

*This transcript was lightly edited for readability.*

## Introductory Remarks

### Moderator, RTI International

Hi, everyone. My name is **[Moderator]**. I am joining you from RTI International. I also want to introduce you to my colleague, **[Secondary Moderator]**, who you can see on screen here. We may hear from **[Secondary Moderator]** at different points during the discussion today.

The Centers for Medicare & Medicaid Services, which we'll be referring to by the acronym CMS today, 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 the selected drugs, patients' experiences with the selected drugs themselves, as well as patients' experiences with other drugs that are used to treat the same conditions as the selected drug. The information shared during these events will also help CMS identify other medications used to treat the conditions treated by the selected drug, what matters most to patients in managing their conditions, and other important factors that CMS may consider in negotiating Medicare pricing with the manufacturers of the selected drugs.

The purpose of today's event is to hear from you, a group that may include patients, caregivers, and patient advocates, about your experiences with the conditions and diseases treated by Trulicity, and that includes type 2 diabetes mellitus today, as well as type 2 diabetes with cardiovascular disease or multiple cardiovascular risk factors. In other words, type 2 diabetes with or without cardiovascular disease or cardiovascular disease risk factors. We're really interested in hearing about your experiences being treated with Trulicity itself, as well as with other medications for the same conditions. I do want to emphasize that our focus today will be on the patient experience. If you do wish to share input on other topics related to drug price negotiation that are not directly focused on the patient experience, we ask that you send that input to an email inbox that was included in your welcome packet. It's the [IRARebateAndNegotiation@cms.hhs.gov](mailto:IRARebateAndNegotiation@cms.hhs.gov) email. Again, that's in your welcome packet. We ask that you share that feedback via email instead of during today's discussion.

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

## CMS Remarks

00:03:08

### 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.

**00:05:00**

### **Moderator, RTI International**

I also want to make you aware that staff from CMS will be sitting in on this event so that they can hear your experiences directly from you. And let me hand it over to them quickly so they can say hello. **[CMS Staff]**, are you here?

**00:05:14**

### **CMS Staff**

Yes. Hi everyone. I am **[CMS Staff]** from the CMS Drug Price Negotiation team. There are other CMS members on the call today, and we're here to listen in, to get your information, and enjoy the discussion. We're going to go off camera so that the focus will be on the discussion. Thank you.

## Housekeeping

00:05:34

**Moderator, RTI International**

Before we begin, I want to review some quick ground rules for our discussion today so that everyone knows what to expect for the next couple hours we're together. Technical assistance, if you get disconnected at any point, please attempt to simply rejoin the Zoom meeting. If you cannot reconnect, there's this tech support email address that has also been dropped in the chat, the [IRADAPSTechsupport@telligen.com](mailto:IRADAPSTechsupport@telligen.com). You can shoot them an email, and they will do their best to troubleshoot with you and get you rejoined.

Regarding privacy, this discussion is not open to the press or the public. We will use first names only today to protect your privacy. Please do your best not to share any unnecessary protected health information. That includes your doctors' names, the name of a medical facility where you received care, or any personally identifying information, including things like your employer's name, the city you live in, schools you attended, during our discussion. Following the event, CMS will prepare transcripts that have participant names and any identifying information removed, and those de-identified transcripts will be made available to the public. On a related note, we are recording today's event. These recordings will not be shared publicly. The recordings are only for our internal program documentation use and will help us produce the redacted transcripts for public release. And by participating, you consent to being recorded for these purposes.

Regarding participation, we hope that you will contribute your perspectives throughout our time together today. However, if any questions arise that you do not want to answer, that is perfectly fine. Please do your best to minimize any background noise by silencing your cell phone and any other devices if you haven't already done so. Also, please do your best to mute yourself when you are not speaking to avoid any background noise on the recording. And thank you in advance for keeping your video on throughout the discussion. It really does help to be able to see each other as we're talking today.

We have reserved up to two hours for this session. However, it's possible that we may not need that full time to discuss all of our planned topics. If that happens, we will let folks go a bit early. And I do have a discussion guide in front of me to help us stay on track. We have a lot of topics to cover, so I may need to redirect our conversation or cut a conversation short, to make sure that we're able to cover all the topics and that everyone has a chance to speak.

If you need to step away briefly at any point during our discussion, that is okay. We ask that you turn your camera and microphone off and rejoin as soon as you're able to. You don't need to let me know that you're stepping away, please return to the discussion when you're able to. And please do your best to speak one at a time. I know it can be challenging on Zoom. I may occasionally interrupt you if more than two people are speaking at once, to make sure that we have a clear recording for the transcript. You may also use the raise hand feature in Zoom if that's helpful, and that can help us know when someone would like to speak next.

And finally, we're hoping that everyone will be able to focus on our oral discussion today, but you may also add your comments into the chat function here in Zoom if you don't get a chance to share them orally. If you need to come back to something, or something comes up later in the discussion, please feel free to drop that thought in the chats. Does anyone have any questions before we go ahead and get started?

## Discussion

00:09:02

**Moderator, RTI International**

We can go ahead and get started. I would like to begin our discussion with some brief introductions. If it's okay with you guys, we'll go around the room, and I ask that you take a moment to tell us your first name, what perspective you're bringing to the discussion today, whether you'll be sharing your experiences as a patient, a caregiver, a patient advocate, or if you wear multiple hats, and then finally, the condition or conditions that Trulicity treats that you have experience with as a patient, a caregiver, or an advocate. **[Participant 1]**, you are first on my screen. Do you mind kicking us off?

00:09:43

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

Yes, thank you very much. I'm basically representing myself as a patient [and] a patient advocacy group. I'm very familiar with Trulicity and its use in type 2 diabetes. It was one of the first long-acting insulins that actually worked for 24 hours versus having to split and do multiple dosages in prior years. My experience with diabetes started in 1977. The only perspective I can provide is diabetes in your twenties is not diabetes in your thirties, forties, fifties, sixties, or going into your seventies. My diagnosis, I started out with urine strips, glass barrel syringes, and pork insulin. To see the advancements in medications and devices, being able to see the advancements and live the advancements has been an incredible journey.

00:10:46

**Moderator, RTI International**

Wonderful. Thank you for being here, **[Participant 1]**, and I'm looking forward to hearing more from you about all that throughout our discussion. **[Participant 2]**, you are next on my screen. Would you mind introducing yourself?

00:10:57

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

Sure, my name is **[Participant 2]**. I have type 2 diabetes. I also have rheumatoid arthritis. I am coming as a patient and a patient advocate, as I do also advocate for rheumatoid arthritis with AiArthritis [International Foundation for Autoimmune & Autoinflammatory Arthritis].

00:11:18

**Moderator, RTI International**

Thank you, **[Participant 2]**. **[Participant 3]**, you are next on my screen.

00:11:22

**Participant 3 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

Thank you. I'm **[Participant 3]**. I'm a patient advocate and I have experience with type 2 diabetes as well. I think it's very important to keep these topics in discussion, and to ask families and people with lived experience, so I applaud you for doing that, and thank you.

00:11:46

Moderator, RTI International

Thanks, [Participant 3]. And [Participant 4], would you mind introducing yourself?

00:11:50

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

Hi everyone. I'm [Participant 4], and I am at a patient advocacy organization that represents community health center patients. They have oftentimes a lot more chronic diseases than the rest of the population, and a high percentage do have type 2 diabetes, so I'm really excited to be able to represent their interest in this discussion. I'm looking forward to this.

00:12:17

Moderator, RTI International

Thank you, [Participant 4]. Thank you for introducing yourselves, and for my clarity here, I want to make sure that I know, we have folks speaking to the type 2 diabetes aspect, obviously. I wonder if folks could give a raise of their hand if the type 2 diabetes with cardiovascular disease or multiple cardiovascular risk factors is also something that is relevant to your experience. Could folks raise their hand? [Participant 4]. [Participant 3], fabulous. I'll be sure to refer to those two things separately throughout our discussion. And we realize that experiences with Trulicity and other treatments may differ by condition, so when you speak, it would be helpful if you could remind the group what you're referring to, if it's a type 2 diabetes piece, or that additional piece with the cardiovascular disease and risk factors to the extent possible, that will help us all stay on the same page. And I want to start with talking about patients. [Participant 1].

