

*This transcript was lightly edited for readability.*

## Introductory Remarks

### Moderator, RTI International

Hey, everyone. I'm **[Moderator]**, and I am from RTI International. I want to thank you so much for coming today. I also wanted to introduce my colleague, **[Secondary Moderator]**, who you see on the screen as well, and you might hear from her during today's discussion in addition to talking to me, of course. The Centers for Medicare & Medicaid Services, which we will refer to throughout today's event using the acronym CMS, is convening this patient-focused roundtable event and others as part of the Medicare Drug Price Negotiation Program. The information shared during these roundtable events will help CMS understand patients' experiences with the conditions and diseases treated by selected drugs, patients' experiences with the selected drugs themselves, and patients' experiences with other drugs that are used to treat the same conditions as the selected drug. The information shared during these events will also help CMS identify other medications used to treat the conditions treated by these selected drugs, what matters most to patients in managing their condition, and other important factors CMS might consider in negotiating Medicare pricing with the manufacturers of these selected drugs.

The purpose of today's event, what we're going to talk about today, is to hear from you all. The group may include patients, caregivers, and patient advocates, and we want to hear about your experiences with the conditions and treating diseases treated by Tradjenta, and for that, we're talking about type 2 diabetes [mellitus] today. We want to hear about your experiences with Tradjenta itself, and with other medications for the same conditions. I want to emphasize that our focus today is on the patient experience. If you wish to share input on other topics related to the Drug Negotiation Program that are not directly focused on that patient experience, we ask that you send that input to the mailbox, which I think is in the chat, and it is [IRARebateAndNegotiation@cms.hhs.gov](mailto:IRARebateAndNegotiation@cms.hhs.gov), instead of talking about it during today's discussion.

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

## CMS Remarks

00:02:27

### 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.

**00:04:18**

**Moderator, RTI International**

I also want to make you aware that staff from CMS are sitting in on this event so they can hear your experiences and opinions directly from you. I'm going to hand it over to **[CMS Staff]** for a moment and let him say hello.

**00:04:32**

**CMS Staff**

Thank you, **[Moderator]**. Hello, everyone. I'm **[CMS Staff]** from the CMS Drug Price Negotiation team. There are other CMS staff members on the call today, and we are part of the team that helps get public input for the Negotiation Program. On behalf of CMS, we want to thank you for participating today. We're going to be on the call, but we're going to have our cameras off so that the discussion can be focused on you guys.

## Housekeeping

**00:04:54**

**Moderator, RTI International**

Thanks so much, **[CMS Staff]** and team. I'm going to go through a few housekeeping items and ground rules, so everyone knows what to expect before we get started with our discussion. First, if you get disconnected, please attempt to rejoin as soon as you can. If you cannot connect, please reach out to the email that's here on the screen. It's [IRADAPStechsupport@telligen.com](mailto:IRADAPStechsupport@telligen.com).

This discussion is not open to the press or the public. We are, as you see, using first names only during the discussion to protect your privacy, and we ask that you do not share any unnecessary

protected health information, for example, your doctor's name, the name of a medical facility where you received care, or any personally identifying information, for example, your employer's name, the city you live in, or names of schools you attended during the discussion. Following the event, CMS will prepare transcripts that have participant names and identifying information removed, and those transcripts will become available to the public.

You can see, and we've talked about, that we are video recording today's event, and these recordings will not be shared publicly. The recordings are only used for internal program documentation and to produce those redacted transcripts for public release, consistent with Federal privacy guidelines. By participating, you are consenting to being recorded for these purposes.

As far as participation goes, we of course hope that you will contribute your perspectives throughout the session. However, if there are questions that arise that you don't feel comfortable or don't want to answer, that's okay.

We ask that you minimize background noise by silencing your cell phone and other devices if you haven't already done so, and we ask that you mute yourself when you're not speaking. If you can try and minimize other expected background noise, that would be great.

We are also asking that you keep your video on throughout the discussion, and we have reserved up to two hours for the session. However, it's possible that we might not need that full two hours to discuss everything we have planned, and if that happens, we can let everyone go a little bit early.

