Transcript: Tradjenta Roundtable Event, April 24, 2025, Medicare Drug Price Negotiation Program Public Engagement Events

This transcript was lightly edited for readability.

Introductory Remarks

Moderator, RTI International

Welcome, everyone, and thank you for joining us today. Hi, I'm **[MODERATOR]**, and I'm from RTI International. And I also want to introduce my colleague, **[SECONDARY MODERATOR]**, who you will hear from a few points throughout the discussion today. The Centers for Medicare & Medicaid Services, or CMS, is convening this patient-focused roundtable event and others as part of the Medicare Drug Negotiation Program. The purpose of today's event is to hear from y'all, a group that I can see includes patients and patient advocates, and potentially some caregivers.

And we want to hear about your experiences with type 2 diabetes, which is treated by Tradjenta as well as about Tradjenta, and your experience with Tradjenta itself, and any other medications that you've taken for type 2 diabetes.

Just wanted to make a note that CMS does welcome other comments related to the Drug Price Negotiation Program. But for today, we would really like to hear patient voices. So, if you do have a policy statement or a research article to submit, I just want to encourage you to use the mailbox, and that is IRARebateAndNegotiation@cms.hhs.gov, and we'll have that on the screen at the end. So, if you didn't catch that now, don't worry. It will be on a slide at the end.

All right. So, the information y'all share during these events will help CMS understand patients' experiences with diseases they're interested in, treated by the selected drugs, as well as patients' experiences with the selected drugs and other drugs that are used to treat the conditions.

CMS may use this information in negotiating Medicare pricing with manufacturers of the selected drugs. Your experiences and perspectives are very important. We genuinely appreciate the time you've given us today. We do have a brief video from CMS leadership, so that you can hear from them about how much they value your time and input. So, I'll hand over to our colleagues to share that video.

CMS Remarks

00:02:16

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.

00:04:11

Moderator, RTI International

Thank you. I also want to make you aware that we have staff from CMS who will be sitting in on this event so that they can hear directly from y'all about your experiences. I'm going to hand it over to **[CMS STAFF]** for a moment so you can say hello and say a few words.

00:04:27

CMS Staff

Hello everyone. I want to welcome you guys on behalf of CMS and the Drug Price Negotiation Team. I want to thank you for participating in this session. And we look forward to hearing about your experiences during this discussion. We're going to go off camera just so that we can continue to focus on the discussion. But know that we are here in the background, and we'll be listening.

Housekeeping

00:04:50

Moderator, RTI International

Thank you, **[CMS STAFF]**. All right. We'll get underway in a moment, but I have a few housekeeping items. I know some of y'all are veteran speakers and are very experienced in this. But we also have some new faces today. First of all: participation, we genuinely hope that you'll contribute your perspective throughout the session. If there are questions you don't feel comfortable answering, or you don't want to answer, don't even worry about it. Just skip that question.

Background. Please minimize your background noise, silence your cell phone, turn off your devices, and when you're not speaking, please just hit mute, so we don't get a lot of crackling or other unwanted sounds.

Privacy. The discussion today is not open to the press or to the public. As you can see, we're using first names with last initials only during the discussion to protect your privacy. We also ask that you not share any unnecessary personally identifying information or unnecessary personal health information during the discussion.

As you noticed, we are audio and video recording today. But these recordings will not be shared publicly. But, following the event, CMS will prepare transcripts that have participant names and identifying information removed. And then these transcripts will be shared with the public.

Okay, a few other housekeeping items. Video, I would thank you in advance for keeping your video on throughout the discussion.

Timing, we'll keep the session to about 1 hour and 30 minutes. I have a discussion guide in front of me to help us stay on track, and we have a lot of topics to cover, so I may need to redirect the conversation, or cut some conversation short from time to time to make sure that we can cover everything. So, please know in advance, I'm not being rude, just trying to do a little timekeeping.

Technical assistance. If you get disconnected, please attempt to rejoin. If you cannot connect, please reach out to the mailbox on the screen. That's the IRADAPStechsupport@telligen.com.

Breaks, taking a little break. If you need to step away briefly from the conversation, it's not a problem. Just turn off your camera and turn off your microphone. You don't have to wave me down and say I'm leaving for a few minutes. Just turn those things off and step away and rejoin when you're able.

And then speaking, please try to speak one at a time. I may interrupt again occasionally if two folks try to speak at the same time. Again, we just want to have a nice clear documentation recording for the transcripts.

You're welcome to use that raise hand feature, or **[Participant 1]**, you can wave or put your hand up, and we'll keep an eye out to make sure that you have a chance to be heard. You can also feel free to put comments in the chat, as well.

And finally, honest opinions. You know, everyone will have a different perspective or opinion. And that's great. We want to know what each of you honestly thinks today. So, those are our housekeeping items. Before we get underway with introductions, do folks have any questions?

Okay. I think we are ready to get started here. I'd like to start with introductions. I want to ask each person to take about 30 seconds. Say your first name and share what perspective you'll be bringing to the table. Are you sharing personal experiences? Experience of a loved one or patient experiences from the position of a patient advocacy organization? Or are you wearing multiple hats today? I'll just start by order on screen. So, **[Participant 1]** you are my first person on the screen. If you wouldn't mind introducing yourself and saying what position you're going to be talking from today.

Discussion

00:09:04

Participant 1 (registered as a patient)

My name is **[Participant 1]**. I am **[REDACTED]** years old. I live in **[REDACTED]**, Michigan. I was employed as **[REDACTED]** a social worker, working mainly with children, as a worker and as a supervisor. Because I am a retiree from the state of Michigan, I am fortunate to have very, very good benefits. I live on a fixed income, and the fact that I am able to afford many of these medications that I need to take including Tradjenta, my health finances are more or less under control. I'll talk more about Tradjenta later. I think that's enough personal stuff to start out with.

00:10:01

Moderator, RTI International

It sounds like you have a lot to share today. I'm very glad you're here to share, **[Participant 1]**. I'm going to hop over to **[Participant 2]** to introduce yourself, **[Participant 2]**, and what perspective you're bringing to the call today.

00:10:15

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

I'm **[Participant 2]** and I have a nonprofit organization that works on both advocacy and health education for older adults.

00:10:27

Moderator, RTI International

Thank you, **[Participant 2]**. **[Participant 3]**, you look like you're next on my screen.

00:10:34

Participant 3 (registered as a patient)

Good afternoon. I'm **[Participant 3]**. I wear all three hats. I am a patient with type 2 diabetes. I have loved ones, family members also with type 1 and type 2 diabetes. And I represent a patient advocacy organization that focuses on health policy and advocacy. So, I'm wearing all hats and happy to be here today.

00:11:01

Moderator, RTI International

I'm happy you're here, as well. Thank you, I'll jump over to **[Participant 4]**. Do you mind going next and introducing yourself?

00:11:08

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

Hi, everyone. My name is **[Participant 4]**. I am representing a nonprofit organization that represents the interest of women, girls, and families, particularly Hispanic women, girls, and families.

00:11:21

Moderator, RTI International

Fantastic. You'll talk about type 2 diabetes from their perspective, as well?

00:11:28

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

Yes, from a broad community perspective of how the entire community is impacted.