00:13:24

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

From a patient and a patient advocacy perspective, there's no such thing as just diabetes. If you're over 40 years old, you've got diabetes, hypertension, hypercholesterolemia, ischemic, you have the beginnings of heart disease, your kidneys are starting to be impacted. I was an author of one of the studies published in *Diabetes Care*. If you look at the Medicare beneficiary population with diabetes, 50% of them have congestive heart failure, 23% of them have atrial fibrillation and flutter, Stage 3 kidney failure. Diabetes is like a gateway disease that compounds things, it's the leading cause of blindness. Uncontrolled diabetes is the leading cause of dialysis. If you're not controlling your sugar, pay me now or pay me later.

00:14:25

Moderator, RTI International

That point is well taken, [Participant 1]. I know it might not be possible to refer to diabetes without referring to the cardiovascular element, so well taken. As we continue our discussion, if there are certain questions that it does make sense to tease out those differences, please do so, but well taken. We understand that those are not necessarily separate conditions.

Let's start by talking about patients' experiences with the conditions treated by Trulicity. With type 2 diabetes with the cardiovascular element, I know we're here to talk about the drug Trulicity and other treatments, but I want us first to focus about the conditions itself that you have experience

and the patients you advocate for have experience with. With that in mind, the first question is thinking about the different ways that type 2 diabetes, as well as type 2 diabetes with cardiovascular disease or multiple risk factors for cardiovascular disease, what would you say are the most important aspects of the conditions to have managed or treated? These could be things that affect patients in the short term or the long term. Does anyone want to kick us off thinking about the most important aspects of these conditions to have managed or treated? **[Participant 2]**, please go ahead.

**00:16:09**

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

I think for me it is, was getting my blood sugar under control, making sure every year I'm going to see ophthalmologists to make sure my eyesight is good, there's a lot in making sure I could get the Dexcom [the brand name of a continuous glucose monitoring device], something that could read my blood sugar continually. There's a lot that goes into the diabetes diagnosis. My A1C [hemoglobin A1C] was out of control. And so getting that under control as well was a challenge. Starting with the lowest common denominator drugs, like metformin before you are allowed to go to the next level, sometimes, could be it would be easier to start at a higher level drug. Metformin is great, but it was so much better once I was able to get with Trulicity and GLP-1s [glucagon-like peptide-1 medications].

**00:17:26**

**Moderator, RTI International**

Thanks, **[Participant 2]**, and we will certainly return to that point later in the conversation. I would like to hear about the comparison between those different drugs. **[Participant 1]**, please go ahead.

**00:17:38**

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

I think the biggest piece is early screening. A lot of type 2 diabetes is diagnosed by mistake. You go in for an annual physical. They do your blood work, all of a sudden they see your A1C, or what your fasting blood sugar is based upon the blood draw, a fasting blood draw. And then it's getting the physician. You look at primary care, God love those young men and women who are out treating people. But they're asked to see 30 to 40 patients a day at ten minutes or less. If somebody has diabetes, it takes time. They're reimbursed and paid for doing procedures, not providing cognitive services. It becomes a real challenge, and everybody wants to go with this stepwise program, and I'll echo exactly what the previous commenter had was, you have to treat diabetes where it's at right now. You can't start with metformin with its GI [gastrointestinal] side effect profile. And then hope that the patient gets religion because what they tell you to do is eat a healthy diet and exercise. Well, define a healthy diet. It's what my mother taught me. I grew up in the South. Everything was fried, add salt back in it.

Once you get diagnosed with diabetes, your D [diabetes] gene kicks in, and you're supposed to be all-knowing about how to manage your condition. The access to a certified diabetes educator is abysmal at best. And they're the ones that help patients with diabetes literacy. I'm saying literacy purposely because it's not education. People are not stupid. They just don't know what they don't know, and by helping them understand the simple life choices, those simple improvements can make significant investments. Because if you don't control it, amputations, vision, kidneys, heart, neuropathy, blindness, that all comes, that's all part of the package if you don't take care of it.

00:20:09

**Moderator, RTI International**

Thanks, **[Participant 1]**. I'm hearing that management piece is a big part for you, a factor that needs to be treated with type 2 diabetes patients.

00:20:21

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

Regardless of diabetes, type 1 or type 2. I've basically been practicing endocrinology without going to medical school for darn near 50 years. Because guess what? I see my clinician less than 1% of the time during the course of a year. All the decisions about my management, insulin administration, other drug administration is all on me. I'm the doctor. I didn't join up to be a doctor. But for me, I've been trained on how to screw up one patient. Me.

00:21:00

**Moderator, RTI International**

It sounds like you're doing great. Thank you, **[Participant 1]**. Others, what are some of the most important aspects to have managed or treated amongst yourself and your own experience with type 2 diabetes or patients you advocate for? **[Participant 4]** or **[Participant 3]**, I wonder if you have thoughts on that.

00:21:28

**Participant 3 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

I was going to say that **[Participant 1]** pretty much stole the show there. I was going to say what he did, so thank you.

00:21:36

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

To round it out from the health center perspective, I think we're really focused on, as a patient advocacy and provider organization, HbA1C is obviously the easiest to measure, and so it's like, if we can try to help get that under control, then we can help address some of those other risk factors around that, but I think from an intervention standpoint, that's been the most helpful, but again, as everyone has talked about, there are other risk factors that then have to be really addressed and they can't also be seen disparately. They all have to be happening at once, but HbA1C levels probably has been something that we've been really focused on with clinical pharmacists, and then them working with their providers and such.

00:22:32

**Moderator, RTI International**

**[Participant 4]**, you mentioned these other risk factors to deal with after the A1C management. I wonder if you could give us a few examples of some of the primary risk factors that you're seeing.

00:22:44

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

I think there's a lot of non-clinical social risk factors, like SDOH [social determinants of health] that we're really focused on. I think **[Participant 1]** made a really good point about making sure that folks have a good understanding of what does a healthy diet actually look like, and not assuming that everyone knows what that is. We use a lot of clinical pharmacists to try to provide some of that education on diet, lifestyle, and self-monitoring techniques. And then also helping with complex medication management, because I think that could be another issue. A lot of folks have talked about, maybe you're not just having type 2 diabetes, you have all of these other conditions that you want to monitor and take care of alongside of type 2, so I think that's really important. And then that can lead to better quality of life if we're trying to look at this whole person-centered care.

00:23:58

**Moderator, RTI International**

Thanks, **[Participant 4]**. How do the effects of type 2 diabetes impact quality of life? We've talked about it a little bit, but what are the impacts on a patient's quality of life?

00:24:15

**Participant 3 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

I think it's everything. Everything is impacted by that. I've experienced with things like going to a conference. I have to plan around everything. I have to plan around my breaks to check blood sugar levels, all kinds of things like that. I have to plan around my meals, what I'm going to eat, where I'm going to eat it at, everything.

00:24:40

**Moderator, RTI International**

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

00:24:43

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

Diabetes is 365, 24/7. You don't get a break. Diabetes is like a bad tattoo. Once you get it, you can't get rid of it. It's there and it's almost haunting. The stress and the anxiety that you have. I understand, **[Participant 3]**, because I've traveled extensively. When you pack for a trip, you pack all your diabetes medications first before you even think about clothing. Do I have enough insulin? Do I have enough devices? Do I have enough of these pills or that pills? And you calculated that down and make sure you have three or four extra days. How am I going to keep my insulin chilled?

00:25:30

**Moderator, RTI International**

Thanks, **[Participant 1]**. Point well taken, and you touched on the anxiety and the stress component of it and the impact of the mental health impact on quality of life. I wonder if others can speak to that. How do the effects of type 2 diabetes impact one's mental health?