You can see me looking down, I have a discussion guide in front of me, and that's to make sure that we keep on track. We have a lot of topics to cover, so if occasionally I need to redirect our conversation or cut a conversation short, to make sure that we're covering all the topics that we have and that everybody gets a chance to discuss their perspectives. There's only two of you here today, so I think you'll get plenty of chance, but we want to make sure everyone feels comfortable and has that opportunity.

If you do need to step away briefly during the discussion, that's totally fine. Turn your camera and microphone off and rejoin when you're able to. You don't need to tell me you'll be away from your computer, return to the discussion when you're able to. And if you completely cut off, of course, we'll try and reconnect you.

With only two of you, this is probably less of an issue, but we ask that you try and speak one at a time. If for some reason there's some crosstalk, I might interrupt you to make sure that it's getting picked up by the recording and that everyone has a chance to share their thoughts. You heard we tested the raise hand feature. We might not need that today, but if you feel like there's something that you need to discuss and you want to make sure it gets recognized, you can go ahead and use that, and I'll keep an eye out for that, too.

We are hoping that everything will be focused on our oral discussion, but you can also add comments into the chat if you don't get a chance to share them orally. This might be the case, for example, 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 else that you want to add after we've moved on. We ask that you try and note what question you're answering in the chat so we can track that.

We'll get started, and I'm going to ask you to introduce yourselves, and if you could take a moment to let us know, we see your first names, but if you could tell us your first name or what you'd like to be called today, and whether you will be sharing your experiences as a patient, a caregiver, or from the perspective of a patient advocate. **[Participant 1]**, you are first on my screen here.

## Discussion

00:09:17

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

Hi there, [Participant 1]. I will be sharing perspectives as a patient advocate that focuses on older adults.

00:09:23

### Moderator, RTI International

Thanks so much, [Participant 1]. And [Participant 2]?

00:09:27

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

Hi there, great to be with you all. I'm [Participant 2], and I am a patient advocate today, working on behalf of a group that advocates for lower drug prices and mobilizes patients to do so, Patients for Affordable Drugs.

00:09:41

### Moderator, RTI International

Thank you for introducing yourselves. We're going to get started with our discussion, and I want to note that I know we're here to talk about Tradjenta, but before we get into that, I want to focus this first part of our discussion not on the medication, but on patient experiences with the conditions treated by Tradjenta. So first, thinking about the different ways that diabetes affects patient lives, what would you say are the most important aspects of the condition to have managed or treated? These could be things that affect patients in the short term or in the longer term. [Participant 1]?

00:10:33

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

I'm happy to jump in. I don't have the experience of just diabetes here, but I would like to underscore that when we're talking about effective diabetes management for older adults, we're also thinking a lot about other comorbid conditions, other medications that they're using, and coordinating care effectively across those conditions. Not often that we're dealing with just someone with diabetes when we're talking about the older adult population.

00:10:58

### Moderator, RTI International

In consideration of those comorbid conditions, that makes sense. [Participant 2]?

00:11:08

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

Similarly, I would say a lot of our patient advocates in our community have additional conditions on top of diabetes, and because it's a chronic condition, I think folks are concerned not only with managing their health day in and day out for years, or in some cases decades on end, but also thinking about the financial impact that this has on their lives over the span of a long window.

00:11:33

Moderator, RTI International

So the chronic aspects of it, and what that can mean more holistically. **[Participant 1]**?

00:11:43

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

I would add to **[Participant 2]**'s point about the long window of care, we also know that effectiveness of medications can change over time as the disease progresses, and as they may be diagnosed with other conditions that, as I mentioned, need other medications, so being able to have access to the appropriate medications as the disease progresses and medication needs change is especially important.

00:12:08

Moderator, RTI International

Appreciate that. **[Participant 2]**?

00:12:15

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

I think, like any condition, people who are managing diabetes want to be able to have a normal life. They want to be able to work, participate in sports, spend time with families, grandkids, dogs, and so I think there's really a desire to have therapies that, in terms of side effects, but also finances, can fit into a full, rich life, and where folks aren't giving up other things that are really important and affirming as part of having a medication.

