, the only thing I would say about major depressive disorder is that this particular drug is, at least according to the indication I saw, this is when other things aren't working that it's prescribed to you. So, all the more reason, just important that it be available, and it also looks like it causes less sedation than some of the alternatives as well, which is always nice, right? None of us want to feel like we're going through the day like a zombie.

00:56:38

Moderator, NORC

Thank you. So now we move on to schizophrenia. Same questions. So, when you're considering potential medications for schizophrenia, what matters to you, your loved one, or patients the most?

And I have repeated those questions multiple times. And we've covered a lot of topics. So, if you're like, I've already said what needs to be said. Just let me know that, and I'll start with **[Participant 1].**

00:57:04

Participant 1 (registered as a patient)

I was told that for bipolar, the general rule of thumb is an antidepressant, a mood stabilizer, and an antipsychotic, and the atypical antipsychotics that came out through the years are amazing. However, the side effects can be pretty more debilitating than others. For instance, when I took Risperdal I had to take Cogentin because I had lockjaw, and also I do have to go back to my mother. My mother has schizophrenia, and she had lithium poisoning one time. At one point she was taking medicine without telling the other doctor what medicine she was on. As a result of it, she received a diagnosis of progressive supranuclear palsy, which is almost like a Parkinson's on steroids, and that was a result of doctors not hearing, not working together to find out what she was taking.

So, when it comes to medication of, even schizophrenics all the way through people who have [inaudible] disorder, I think it's important to make sure to know how all the medications work together. Antipsychotics or atypical antipsychotics are definitely a game changer. However, they've been through a lot of generations, and they could be a lot further. However, unfortunately, when you say antipsychotic, you assume that's connected to the word psychosis, which can be seen as a horrible word. But I do think that it's come a long way, but I think it could go further. I think that mental illness tends to be an orphan disease, that it's not pretty, and so, as a result of it, there's not a lot of funding for it. So, I think that I wish that I could see that atypical antipsychotics becoming more affordable and definitely more nuanced to work with other medications because they're almost never taken by themselves.

00:59:09

Moderator, NORC

Thank you, **[Participant 1]**. **[Participant 2]**? Nothing. Good. **[Participant 3]**, do you have anything to add? Okay, so now we're moving on to the next question. So, the next two questions focus specifically on Vraylar. And I just want to clarify that because this one was Vraylar and therapeutic alternatives. So, question five, bipolar 1 disorder with manic or mixed episodes. What are the main benefits you, your loved one, patients have experienced with taking Vraylar?

What do you like about Vraylar? How well it works, how quickly it helps, safety, low risk, adverse event profile?

And also, it would be great if you merely discuss the non-clinical benefits, like I function better, or I feel better because I'm not gaining as much weight, sort of that sort of flavor. With that, I'm going to turn to **[Participant 1]**.

01:00:10

Participant 1 (registered as a patient)

One [of] the benefits of it are, I'm not cutting myself, and I think that Vraylar is a regular, there are no positive medications, because in a perfect world we wouldn't take medication. Everyone would not need medication. However, I think that the absence of negative is the number one thing that drew me to Vraylar. I think the other medications had too many side effects. So, what does it do for me? It allows me to be more of myself. As far as, what do I like about it, I don't like taking any medication. I don't like having mental illness. I don't like being different than anyone else. However, what I do like is that I get to be like everyone else if I take Vraylar.

01:01:12

Moderator, NORC

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

01:01:15

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

So, what I think is very positive about it is that we have medications that help manage these illnesses. But they don't quite do enough, and Vraylar takes it another step. It improves things even more, so what an advantage that is to have just more improvement. And so, I think it's a huge benefit for the patients.

01:01:49

Moderator, NORC

[Participant 3]?

01:01:50

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

Yeah, so, I'm just going to give you a summary for all the different indications, rather than going through. So, I don't know about the others, if they're going to, if **[Participant 1]** and **[Participant 2]** are going to have other things to say. But I would say, for all bipolar, depression, and schizophrenia, most of the folks that we know through our Talk Nerdy program, which is our patient engagement program, and then also from conversations with professionals that we interact with, geriatric psychiatrists for the most part, the patients describe experiencing more stable moods, clearer headspace. Many report both manic and depressive symptoms become easier to manage compared to other antipsychotics, it tends to cause less sedation.