00:25:59

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

For me, I tend to have low lows, so I have to be very careful that I have either glucagon or some candy or something to bring my A1C, to bring my blood sugar back up. That can happen while I'm sleeping. That's why I get a little bit of respite because I have the Dexcom. But that's not always true, so I have to be able to check my blood sugar. I think being very wary of when I get dizzy because I work retail, so I'm running around, I have to make sure that if I'm getting dizzy because of my rheumatoid, or because my A1C, or my blood sugar is going low.

00:26:50

**Moderator, RTI International**

Thank you, **[Participant 2]**. Anyone else have thoughts on the mental health impact of type 2 diabetes?

00:27:00

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

I think she hit on a big point, is the hypoglycemia. The first thing to go when your blood sugar starts to drop is your mind. You can't think straight, you're breaking out in a cold sweat. The biggest challenges? Glucagon, whether it's the nasal inhalers or the two injectables, are not covered by CMS. They'll cover insulin, which can trigger a low blood sugar because my diabetes today is not what it was yesterday, nor is what it's going to be tomorrow. And just because you have diabetes, guess what? You're going to get a low, and the older you get, the lows come. Almost 40% of Medicare beneficiaries have low blood sugar events. But that rescue medication is a non-covered benefit. When I go in to get it, before I convinced my Medicare Part D plan, it was \$400 for two pens. That's getting me out of one event.

00:28:11

**Moderator, RTI International**

Thanks, **[Participant 1]**. And I want to follow up on something you just mentioned, which is the worsening of the condition over time, so managing type 2 diabetes as you age. Can you speak to how do the effects of type 2 diabetes impact the worsening of the condition over time? Or can folks speak to the management or the treatment, or the patient experience of type 2 diabetes over time?

00:28:38

**Participant 3 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

I can speak about that for mental health a little bit. I never thought it would happen to me. I thought it would happen to my grandparents or older senior citizens, and then when it did, I thought, "Wow, what's going to happen next? Am I going to end up like that? Am I going to end up with kidney problems and vision problems and all that stuff?" And it took a toll for mental health, for sure.

00:29:03

**Moderator, RTI International**

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

00:29:10

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

From a physiological perspective, your beta cells wear out over time with type 1, your beta cells, they left the building. So you have to have insulin. And type 2 diabetes, over time, those beta cells within the pancreas, they produce less and less insulin and almost 30% of all patients with type 2 are on insulin today to support what the pancreas can't do. And a lot of people are not type 1 or not type 2, but they're type 3. They're a type 2 patient, their pancreas is gone and they treat them like a type 1.

00:29:54

**Moderator, RTI International**

Okay, interesting. Thanks, **[Participant 1]**.

00:29:57

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

CGM [continuous glucose monitoring] insulin pumps are growing in use because of that.

00:30:06

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

Some issues that I've been having are issues with my feet as far as where my feet feel numb sometimes. I have that issue. It's not super bad right now, but that's something that I worry about going forward, that I lose feeling in my feet, things like that. That can happen with type 2 diabetes.

00:30:40

**Moderator, RTI International**

Thank you, **[Participant 2]**. I'm going to move us along to our next topic. Thank you all so much for sharing your experiences with managing and the patient experience with type 2 diabetes. It's really helpful, thank you, **[Participant 1]**.

Now I'd like to turn our attention to patients' experiences with medications for type 2 diabetes, as well as the type 2 diabetes with cardiovascular disease or cardiovascular risk factors. In this question, I'm actually going to ask you guys to type your response in the chat here in Zoom. And the question is, what medications, if any, have you or patients you advocate for taken either currently or in the past for type 2 diabetes, or type 2 diabetes with cardiovascular disease? Again, the medications that you or patients you advocate for have taken, either now or in the past, for type 2 diabetes. I'll give folks a moment to get to the chat and enter your responses there. Let me know if you have any issues navigating to the chat window. Thank you, **[Participant 2]**. I see your response there. Thanks, **[Participant 3]**. I see folks typing, so we'll give it another minute here. Thank you, **[Participant 1]**. It's helpful to see what folks have had experience with, and is good context for these next few questions we'll get into.

For the next few questions, I want to note that we want to hear about any experiences you or patients you advocate for have had with Trulicity, as well as these other medications that are used for type 2 diabetes. Thinking holistically about Trulicity, but also any other medications that you have experience with type 2 diabetes and with that in mind, my first question here is, what benefits have you or patients you advocate for experienced with medications used for type 2 diabetes, as



well as type 2 diabetes with cardiovascular disease or risk factors? And as a reminder, to the extent that you're able to, please let us know which medication you're discussing. What benefits have you or patients you advocate for experienced with these medications?

**00:34:18**

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

With Trulicity, I was able to lose 40 pounds. It was the very first medication, metformin was great, it almost kept me in range, but Trulicity actually brought my A1C down, and also it helped me to lose some weight while I was on it, and I was on it for a good year and a half before we decided to try some of the other GLP medications.

**00:34:54**

**Moderator, RTI International**

Thank you, **[Participant 2]**. Others, what benefits have you experienced, or patients you advocate for experienced with these medications?

**00:35:09**

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

The key is glycemic control. They're able to reach their target, and to be able to be, like **[Participant 2]** said, are you in range? Is your blood glucose between 80 and 140? Are you trying to keep your blood sugar, you still got diabetes, so it's going to go up. Guess what? You've got diabetes. But these medications, so you could start out with Lantus, which is a long-acting insulin. But it didn't last 24 hours. Trulicity, one injection, it lasted 24 hours. You didn't have these peaks and valleys of your blood sugar. You didn't have the side effects like you'd have with metformin. I don't know if you're familiar, the metformin has some significant GI consequences. You spend a lot of time in the bathroom.

**00:36:10**

**Moderator, RTI International**

Thank you, **[Participant 1]**, and save that thought, we're going to switch to the drawbacks of these medications shortly, so I appreciate you bringing that up. **[Participant 1]**, you touched on the importance of blood sugar management with these medications. I wonder, because you mentioned you have experience with multiple medications, could you speak to, how do the benefits of these medications differ with respect to that blood sugar management piece?

**00:36:39**

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

They're all formulated to do different things. It's really the size of the molecule. Lantus wouldn't go full 24 hours. Trulicity would go a full 24 hours.

I think the challenge that people face is, you have your blood sugar in good control. January shows up, if you've been taking Humalog, now the formulary wants to switch to NovoLog. No, I don't want to go on Trulicity anymore because I'm getting a better rebate to go to Basaglar. You know what that means? I have at least two additional visits to my endocrinologist, which is really hard to get in to see them. I've got two office visits, two copays, and I keep adjusting it via MyChart communications with my physician. So again, I'm back to playing endocrinologist, and why fix it if it's not broken?

00:37:54

**Moderator, RTI International**

Thank you, **[Participant 1]**. Others, what benefits have you or patients you advocate for experienced with medications for type 2 diabetes?

00:38:08

**Participant 3 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

I think consistency is key. Definitely, that's been my experience. Once something works, you stick with it, and you stay with it.

00:38:17

**Moderator, RTI International**

Talk to me a bit more about that, **[Participant 3]**. What does consistency mean or look like for you?

00:38:23

**Participant 3 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

Managed. Managed and managed well, or well as can be expected, and without a lot of side effects, complications, like you said, if it's not broken, don't fix it.

00:38:33

**Moderator, RTI International**

It sounds like sustained management is a benefit of some of these medications.

00:38:41

**Participant 3 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

Yes, definitely, yes.

00:38:44

**Moderator, RTI International**

And thinking about these benefits we've mentioned, I'm curious about how administration is or how it's taken. Is that a benefit of some of these medications? **[Participant 2]**.

00:38:58

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

I was going to mention that taking Trulicity is much easier than me having to take metformin every day, two times a day, whereas you take the shot once a week. You tend to stay on the medication, or do the medication correctly more often because I can forget to do my metformin by falling asleep early. It really does help you be able to set a day and a time that you're going to actually do the shot and follow that schedule.