00:12:50

Moderator, RTI International

You touched on some of those quality of life aspects of that, or day-to-day activities, and I think you talked again about the financial aspect of that and treating those. Anything else? The things that are aspects of diabetes that you think are important for patients to have managed or treated? We talked a little bit about quality of life and how they're feeling or functioning. Any specific symptoms or progression-related concerns, complications, mental health, independence, anything like that that you've heard as patient advocates? All right.

We're going to move on, and we're going to talk about patients' experiences with the medications for diabetes. For this next question, I'm going to ask you to put something in the chat. As patient advocates, I'm going to ask you to think about what medications you and the patients you advocate for have taken, whether currently, in the past, for diabetes. I realize that there are a wide range of options here, so if you could think about those that maybe you hear about most frequently even, or more rarely used medications, that's fine. I don't want you to feel like it has to be this exhaustive list of everything that's ever been used, but if you could include those in the chat. Thanks, **[Participant 2]**, I see that you've added a few. You don't have to know what is most typically used. We're trying to get a sense of what other medications diabetes patients use. **[Participant 1]**, I see you added GLP-1s [glucagon-like peptide-1s]. As a point of discussion as we talk through this next section, we're going to talk about Tradjenta, but also about some other medications. We want to have a baseline of what that might include. Thanks so much for sharing that.

For these next few questions I want to note that we are going to talk about experiences that you, your loved ones, or patients you advocate for have had with Tradjenta and with other medications used for diabetes. Some of those that you included, and if you think of others, that's certainly fine to include that as well. As we're talking about these, if you could specify which medications you're talking about as you share those experiences. If it's Tradjenta, or if it is something else, that's fine. First we're going to talk a little bit about benefits. What benefits have you, your loved ones, or patients you advocate for experienced with medications? Again, any medications used for diabetes. I'm asking if you will make sure you're indicating which medication that is. These could be related to, for example, effectiveness, dosage, how it's taken, administered, safety, all of those categories of things. What benefits do you see? Or have you heard? **[Participant 1]**.

**00:17:32**

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

One of the things that we hear with Tradjenta is the ease of use, so the single pill once a day is especially important when we're talking about older adults with potentially multiple medications, it's that familiarity, that routine is especially important for older adults.

**00:17:51**

**Moderator, RTI International**

And **[Participant 1]**, talk to me a little bit more about that. You said it's especially important in the familiarity and routine. Can you expand on that a little bit?

**00:18:01**

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

What we find is that when we're talking about older adults and taking multiple medications, oftentimes, that the pills that they're taking, the pill schedule, it may not all be pills, the medications that they're taking and the schedule, changes from that can cause distress and confusion, when we're talking about anyone who might be dealing with any sort of dementia. It's the ease of use, making it simple is important, and on the flip side of that, changes from that can definitely produce confusion, distress, and affect adherence, ultimately.

**00:18:42**

**Moderator, RTI International**

When you say ease of use, tell me a little bit about that. I think you said the routine is maybe part of that ease of use. Are there other aspects of the way Tradjenta is administered, or the frequency, or anything like that?

**00:19:01**

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

The once a day and taken orally.

**00:19:04**

**Moderator, RTI International**

I think you mentioned that early on. **[Participant 2]**, anything to add related to benefits of Tradjenta for treating diabetes, or of any other medications?

00:19:20

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

I would say we've had plenty of folks talk about how it's helped them with managing their blood sugars and their A1C [hemoglobin A1C] as a whole, and so it's been an important part of diabetes management and very effective.

00:19:33

**Moderator, RTI International**

So the effectiveness is a part of that. Any benefits of any of those other medications that you shared that could be used to treat diabetes? Maybe on the flip side, we've talked about benefits, and if you think of others we can certainly talk about that as well. Thinking on the other side of that, there could be drawbacks or challenges, both for Tradjenta and other medications used to treat type 2 diabetes. What would you say some of those drawbacks or challenges have you or the patients you advocate for experienced with medications used for diabetes? Again, tell me what those medications are and what those challenges might be. **[Participant 1]**.