00:11:33

Moderator, RTI International

Wonderful. Thank you for being here. All right, **[Participant 5]**. You're up.

00:11:38

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

Hi, my name's **[Participant 5]**. I work with an organization that is made up of people with diabetes working for people with diabetes. We do not directly work on Tradjenta. We more work on access to medicines and diagnostic materials access, a lot more specifically on insulin and glucose self-monitoring supplies. I, myself, am a patient living with type 1 diabetes for which Tradjenta is not an approved drug, although some do take it. I have never been prescribed it. I'm also not 65 years old. I'm not a Medicare beneficiary, however, many of our members and people who we serve are patients living with type 1 type 2 diabetes or other types of diabetes and do have Tradjenta prescriptions.

00:12:21

Moderator, RTI International

Thank you, **[Participant 5]**. Thanks for bringing their voices forward today, and I think that leaves **[Participant 6]** for our last introduction.

00:12:28

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

Thanks. Hi, nice to see you all and see some of you again. My name is **[Participant 6]**. But caveat, I don't write prescriptions. My doctorate is in health policy and public health, but I work for a small not-for-profit that focuses on a number of issues, including things like voting rights and broad consumer affairs issues. I'm a health services researcher there. And one of the things we spend a lot of time doing is tracking issues of interest to the Department of Health and Human Services, including FDA drug regulation. We also spend a lot of time educating individual consumers, of which there are over half a million that support our organization and that educational support that we offer, my group in particular, involves giving people very specific advice about the risks and benefits of a variety of prescription medications, and especially included in that are medications that treat metabolic disorders like diabetes and type 2 diabetes which we're going to be talking about today.

I should add, I have no financial conflicts of interest whatsoever. Nor does my organization. We don't take any pharmaceutical or corporate money at all. All of our money comes from individual donations. Thanks.

00:13:50

Moderator, RTI International

Thank you, **[Participant 6]**. We look forward to hearing what you're hearing from folks you work with who have type 2 diabetes.

Have you, or the loved ones, or folks, you know, taken Tradjenta either currently or in the past? We'd like you to put that in the chat, and it can be a "yes" or "no." Just a simple yes or no in the chat. That just helps orient me to folks who have a direct experience or know someone who has direct experience with Tradjenta.

Our first set of questions is about life experiences with type 2 diabetes. So, my question is, how does type 2 diabetes affect your life or your loved one's life, or the patients you work with? How does it affect their life? How does diabetes affect daily life?

00:14:49

Participant 1 (registered as a patient)

Want me to start as the one and only patient here?

00:14:53

Moderator, RTI International

Please, do.

00:14:54

Participant 1 (registered as a patient)

I was diagnosed with type 2 diabetes back in 2002, and was put on metformin, which is the worst drug out there. It is a nightmare. The side effects are terrible. I had many years of constant diarrhea that I couldn't do anything about, and it was not a lot of fun. The doctor that I was going to that I subsequently fired, whenever I said, "isn't there something else I could take?" It was like she didn't even hear me.

I got a new doctor, and I said to him, "Do I have to take metformin?" He said, "No, you don't. We'll put you on Tradjenta." When I get a new medication, most of the time, I don't read the stuff from the pharmacy because it's just designed to frighten people, but I didn't know anything about Tradjenta, and I wanted to know what the side effects were. I read the statement, and then I got to, there are virtually no side effects to this medication. I thought, "Hallelujah." That is absolutely true. I've been on it for eight years, and my diabetes is fairly stable, and I have other medical issues that go right hand-in-hand with being diabetic. I have heart issues, and I have AFib [atrial fibrillation] and various and sundry things, and I take lots of medication for that. The only thing I take for diabetes is the Tradjenta.

That's the good side of it. The downside is the cost. Now, it is not bad for me. It started out $180 for a 90-day supply that went down to $120. And now it's down to $60. But if I did not have these wonderful benefits from the State of Michigan which pays my Medicare Part D, I wouldn't be able to afford $525.08 a month.

This medication is absolutely a godsend to people that have type 2 diabetes.

00:17:07

Moderator, RTI International

[Participant 1], you said it's a godsend. What is it like managing diabetes for you in your daily life? How does it affect how you go about your day-to-day?

00:17:16

Participant 1 (registered as a patient)

My diabetes has been fairly stable. I can pretty much eat whatever I want, but in moderation, and I do try not to overdo it. The problem for me is because of the heart issues. I have to pay attention to both the diabetes and the other stuff. I have wonderful doctors. I'm very fortunate, my heart doctors, I have two of them. They're great. My primary care doctor is wonderful, and I'm very fortunate with the medical care that I get. I'm able to live a fairly normal life. I go to the gym four or five days a week, and I try and take good care of myself, and so far, I'm thrilled with the results of the Tradjenta, and I think my health is in pretty good shape right now.

00:18:14

Moderator, RTI International

Thank you, **[Participant 1]**. Now, **[Participant 3]**, you also mentioned having type 2 diabetes and also having loved ones with type 2 diabetes. Do you mind sharing what it's like managing diabetes in your life, or what you've witnessed for your family members?

00:18:28

Participant 3 (registered as a patient)

Sure. Thank you. My mother had type 2 that went into type 1. It runs on her side of the family, so I had aunts that also had type 2 and type 1 and then cousins that also had it. More of the next generation, more into my generation, more of type 2 than type 1.

And for myself, I always said, "I'm not going to be like my mother, and I'm not going to get it. I'm not going to have type 2 diabetes. I'm not going to have diabetes period." And then, after I got to a certain age, you could see my number starting to change.

I was really disappointed that when I was diagnosed with it, but it is under control now, but it took two different fails to get to the medicine that I'm on now. I do not take Tradjenta. I'm really happy to hear, **[Participant 1]**, that it's worked so well for you. I'm happy with where my numbers are. My numbers were tested this week, and they're really good. But I do have side effects. Some side effects, but not as bad as what I had in the first two. I'm pretty stabilized on the medicine that I'm on now.

00:19:56

Moderator, RTI International

And **[Participant 3]**, I don't know, maybe you can comment on, what is it like? If you could take me through a typical day of living through and managing diabetes for either you or a family member. What does that day look like?

00:20:06

Participant 3 (registered as a patient)

Sure. For me, because my side effects are low, my daily life is normal. I'm still running. I'm in my seventies. I still work as hard as I did when I was 18, and I keep saying, as long as I have my energy, I could keep going. They call me the Energizer Bunny. But I always worry, if I lose my energy, I'm going to have a problem. But I haven't allowed it. I've learned to live with it, not to allow it to get me to a place where it's going to really have a major effect or a downside to me.

I'm pretty happy with the results of where we are now. But I think the technology and innovation of some of the newer meds that are on the market, and so much more that we've learned. I represent a group that represents people with chronic conditions, the diabetes organizations, cardiovascular groups, they're all members. We have lots of conversations, and we try to help others get through bad days. My days are more good than bad.

00:21:17

Moderator, RTI International

What does a bad day look like? And I'll open that to the floor, what does a good day versus bad day look like for patients with diabetes?

00:21:28

Participant 1 (registered as a patient)

Depends on the medication you're on. It's not good for people on metformin. That's a terrible drug.