00:39:35

**Moderator, RTI International**

Thanks for sharing that, **[Participant 2]**. Do others have thoughts on either dosage or administration? **[Participant 4]**, please go ahead.

00:39:42

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

Jumping off of what **[Participant 2]** was saying, that the patients that we're seeing, definitely having that once-weekly administration, it helps, obviously, it keeps the regimen for medications simplified, especially if patients like ours are managing multiple chronic conditions and it reduces the number of times that they have to think about that. But then also, injection anxiety is definitely a real thing. I don't like shots, and so if I were managing this disease, then I would definitely appreciate only having to do that injection once a week.

00:40:29

**Moderator, RTI International**

Sure. And we've touched on this a bit, including just now thinking about the different administration routes for these medications, but if you have experience with more than one medication for type 2 diabetes, how did the benefits differ? Could you compare and contrast the benefits of these different medications?

00:40:57

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

All the medications work physiologically differently. Some work on the kidneys, some work on the liver. Some block different responses. Think of it in two different ways. I've got a basal rate. To **[Participant 2]**'s point, the basal helps keep your blood sugar like a smooth line, your short-acting insulin, you have a meal, it bumps up. You can calculate what carbohydrates you're eating, and it can bring it back down. But it also depends on what other comorbidities you have. Something that works on the kidney, if your kidneys are starting to fail, may not be the best for that patient. You've really got to look at each individual patient and what's physiologically sound for that patient. And like **[Participant 4]**'s comment, very familiar with her organization. Coordinating pills. The little plastic devices where you have, here's your morning, here's your nighttime, to avoid medication confusion because as you get older, 50% of your nutritional intake is through excipients in your prescriptions. Did you take a handful in the morning and a handful at night?

00:42:25

**Moderator, RTI International**

Thanks for that that point, **[Participant 1]**. **[Participant 2]**, please go ahead.

00:42:31

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

For me, Trulicity was a really good jumping-off point. It actually got me under control. I wanted to get more effects because we were seeing more effects from Ozempic. I did Ozempic for a year. It is something that did not work well for me. I was still under control, but it wasn't the best one for me.

Then we switched me to Mounjaro, which has brought my A1C way down, and was able to get me where I need to be. Plus, with the comorbidity, or the other chronic illness I have, rheumatoid arthritis, it also helped bring down my inflammation. My rheumatoid arthritis medications are actually working better with that one medication, with Mounjaro.

**00:43:26**

**Moderator, RTI International**

Thank you, **[Participant 2]**, really helpful. Anyone else, before we switch to the flip side of things, any other benefits folks want to mention with these type 2 diabetes medications? With that, let's think about the flip side. What drawbacks or challenges have you or patients you advocate for experienced with medications used for type 2 diabetes, as well as type 2 diabetes with cardiovascular disease or cardiovascular risk factors? And again, you're all doing great, but as a reminder, please try to let us know which medications you're discussing. Drawbacks or challenges with these medications? Yes, **[Participant 4]**.

**00:44:14**

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

I wish that I could be specific about the different medications, but this is an issue that our patients see in general. We see a lot of people that don't have insurance, or have Medicaid, and are lower income in general, and so cost is definitely a prohibitor, but for Trulicity, NovoLog, all of these different medications that help treat type 2 diabetes, and obviously, health centers with our pharmacies and our community pharmacies that we contract with, we do provide them on a sliding fee scale. We really try to work with manufacturers to get those copay coupons, so we can try to make them as cheap as possible, but there are still, I think, persistent cost issues that are happening, and then I think **[Participant 1]** was the one who mentioned this, that there are times when the preferred formulary changes for, through PBMs [pharmacy benefit managers] and the pharmacies, and patients are saying, "Oh, this medication, I'm going to have to pay this high price in order to continue to get this medication that's working really well for me." Again, we try to get those discounted for them, but even having to pay \$15 for that prescription can be really cost prohibitive for people that are trying to make rent, or pay for childcare, things like that. I think that is definitely, the cost issue in terms of trying to make those affordable for patients, but then also things can change based off of those preferred formularies.

**00:46:06**

**Moderator, RTI International**

Thank you, **[Participant 4]**. Others have any drawbacks or challenges that come to mind with these medications? **[Participant 3]**, please go ahead, then **[Participant 1]**, you're next.

**00:46:22**

**Participant 3 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

Thank you. I have seen many people have trouble with managing their medications. I've seen people have to have caregivers to manage their medications, to manage their doses, to manage how to do their dosages because doctors don't talk to them about that stuff. They send them home with a prescription and say, "Here you go." And that's it. But the blood testing and all that stuff, they don't show you how to do that stuff. You have to learn on your own, or look it up on YouTube.

00:46:53

**Moderator, RTI International**

Thanks, **[Participant 3]**. I hear what you're saying, and is it literally how to administer the medications, do the blood? Talk to me about what that can look like, the full scope of having to manage that medication.

00:47:09

**Participant 3 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

It's like a routine. You have to have a set routine, like writing it down in a journal, or having it on the fridge every day to know what to do every single day. People don't have that kind of luxury to know that stuff every. You have to have a caregiver to do that stuff for you, or help you manage it, and even that's not cost-effective either.

00:47:28

**Moderator, RTI International**

Thank you, **[Participant 3]**. **[Participant 1]**.

00:47:31

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

I think the biggest challenge is access, and I think **[Participant 4]** hit on that. Access is not only to the medications, but how do they get transportation to go to the community health center? How do they get to the appointment? And then when she was talking about the organization, people are very intelligent in their chosen profession. You start getting into medicine, we're all on our heels. The organization of, "How do I get a pill coordinator so I know what I'm supposed to take in the morning and what I'm supposed to take at night?" And with diabetes, as you get older, your vision is one of the first things that gets impacted. Try reading the labels on a prescription bottle, and they all look like little white pills or little yellow pills. Some are oblong, most of them are round. The confusion of people getting in trouble with not taking the right medications at the right time, or taking too many, or did I forget to take this one this morning? Should I take two tonight? People are outside of their boundaries. That's why Trulicity, you do it once a week. You pick a Monday, Friday, whatever day of the week you're going to do. You're done.

00:48:57

**Moderator, RTI International**

Thank you, **[Participant 1]**. I'm hearing access, costs, the management, these are all challenges with these medications. **[Participant 1]**, you talked earlier about some of the side effects of these different medications. I wonder if you all could speak to how easy or difficult it is to tolerate some of these medications, and any drawbacks related to that or any side effects.

00:49:24

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

I can talk a little bit. Trulicity, I never had any side effects. Now, metformin, when I was taking that, that could be a problem. If you're not used to it, you will have to be by a bathroom very shortly. With

the Ozempic, I've never had any issues. When I went to Mounjaro, there are some things that I now cannot eat because if I eat it, I will have horrible gastric issues. That's what that did to me, is it stopped me from eating certain items.

**00:50:03**

**Moderator, RTI International**

Thank you, **[Participant 2]**. Anyone else want to comment on any other drawbacks related to these medications, or if anything comes to mind related to side effects, tolerating these medications?

**00:50:21**

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

Probably half the people start on metformin don't stay on for the exact same reason that **[Participant 2]** talks about. In the diabetes community, once you find a partner that knows and understands you, they'll all say, "Did you try metformin?" And everybody's eyes roll. They said, "I couldn't stay on it, I couldn't tolerate it."

**00:50:45**

**Moderator, RTI International**

Thanks, **[Participant 1]**. I'm hearing, among those who have experience with more than one medication, it sounds like the side effects with metformin are especially challenging. Any other drawbacks that you can compare between medications, any distinct differences between, if you have experience with multiple medications, any drawbacks or challenges that rise to the surface?

I do want to ask, specifically, related to the cardiovascular disease element. Among type 2 diabetes patients, or patients you advocate for with type 2 diabetes as well as cardiovascular disease or cardiovascular disease risk factors, are there certain benefits related to cardiovascular disease management that are associated with these medications?