Some people notice improvements quickly even within the first week, although I know **[Participant 1]** said it could take two weeks, but some have noticed within the first week boosts in mood, motivation, overall energy.

And then again, I mentioned this before, but for the treatment-resistant depression, it sometimes is the last stop at the train station, so it can sometimes work when other things have failed. And the tempering of both manic and depressive episodes with the bipolar 1 and highs and lows of schizophrenia.

Now, in terms of the effects, the restlessness is separate from TD, like the need to move and all that can be a side effect. But TD tends to be less. It can sometimes happen, I guess, in people who are on it for a long period of time. But compared to a Haldol or something else, it's much less. You have to be monitored for that, and then, if you're on it, and you have a risk of diabetes or high cholesterol, or all that, and you certainly have to watch if you have other types of kidney disease, or anything that can be adjusted with dosage. But that's what I have down in terms of what folks reported back. And overall, it seems to have a pretty good profile, and I don't think doctors just prescribe it willy-nilly, it seems to be there are guidelines around this and in the cases where it's needed, it's well-respected. FDA has approved it. It's well regarded in the specialty clinician community.

01:04:37

Moderator, NORC

Thank you, **[Participant 3]**. So, then I will put it out to the speakers. We will be talking and everybody here today bipolar 1 disorder with depressive episodes, major depressive disorder and schizophrenia. And the question is the same, main benefits, experience and taking it. And **[Participant 3]** sort of provided a summary. So, I'm going to go around and ask **[Participant 1]** and **[Participant 2]**. Do you have anything to add? Would you like to go different indication by indication? I know, **[Participant 1],** you have experience with different ones, with family members, and **[Participant 3]** and **[Participant 2]**, as well. So just let me know if you wanted to add, or you just want to give me a summary.

01:05:18

Participant 1 (registered as a patient)

Frankly, I don't mean to tell you how to do things. It's just that I think that we can get cover a lot more ground if we summarize like **[Participant 3]** did all three of those conditions, because really we're talking about Vraylar and Vraylar is something to do with mental health issues. All three of those issues are mental health. So I think, going over just each question as all three would be better.

01:05:48

Moderator, NORC

So, do you have anything to add? That would be my next question, because then, if not, we would move on.

01:05:53

Participant 1 (registered as a patient)

I apologize. I do not.

01:05:57

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

No, I thought **[Participant 3]**'s summary was wonderful. So I think we're pretty complete with that from my perspective.

01:06:05

Moderator, NORC

Thank you. Moving on to question six. And for this, based on all your input, we're going to talk about bipolar 1 disorder with manic or mixed episodes, bipolar 1 disorder with depressive episodes, major depressive disorder, and schizophrenia. And the question is, what are the main drawbacks or challenges you, your loved one, or patients have faced with Vraylar? So, what do you wish was different about Vraylar?

Do you have perceptions about the risk of experiencing harm from the medication, adverse event, risk profiles, predictable side effects, anything you would like to sort of address as main drawbacks or challenges? This would be the question.

01:06:54

Participant 1 (registered as a patient)

So, the two main drawbacks I have about Vraylar, number one is, it's advertised on television. And therefore, if I take it, everyone knows that I've got a mental health issue. All these medications that are normalized by being on television. It doesn't do any good, because all of a sudden, everyone knows. Everyone can Google even like Crohn's disease. Suddenly, someone has Crohn's disease. You see it. It follows their rectum.

It kind of crosses boundaries for the people who are taking these medications. It almost as far as HIPAA [Health Insurance Portability and Accountability Act of 1996] protects us from privacy of our medical condition. But once someone says Vraylar, they know it's a mental health issue.

The other drawback of Vraylar specifically is, it takes 13 years to go from being on the market to being generic. So, it's always going to be more expensive until it's generic. And nine times out of ten, the pharmaceuticals come up with another reason to change it. So then, suddenly, it's another 13 years before it becomes generic. So Vraylar, if Medicare could truthfully negotiate that price down, then I would hope that other, that that would be a starting point for even the private insurance companies to do that, because, for instance, there's a medication that's out there for hypertrophic cardiomyopathy, Camzyos, or something like that. I saw the commercial for it. If you look at it, it's $8,000 a month. That's $101,000 a year for heart medication, and people don't blame someone for heart medication for heart disease. They blame someone for having bipolar, for having schizophrenia, for having major depression. So, to make these medications, $1,500, $1,600 a month is really, that's a drawback, in my opinion.