00:21:37

Moderator, RTI International

What does that day look like, **[Participant 1]**?

00:21:39

Participant 1 (registered as a patient)

You're in the bathroom a lot.

00:21:42

Moderator, RTI International

Organizing your day around the bathroom.

00:21:44

Participant 1 (registered as a patient)

Yup, some days are good. Some days are not. It was very difficult, because I never knew what was going to happen. That was my only major symptom, but it was a terrible one. I had to be really careful, know where the bathroom was wherever I was. Getting taken off of that was a miracle. My life has improved greatly since I've been taking Tradjenta, and I'm also the only person I know around here that takes it.

I don't know why doctors aren't, well, they may not be putting their patients on it because for some of them the cost would be cost-prohibitive. But, as I said before, I'm very fortunate with my medical coverage. I have no complaints about it.

00:22:49

Moderator, RTI International

Thank you, **[Participant 1]**. **[Participant 5]** or **[Participant 6]**, it looks like you both have come off mute. Did you want to add what it's like to live with diabetes?

00:22:59

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

Yeah, **[Participant 6]**. You go ahead.

00:23:02

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

Thanks, **[Participant 5]**. Speaking from an advocate and expert advocate perspective, it's great. **[Participant 1]**'s experience is great. She's found a medicine and that's really important. Diabetes affects one in 10 Americans, 95% of those are type 2 diabetes. Glycemic control is a huge problem. There's 12 different ways to approach it, including, I'm sure everybody on this list knows but just a reminder, what we try to remind people who are especially new to the illness, is diet and exercise are always part of the story in terms of responding to when your glycemic levels change as you age and so forth. It's unfortunate **[Participant 1]** had a bad experience with metformin. Metformin is a good medicine for a lot of people. It works well for a lot of people. It's a first line therapy. I think all endocrinologists around the world would agree that if you have trouble with glycemic control that doesn't respond to diet and exercise, you should go for it.

[Participant 1] obviously had problems and then matched to Tradjenta. That's great. But it is, the data overall and expert commentators on this, the physicians who write for Up-to-Date and The Medical Letter, and then clinical trials, are not supportive overall of the class of drugs that we're talking about, that Tradjenta falls into, called gliptins, because of adverse effects that do happen to some people. Our group and other groups have advocated for not using these drugs in most cases. There's a number of reasons why, which I can go into, but I just want to put that out there and to say that's important. But it is challenging to deal with this disease. And it's not just about blood sugar control initially, but then the consequences of not being able to control your blood sugar that can affect your vision, your cardiovascular health, and so forth. These are really serious illnesses to deal with. Thanks.

00:25:20

Participant 1 (registered as a patient)

Could I respond to that for just a second? Metformin, in terms of controlling my diabetes, worked well. But the side effects were terrible, and I suffered. I'm the only person I know that takes Tradjenta, but so far so good. My numbers are good, and there are literally no side effects that I'm aware of anyway. Nothing bad for certain.

00:25:52

Moderator, RTI International

Thank you, **[Participant 1]**, and I want to get to **[Participant 5]**, because I know you've been trying to get in for a few.

00:25:56

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

Thanks. My lived experience is I live with type 1, not type 2. Obviously, there are differences, but overall, organizationally and personally, we really live by a disability justice framework of recognizing that diabetes is a disability. That means that it is disabling at times. Living with diabetes can be really, really hard, really complicated. Our work is to make sure that access to life-sustaining medications doesn't have to be.

My experience of living with diabetes is that no day is the same. They say, "Do the same thing every day, and the routine will be good." That's definitely not my lived experience. I usually, with diabetes, want to say between like 70 and 110. Yesterday, my insulin pump failed, and I went up to 450 before I caught it, and then I went down to 70 before bed, and then overnight I was in the thirties and forties. For anyone with diabetes, you're drenched in sweat. You feel awful. You can't move. It feels awful. I was there for hours, and ate like 200 carbs. I had one of those terrible diabetes days and got to wake up and go to work and take care of the family and do all the things, even though I know that it's okay to not be okay. That was like a technological error; I didn't do anything wrong. There is nothing wrong with my behavior. I did exactly what I was supposed to do, and for whatever reason, the weather's getting warmer, you just have those like really bad days.

Everything impacts my blood sugar. The weather getting warmer, my cycle, going for a walk, going up and down the stairs in particular does me in, like using my quad muscles in that way. Everything impacts your blood sugar. You can learn about what those are with good education and paying lots of attention to your body. And again, every person is different with diabetes. There's no one-size-fits-all, and we really want to make sure that people, everybody is different, and that everyone should have access to the care that they need that works best for their body, and that means access to affordable care or access to their drugs. Access means affordable, too. No matter what we do, we can have bad days, and there's no day I'm in range 100% of the time. I'm not that type of person. I also just wanted to say, too, is that for the different types is that we think we often think of, or I don't know. I've heard that type 2 diabetes is more genetic than type 1, and that there's a lot of people who are doing "everything right," but that you're still going to get that type 2 diabetes. And so wanting to affirm that in this space, too.

00:29:21

Moderator, RTI International

Thank you, **[Participant 5]**. And **[Participant 2]**, I'll grab you, and then we'll go on to our next question.

00:29:27

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

[Participant 5], I really appreciated the last point you made, especially with regard to age, because often, age is one of the biggest risk factors, and oftentimes if you have had it in your family among older adult family members, it does increase your risk. That is important to note, and certainly diet and exercise, and all the things that that we're talking about more and more each day are important. But I did appreciate the shout out that you gave around genetics, and also the presence of it running in your family and about a quarter of older adults have diagnosed diabetes to about 25% in the 65 and older. But there's estimated to be between another 4- 5% that are undiagnosed.

And there's increased mortality and a diminished quality of life. It ages you, having the disease, and it's often complicated by other chronic conditions. A lot of polypharmacy, if you have other chronic conditions. Medications that are on target for you and right, and I think other people made the points that your medication needs might change over time. This drug is not a first line, but it could be a good second line if people don't have a good experience with the first line, and that's really common. I am not a caregiver of somebody with diabetes, but I am a caregiver of someone with both dementia and hypertension, and with hypertension, there's also a lot of need for monitoring and for changes to medication over time.

It's similar to diabetes in that way. So, making sure that you have different options available, that your clinician has them, and that patients are able to access them is really important, and not having too much hassle in order to be able to get them. I mean, when I look at the chart that CMS has up, you have about 278,000 folks over a year's period, and I'm grateful that the program has supported them getting it. And hopefully, this won't erect any unnecessary barriers on the part of Part D plans.

00:32:01

Moderator, RTI International

[Participant 4], I'm running out of time for this section. But I wanted to ask one question, one more question, and maybe you can piggyback your response on this question, or that's my hope at least. What aspects of type 2 diabetes are most important to you or the patients that you work with to have managed or treated? **[Participant 4]**, why don't you kick us off with this question? And if you had something you wanted to build in related to kind of lived experience, we can do that before moving on. So, what aspects of type 2 diabetes are most important to you or the ones that you work with to have managed or treated?