**00:51:50**

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

Absolutely, with the GLP-1s and Trulicity, losing the weight does help with cardiovascular. I think almost all of them have benefits for cardiovascular disease. I have not had any issues, although I do see a heart doctor because I have rheumatoid arthritis. I make sure to go and see him once a year to ensure that my heart is good because rheumatoid can affect anything. It's a good thing that I did that because I had the rheumatoid before I had the diabetes.

**00:52:30**

**Moderator, RTI International**

Thank you, **[Participant 2]**. Anyone else? Any benefits or drawbacks specific to cardiovascular disease that come to mind for these medications?

**00:52:41**

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

I think if you look at all the recent data that's been published, GLP-1s, whether it's been done by Novo [Nordisk] or by [Eli] Lilly [and Company], they've shown they reduce cardiovascular risk and

risk of heart attack. It reverses the progression of kidney dysfunction to going into dialysis. They're showing that it's stopping retinopathy to progress to blindness. In seniors, a significant number of high blood sugars leads to dementia. If I start looking at what's the cost of kidney transplants, what's the cost of mental care in this country, senior care, memory wards, we're pennywise and pound foolish. We're fighting coverage for the GLP-1s for patients with type 2, unless you're on insulin, or unless you've got documented Level 2 or Level 3 low blood sugars. But we will pay for the heart attack, we'll pay for the hospital admissions, but we won't pay for prevention. And I think the GLP-1s have definitely proven that they should be a reasonable and rational medication for coverage for type 2 patients. The diabetes pandemic is not getting any better. These drugs have great side effects because they reduce, they treat obesity, and all of a sudden, everything improves. You have more productive workforce. You have more people who are present at their jobs. I think part of the challenge is, as we start looking at it, can we afford to pay for these medications? And I'll ask you another question, can we afford not to pay for them?

**00:54:46**

**Moderator, RTI International**

I see nods. Thank you, **[Participant 1]**. It sounds like, and some folks' experience, the GLP-1s are coming with cardiovascular benefits. Anyone else want to comment on any benefits or drawbacks with these medications before we move on? Thank you so much for all this input so far.

I want to switch gears a little bit, and thinking overall when considering a potential medication for type 2 diabetes, as well as type 2 diabetes with cardiovascular disease or cardiovascular risk factors, what factors matter to patients the most? When considering a medication for type 2 diabetes, what factors matter to patients the most?

**00:55:39**

**Participant 3 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

I would say side effects. I have children, I have to have energy and be able to take care of them, so side effects really affect my ability to do that day to day.

**00:55:50**

**Moderator, RTI International**

Thanks, **[Participant 3]**. I heard you mention energy. Are there other key side effects that would that would most impact your decision?

**00:55:59**

**Participant 3 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

Being able to manage it, navigate it, tolerate it throughout my day, that's huge, but that can make or break my day pretty quickly.

**00:56:10**

**Moderator, RTI International**

Thanks, **[Participant 3]**. Anyone else? What factors are most important to you or to patients you advocate for when deciding on a medication?

00:56:28

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

For me, it's ease of use. The once a week thing is great for me. I would rather do a shot once a week than take a pill every day because I do not always remember to take the pill.

00:56:45

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

And I think one of the biggest challenges of the type 2 community is the stigma.

00:56:51

**Moderator, RTI International**

Talk to us about that, [Participant 1].

00:56:53

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

Everybody views type 2 that if you're a little bit on the medium husky side, it's like, you ate your way to diabetes, how can you expect me to pay for it? And there are environmental issues. If you have a long family history of diabetes, blame your parents. If you're from a minority group, where we know the prevalence of diabetes is higher in Black, Brown, and Asian communities. The challenge is, it's also not only the stigma, but then the denial. Type 2 diabetes is not the good diabetes. That's what will bankrupt our hospitals. Medicare beneficiaries with a diabetes diagnosis have an annualized hospital encounter rate at 60% annually. That's either an admission or an emergency department visit. We don't have enough beds or enough emergency rooms with the way hospitals are closing, and if you live in rural America, or you're in an underserved community, people are in a bad way. They're cutting back on Medicaid funding. The true pain is not going to be really felt until 2027.

00:58:21

**Moderator, RTI International**

Thanks for raising that, [Participant 1]. I'm curious about the stigma component that you mentioned. Do you think that there's factors of certain medications that can ease that stigma burden on patients, or are there elements of certain medications that can make the stigma less of a burden to patients?

00:58:44

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

I think the first part of it's denial. And then, once you get to the denial and they start having other side effects because the average patient has diabetes for 10 years before they're diagnosed, particularly with type 2. The damage has already been done. It's just starting to abate that rapid progression.

I think it's, how do we get there? When I was diagnosed, A1C didn't exist. Metformin didn't exist. Back in the old days, a physician would taste your urine if it tasted sweet to know if you had diabetes. I'm glad things have progressed.

That is the challenge. There's a social stigma to diabetes. Nobody wants to reveal it. If I look at the demographics of Congress, diabetes is running rampant through the halls of Congress. But nobody wants to admit the fact that they have it because they're going to look at it as it's a weakness. It's a chink in my armor.

00:59:56

**Moderator, RTI International**

Thank you for sharing that reflection, **[Participant 1]**. I think it is an important part of all this. Do others have thoughts on what factors matter most to patients with type 2 diabetes when picking medications? **[Participant 4]**, I wonder if patients you advocate or you hear from have thoughts you could share.

01:00:16

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

I think it's a combination of, again, really can depend on someone's financial situation. I think a lot of patients that are juggling a lot financially, thinking, "Okay, what is going to be the best bang for my buck?" And it's tough that they have to think that way, where it's like, "Okay, I'm getting advice from my doctor and my pharmacist about what medications are covered by the formulary or not, what's working best for me. And then also, what can I afford?"

And then, obviously, I think the ease of use, but it can come down to sometimes, can I afford this or not? Because the ease of use, if they can't afford it, then that almost is not in the factor for them, or not in the equation for them. That's definitely always a challenge on our patients' minds. And again, health centers, we do our best to do the sliding fee scale. There's patient assistant funds at some of the pharmacies that are entity-owned by our health centers, but at the end of the day, sometimes that cost can be really prohibitive, and patients with their doctors and pharmacists have to make tough decisions of, "Okay, this medication has been working the best for me, but now it's out of my reach because it's off the formulary," or, as we're thinking about, too, health centers having to pay for these medications up front and wait for a rebate on the back end, as **[Participant 1]** was mentioning, there's all of these other financials, or changes, policy changes that are impacting the broader health care industry of, health centers are operating on very thin margins. Can we afford to buy some of these medications up front at such a high cost? And then that trickles down to the patients of, we really want to be able to stock these medications. But if we're operating on financially thin margins, which a lot of health centers are operating at below 4%, or negative 4% operating margins, we're trying to serve the patients, but also keep our doors open. I wanted to bring that up because it does have a trickle-down impact on patient access, as we've continued to talk about. There's a lot of things that impact patient access, but keeping these medications stocked on our shelves is definitely something that's on our minds.

01:02:45

**Moderator, RTI International**

Thank you, **[Participant 4]**. Certainly that access component is a huge factor in these decisions. I want to ask quickly about the cardiovascular disease element. To what extent does impact on cardiovascular disease management or risk factors, how does that weigh into these decisions, if it does at all? I know it can be hard to tease apart these different impacts, but does the cardiovascular piece play a part in any of these decisions?