And that's a significant drawback for anyone who's already, they're already suffering from a disease. So, to add to it, the cost part of it just adds to another drawback of taking it.

01:09:10

Moderator, NORC

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

01:09:12

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

I don't have anything to offer in this section.

01:09:18

Moderator, NORC

[Participant 3], yeah?

01:09:20

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

I mean just a couple of things, I think, on the flip side, we heard sometimes people can experience insomnia and if the medication has to be stopped abruptly, either due to some kind of barrier that the person's experiencing you can have withdrawal symptoms.

So, I think those are issues. I hear what **[Participant 1]** is saying on price. I mean, the one thing I want to say around the selected medications is, it seems like this was chosen based on volume just because a lot of Medicare beneficiaries take it. If you think about some of the drugs that Medicare pays for that aren't on this list, they can be in the half a million dollar range like CAR-T [chimeric antigen receptor] therapies. This is, at least according, doing just very simple math, your 116,000 beneficiaries that took it over a year at $1.085 billion, that averages about $780 a month, which is not cheap if you're on a fixed income. But it's also not a half a million dollars, or what we originally, I think heard about when we talked about this direct negotiation. So, it seems like it's just very much based on a huge number of Medicare beneficiaries needing the medication. And that to me just speaks to wanting to kind of cut down on use and access, and that worries me, and it worries our organization.

01:11:03

Moderator, NORC

Thank you. So now we're moving on to question 7, 8, and 9. And these questions ask about alternatives, so any other drugs that you've taken that are in the same conditions as Vraylar. And then we're asking you to compare and contrast those therapeutic alternatives to Vraylar from your experience, and I'm keeping an eye on the time, and for the sake of time I'm going to sort of combine those indications together. So again, for bipolar 1 disorder with manic or mixed episodes for bipolar 1 disorder with depressive episodes, major depressive disorder and schizophrenia, what medications, if any have you, your loved one, and or patients you represent have taken currently or in the past? So, I know you all have talked about many different drugs that you've taken in the past, and or your loved ones, or patients who take. Would you like to add to those?

01:12:07

Participant 1 (registered as a patient)

Well, Vraylar is, again as **[Participant 3]** mentioned, it's end of line, and it's not something that someone goes in for the first time in therapy that the doctor will say, this is what you want. I think, even from A to Z alphabetically, it's towards the end of the alphabet. So, I think that I've taken many other medications for antipsychotics. I mean, we're looking at, again, Seroquel, Latuda, Zyprexa, and that's only antipsychotics. But then, I'm taking the mood stabilizers. Topamax, I fall asleep on and even taking the antidepressants, I remember gaining a lot of weight or all these things. So there's a plethora of information as far as other medications, and Vraylar is the lesser of two evils. However, I was looking at a list of medications that make people dizzy, and a lot of the medications I've encountered do make people dizzy, so as far as functionality that definitely affects the taking of medication.

So, if I'm going to compare and contrast, Haldol or Thorazine are things I associate with "one flew over the cuckoo's nest." I hate to say it, but I do, and whereas Vraylar is definitely more manageable and more normalizing. It is not the kind of pill I would take by itself, though, it definitely is not the one that I would call the curative, or even treating of the symptoms, because there are so many nuanced of the symptoms you're talking about. Even the fact you're talking about bipolar type 1 indicates that there's many different types. So Vraylar is not a fix-all, however, to compare it to other things, the side effects are lessened.

01:14:27

Moderator, NORC

Thank you. **[Participant 2]** or **[Participant 3]**, do you have anything to add?

01:14:32

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

Yes, I think I would suggest that there's a lot of medications that treat these mental health issues. And that's a wonderful thing, particularly because the newer the medication, the better it is. And I think that we want to make sure that that continues, that there's always an improvement and new medication until we get to something that cures or fixes all the problems. But, we are very concerned that there'd be some type of non-medical switching potentially going on here because someone gets on a medication and it's working for them. They're in good condition, medications available, but then it just gets switched and it's no longer available on the formulary and then they have to search for another medication that does that. In the meantime, they're having episodes and

are uncomfortable, unable to work, and all those things we've talked about throughout this. So, it's important to achieve that continuation of care and having the alternatives is wonderful, because maybe Vraylar isn't going to work for someone, and we'll have a next medication that does work for them. But it's very concerning that we would develop some kind of situation when there's non-medical switching, and it's not a benefit to the patients to do that.