00:20:52

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

I'm jumping back to a point I made earlier, but we know that as the disease progresses, the medication needs can change. Getting used to a certain medication or combination therapy and then having that change over time can be a definite drawback for patients. And any changes that are made outside of that are especially troubling. The disease may warrant a change, but that's why I think it's especially important that the medication that the patient and clinician decide on is accessible to them, because those changes can be so disruptive.

00:21:31

**Moderator, RTI International**

So the change itself can be the challenge then, acclimating or adjusting to those changes. And **[Participant 1]**, as far as the reason for the change, you mentioned there could be something related to the disease itself that warrants that, or there might be changes in the progression. Can you talk a little bit about the reasons that a patient might need to change their medication?

00:21:58

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

Beyond those two, you mean?

00:21:59

**Moderator, RTI International**

Or expand on that, that's fine, too.

00:22:02

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

I'm not sure how in-depth I can get beyond that, but I would say, if the disease is changing in a way that the medications are no longer effective, they're going to have to have a conversation with their

clinician and find a different protocol. If they are diagnosed with new conditions, things often have to be adjusted to accommodate the new medications, or they may now have contraindications. There may be reasons why they can't. We know that with Tradjenta, it's especially effective for people with kidney problems. On the flip side, if they're diagnosed with other diseases that contraindicate, there could be a switch. And then, outside of that, if there's not changes to their health, but changes to what they have access to in terms of medications that could warrant or demand a change in what they're prescribed.

**00:23:00**

**Moderator, RTI International**

That's really helpful. **[Participant 2]**, I don't want to you to lose your thought at all, but, **[Participant 1]**, I want to mention or talk about this. You said something that may actually be somewhat related to a benefit, but you said that Tradjenta could be particularly used for people with kidney problems. Can you talk a little bit about that, and what your experience has been?

**00:23:26**

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

Not being a clinician, I'd have to defer on that.

**00:23:31**

**Moderator, RTI International**

That's fine. I wanted to make sure we captured if that was something that you had heard from patients as a benefit. **[Participant 2]**, challenges or the drawbacks of Tradjenta or other medications?

**00:23:50**

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

I touched a bit on this earlier, but I think what we hear overwhelmingly is the financial impact and we hear stories from across the country of folks choosing between Tradjenta and food, Tradjenta and gas, and if they take multiple medications for diabetes, say they're on metformin as well as Tradjenta, they simply can't afford all of them. In some cases, even folks with insurance, with Medicare Part D plans, are still really struggling with the financial affordability of this drug. I think that is something where people want to take it, they experience a lot of clinical benefits, but in terms of the impact on the rest of their lives, it's not tenable to be on it for the long haul or they have to give up a lot of other things that they need.

**00:24:41**

**Moderator, RTI International**

We'll definitely touch on that in a little bit too, but that's really helpful to hear those experiences. As far as any drawbacks or challenges related to any other medications used, to some of those that you put in the chat, or if anything else has come to mind? Have you heard about any challenges or drawbacks of Tradjenta or these other medications as it relates to effectiveness, how it's taken or administered, some of those frequency or dosage things that we were talking about earlier, any safety or side effect profiles, those contraindications, anything that you'd like to add for any of those medications? Or that you've heard from the patients you advocate for? **[Participant 1]**?

00:25:44

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

Were you phrasing that as drawbacks, or anything else that we've heard?

00:25:48

**Moderator, RTI International**

Yeah, drawbacks. We will get into some comparisons in a moment, but we're generally trying to understand the patient experience as it relates to drawbacks or challenges for medications used to treat diabetes.

00:26:08

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

What I have heard is that the side effects are considered to be very tolerable. That is going to be patient to patient, but one thing that is a benefit that I didn't say earlier, so I'm going to squeeze in here, is I mentioned the oral and the once a day, but it doesn't require the dose adjustments, which can be very burdensome, so that is also a positive aspect for many patients.

00:26:33

**Moderator, RTI International**

And that's specific to Tradjenta, [**Participant 1**]?

00:26:36

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

Yes, thank you for clarifying, yes.