01:03:16

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

From the physician perspective, physicians do not treat disease. Physicians treat patients. And the patient presents with five to six diagnostic codes. The clinician is the one that has to try to figure out what medications do I use that's not going to exacerbate or could potentially then help improve the other conditions that the patient has? And I think to a clinician's, god love them, if you've seen one patient, you've seen one patient. They have to use their skill and education and experience. That's why they still call it the practice of medicine. What do I do that's going to help the patient, but not hurt them? And their challenge is they prescribe what they think is the best thing for that patient and then turn right around, have the patient come in, to **[Participant 4]**'s point, they hit the pharmacy, and they're on a high deductible plan, say, "Oh, my insulin's \$1,200, I can't afford it." They call the physician, or they call the clinic, and say, "Help, I can't get my medication. Doctor, what can you prescribe?" And then the physician's frustrated. I don't know what's on formulary. And the pharmacist doesn't know what's on formulary. And if they're not adept with Googling and trying to figure out what their formulary is, now all of a sudden you're creating treatment gaps. You're escalating frustration amongst the patients. And they say, "Screw it, I'm not going to do anything, I'll just quit taking it." And then, people are going to the emergency room, or they're getting admitted to the hospital, and they're a train wreck.

01:05:08

**Moderator, RTI International**

Thank you, **[Participant 1]**. **[Participant 2]**, please go ahead.

01:05:12

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

I agree with **[Participant 1]**, it's hard because we don't know what's on formularies, even me, who is on a private insurance, I've had to go with a different medication because of primary not covering, say, Mounjaro, the first time I went to try and get Mounjaro, that's why I went on Ozempic. As far as treating the heart problem, I'm trying to treat the diabetes right now, so I don't really think about the heart problems down the road. I would rather get this diabetes under control, so that is what I look at when I'm looking at a drug.

01:05:54

**Moderator, RTI International**

Thank you, **[Participant 2]**. Really appreciate that input. I want to follow up quickly on something **[Participant 1]** mentioned before we move on, and it's this idea of whether a medication was recommended by a provider or a health care provider. How important is that in the decision-making process?

01:06:14

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

We're patients. We go to see the physician based upon their expert opinion. In order to get these medications, they require a prescription. Without working with the physician, the challenge is, the treatment room doesn't have the patient and the physician in it anymore. You need bleacher seats. You need somebody from the PBM. You need somebody from a Medicare Advantage formulary. You



need an insurance formulary. And you almost have to look back at them and say, is this okay? **[Participant 2]**'s experience with Ozempic, the patient, we're stuck with having to figure out how to file a prior authorization. Do you have all the documentation that qualifies you for these medications? Now, you can probably understand my personality, they hate when I call. Because I push and challenge, and I know I've played this game way too many years. I don't take no for an answer because I know what their game is. They're trying to enhance their margin based upon a better rebate from another pharmaceutical company and those rebates don't make it to the patient.

**01:07:28**

**Moderator, RTI International**

Thanks so much, **[Participant 1]**. Anyone else have any final thoughts on the most important factors for patients when selecting medications?

**01:07:40**

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

I think for someone who's new to a disease, I've always followed whatever my doctor has wanted me to start. However, once you're in the disease for a long time, you do a lot of research, and you want to go with the next best medication that you see. So that's going to work on your issues.

**01:08:03**

**Moderator, RTI International**

Thank you, **[Participant 2]**, I appreciate that. Thank you all, you've provided so much helpful input so far, we really appreciate it. I want to move on slightly to our closing module here. And I want to talk about how well Trulicity and other treatments meet patients' needs. How well Trulicity and other treatments are meeting the needs of patients with type 2 diabetes, as well as those with type 2 diabetes with cardiovascular disease or cardiovascular risk factors. At the very beginning of our discussion, we asked you to reflect on the most important aspects of type 2 diabetes to have managed or treated. And so aside from those aspects that we discussed at the top of our time together, what other medical needs related to these conditions are important to you or to patients you advocate for? And these can be medical needs, these can be other lifestyle needs, but what needs are most important to patients with type 2 diabetes, in general?

**01:09:23**

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

For me, because I am still working, and that's amazing with the rheumatoid and the diabetes that I'm still working, it is being able to continue working to make sure that I am able to walk, that I am able, because I am running, because I do retail. I need to be able to walk and work and do what I need to do.

**01:09:51**

**Moderator, RTI International**

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

01:09:54

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

I think the first one for me is, can I tolerate it? Can I afford it? And is it effective? The movement from Lantus, which was supposed to be a once-a-day insulin, nope, I was having to take divided doses twice a day. Going to Trulicity, it was one shot on Friday, and I was done. My glucose trends were flat, my A1C improved. To me, it was unbelievably convenient, but it worked. There's nothing more frustrating that goes into the psychological profile, you try to do everything you can, and one day your blood sugar, you can't control it, and the other one, you can't eat enough sugar to keep you from bottoming out. It is what it is. It's riding a roller coaster. And what scares me is if you know when your blood sugar goes up, your cholesterol goes up, and if you've got some circulatory problems in your heart, that's the last thing you want. But to **[Participant 2]**'s point, the longer you have diabetes and a chronic condition, you become a self-advocate because you start researching, you start Googling, you start reading scientific articles, drives my physician nuts because he wants to know, "Okay, what's the journal update this week?" But you have to be informed or be a victim of the system.

01:11:33

**Moderator, RTI International**

Heard. Thank you, **[Participant 1]**. Anyone else, what other medical needs are important to you or to patients you advocate for?

01:11:46

**Participant 3 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

I would say, advocate for my mental health, advocate for my environmental condition, advocate for my ability to get to and from the doctor's office. That stuff doesn't come up very often. People don't think of that kind of thing, usually.

01:12:02

**Moderator, RTI International**

Thank you, **[Participant 3]**. And when you say environmental condition, I'd love for you to speak on that a little bit more, if you're able to.

01:12:09

**Participant 3 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

Home life, where you're living at, who's living around you, are there a lot of things going on like, different cooking stuff outside that are happening, all kinds of things.

01:12:24

**Moderator, RTI International**

It sounds like all those factors that you're saying can also impact management of type 2 diabetes, am I understanding correctly?

01:12:33

**Participant 3 (registered as a patient, caregiver, and representative of a patient advocacy organization))**

Yeah, definitely.

01:12:34

**Moderator, RTI International**

Thank you. To that point, how about quality of life? What other medical needs related to quality of life are important to you or to patients you advocate for? Anything we haven't talked about yet?

01:12:49

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

It's the families. I have the diagnosis. My wife, my daughters, and my grandchildren, they're all impacted by my diabetes. Before the stable glucagon was available, my oldest daughter, God love her, she saw the squad come in when I bottomed out. And she saw the medics give me the lyophilized glucagon, which was a harpoon-type needle, and they jammed it in my thigh. That's tremendous, that was traumatic for a 12-year-old little girl watching all that. And today, she gets my CGM reports on her phone, just like I get them on my phone. Three o'clock in the morning, my phone rings, "Dad, you're tanking."

It's the family. It's the dynamics of the family, and if you have a child with type 1 diabetes, it's even more, those dynamics are very difficult because if you're a sibling, they like **[Redacted]** best because she's got diabetes, and they spend all their time with her. But we have to understand, it's pervasive in the family.

01:14:21

**Moderator, RTI International**

Great. Thanks for sharing that, **[Participant 1]**. And **[Participant 2]**, please go ahead.

01:14:27

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

Another issue that is arising is the cost of food for people. We're having a lot of people unable to get good food that a diabetic can eat and maintain their blood sugar. We're ending up buying ultra-processed food because it's cheaper. I think that's an issue that's arising right now for a lot of people.

01:15:00

**Moderator, RTI International**

Thank you, **[Participant 2]**. Any other feedback? **[Participant 4]**, I don't know if there's things that haven't come up that you hear from your patients, any unmet needs that patients are wanting from these treatments?

01:15:18

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

I don't I have anything new to add. I guess I'll echo what we hear from our patients through our pharmacists and providers is, access is huge, and that comes with financial access, being able to get to our clinics, being able to not be worried about other financial issues that can really impact their ability to manage this type of complex condition. I'll let you know if I think of anything else, but I feel like a lot of what the other participants have hit on is what we do hear from our patients.