01:16:15

Moderator, NORC

Thank you. **[Participant 3]**, do you have anything to add? You're faint. You're sounding very faint.

01:16:25

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

Can you hear me better now?

01:16:27

Moderator, NORC

No.

01:16:28

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

Is that better?

01:16:29

Moderator, NORC

Yes, much better. Thank you.

01:16:30

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

In terms of bipolar 1, I think it's like the only atypical that's approved for treatment in depression, in addition to the manic and mixed episodes. So, I think **[Participant 1]** was kind of making this point. It's like anything that can kind of cut down the number of pills you have to take.

And I know that a lot of times it's sort of looked at paternalistically like, oh, we're just paying for convenience, but really you're paying for adherence, and that could mean saving somebody's life, right? So, I think that's a breakthrough, and that's worth it.

I understand, again, people are on fixed incomes. We believe in looking at things within Medicare that increase affordability. And we're really excited about the cap and smoothing, and all of that. This, I don't know that it's going to necessarily increase affordability. I'm more worried that it's going to hamper access to folks and just really want to make sure that it's still available at the level that it's available now.

01:17:51

Moderator, NORC

Thank you. So, all of you sort of touched on the unmet needs. So, I'm gonna combine the next three questions so that we have enough time for the unmet needs discussion. So, it's for the four indications we've talked about already, and it's therapeutic alternatives. And we've heard some

great points about how Vraylar is sort of the lesser of the two evils, how it's still not the first line like you have to go through other things. And then non-medical switching and things like that.

So, for questions 8, 9, and 10, what are the benefits of the therapeutic alternatives, if there are any? What are the drawbacks of using therapeutic alternatives? How do these medications differ from Vraylar? And then, the last question is, if you've tried multiple medications, or if you know of patients going on multiple medications, what are the reasons for changing or what would prompt a switching?

So again, **[Participant 1]**, just in case you didn't hear, we're talking about all the other medications that you just talked about, and in comparison to Vraylar. And the question is, what are the benefits of using them versus Vraylar? What are some of the drawbacks of these therapeutic alternatives? And if you've tried multiple medications, what are the reasons for changing medications? What prompted you?

And I prefaced all of this saying that you started by saying it's the lesser of two evils and it's never the first one. And if you would have anything to add to that on those two [inaudible] buckets, that would be great, because then we'll have time for the unmet need, which I think would be great.

01:19:46

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

Can you repeat what the core question is here, because I'm getting confused? I don't know if I'm the only one.

01:19:53

Moderator, NORC

Yeah. So, one is, how do the benefits of these therapeutic alternatives differ from Vraylar? So that's the first one.

Then the second one is, how do the drawbacks of these medications differ from Vraylar? And for drawbacks we're again talking about predictable side effects, risk of experiencing harm from the medication.

And then the final question is, if you've tried multiple medications, including Vraylar, what were the reasons for changing the medication? What prompted this change? What prompted the switching?

So, I'm combining those three together for bipolar 1 disorder with manic or mixed episodes, bipolar 1 disorder with depressive episodes, major depressive disorder, and schizophrenia.

So, that's a big question. But I'm also keeping an eye on the time. So, making sure we get to the unmet needs.

01:20:51

Participant 1 (registered as a patient)

So, first of all, I very much apologize. I'm in a grassroots nonprofit that only 10 people have keys in, and I can't believe three of them are watching. I'm so sorry, so, as far as, like the drawbacks and benefits of the other medication, I think the scariest part about starting Vraylar, was it's a new thing. I was already used to my other medications and to start something new, the fear of the side effects, the fear of like, oh, no, all over again. I think having the cocktail of what works, and to add something new, it's just always a new step.

However, as I think it was **[Participant 3]** said that it is good to have alternatives and as far as switching too, I do want to address that. There have been times when I remember when I was taking, I think, Zoloft, and the insurance company at the time said I couldn't take Zoloft anymore. I'd have to take Prozac.

And I think, the insurance company, the medical director who I'm assuming is not an MD [doctor of medicine], didn't understand that I didn't have depression. I had bipolar, and Zoloft helps with that. So, I think the drawback of a new medication, too, is trying to get the insurance company to understand why it's necessary. So especially with new medications, we want proof that it works. They don't want to try alternatives. They don't want to be the first one on the block to pay for it, and so it becomes a tier 1, tier 2, tier 3 medication. So, that's the drawback of taking a new medication like Vraylar and the drawback of some of the other medications I do take, I've talked about with the weight gain, with the sedation, with the I know definitely like when I took Tegretol, suddenly I realized that I had a violent rash that could have been fatal.