00:26:37

**Moderator, RTI International**

And [**Participant 2**]. Are there drawbacks or challenges?

00:26:43

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

Something we hear from our patient advocates with diabetes is simply the mental burden and the tightrope that folks walk with diabetes and trying to make sure that your blood sugar stays in range, and that you don't experience any scary episodes associated with being too low or too high. That's a lot to bear day in and day out, and that is something that folks sit with and always have to have in the back of their minds while they go about everything else that they're doing.

00:27:13

**Moderator, RTI International**

That's something with the condition that they're managing. That definitely makes sense. You all talked about some of the comorbidities and other things that people would have to consider. Anything else related to treatments for this condition? You all mentioned some of the GLP-1s, metformin, insulins, Jardiance, were all brought up. Any benefits or drawbacks that you've heard

specifically for any of those medications? Or the patients, and I understand you all are representing patient advocacy organizations, so it would be the perspectives of those patients. We've touched on this a little bit, and I said we were going to get a little bit more into it. Overall, when patients are considering potential medications to treat their diabetes, what would you say are the factors that matter to them most? Those could, of course, be things related to effectiveness, safety, side effect profiles, the contraindications, comorbidities, and then some of those financial aspects that we've talked about as well, but we really want to get the full picture of the things that patients are considering when they're making these decisions. **[Participant 1]**.

**00:29:12**

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

I feel like you reiterated a lot of what I would say, because I've already said it. Clearly effectiveness is important. But beyond that, recognizing that it is a complicated condition to manage, that usually, Tradjenta is taken with other medications, whether for diabetes or for other conditions, that it's particularly important to have those more simplified regimens, so that we're effectively making sure that we're not at risk of, especially in the older adult population, not managing glycemic control properly, which can lead to cognitive impairment and falls, and decreased independence. Effectiveness, but also simplifying the regimen and making it as easy as possible to manage can really prevent a lot of serious side effects.

**00:30:09**

**Moderator, RTI International**

That's great, and **[Participant 2]**, I want to make sure we get to you, but I want to follow up with **[Participant 1]** for a minute. When you're talking about effectiveness, you touched a little bit on this, but if you could expand on what effectiveness looks like to the patients you advocate for when it comes to diabetes management.

**00:30:27**

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

Again, I feel like we're getting a little bit into the clinician territory, but managing their symptoms, managing good glycemic control, and very few side effects, and then avoiding things like downstream consequences of falls and cognitive impairment. But I would normally leave that to the clinicians.

**00:30:52**

**Moderator, RTI International**

Sure, and really we're looking for the patient experience versus the clinical experience, we're really most interested in what patients would be reporting, and what they would view as effective for them. I think you're touching on exactly the right things in terms of what we're looking for, **[Participant 1]**. **[Participant 2]**.

**00:31:20**

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

I think we see a lot of the same factors in terms of flexibility, quality of life, clinical effectiveness, and all of those things are intertwined, so if you're having fewer highs and lows, that's better for your

health outcomes, and you're going to have a much more pleasant week. But then, certainly, I think that the financial component matters, insurance coverage matters, is there a pharmacist in your area? How easy is it to procure a drug? Because a lot of diabetes products need to be refrigerated, or if you need to inject yourself, gaining confidence doing that is going to be a whole journey as well. I think there are a lot of layers when it comes to the ease of obtaining and using a diabetes treatment.

**00:32:10**

**Moderator, RTI International**

A lot of things that we need to consider, or that a patient would need to consider, when making these decisions. **[Participant 2]**, you talked a little bit about the quality of life, and you touched on some of those layered aspects of what that might mean, but for the patients you advocate for, specifically those with type 2 diabetes, what would a quality of life look like to them in management of their conditions?

**00: 32:39**

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

I think in a lot of ways, it has to do with having your blood sugar range be in a place where you can go about your daily routine in a way that is comfortable, in a way where you can do what you need to do. Whether it's family obligations or working out, doing well at your job, I think all of those things are in the mix. I think being able to go about a day and not have diabetes affecting you is really significant.