00:32:37

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

I think that the way I feel it ties in is the cost. Because I feel like we haven't gotten back to that. When you were talking about the day-to-day and what that looks like. When you're talking about needing supplies for testing. When you're talking about the adequate foods needed to either increase or decrease your numbers, and how to navigate that throughout the day. The part that I wanted to add there was that one in five women in the United States, and it doesn't matter what your ethnic background is, one in five women in the United States live in poverty and retirement over the age of 65.

If we're talking about Hispanic women, who I represent specifically, of those women who live in poverty, the average Social Security benefits each year is less than $14,000. **[Participant 1]** was mentioning the cost, even the $180 for a three-month supply. Where are you going to get that money from if you're thinking about the cost of food, the cost of supplies, the cost of your Medicare, and maybe the [Medicare] Advantage, and maybe your Part D, all before you think about the actual cost of medication.

And this is why diabetes has been so devastating to so many communities. Because the problem is they don't have the money upfront to get whether it's preventative care, whether it's that kind of support, and then they get to the point where they need catastrophic care. To where they've already got mobility issues. They've already got vision issues. They've already got chronic pain. They may need an amputation. When we're talking about overall cost, it's not just cost to the individual that keeps them from treatment. That's what keeps them from staying healthy in the first place. But then it's the cost of the Medicare system on the back end. And we learn this lesson over and over again, that the preventative care is really what keeps us from those catastrophic costs of care later. That's where I think it's about quality of life for most people. I think of my own dad, who has type 2 diabetes. I think of elderly aunts and relatives, because if you're thinking about a patient who has to rely on someone else, because they do have limited resources, limited mobility, they have to rely on someone else to take them to the doctor, and that person has to take time off of work and maybe lose wages.

Maybe they don't have reliable transportation. Maybe they don't have money for the medications that are prescribed to them. All of these things start building up, and folks get to the point where it's just overwhelming, and the sickness just keeps continuing to happen to them. When we're talking about how to help people understand that, and I think if you could, until the advent of these GLP-1's [glucagon-like petptide-1] and this conversation, most people wouldn't go to the doctor because they would say, "Oh, the doctor is just going to tell me to lose weight anyway."

And why would I go through all the steps to go to the doctor if that's just what I'm going to be told? But then, on the other hand, then it would go from, how you lose weight to all of a sudden you need a surgery. A bariatric surgery, I mean, it feels like two ends of a really devastating spectrum. And this feels like there's space in here for the conversation of, "If it works for you, and it has the potential to help with your quality of life," this is where we need to be talking, having the conversation. And then obviously helping the affordability piece, because we are talking about a community of people who are on Medicare, who are on a fixed income, and most people do not in retirement planning plan for the costs of those health care costs, and so it compounds at a point in your life where you're not able to make more money to be able to afford those later in life.

00:36:41

Moderator, RTI International

Thank you, **[Participant 4]**. And **[Participant 3]**, we need to move on to another section. But I have a feeling that some of your experiences will come in, as we have additional discussion. So, we have talked a little bit about the experiences with Tradjenta and other drugs. But this section will focus on that.

My first question in this section is, when considering any of the potential medications for type 2 diabetes, what matters most to you, your loved ones, or the patients you work with? And that could be, how does it work? How quickly it helps safety, side effects, etc.? So, I'll open... **[Participant 3]**, why don't, since you had your hand up, why don't we start with you? I want to give you a chance to weigh in.

00:37:20

Participant 3 (registered as a patient)

Sure. Thank you. I mean, this is a really great discussion that we're having. We're hearing a lot about access. Fear, we have to get rid of the fear that surrounds this. I was in an education class when I was first diagnosed, and other people that were in the class were crying because they thought they had been given a death sentence, and we said, "No, you can learn to live with it." Getting it under control, understanding the comorbidities that also play into diabetes. Obesity, which is something we don't talk a lot about, but has such a major play. The stigma that surrounds having a chronic condition and not someone saying, "Well it's the food that you put in your body." It's not always the food you've just put in your body. It's the whole picture of the whole person, and getting it under control.

I think one of the most profound experiences that I had—we were working out in a very underserved area, down in Southern California, and we were working with Black ministers. We had taken a whole group of doctors in and we were talking about diabetes and heart disease. One of the clergy actually went and got tested, found out that he had type 2 diabetes, and was put on medicine, and I think I'll never forget what he said. He said, "I didn't know I was sick until I got well."

He didn't know how bad he was until he learned he had something and what he needed to do to get better. And that's the engagement and what matters, is we get the diagnosis. Get the right med at the right time in the right dose, work with the doctor, work with the pharmacist as part of the care team and get type 2 under control.

00:39:23

Moderator, RTI International

And **[Participant 3]**. I wanted to follow because you've used the phrase getting it under control. What does that mean to you?

00:39:29

Participant 3 (registered as a patient)

Well, you're looking at your HbA1C [glycated hemoglobin] levels, right? You're looking at your glucose levels. What also stems from that is your energy and all the other side effects that you're feeling that people feel with that. I've watched my HbA1c spike up, different meds going higher and higher. Now I'm on a meds, coming down, down, down, every time I'm getting tested, it's coming down. I think that educational piece for the public to understand not just be given a diagnosis and say, "You have type 2 diabetes." But "What do I need to do to understand how to control it?"

You know, another really good tool is a continuous glucose monitor, which isn't always covered for type 2 diabetes. But I think that would be super helpful in keeping people understanding. How are you spiking? What's happening to you during the day, like **[Participant 5]** was just saying. And **[Participant 5]**, you look so fantastic today having to go through that during the night. Oh, my gosh. I'm so sorry for you. But her pump stopped working. Having the tools working for us, the educational, the engagement, that we have to be engaged in our own health care. You know, we can't just say "We're going to take a pill, we're good. We're going to go eat whatever we want." We have to be engaged in our own health care. That is very difficult at times, so I think **[Participant 1]** talked to that too. My husband thinks, I have to talk to him all the time, he also has type 2 diabetes, "You can't eat that," and he comes back to me, says, "Well, you shouldn't have that slice of cake." I mean, it's these conversations that are going on all the time. And he's right, and I'm right. And how do we better come to grips with what we need to do as patients to ensure that we have a good quality of life living with diabetes?

00:41:37

Moderator, RTI International

Thank you.

00:41:38

Participant 1 (registered as a patient)

Could I respond for a second?

00:41:40

Moderator, RTI International

Please.

00:41:43

Participant 1 (registered as a patient)

What **[Participant 3]** said about education brought back the fact to me that one of the best things that ever happened after I got diagnosed... and I have to say I was surprised when I was diagnosed, because I was not feeling sick. It was a big shock to me. But my doctor sent me to diabetes classes and they were just wonderful. The nurse educator that taught them was excellent, and some of the people had helpers with them, but the group bonded, and we had fun, and we learned so much. It really helped me understand what was going on in my life and I would recommend that to anybody that's newly diagnosed.

00:42:27

Moderator, RTI International

Thank you, **[Participant 1]**. And **[Participant 6]**, I saw you came off to weigh in about, considering medications, what matters most to the patients that you work with?

00:42:37

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

We've heard some important things. Thinking what **[Participant 4]** and **[Participant 3]** said, it can be really frustrating to be a patient in the world with a chronic condition like this, trying to make choices about what you should do, and being well educated about it. That's a big part of what my organization tries to do, is to give people information that they need to make good decisions, and that's complex. There are a lot of choices to be made. The other thing that we try to do is when we educate people, to try to expose the perverse incentives that exist in the biomedical enterprise in the United States.