Any medication that I put in my body, my body is going to react to, because it's a foreign object. So, I think one thing that Vraylar does address was that it did, I think the researchers did look at all the other drawbacks of other things. For instance, back in the Caroline Kennedy days when they used to do lobotomies on people with mental illness. Suddenly they realized that, okay, that's not working. Let's see what else we could do. Then they introduced the talk therapy for just all these talk therapies. Then they introduced medication, and medication has evolved over the past 50 years. But so, Vraylar is good because they've looked at all the drawbacks of the previous medications. However, it's not great, because it's still in the making. It's not been tested.

It's like getting a 2026 Outback in March. It's just, you don't know what other people have gone through yet. So, that's definitely one of the drawbacks of taking a new medication. And I think, yeah, having to go before the judgment of a Utilization Review Board of saying that this is why I'm doing this one as opposed to another one, because the insurance company is going to say, why are you taking Vraylar where you could just take lithium or something? I think that there's not a lot of talking to psychiatrists talking to patient advocates, talking to patients themselves when they try to figure out about a new drug.

01:24:51

Moderator, NORC

Thank you so much, **[Participant 1]**. So, for the sake of time, I'm going to ask **[Participant 3]** and **[Participant 2]** if they have anything to add? So, we've heard about the weight gain and all the other side effects previously. We've heard about why drugs are getting switched and the whole theme of it's still a drug. It's still a foreign chemical in your body. And some of the issues with that and the evolution of treatment in this area. Do you have anything to add to the therapeutic alternatives, drawbacks, risks, and reasons for switching? And you've all covered utilization review and **[Participant 3]**, you've talked about it, and even **[Participant 2]**, and non-medical switching. So, anything else to add to that bucket?

01:25:34

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

No, I don't think so. I have one more thing, which the whole discussion in these sessions about these medical alternatives, I just want to get it in the record that it concerns me because the first provision of the Medicare statute is that the program not interfere in clinical care. And I feel like the questions around the therapeutic alternatives are in, even in the context of establishing value for

the medication, it is veering into how it's going to end up being applied by Medicare as a payer and other payers in the Part D program.

So, and also especially because we're such a tiny group here. Anyway, I know there's a lot of other things that go into it. But, I just want to get it on the record that Medicare should not be interfering in clinical care, and the whole thing with therapeutic alternatives, as we've said a number of times here, every patient's an individual. The discussion really needs to be between clinicians and their patients and their family caregivers. End of story. Thanks.

01:26:53

Moderator, NORC

Thank you. So now we're getting to the end of our time and counting down. So, I'm going to combine the two unmet medical needs question for all the different indications, so the indications would be again, bipolar 1 disorder with manic or mixed episodes, bipolar 1 disorder with depressive episodes, major depressive disorder, and schizophrenia.

And the question to you all is, what would it be like to live with any of these conditions if Vraylar or other medications for these conditions were not available? So, there was no treatment available. And so, there's that. And then, how would an individual manage or cope or not manage or cope, as part of that, if Vraylar or other medications were not available?

The second part to that question is, what aspects of these condition indications, if any, are Vraylar or other medications unable to address? So, the first is, if there was no treatment, what would it be like? And you've all alluded to that, and especially **[Participant 1]**, with your mom and the history, and then the second is, what is it still unable to address?

[Participant 1]?

01:28:15

Participant 1 (registered as a patient)

The answer to the first part is very clear. And very honestly, it's very black and white. I would be dead. I hate to be morbid or anything like that. But the truth is that the suicidality of these diseases is across the board, the end result. And when I've been off my medication, I have to keep journals of when I've been off my medication to remind myself why to continue to take my medication.

So, if Vraylar was not around, I'd probably be continuing to cut myself, and the self-destructive behavior would rise into the point where the cutting would not be enough anymore. So as far as like, what it would be like without it, that's for me a no-brainer, because I know what would happen.