01:16:05

**Moderator, RTI International**

Thanks so much, **[Participant 4]**. That's really helpful. For the next couple of questions, as we finish up our time here, I'd like to reflect on your experiences with these treatments for type 2 diabetes, as well as type 2 diabetes with cardiovascular disease and cardiovascular risk factors. Treatments could include Trulicity, as we've talked about, other medications, or other types of available treatments for type 2 diabetes. This can be medical or non-drug treatments. And my question is, which important aspects or needs of the condition are being addressed, or partially addressed, by existing treatment options. In your experience, what needs of type 2 diabetes do you feel are currently being addressed or partially addressed by the available treatments?

01:17:09

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

The biggest challenge is coverage. Patients know what's available. They can't get access to it. It's the affordability. You can buy the GLP pills, you can buy the GLP injectables directly from the manufacturers, but you're still looking at \$300 to \$400 a month.

01:17:35

**Moderator, RTI International**

Thanks, **[Participant 1]**. I do hear that cost, access is a big barrier. Thinking about the flip side, we have these medications, are there needs or aspects of the condition that you feel are being addressed by the available treatments, both drug and non-drug? Go ahead, **[Participant 2]**.

01:18:07

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

Better A1C levels with these new drugs, with the GLPs, and of course, losing weight, for sure, helps with the type 2 diabetes.

01:18:17

**Moderator, RTI International**

Thank you, **[Participant 2]**. It's sounding like with some of these GLPs, the weight management, the blood sugar. Anything else? Any other needs of the condition that you do feel are being partially or fully addressed?

01:18:35

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

It's not that they're fully addressed, but if you look at the advent of the GLP-1s, the advent of continuous glucose monitoring, the research has clearly shown that when people go on a CGM, it reduces their hospitalizations by 50%.

You want to save money, keep people out of the hospital. Keep them out of the emergency department, keep them from having a heart attack, keep them from going to dialysis, keep them from a kidney transplant, keep them from fatty liver disease going to cirrhosis. Prevention's worth a pound of cure. But right now, there's no coverage, and Medicare sets up that coverage.

01:19:25

**Moderator, RTI International**

Thank you, **[Participant 1]**. Thanks for raising that hospitalization piece. That's an interesting point that I don't think we talked about previously in this group. How about with respect to the cardiovascular disease component? I know it's all intertwined, but are there certain needs with respect to cardiovascular disease or cardiovascular disease risk factors that you feel are being addressed or met by the existing treatments? **[Participant 2]**, I know you'd previously mentioned the weight management, the weight loss, anything else? I know this is redundant, but anything else that comes to mind?

01:20:03

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

You lose the weight, your cholesterol gets better, your blood pressure gets better, everything gets a little better, your energy gets better, you're more productive, you can maybe stay at work, stay working a lot longer, things like that, that definitely do impact the person, and also cost less money for the government. If you are treating that person, then the government doesn't have to step in as much.

01:20:40

**Moderator, RTI International**

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

01:20:44

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

The other big challenge is with these drugs, the access and inequity in rural health, rural America, on underserved communities, and if you're from a community of color, politically, I'm not afraid to say the word equity. But we have a health care system that delivers to the haves but not to the have-nots. And I think **[Participant 4]** sees that in her clinics where you said people that are struggling, that they can afford health care, then the others that can't afford health care and they get worse, and they cost more.

01:21:25

**Moderator, RTI International**

Thank you, **[Participant 1]**. I think that's a good segue to the next element of this question, which is, and we've touched on this, but what important aspects or needs of type 2 diabetes are not being addressed by existing treatment options? This could be shortcomings of Trulicity, any other medications, or non-drug treatments for type 2 diabetes. What are some of the shortcomings or needs that are not being met?

01:21:55

**Participant 3 (registered as a patient, caregiver, and representative of a patient advocacy organization)**

I can speak to that a little bit. I live in a rural area, in the middle of nowhere, nothing around, and I don't drive. Due to my disability, I have trouble getting my medications, going to the store, going to anywhere, and I asked my managed care plan, "Can I get my prescriptions today?" "No, we don't do that for you. We can't do that for you," they said. I said, "Well, what am I supposed to do?" And they're not always correct when they say, "No we can't do that." That's also another big factor.

01:22:28

**Moderator, RTI International**

Thanks for sharing that, **[Participant 3]**. Others? Any unmet needs? Or factors of type 2 diabetes that are not being addressed that you'd like to see addressed?

01:22:48

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

I think one of the big things is that the vast majority of patients with diabetes are seen by primary care physicians. If you look at the curriculum of all the years they're in medical school, diabetes gets all but 90 to 120 minutes. The prevalence of diabetes, because it's estimated there's 40 million of us with a diagnosis and they're at a loss of keeping up with all these new medications. If you're doing hospital rounds, 30%-40% of all hospital admissions have a diabetes diagnosis as part of the chart. We're running out of endocrinologists. Who are we going to see to take care of us?

01:23:39

**Moderator, RTI International**

**[Participant 4]**, please go ahead.

01:23:44

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

**[Participant 1]**, what you said, it sparked an idea that I was like, oh, we've advocated for this before, and this is perfect. Pharmacists are great providers that could help fill this gap; however, they are not billable providers under Medicare, and oftentimes, there's a patchwork at the state level if they can actually be those providers and see patients and get reimbursed for that. I think that there are great clinical pharmacists that are employed in countless areas across the country that could either do a virtual visit or in person to try to bridge those access gaps that people have talked about, but they aren't recognized as billable providers under Medicare, and so I think that when we're

thinking about, there's such a provider shortage across the country, especially primary care, or maybe within rural areas, pharmacists could really help treat all of the comprehensive care needs of folks that have type 2 diabetes and help, again, as I talked about with that medication management, all of these different areas of education, but right now, they aren't billable providers. And I know this is more of a policy issue, but it does trickle down to the patient impact. And it's something that we've advocated for, and I think I know a lot of organizations have as well. And patients develop really great relationships with their local pharmacists, and they trust them. And so if we can lean on those folks more to address some of these issues that maybe, the primary care doctor might not be best suited, or they're behind, it's hard to get in to see them in a timely manner, you can go to your local pharmacist that's down the street, or even have a telemedicine appointment or something along those lines. Thanks, **[Participant 1]**, for sparking that idea.

**01:25:42**

**Moderator, RTI International**

Thank you both. I'm hearing these structural impacts and policies that obviously trickle down to the patient experience. **[Participant 1]**.

**01:25:52**

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

I think, **[Participant 4]**, pharmacists are all PharmDs [Doctors of Pharmacy] now. They do a year of clinical rotation in their six-year program, so they're well-conditioned to do that. You also have certified diabetes educators. They're not recognized as providers. They were staffing the diabetes clinics in many hospitals, but because they're not recognized as a provider, they were not a revenue-producing FTE [full-time equivalent], so hospitals were closing them down. Because if we're not getting paid for it, we have great results, we've documented what we've been able to do to help people and improve their outcomes, but we're not making any money, so love you, but we'll miss you.

And diabetes is growing. Still growing at a CAGR [compound annual growth rate] of 5% to 7%. And those certified diabetes educators, like the community pharmacist, in rural America, you call your pharmacist doctor, and those people are the ones that actually spend the time to teach, coach, counsel, and provide literacy. The doctor's role is Dx, Tx, and Rx: diagnose, treat, and prescribe.

**01:27:09**

**Moderator, RTI International**

Thank you, **[Participant 1]**. And as we wrap up here, I want to reflect back on the treatments for these conditions, so thinking about Trulicity, the selected treatment for type 2 diabetes, and other medications, do you feel that certain medications or treatments address the medical needs of the type 2 diabetes patient to a greater or lesser extent? Thinking about these different medications that you have experience with, are some meeting patients' needs better than others? Or less than others?

**01:27:53**

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

Depends on who you ask.

01:27:56

**Moderator, RTI International**

How about from your perspective, **[Participant 1]**?