Taking this particular drug, or any drug, that's still on patent in the United States, there's a lot of pressure from shareholders in these companies who own these drugs and these patents to up their sales with advertising. And we are unique in the world that we allow direct-to-consumer advertising. Even though doctors and patients don't like to admit it, the reality is, we know that when you see an ad on TV for a certain medicine, it's more likely you will be predisposed to go to your doctor, and it's more likely your doctor will be predisposed to prescribe you that medicine, and these things create distortions in pricing that, I think, then come back to be a big problem, especially for low-income or moderate-income people who have to pay hundreds of dollars per month for a medicine that doesn't cost anywhere near that much to make. These are all really complicated things.

We try our best to sort of just educate people about that whole enterprise to create these things. And I think certainly it's one of the reasons that why we're here talking about this drug and other drugs like it. And while CMS, bravo, is collecting information and getting ready to go to the table and be rational on behalf of consumers, especially to make sure they have the medicines that they need and understand the risk benefits and get a fair price on top of it. That's my long response to your question.

00:45:05

Participant 1 (registered as a patient)

I've noticed that I've been taking Eliquis for now for as long as I've been taking Tradjenta, and if I want to set off my cardiologist, all I have to say to him, "Is this patent ever going to run out on Eliquis?" And he's off and running. He has not a very good thing to say about the drug industry, and I can understand that. I'm at the point, because of heart issues where I'm going to say to him, "I want Watchman. I want to stop taking Eliquis. That's the only way I can do it." But he's going to tell me that I'm not ready for that.

00:45:42

Moderator, RTI International

All right. **[Participant 2]** has a comment on what matters most to the patients she engages with related to medications for type 2 diabetes.

00:45:53

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

I want to say a couple of things that we hear from folks who participate in our Talk Nerdy patient engagement program, which is something that we've done. It started out with as a project with PCORI [Patient-Centered Outcomes Research Institute], and we've been doing it now for a number of years. And we've had people with diabetes along with other conditions, including AFib, **[Participant 1]**.

I think what is really important is that the doctor-patient relationship is sort of first and foremost, that folks can lean on clinical experience of health care professionals that they go to see, to see based on their experience what they recommend for the individual that's in front of them, and not have a payer be making those decisions for them or creating barriers that require a lot of paperwork or having to take another drug first to fail on that drug before you're able to get the one that your doctor is actually recommending. I think those things are what we hear a lot about.

I want to say to **[Participant 1]** and others that are on here, the way that things work in the United States, there are bad incentives. There are middle people through pharmacy benefit managers that make a lot of money off of insurance companies. This sort of dialog between the insurance company and the pharmaceutical company. We tend to just focus on the pharmaceutical company. There's a lot of people at the trough taking money, and wanting to save money, and often, the patients are usually in the middle of all that.

We're really about recognizing what's everybody's role, and there's a lot of concerns about pharmacies not carrying these types of drugs that are selected. There are also concerns about a lot of utilization management that's happened on the selected drugs, and those are things that we hear from the people that we work with, that they've experienced changes in their Medicare drug plans and it's not always apparent until they get right up to the pharmacy counter. And then they're told. And again, I help take care of my mom with some other really important, lovely people that I'm lucky to have as day helpers, and when my mom's medication changes, she notices it. Even with the dementia, she notices a color change or a pill shape change and she gets afraid sometimes. "Are you poisoning me? Is this dangerous?" When things get switched up on people, as you get older especially and you're taking multiple medications, it can be really scary.

All those things are also really important factors for a lot of patients. Thanks.

00:49:03

Moderator, RTI International

Thank you, **[Participant 2]**. I think the next question, **[Participant 1]**, you may be best positioned to answer. We're interested in learning, what are the main benefits that you've experienced with taking Tradjenta? You've professed your love multiple times for Tradjenta, **[Participant 1]**. What are the main benefits that you've experienced?

00:49:24

Participant 1 (registered as a patient)

It's controlled my diabetes well. My primary care doctor has always been very happy with my A1C when it's tested. The fact that it has no side effects has been wonderful. It's easy for me to take. I have faith in it. It's not like I didn't have good numbers with metformin. It was just all the other stuff that went along with it.

Metformin is very cheap, but Tradjenta has settled my diabetes into a comfortable place. And I don't worry about it too much anymore. I know what I have to do. I'm not always perfect, but I do know what's required. Because of the heart issues, which go hand in hand with the diabetes, I have a lot that I have to pay attention to, but I'm not complaining because things seem to be pretty much a-okay for me right now.

00:50:35

Moderator, RTI International

We talked about benefits. What are the drawbacks that are the challenges that you may have experienced, if any?

00:50:42

Participant 1 (registered as a patient)

With the Tradjenta?

00:50:44

Moderator, RTI International

With Tradjenta.

00:50:45

Participant 1 (registered as a patient)

It did start out with a $180 copay, but my doctors are really good about giving me 90-day prescriptions, so they do save me money. That was a little bit of a challenge, but it's now down to $60, which is probably where it will stay until the patent expires if that ever happens. And that's something I can manage. The only other one that I have that's a little bit high is Eliquis. And I don't think that patent is ever going to expire. I'm convinced.

My health right now, I think, is pretty much under control. I have a whole raft of doctors, which I see regularly, and they take good care of me, and I try and take good care of me, too.

00:51:46

Moderator, RTI International

Thank you, **[Participant 1]**. I want to open the floor also, if anyone else has some benefits or drawbacks to Tradjenta that you want to raise, and as we talk about Tradjenta itself.

00:52:02

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

I want to go over some of the concerns that we have about this class of medicines, gliptins. Make sure that gets on the record. And as I begin to say this, **[Participant 1]**, I don't want to jinx it for you. It's good that you're responding. It's good that you have good care. And you're self-aware and all that stuff. And because these adverse effects exist doesn't mean that they happen in everybody. Just the same way that it is true that not everybody responds to medicines the same way.

00:52:43

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

You're also not a medical doctor, right? Just to clarify.

00:52:46

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

No, I'm not a medical doctor, but I have...

00:52:49

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

Right.

00:52:50

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

Years of clinical research experience. I work with medical doctors and the information I'm giving you comes from medical sources. Here are the concerns, and, moreover, comes directly from the label of the medicine. These labels can be another thing for consumers, to have to wade through. I don't know when's the last time you read a label, I do it all the time. There are dozens of pages, and then they refer to themselves to clinical studies as well. But, here are the concerns...

00:53:18

Moderator, RTI International

Really quick, if you want to kind of give us the highlights for this conversation, I would welcome that.

00:53:26

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

Acute joint pain, acute pancreatitis, heart failure, skin reactions. The pancreatitis stuff is one of the concerns that led us and other groups to put gliptins on "do not use." Even if you just look head-to-head at placebo versus the drug, you see higher rates of diarrhea, cough, nasopharyngitis or something going on with infection issues, urinary tract infection as well when you use it in combination. Constipation is another problem when you use it in combination with other drugs. Another important point that I think has led people to say that these gliptins are not worth using most of the time is that there are other drugs, [inaudible], for example, that actually work as well in head-to-head clinical trials. So, want to get that out there. Thanks.