**00:33:14**

**Moderator, RTI International**

So being able to have those daily activities without, it sounds like, considering the effects there. Anything else that you think patients are considering when thinking about treatments for their diabetes? **[Participant 1]**.

**00:33:40**

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

I would jump off of what **[Participant 2]** said, that we know with older adults with any disease, but especially with something like diabetes, that quality of life, that independence is so critical. Independence because of how the disease is impacting them, but also independence in terms of the management. What is their regimen for management, and is that constricting their day? Is that impacting their ability to take care of themselves, their loved ones, to be at the events that are important to them? Both with the disease management, in terms of how the disease is impacting them, but also in terms of how the actual medication impacts their day.

**00:34:19**

**Moderator, RTI International**

With independence as it relates to the medication, are there aspects of the various treatments that you think, or that patients have reported, as being more difficult in terms of maintaining their independence? Do they have to be close by to take their medication? Is there something that's

restricting them that way? Tell me a little bit more about independence as it relates to the treatment itself.

**00:34:47**

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

I would be speaking about medications that are not necessarily therapeutic equivalents, but we know with the GLP-1s, it's requiring injections. If it's multiple times a day, it may require taking medications with you. If it has to be something that's taken with food, it can interrupt your day because you have to make sure that you're also having a meal. But that's broad, and it's not necessarily comparing apples to apples, because they may not be therapeutic equivalents, especially with Tradjenta being that second-line therapy, typically. But it's striking the ease of use that people report with Tradjenta, because it's the oral once a day without need for adjustments. It's really thinking about what might interrupt your day in order to take the alternatives.

**00:35:43**

**Moderator, RTI International**

That's really helpful, and you talked about that ease of use as a benefit, too, and so now, since we're talking about that as it relates to independence, as it relates to the medication, and then also quality of life independence. Anything else? All right, so we're going to move on, and I want to thank you, of course, for thinking through these tricky, nuanced questions with me and being patient as we do our follow-ups. We're going to talk now about how Tradjenta and the other treatments for diabetes meet patients' needs. Right off the bat, we asked you to reflect on the most important aspects of diabetes to have managed or treated. Aside from those aspects that you've already shared, and we talked about that some with benefits as well, what other medical needs related to diabetes are important to you, your loved ones, and the patients you advocate for? And it's okay if we do repeat some of what we discussed in the past, that's fine too. Again, we're looking for medical needs related to diabetes that are important, I think in your case, to the patients that you advocate for. For example, there might be medical needs that patients report related to specific symptoms, or aspects in terms of the way people feel, what the results are, or side effects of the available treatments. We've talked a lot about quality of life, but if there are additional, medical-related quality of life factors that they would consider, the other comorbidities that could come along with diabetes for the populations you represent. **[Participant 2]?**

**00:38:19**

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

I think we've covered all the broad strokes in terms of the patient experience and the medical component, at least with the community I work with.

**00:38:31**

**Moderator, RTI International**

Let me rephrase it a little bit. What medical needs are patients hoping that treatments, any treatments for this condition, would address? It's okay if we've talked about it before. As a whole, when patients are considering treatments for diabetes, what medical needs are they hoping that those treatments would address? **[Participant 2]?**

00:39:03

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

I think folks want to have blood sugars that are in range, have an A1C that is in range in the most immediate sense, but folks are also looking to prevent long-term complications and ideally other comorbidities. I think those are a lot of the priorities, thinking clinically, that folks are looking for.

00:39:34

**Moderator, RTI International**

That's really helpful, **[Participant 2]**. So getting the blood sugars, preventing the progression or the comorbidities. Anything else to add? **[Participant 1]**.

00:39:50

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

I want to echo that. I don't think that patients are always thinking it's about my blood sugar being in this range, or, they're seeing lab results and they're having those conversations, but what is important is how is it impacting my quality of life now, and how is it impacting my quality of life down the road in terms of complications, as **[Participant 2]** brought up. As much as it is a factor, thinking about the biomarkers and what they're seeing on their lab results, they're really thinking about how is the disease progressing, and how is it changing my life, and the ability, as we've already spoken about, to do the things that I want to do. And, thinking about the complications that can come with diabetes, "Am I preventing that? Am I doing everything that I can to make sure that hopefully I don't have to suffer from those complications?"