And as far as like, what is it unable to address? I think, what medication in general is unable to address is behavior modification. If someone was only taking medication, then they become stagnant in their growth. So, I think that it has to be coupled with talk therapy, and I'm grateful that Medicare made two significant changes this year. Number one, they were able to cover more degrees as far as who they would pay for from a therapeutic level. That was great. Number two, they eliminated the need for certain tests for the LCSW [licensed clinical social worker]. And I'm very grateful for that, because I think it becomes a more even playing field. Because the things that Vraylar and other medications is unable to address, is the cause of why someone's feeling that way. The education of what your body, the amygdala, the frontal lobe, all that stuff is doing. Had I not had a person to talk to, and I just was given a pill, it wouldn't address. I need a combination of support systems. It's a three-prong support system. So, that's what it's unable to address. Thank you.

01:30:32

Moderator, NORC

That was great, and I love the fact that you've also summarized the importance of Vraylar and the field in itself. So, anything else to add, for **[Participant 2]** and **[Participant 3]**?

01:30:44

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

Well, I would say absolutely that hospitalizations would be up, fewer people in the workforce, more suicide, as **[Participant 1]** said, conservatorships. You'd have more people in need of those through family or some public facility, and just fewer people able to function in the world and take care of their children and their homes and families, and instead, sometimes the opposite. They are being taken care of by other people. So, progress in these medications and treatment has been spectacular, and I hope it continues because there's no cure. And we need to continue to help the people with these illnesses manage as well as they can and enjoy their lives and get it, get better, and address all the subtle and individual aspects of the illnesses because they are not everyone.

If you, **[Participant 1]**, if you don't mind if I use your example, not everyone cuts themselves, but they may do something else, pull hair out, or other aspects of the disease and the illness. So, I think Vraylar has filled a hole to advance the care of people with these illnesses. So, I think it's very important to have access.

01:32:36

Moderator, NORC

Thank you, **[Participant 2]**. **[Participant 3]**, you nodded. Okay, so this ends the official questions I have. So, then the last question I have for you all is, is there anything else you'd like to add quickly? And then we'll start wrapping up. But, is there anything else you would like to say that you haven't covered already, or you'd like to emphasize that you've covered already?

01:33:01

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

I've done a couple of these meetings, and this is the first time where other people who are on the call seem to be unidentified, or they just have, like their last initial. And CMS staff don't seem to be identifying themselves. And I understand on our end, because people might be sharing HIPAA-related information. But I was just wondering if it's possible to get the names of the people who are participating today.

01:33:27

Moderator, NORC

Sure. So, at the end, once all of these are done, there'll be a redacted transcript that will be available, so it will be redacted to protect everybody's privacy and personal information. But it should be out there and as soon as we start wrapping up.

01:33:45

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

Yeah, no. And, **[MODERATOR]**, I'm not talking about like **[Participant 2]** and **[Participant 1]**. I mean, we're here. It's our last initial. I mean, **[SECONDARY MODERATOR]** has her full name on

here. CMS staff, and whoever, like **[NORC STAFF 1]**, **[NORC STAFF 2]**, and **[NORC STAFF 3]** are, are not giving anything at this meeting. They're listening, so I'm just wondering if it's possible to know who they are with.

01:34:07

Moderator, NORC

Oh, sure, yeah. So yeah. So, **[TECH SUPPORT]**, as you know, is our Telligen person. **[NORC STAFF 1]** and **[NORC STAFF 2]** are notetakers. So, they are NORC staff. So, we have facilitator, co-facilitator, notetakers. **[NORC STAFF 3]** is also a notetaker to help us sort of the administrative side. Then we have Telligen staff, and that person is there for any tech support, and then from CMS, I will quickly wrap up, turn it over to CMS to say their thank you's, and then I'll leave it up to CMS to let you know who's there, because I don't want to speak for people that I know by name, but not necessarily by function. So, thank you again for participating in today's group. This was great discussion. We covered a lot. We had four indications. And we got through all of the indications and questions. So, we really do appreciate you taking the time to do that. Your experiences and input were extremely valuable and will help inform CMS' negotiations for these drugs. And CMS staff has been listening, and I see **[CMS STAFF 1]**'s on. So, I'm going to turn it over to **[CMS STAFF 1]**.

01:35:16

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

Thank you.

01:35:18

CMS Staff 1

Thank you. Yeah. I just want to say thank you to you all for participating today on behalf of CMS and on behalf of my colleagues that are joining the call today and were listening for the duration of the discussion. We've got folks here today from the Medicare Drug Price Negotiations team. And so, I just want to say that we're really, really appreciative for the experiences and knowledge that you all shared during today's discussion. You guys have given us a lot to think about. And we're just deeply grateful for your participation today. So, thank you.