00:54:26

Moderator, RTI International

Thank you, **[Participant 6]**, and like I said, it sounds like you have some research. If you want to submit that to the mailbox, too, you can definitely get that on the record that way as well.

00:54:34

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

Yes, and since you asked, **[MODERATOR]**, we did already submit written comments to the docket, too. You also have that.

00:54:42

Moderator, RTI International

Great. Thank you, **[Participant 6]**. And **[Participant 4]** has her hand up, so I will ask you to weigh in on benefits or drawbacks to Tradjenta.

00:54:52

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

Sure, I would also say because of all of the connectivity to other conditions, whether it's obesity and weight, heart disease, stroke, all of these things, that when you're able to get your diabetes under control, if weight loss is able to take place as part of that, all of those things help your health overall. I think where folks see benefit is when they just start to feel better, overall, and then have that ongoing conversation with their doctors about whether or not it's right. Because **[Participant 6]** makes a valid point. You need to make sure that you're in constant communication with your doctor and that your medications are doing the right things for you.

But I think that overall, when you're talking about better quality of life, you're talking about how you're able to start getting your other ailments under control. Especially as you age, that these are the types of things that, coming back to the conversation that **[Participant 5]** started earlier, it's about access. And making sure that you have access. These medications are available if and when they are applicable to your specific circumstance.

00:56:03

Moderator, RTI International

Thank you, **[Participant 4]**. So, we talked about Tradjenta, and I know, **[Participant 6]**, you've brought in some of the other drugs that my next set of questions is about, the benefits and drawbacks to other therapeutic alternatives. So, the other drugs used to treat type 2 diabetes. I want to open the floor to if someone who has experience with another drug, if you could comment on the benefits of that other drug for you and maybe, **[Participant 3]**, that might be something you can speak to as a person with diabetes or as a caregiver and loved one.

00:56:35

Participant 3 (registered as a patient)

Sure. Thank you. I do take an injectable now. That was just my third time of what they tried on me. I think what we're talking about is no one-size-fits-all. Having that conversation with your doctor and your pharmacist, because I think they play a key role when looking at all the medicines that you're taking.

I'm very lucky that I had a pharmacist assigned to me through my health plan that's worked with me all the way through getting control of my type 2 diabetes. I like the fact that I only have to take it once a week. And I'm having better results. I'm actually having better results. But in talking with and listening to **[Participant 1]** and others, it comes back to the doctor-patient relationship and what they feel is best, and what worries me a little bit under the negotiations with CMS and the IRA [Inflation Reduction Act] is that there would be, you decide on a particular drug. Don't just leave that drug on the formulary and get rid of the other ones. There's a reason there's so many.

It's coming back to **[Participant 1]**'s had an amazing experience. I'm having an amazing experience on the medicine I had third round. Other people that I talked to are doing really well. The benefit for me also is, I lost 20 pounds, which I struggle with my weight all the time, and finally, I could see a change, and I was able to drop weight. When we start to drop weight, we start to see improvement in our cardiovascular care. We see our inflammation in our bodies going down. People that have hip and knee problems may see a reduction in that. And so, there's a whole range of things that get better when you get under control. You're able to work with your metabolism with that particular metabolism coming back to that doctor. That team care, the value of coordinated team care, I think, is huge, and then the plethora of able to make decisions based on what your doctor thinks is best for you.

00:59:11

Moderator, RTI International

Thank you, **[Participant 3]**, and you said, the benefit of the injectable you're taking is that it's convenient, once a week, and the weight loss. Are there drawbacks to that medication that you're using relative to something like Tradjenta?

00:59:26

Participant 3 (registered as a patient)

Yeah. When I first started taking it, one of the other drugs I took, I felt amazing on. But I had a huge side effect from it, so they had to stop it. And I was upset with that, because I felt really good. If you don't feel good or you feel like you're having all these side effects, you're not going to take it. It's going to be difficult for you to take. For me, I think in the beginning when I got on the injectable, it shrinks your ability, and it's telling your brain that it's not as hungry.

You start to feel full. But sometimes that fullness doesn't feel good. You know, you only eat a little bit, and you're full, and so you just learning how to maneuver through that. Once I had taken it for a while, that pretty much has gone away, but it still helps me control the amount of food that I eat. Which hence has helped with the weight loss, so I didn't like how that made me feel at first. But now I'm okay. I understand what it is and how it's making me feel, and I can live with that.

01:00:39

Moderator, RTI International

Great. Thank you, **[Participant 3]**. **[Participant 6]**, I have a sense that this is your jam, the benefits, and then we can get into drawbacks of therapeutic alternatives.

01:00:49

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

Yeah, as I said, looking at my list, there's something like eight or so other types of drugs. Of course, the GLP-1 agonists, the Ozempic, etc. have made a big splash in the last year, and I know it's part of the price negotiations, too. So, you have experts who are coming to the table to talk about that. The general comment I would make overall, and I think this represents the attitude of our consumers, and how we try to help them is that even though there's a lot of choices and some good ones, it is a treatable illness and a difficult illness. Diabetes type 2. But it is treatable and there are lots of options for it. Having good care, general medical care at least, if not regular endocrinology care, is critical, and then trying to figure out what works and what doesn't, is complicated. Even the new GLPs have adverse effects that are challenging and make it a non-starter for certain people.

The other thing, I think, that consumers want and need is continued research in the area at universities, NIH, and so forth, that develops the next class of drugs. And other interventions that address this constellation of illnesses, which have wide impact and somewhat unique to our economic situation, right? These are diseases that largely manifest in wealthier countries. There's obviously a number of other factors that go into it besides just pure physiology, perhaps, that are being researched as well. All those should come into play in terms of thinking about alternative medicines. Thanks.

01:02:47

Moderator, RTI International

Would anyone else like to comment on either a benefit or a drawback to a drug for type 2 diabetes that you tried, or a loved one. **[Participant 2]**, thank you. I see your hand up.

01:02:58

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

Yeah, I wanted for the purposes of the record, since **[Participant 6]** did that, that the first section of the Medicare Act precludes the Medicare program from interfering in clinical care. And that's actually in the statute for the Medicare program. I'm finding these questions really interesting. It's definitely an interesting process this time that is slightly different from last year. But it's veering towards just an interesting place on that line and would love for that to also be in the record. Thank you.

01:03:47

Moderator, RTI International

And when you say an interesting place on that line in terms of interfering with clinical care or...?

01:03:54

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

Yeah, exactly. There's a lot of discussion about alternatives and identification and comparing, and all of that. And these are FDA-approved medications. There's a recognition that there are specialists. People go to health care clinicians to get their advice and work with them and understand the risk and benefits. And there are risks associated with diabetes itself.

Patients need to, and family caregivers need to take those things into consideration with their health care clinicians in terms of what's right for them. It's not really under Medicare's purview, the program's purview to determine that for anybody.

I wanted to make sure that that was also included on the record as we're having this discussion and talking about all these things, and I understand part of this also has to do with deciding a negotiated price, and how that sort of fits into things.