00:40:49

**Moderator, RTI International**

That's a great addition, and good additional context. We're talking about the biomarkers, but then also that quality of life, and how do you feel in the day-to-day, and then, preventing the progression or the additional complications that could come from that. I think we've covered all of those. I'm going to shift a little bit now. We're talking about the things that they hope would be covered by treatments for diabetes. But for the next couple of questions, I want you to think about the experiences that the patients you advocate for have with the treatments for, or the conditions that are treated by Tradjenta. Again, those treatments could include Tradjenta or other medications, and other types of available treatments for conditions for that condition, or for diabetes, even if they might be outside of the ones that we've mentioned. Which important aspects or needs of the condition are being addressed? If we're thinking about all of those factors that you hope would be treated, which are being addressed or at least partially addressed by the existing treatment options for diabetes? We've talked about some of the things you would hope a treatment would address, which are being addressed by the available treatment options. And as a reminder, it's not necessarily limited to the needs discussed in the previous question, or to the medications only, it could be other treatment alternatives. **[Participant 2]**?

00:42:42

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

To be frank, I think it's a bit of a challenging one because diabetes management can vary so much for one person over the scope of their lifetime in terms of, if you're going through this life change

and you have different hormones, you might need different medications, your blood sugar ranges might vary, and so I think it can be hard to pinpoint exactly, because we see so much variety. And so many factors that happen outside of the doctor's office are in the equation. I know I've talked a lot about the financial component, but if you are struggling to buy your medication and the consideration is drugs or food, you really need to be thinking about what you eat when you are living with diabetes, and so it's also really not ideal for folks to be experiencing food security, or not to be able to access nutritious foods. I think we see all sorts of factors coming into play when we're thinking about the medications on the market, and so I think a lot of our patients would say, sometimes frequently, that the medications can meet my needs, but there's definitely room for improvement.

**00:43:59**

**Moderator, RTI International**

I appreciate that, and we're going to talk about that room for improvement, for sure. I appreciate you bringing that up. **[Participant 2]**, you also pointed out that for an individual who has a chronic condition like diabetes, that their needs might change over time. Maybe there are times when it does meet their needs, and sometimes when there are aspects that are not being met. I appreciate that. **[Participant 1]**, anything from you, and thinking about the aspects or the medical needs, or other needs of the condition that are being met by the available medical and non-medical treatments available?

**00:44:47**

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

I'm not sure I can add anything that **[Participant 2]** didn't say. I think really recognizing that it's variable, it depends on all the myriad other conditions that they may be dealing with, the time in their life. I'm sure there are times when they would say, "No, my needs are being met," and there's times, and patient to patient, when there are gaps.

**00:45:12**

**Moderator, RTI International**

In addition to within an individual patient, there could be changes over the course of their experience with the condition. It sounds like, **[Participant 1]**, you're also saying it could vary from patient to patient.

**00:45:24**

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

Oh, absolutely, yes, yeah.

**00:45:26**

**Moderator, RTI International**

I appreciate you adding that detail, too. On the flip side, this is what we were getting at, **[Participant 2]**, and I think you touched on this and anticipated this question. What aspects or needs of the condition are not being addressed by existing treatment options? And again, we're looking for information related to the gaps in treatment or concerns that remain despite the available

treatment options. And I think you all have touched on some of this, but, to pull it together. **[Participant 1]**?

**00:46:20**

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

I don't want to repeat everything I have said, but I also want to echo, affordability is critical. I also think that patients expect that when their provider and they make a decision on a medication, that they're going to have access to that. I think that access is not always guaranteed. It's the affordability and access in addition to all of the other factors that we've discussed.

**00:46:48**

**Moderator, RTI International**

Affordability and access, and it sounds like a key component, no matter what the treatment is. Appreciate you sharing that. **[Participant 2]**.