01:35:56

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

Thank you. So, we can't learn your names?

01:36:00

CMS Staff 1

Oh, yeah, I'm **[CMS STAFF 1]**, it's nice to meet you.

01:36:02

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

Thank you. Anybody else? No?

01:36:15

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

So, I just wanted to say, thank you for having these sessions and thank you for listening. Really appreciate you involving the patient voice and the work you're doing.

01:36:30

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

I appreciate it, too. But I just want to say, from a transparency perspective, it would be nice to know who's on the call. But thank you for today.

01:36:38

CMS Staff 1

No, and certainly let me, I can introduce my colleagues as well. But, **[Participant 1]**, did you want to go ahead?

01:36:44

Participant 1 (registered as a patient)

I want to say that I appreciate this opportunity to be on here. I'm kind of sad that I'm the only patient on here. I wish that you could have more perspectives, because I'm just one person. I can live a life where I don't have to work, where I have the time to do this right now, I can live a life where I can afford medication. I wish other people could have this opportunity as well. **[Participant 3]**, I appreciate you speaking up as far as transparency. And **[Participant 2]** and **[Participant 3]**, I appreciate both of you doing patient advocacy. That is something I'm learning a lot more about. And it's such thankless work. So, thank you.

01:37:24

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

It's great meeting you, **[Participant 1]**.

01:37:27

Moderator, NORC

[CMS STAFF 1], you were going to introduce everybody?

01:37:29

CMS Staff 1

Yeah, yeah. So, I can just say, we also have on-screen **[CMS STAFF 2]** and **[CMS STAFF 3]** on the call as well for you all today.

01:37:37

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

I'm sorry, I didn't catch. What did you say, **[CMS STAFF 3]**?

01:37:39

CMS Staff 1

Sure. **[CMS STAFF 3]**, **[CMS STAFF 4]** and **[CMS STAFF 2]**.

01:37:46
Participant 3 (registered as a representative of a patient advocacy organization)

[CMS STAFF 2]?

01:37:47
CMS Staff 1

Yes.

01:37:49
Participant 3 (registered as a representative of a patient advocacy organization)

And then, who's the other gal?

01:37:53
CMS Staff 1

Oh, **[CMS STAFF 4]**, I think. Did you…

01:37:55
Participant 3 (registered as a representative of a patient advocacy organization)

No, no, that's three names, right? You're **[CMS STAFF 1]**?

01:37:59
CMS Staff 1

Yes.

01:38:00
Participant 3 (registered as a representative of a patient advocacy organization)

[CMS STAFF 3], **[CMS STAFF 2]**, there's four. There's four of you it looks like.

01:38:05
Participant 3 (registered as a representative of a patient advocacy organization)

Who's the gal in the orange?

01:38:08
CMS Staff 1

[CMS STAFF 3].

01:38:11
Participant 3 (registered as a representative of a patient advocacy organization)

Oh. And then I see two others. No?

01:38:16
CMS Staff 1

Yes, **[CMS STAFF 4]** and **[CMS STAFF 2]**.

01:38:19

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

Oh, okay. Okay, all right. Thank you.

01:38:28

Moderator, NORC

Well again. Thank you all for joining this roundtable event. If you have any questions following up today's session, please feel free to email, IRARebateAndNegotiation@cms.hhs.gov.

01:38:42

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

Thank you.

01:38:44

Moderator, NORC

Thank you all.

01:38:47

Participant 1 (registered as a patient)

Thank you.

=== END OF TRANSCRIPT ===

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

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

Appendix

Participant 1: Registered as a patient who has experience with the selected drug; a patient who has experience with the condition(s) 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 a company with direct/indirect interest in the Negotiation Program, in excess of $10,000 by you, your spouse, or an immediate family member
No	Direct assistance preparing your remarks from someone who is NOT a family member, caregiver, friend, or your healthcare provider
No	You, your spouse, or an immediate family member is employed by or holds equity interest (stock or ownership interest) in excess of $10,000 in a company or related association with direct or indirect interest in the Negotiation Program
No	Any other personal or professional relationship or interaction with a company or related association with direct or indirect interest in the Negotiation Program that may be considered a financial conflict of interest

Participant 2: Registered as a representative of a patient advocacy organization

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

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

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