I've heard this as a theme going through this, and also the one that we did previously on Janumet. It really is Medicare's job to preserve the patient and clinician relationship, and not to interfere in that in any way.

01:05:29

Moderator, RTI International

Thank you. And **[Participant 4]**, would you like to weigh in with benefits, drawbacks to alternative therapies for type 2 diabetes?

01:05:38

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

Sure. I think that part of it is there's validity to the nuance of the conversation and the fact that everyone is different. Their access to care, their access to medication is different. There's some trial and error that has to take place, so I don't want us to lose that. I think it goes along with what both

[Participant 2] and **[Participant 6]** were saying, that this is a complex issue that we're, in some ways, trying to boil down to a 90-minute conversation.

The example that I'll give is a friend who has pretty severe type 2 diabetes. She has been on Ozempic, and she's lost weight. But what she needs is Farxiga to also help bring her A1C numbers down. But what her doctor has explained to her is that in order for the Farxiga to work better, she does need the Ozempic to bring her weight down. I think it's just illustrative of the point that we're all trying to make here, that it really is about having access to those options and then figuring out which end of the spectrum works for you. Because it sounds wonderful that Tradjenta has worked so well for **[Participant 1]**. But that may not be the case for everyone. So, really the truth in figuring out which options work for everyone. The crux of it is whether or not those options are going to be affordable when people need them and as they need them.

01:07:07

Moderator, RTI International

Thank you, **[Participant 4]**, and before we move on, so **[Participant 1]**, you mentioned taking metformin at first, and you said it had some adverse gastrointestinal side effects, as well as, but it did control your A1C. Were there other benefits or drawbacks of metformin you wanted to share with the group?

01:07:28

Participant 1 (registered as a patient)

No, I think I pretty much covered it. That was an unpleasant experience for me. But and Tradjenta, I've been fortunate, I've not had any bad side effects from it, and I've been taking it for eight years now.

01:07:48

Moderator, RTI International

Let's see. Thank you, **[Participant 1]**. And **[Participant 3]**, you may be able to comment on this because you mentioned trying multiple medications for type 2 diabetes and needing to switch because of adverse side effects. What would prompt you to consider switching from your current medication? What sorts of things would need to happen to make you consider switching?

01:08:13

Participant 3 (registered as a patient)

Losing control of my HbA1c, watching it rise would be, any new side effects that would come up that would make me feel sick or not wanting to take it. But I think looking at how it affects your body, and that control is imperative, because once we see things, I don't want to go to type 1, and right now I am stable and very happy. I think the best thing that could happen to us is if we found a cure. And we're looking at cures on in other areas, you know, hepatitis C, and things like that, different cancers, sickle cell, innovation. Finding that cure to say, "Okay, here's the miracle that's going to stabilize your pancreas, and you don't have to worry about having type 2 diabetes anymore." We found, we unlocked that. That would be awesome, we're not there yet. So, we want to keep that innovation going so we can find that miracle. But for me right now, I'm content with where I am, and I'm not having bad side effects. So, I'm okay.

01:09:45

Moderator, RTI International

And **[Participant 1]**, what would make you want to consider switching from Tradjenta? What would need to happen?

01:09:50

Participant 1 (registered as a patient)

Somebody would have to convince me that there was a better medication. I'd be willing to try it, but I would have to have a serious talk with my primary caregiver or health caregiver before I would really want to do it, because I've been happy with it, and he's certainly been happy with my A1C numbers, and I'm not aware of any side effects that I have. Most of the time I feel pretty good.

01:10:21

Participant 3 (registered as a patient)

[MODERATOR], can I add something to that too?

01:10:22

Moderator, RTI International

Please do.

01:10:24

Participant 3 (registered as a patient)

What we don't want to see is a non-medical switch. So, if we're stabilized on a medicine, we don't want our bureaucrats to come to us and say, "We're taking that off the formulary, we're going to switch you to something else, even though you are stabilized on the medicine that you're taking." I think that's a huge key, and that is a fear of when they restrict formularies, or they say "You're going to have to pay this out-of-pocket" or other matters that would affect that bottom line of rather than looking at the patient, because the patient needs to be in the center. That's where we need to focus on, what's it going to take to get this patient better? What's going to keep them stable? And non-medical switching happens and that can create havoc in people's lives.

01:11:13

Participant 1 (registered as a patient)

I would agree with that.

01:11:15

Moderator, RTI International

I think, **[Participant 5]**, you're going to get the last word on this section. So, yes, would you…

01:11:20

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

I want to make sure that we're working all together to destigmatize the different medications that people are on. Being on insulin is necessary for some people and does not mean that you have type 1, does not mean that you failed other treatments. Everyone needs to have access to whatever medicine works best for their body, and that if people are finding an insulin to work best many times. It is just because of this non-medical switching, that is why they have to move off it. And especially that midyear, non-medical switching is so traumatizing and really impacts people's care. If people need to switch that is okay. We want to make sure people have access to whatever meds they need.

01:12:09

Moderator, RTI International

Thank you, **[Participant 5]**. For my next question, I would just like for us to take a moment and imagine what it would be like for someone who has type 2 diabetes that Tradjenta or other medications weren't available, where they didn't exist. So, imagine a world where they didn't exist.

What needs of people, what needs of people with type 2 diabetes, what would they be lacking? What would the world be like without these treatments?

01:12:39

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

I can just start us off here.

01:12:41

Moderator, RTI International

Yes, please, **[Participant 5]**.

01:12:43

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

We don't have to imagine this. We can see this all over the globe, and we can see this right here in the United States. I think many, many people don't have access to these treatments, whether because of social reasons, economic reasons, other access reasons that we know what this world looks like. We don't have to imagine it. We know a lot of people are not able to go to the doctor to get any type of medication, any type of care, or when people go there, they're stymied by their access needs. We have lots of folks in our network who are not citizens of this country and are not able to access care in that way. We know folks who are scared to go to the doctor. We've heard some of those stories already of people just being so stigmatized that it makes it uncomfortable to go to the doctor, so they don't. And we see really disastrous health outcomes when people are not able to access the care that they need.

01:13:40

Moderator, RTI International

And could you say a little bit more, like we see more disasters. Could you say a little bit more about what you've observed with the folks you work with?

01:13:47

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

Diabetes has a ton of different complications. Vision impacts, kidney dialysis, gastroparesis, heart impacts. You know, some of our community, our chapter leaders have died overnight. There's a lot of impacts that folks can face with all types of diabetes, no matter the care and wanting to make sure that everyone has access to the best care that they can have is most impactful, because even just like a couple of months or years of less than quality care can have this long-term health impact.

We know folks who had rationed medications due to cost for a couple of months even, and a couple of hospitalizations of going into diabetic ketoacidosis, or of having that strain on their bodies just for a little while, led to them having significant nerve damage and being in a wheelchair for the rest of their lives. We want to make sure that people have access to all of the medicines that they need for all of those complications as well, and we want to avoid those complications as much as folks can.

01:15:10

Moderator, RTI International

Thank you, **[Participant 5]**. And **[Participant 3]**, what would life be like for you without these medications?