**00:46:58**

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

I think that that's the issue that we hear the most about, and in a lot of cases, folks have desired outcomes with these products, but it's staying on them consistently can be really challenging because of the price tag, because of what can happen when you change insurance, and so it's not easy for folks to have the diabetes management that they're really looking for.

**00:47:24**

**Moderator, RTI International**

Understood. Again, challenging to stay on because of some of these affordability and access-related concerns. Anything else? Any gaps in treatment or concerns that remain for the patients that you advocate for? It doesn't look like we have any follow-ups from our back channel. Before we leave and close out today's session, I want to give you each an opportunity to summarize your thoughts on the importance of Tradjenta for patients, and also, this is an opportunity to raise any topics that you feel weren't adequately covered during our discussion today. To ask it very directly, do you have any final thoughts about Tradjenta, conditions treated by Tradjenta, or other medications used to treat diabetes that you feel are important to share with CMS? And, either one of you, **[Participant 1]**, if you want to go ahead?

**00:48:41**

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

I want to echo everything that I have said. It's really important, especially for older adults, that the medications that they are prescribed and have access to are not only effective and preventing complications and allowing for the independence and the maintenance of the quality of life, but that they are easy to use, that we are not forcing changes that can be confusing for older adults, that can interrupt medication regimens, and ultimately lead to adherence issues. And we really appreciate the opportunity to be a part of this, and that CMS is doing this, and affordability is a tremendous issue. We also want to make sure that we're not dictating clinical care. So the choice is between the patient and the provider, and that whatever medication is determined to be best for them, that they have access. But thank you so much.

00:49:42

**Moderator, RTI International**

I appreciate those thoughts, **[Participant 1]**, and for sharing the experiences for those patients that you advocate for in your organization. **[Participant 2]**.

00:49:55

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

I want to reiterate how happy and grateful I am to be here, and how the patients we work with talk every day about how they're already benefiting from the Negotiation Program and how it is transforming lives. People are really excited to see Tradjenta included and to see other diabetes medications included. I spent all of Tuesday with a gentleman who's been benefiting from the insulin out-of-pocket price cap for years, and so this is really a very needed step in the right direction and people are excited. For Tradjenta alone, I have stories from people from New York, Michigan, Maryland, Arkansas, Florida, of folks really struggling financially, and in some cases, paying... I have a woman from Michigan who went to refill her Tradjenta medication and she was expected to pay nearly two grand out of pocket, and so it's really challenging for folks who need this medication, and I think there are high hopes, as well as a desire, to build on Medicare negotiation.

## Closing Remarks

00:51:16

**Moderator, RTI International**

Thanks so much for sharing those final closing thoughts, **[Participant 2]**, and the perspectives, again, from the patients that you're talking with. I'm going to see if our CMS colleagues want to come back on camera, and I want to thank you on behalf of myself and **[Secondary Moderator]** for taking the time to talk with us and participating in our event and those thoughts and sharing the perspectives, again, from the patients that you advocate for are valuable and help inform CMS' negotiations for Medicare pricing for Tradjenta. I'm going to turn it over to **[CMS Staff]** for a moment with some closing thoughts.

00:51:59

**CMS Staff**

I'd like to echo what **[Moderator]** said, thank you all for coming to this discussion. We listened in the background, it was a great discussion, so thank you for coming here, and thanks.

00:52:09

**Moderator, RTI International**

Thank you so much. We're going to share a final parting slide on the screen here. You'll see if you have any questions following today's session or anything else that you'd like to share with CMS, you can submit them to the mailbox at [IRAREbateAndNegotiation@cms.hhs.gov](mailto:IRAREbateAndNegotiation@cms.hhs.gov). Thank you so much for your time today.

===== 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

<b>Declared Conflicts of Interest</b>	
Yes	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

<b>Declared Conflicts of Interest</b>	
No	Receipt of financial payments (e.g., gifts, funding, research support, honoraria, travel, or other expenses) from companies with direct/indirect interest in the Negotiation Program (e.g., drug companies, health plans) in excess of \$10,000 by you, your spouse, or an immediate family member.
No	Direct assistance preparing your remarks from someone who is NOT a family member, caregiver, friend, or your health care provider.
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