01:27:58

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

If you were to talk with the physicians, they're ungodly frustrated because they're up with the literature, they're up with the newest innovations, and they know what they want to prescribe. But they're frustrated by trying to figure out what can they prescribe. The patient is on board based upon the dialog you had in the treatment room. But then, all of a sudden, they go to the pharmacy, the cost is overwhelming, it's not covered on formulary, they don't know what's on formulary, so they say, "I give up." And the condition worsens.

01:28:34

**Moderator, RTI International**

**[Participant 1]**, from your perspective as a patient of many years, do you feel that certain medications are better meeting the needs of you as a type 2 diabetes patient?

01:28:46

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

The advancements in medicine, metformin, we know it's got its role, but it's got its drawbacks. Lantus was a breakthrough because it was the first long-acting insulin. We realized it wasn't lasting for a full 24 hours. Guess what? You came out with Trulicity. It lasted a full 24 hours.

The advancements in medicine, the health care system is really struggling to try to keep up. And in the past 10 years, the advent of GLP-1s, the advent of CGM, insulin pumps, all these different things. It's a whirlwind trying to keep up with them. But if you don't have access, and the physician will go through the path of least resistance, because I can't have a ten-minute visit with you, and then have to spend another 20 minutes trying to figure out what's on the formulary.

01:29:45

**Moderator, RTI International**

Thank you, **[Participant 1]**. **[Participant 2]**, please go ahead.

01:29:48

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

Something also I wanted to mention is that type 1 and type 2 diabetes can share some medications, but then there are some medications that are different. Something that might work for a type 2 diabetic may not be recommended for a type 1 diabetic. That's something to look at as well. For me, the Mounjaro works better than the GLP-1. But that's for me, because everybody's body is different, and everybody reacts differently to different medications.

01:30:29

Moderator, RTI International

[Participant 2], to clarify, when you say it works better, what are you specifically referring to there?

01:30:37

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

It worked better bringing down my A1C than anything I've ever tried.

01:30:43

Moderator, RTI International

Thank you, [Participant 2]. Any other major gaps in treatment, or concerns, that exist amongst the available treatment options for type 2 diabetes patients. Anything else that folks want to mention? I've heard folks say access is obviously a big barrier, but any other final comparisons we want to make between the available treatments to how well or not well they're addressing patient needs?

01:31:19

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

There's a reason we are advocates, because we have to be. No one's going to do it for us. We have to be, we are forced into it, sometimes we find our purpose, like I have, but sometimes it's not like that either, and we're forced to do it, because no one else will. The doctors won't. Which they should, but that's not the case.

01:31:42

Moderator, RTI International

Thank you, [Participant 3], and to ask, as your role as an advocate and a patient, if you had to pick a couple top unmet needs that you feel like are not being met, what are they?

01:31:55

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

Oh, there's so many, I mean putting the person first before anything else, asking, "How are you doing today," and meaning it, makes a big difference.

01:32:15

Moderator, RTI International

I hear you. Thanks, [Participant 3]. We are reaching the end of our discussion here. Before we close out, I want to give you an opportunity to summarize your thoughts on the importance of Trulicity for patients or to raise any topics that you feel we haven't covered adequately in our time together today. I open it up to you. Do you have any final thoughts about Trulicity, conditions treated by Trulicity, or other medications that treat the same conditions that you feel are important to share with CMS before we wrap up?

01:32:49

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

I want to echo what **[Participant 3]** just said.

01:32:55

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

For me, Trulicity really was the game changer. It is a drug that I think is important going forward for people who have type 2 diabetes. I was able to stay on my medications and take them on the right days because it was a shot, one time. For me, it wasn't cost prohibitive, but I am on private insurance, so I know people on Medicaid and Medicare really need this covered. It is something that I think that they should have covered.

01:33:32

**Moderator, RTI International**

Thank you, **[Participant 2]**. Anyone else? Any final thoughts that you'd like to share today about Trulicity, or any other topics?

01:33:40

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

I'd like to echo **[Participant 3]**'s comment. We have a diagnosis, but we're people first. **[Participant 3]**'s diabetes is not my diabetes. We share a diagnostic code. But the medications that treat our individual conditions are different and if you don't give the patient and the clinician choice, you're tying one hand behind the physician's back by not letting them, based upon their judgment and clinical experience, to do what's best for that patient. Formularies, personal opinion of one, are people practicing without a license in different states? How can you tell me what's good for me when you've never seen me, never met me, never been in a treatment room? You look at it from a policy perspective, how do you appreciate the fact that you want to lower costs? You can lower price, but at what cost? How does it impact the patient?

01:34:53

**Moderator, RTI International**

Thanks, **[Participant 1]**. I hear you saying it all comes back to the patient, right?

01:34:57

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

Yeah. None of us sat down and said a prayer and said, "Oh, Lord, I'd really like a chronic condition, I'd really like diabetes, and for bonus, could you give me the one with the needle?" I wouldn't wish this on the people I don't like.

01:35:17

**Moderator, RTI International**

Thanks for that, **[Participant 1]**, and thanks for sharing so personally today your experience. It is really helpful input. **[Participant 3]** or **[Participant 4]**, any final thoughts about Trulicity, conditions

treated by Trulicity, or other medications that treat type 2 diabetes that you'd like to share before we wrap up today?

**01:35:41**

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

I'll end with my thoughts that it's important that these medications stay affordable to patients, that patients are able to get the medications that are best suited for their type 2. As everyone has mentioned, not everyone responds the same way to different medications and their efficacy. And also, making a plug, too, that prior authorization and the step therapy really are barriers that we see with our patients every single day. Whether or not if they have Medicaid, Medicare, obviously uninsured population, the unaffordability is an issue. So definitely, respect and see CMS' perspective of trying to make this drug affordable, but at the end of the day, we want to make sure that it remains accessible to patients, and so really appreciate this opportunity to provide feedback and appreciate you listening to us.

**Closing Remarks**

**01:36:49**

**Moderator, RTI International**

Thank you, **[Participant 4]**. Thank you all so much for participating in today's event. We really do appreciate you taking the time to talk with us. Your experiences and input have been extremely valuable and will help inform CMS' negotiations for Medicare pricing for Trulicity. CMS staff have been listening in the background to this roundtable and will be able to bring your perspective back to their teams. And I am going to turn it back to CMS for some parting words.

**01:37:20**

**CMS Staff**

Thank you, **[Moderator]**. I'd like to echo what **[Moderator]** was saying. This is a really fruitful discussion, and we learned a lot from it, so thank you all for being here with us today. We're really grateful for it.

**01:37:32**

**Moderator, RTI International**

If you have any questions following today's session, you can submit them to the mailbox. It's going to show up here on screen in a second. Yes, it's that [IRARebateAndNegotiation@cms.hhs.gov](mailto:IRARebateAndNegotiation@cms.hhs.gov) email address. It was also included in your welcome packet. So please do feel free to send any follow-up questions to that email address. And with that, we thank you for your time, and please, everyone, take care. Thank you.

**===== 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 patient who has experience with the selected drug, the conditions treated by the selected drug, or other treatment(s) or drug(s) similar to the selected drug for those conditions; 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 a company with direct/indirect interest in the Negotiation Program, in excess of \$10,000 by you, your spouse, or an immediate family member |
| No                                    | Direct assistance preparing your remarks from someone who is NOT a family member, caregiver, friend, or your 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 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 patient who has experience with the selected drug, the conditions treated by the selected drug, or other treatment(s) or drug(s) similar to the selected drug for those conditions; representative of a patient advocacy organization

| <b>Declared Conflicts of Interest</b> |  |
|---------------------------------------|--|
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| 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 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 3: Registered as a patient who has experience with the selected drug, the conditions treated by the selected drug, or other treatment(s) or drug(s) similar to the selected drug for those conditions; caregiver who has experience caring for an individual who is treated by the selected drug, with the conditions treated by the selected drug, or other treatment(s) or drug(s) similar to the selected drug for those condition(s); 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 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 4: 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 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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