01:15:17

Participant 3 (registered as a patient)

Yeah, I had a cousin who was not stable, type 2 diabetes who was out riding his bicycle, and he just fell over and died. We have family members who have had amputations, higher use of ER rooms, neuropathy. We haven’t really talked a lot about neuropathy, but that’s a big comorbidity. Chronic kidney disease, cardiovascular disease, everything, all these comorbidities of diabetes vice versa, cardiovascular disease ending up with obesity and diabetes. They all play into each other. It comes back to the value of care and having the tools in the toolkit that we need. And we’re so fortunate that we have those tools in the toolkit right now that we can access as long as there’s coverage. If there’s no coverage, then access goes away.

01:16:24

Moderator, RTI International

Thank you. And what aspects of type 2 diabetes are Tradjenta or other medications unable to address for this condition? So, what are the shortcomings of Tradjenta or other medications? What can’t they address for diabetes right now?

01:16:48

Participant 1 (registered as a patient)

I have no idea on that one. Maybe you can talk about that, **[Participant 6]**.

01:16:55

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

We talked about this at the Janumet one. I mean, they don’t cure diabetes. Yeah.

01:17:00

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

No, of course not. Yeah.

01:17:01

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

That’s the main thing they don’t do.

01:17:05

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

It's for glycemic control. They don't seem to have the benefit that GLP-1s have of weight changes. But our position is even stronger than that and is that we just think it's not as good as other medicines and has more risks than benefits overall. That's our position on the gliptins overall, including linagliptin, the medicine we're talking about now, Tradjenta.

01:17:38

Moderator, RTI International

Please, any other thing? It doesn't cure, none of the medications available cure the type 2 diabetes. Anything else folks want to raise that the current body of medications just can't solve for type 2 diabetes?

01:17:55

Participant 3 (registered as a patient)

Sometimes it takes more than one medicine and then a combination.

01:18:04

Moderator, RTI International

And when you say it takes more than one, you have to try different things or multiple things at the time?

01:18:08

Participant 3 (registered as a patient)

Together, yeah.

01:18:12

Moderator, RTI International

Excellent. Anyone else want to piggyback on that?

01:18:15

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

It doesn't cure. But also, it doesn't make life with diabetes necessarily easier. You still have to do all of the other pieces of watching your exercise and your movement, watching what you eat, just paying attention. Having this third shift of caring for diabetes, it doesn't end that. I think that's potentially another way of saying it doesn't have a cure, but I would just like to frame it that way as well.

01:18:47

Moderator, RTI International

Thank you for bringing the third shift of taking care of your health condition as another thing. Okay, so kind of closing question. We'll just take about two minutes, and you can reflect on this for a moment. So, thinking about everything that we talked about today, how would you summarize the importance of Tradjenta for people with type 2 diabetes? Maybe, **[Participant 1]**, you can kick us off with that, since you are our sole experiencer?

01:19:17

Participant 1 (registered as a patient)

As I said, I'm the only person I know that takes Tradjenta. I think it's a good option. I was not aware of all of the side effects that you mentioned, **[Participant 6]**. Now you've scared me. Thank you so much.

01:19:37

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

Didn't mean to do that, just to educate you.

01:19:40

Participant 1 (registered as a patient)

But I would recommend it. It's worked for me. There's many people out there that have had bad experiences with some of the other diabetes medications, and it might give them some hope for a better life.

01:19:59

Moderator, RTI International

Thank you, **[Participant 1]**. Thinking broadly, how would you summarize the importance of this drug for people with type 2 diabetes from your experience, whatever position you're showing, sharing with us today?

01:20:15

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

Yeah, **[Participant 2]** with **[REDACTED]**. I mean the information that we look to, is science-based and from the clinical societies that actually treat these conditions. And **[Participant 1]** hopefully, it makes you feel better that the American Diabetes Association guidelines, specifically the standards of medical care, do recommend Tradjenta as an option for type 2 diabetes management. It's not considered a first line treatment, and you had that experience. You went through metformin first.

But for folks who haven't achieved adequate glycemic control, or who have had excessive side effects, it's considered a very good option. The most important thing, and I do think it's important to have this stated in the record is that people need to look to the guidelines.

And the stuff that **[Participant 6]** ran out, I want to say is, I think it's inappropriate, because people need to connect with their doctors and do what's best for them and do what's in line with medical guidelines and what he is putting out there maybe concerns of some individual clinicians, but they're not in line with the guidelines.

01:21:38

Moderator, RTI International

Right, and we have about one more minute. **[Participant 3]**, can I invite you to wrap us up?

01:21:56

Participant 3 (registered as a patient)

I'll go really fast. First of all, I want to thank **[Participant 1]** for coming on, being our Tradjenta patient, because she proves that the doctor-patient relationship is critical in making a decision about her needs as a patient. That is top line, keeping that patient central. When we're looking at FDA-approved drugs, and we're looking at access, you have to have the options of everything that's in the toolkit to make it matter. In her case, many other people probably are in her case that have had really good results. I want to thank CMS for giving us this opportunity to really come together. It's good to debate issues and talk about issues. I hope that CMS got a lot from the discussion that we had today, and that you keep this type of discussion moving forward and really listen to what all of us have had to say and helping you make decisions about how you move forward.

01:23:00

Moderator, RTI International

Thank you, **[Participant 3]**. **[Participant 6]**, I'll invite you to put, I know you had one more comment to put in, but we are at the time. I wanted to thank everyone for coming together today. I know we had some hard moments of conversation, but as **[Participant 3]** brought this together, it's good to have the debate and discussion and learn from each other. Thank you for taking the time today. Your experiences and input were very valuable and will help inform CMS' negotiations, and CMS staff have been listening to the roundtable, and will be able to take that information forward, the diversity of perspectives. **[CMS STAFF]**, if you want to close us out this afternoon.

01:23:41

CMS Staff

Of course. Thank you for everything. To echo what **[MODERATOR]** said, I want to thank you all for sharing your experiences with us. We were here listening, taking notes in the background, and we're really grateful for the conversation, and being able to get good information from you guys. Thank you all so much.

01:23:59

Moderator, RTI International

Thank you, **[CMS STAFF]**. And so, in closing again, as I promised that folks could share additional information through the mailbox, or if you think of questions or something you wish you would have said today, you can use this mailbox, the IRARebateAndNegotiation@cms.hhs.gov, and then use the subject line, public engagement events, and you can see that there in the chat. If you want to take a screenshot or something to say that you can get access to that mailbox afterwards.

=== 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

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
Yes	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	
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
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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 3: Registered as a patient with experience with other treatment(s) similar to the selected drug for those condition(s); 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
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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 4: Registered as a representative of a patient advocacy organization

Declared Conflicts of Interest	
No	Receipt of financial payments (e.g., Gifts', funding, research support, honoraria, travel, or other expenses) from a company with direct/indirect interest in the Negotiation Program, in excess of $10,000 by you, your spouse, or an immediate family member
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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 5: Registered as a representative of a patient advocacy organization

Declared Conflicts of Interest	
No	Receipt of financial payments (e.g., Gifts', funding, research support, honoraria, travel, or other expenses) from a company with direct/indirect interest in the Negotiation Program, in excess of $10,000 by you, your spouse, or an immediate family member
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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 6: Registered as a representative of a patient advocacy organization

Declared Conflicts of Interest	
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