Transcript: Janumet; Janumet XR Roundtable Event, April 18, 2025, Medicare Drug Price Negotiation Program Public Engagement Events

This transcript was lightly edited for readability.

Introductory Remarks

Moderator, RTI International

Hi, everyone. Thank you for coming today. My name is **[MODERATOR]**. **[REDACTED].** And I work for a company called RTI, and we are a nonprofit research organization. And, I also want to introduce my colleague, who's with me today, **[SECONDARY MODERATOR]**. **[SECONDARY MODERATOR]**, wave to folks. There you go. Thanks, **[SECONDARY MODERATOR]**. You'll hear from **[SECONDARY MODERATOR]** a couple of times, so she'll help with follow-up questions if I have any questions I missed.

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

The purpose of today's event is to hear from you all. And this is a group that includes both patients, caregivers, and patient advocates, about your experiences with the conditions and diseases treated by Janumet and with other medications for diabetes. If you wish to share your input on other topics that aren't as patient-focused, we do have a mailbox that you can email comments to that we'll give you later. It's, for what it's worth, it's IRARebateAndNegotiation@cms.hhs.gov.

You don't have to remember that. We're going to show it to you later. Just so you have it.

Also, for today, just to make things a little less complicated, I'm going to say Janumet. And I'm not going to say Janumet and Janumet XR, because there are two formulations. I'm just going to say Janumet, just to make things easy for today's discussion.

The information shared during the events will help CMS understand patients' experiences with the conditions and diseases treated by Janumet, patients' experiences with the drugs themselves, and patients' experiences with other drugs that are used to treat diabetes.

CMS may use this information in negotiating Medicare pricing with the manufacturers of the selected drugs. Your experiences and perspectives are very important to us, and we genuinely appreciate your time today.

Let's watch a welcome video from CMS leadership, so that you can hear from them about how much they value your time and input today.

CMS Remarks

00:02:12

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

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

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

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

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

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

00:04:08

Moderator, RTI International

Also, I want to make you aware that staff from CMS will be sitting in on the event, just so that they can hear from you directly about your experiences and opinions. I wanna hand it over to, I think it's **[CMS STAFF]** for a moment, just so that they can say, hello. Hey, **[CMS STAFF]**.

00:04:23

CMS Staff

Hello, everyone. Just want to welcome everyone here on behalf of CMS. We have members of the drug price negotiation team here on the call. We will stay off camera to just help with the facilitation of the discussion. But we look forward to hearing all of your discussion topics, and we will be here and listening. But again, we'll be off camera.

Housekeeping

00:04:44

Moderator, RTI International

Thank you, **[CMS STAFF]**. Before we begin, I do want to go over just a couple of housekeeping items and ground rules, so that everyone knows what to expect for today. We hope that all of you can contribute your perspectives throughout this session. However, if there's questions that I ask, and you don't want to answer those questions, that is totally fine. You don't have to answer any questions today that you don't want to.

Be sure to minimize background noise by silencing your cell phone and devices. Also, just mute yourself when not speaking. That helps us so that we don't hear a lot of background noises today.

Today's discussion is not open to the press or public, and I will use only first name today as part of our efforts to protect people's privacy. Please do not share any unnecessary personally identifying information about yourself or personal health information during today's discussions. As you know, we are doing audio and video recording today, which we're doing now. But these recordings will not be shared publicly.

Following the event, however, CMS will prepare transcripts of our discussions, and we will remove names and identifying information from those transcripts, and those, however, will be made public. But again, we will remove people's names from those transcripts.

A few other things, for video, thanks for in advance for keeping your video on. That way I can see when people are ready to speak, and I can make sure I could call on you. Today's session will last about an hour and 30 minutes. I have a discussion guide in front of me with different questions, and I might have to be rude at some point, and if discussion on one question is going too long, I may have to move it to another question. Please forgive me. I'm not trying to cut people off, but I, we do have so many questions we want to ask that I have to keep the discussion flowing.

If you get disconnected, please try to rejoin, and if you can't get back connected, this email address can help you, IRADAPStechsupport@telligen.com. If you email them, a friendly person on the other end will help you get reconnected. If you need to take a break, take a bio break or coffee break and you step away, that's totally fine. You don't need to ask for permission. Just turn off your camera, mute your microphone, and come back as soon as you can.

And I will ask you all to try to speak one at a time. I may have to play traffic cop occasionally, if more than one person speaking at a time, but that should be pretty rare.

Finally, today we want your honest opinions. All of you are gonna have different opinions and different experiences. Like I said, today's group is made up of between patients, caregivers, and patient advocates. So, everyone's gonna come from a different place. And that is totally fine. We want to hear everyone's experiences and opinions about today's topics.

Okay, that was a lot of me talking. Let me pause for a second to see if you all have any questions for me before we start. Awesome. Okay. Let's get started. So, I wanna first get to know the group and get to know all of you a little bit better. So, I'm gonna ask you all to give me about a 30-second introduction and try to keep it to 30 seconds.

Let me know your first name and then, whether you're going to be sharing personal experiences of those of a loved one, personal experiences of yourself, or you're approaching this as a patient advocate, and some of you may be wearing multiple hats. So, again, what your perspective is. I like to start on my screen, the first person I see is **[Participant 1]**. Hey, **[Participant 1]**.

Discussion

00:08:18

Participant 1 (registered as a caregiver)

Good morning.

00:08:19

Moderator, RTI International

Good morning.

00:08:22

Participant 1 (registered as a caregiver)

You want me to go?

00:08:23

Moderator, RTI International

Yeah, go ahead.

00:08:24

Participant 1 (registered as a caregiver)

I am actually wearing the triple hat.

00:08:27

Moderator, RTI International

Okay.

00:08:28

Participant 1 (registered as a caregiver)

So, I'm speaking for my husband, speaking for myself, and advocating.

00:08:35

Moderator, RTI International

Awesome. Thank you, **[Participant 1]**, happy to have you here. **[Participant 2]**?

00:08:42

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

Hi. Like **[Participant 1]**, I'm wearing multiple hats. I am a caregiver for someone with type 2 diabetes, and then also have a number of family members, and then also am an advocate for people living with chronic diseases, more generally.

00:08:57

Moderator, RTI International

Great. Thank you, **[Participant 2]**, and then **[Participant 3]**.

00:09:02

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

I'm **[Participant 3]**, and I'm here as an advocate on behalf of older adults and people living with chronic diseases.

00:09:10

Moderator, RTI International

Great. Thank you, **[Participant 3]**. And **[Participant 4]**?

00:09:14

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

Hi, everyone. I am with a patient advocate organization. So, not just type 2 diabetes. But, helping represent vulnerable populations.

00:09:27

Moderator, RTI International

Great. Thank you, **[Participant 4]**. Thank you, **[Participant 4]**. I just realized we have an **[Participant 4]** and a **[Participant 5]**. We'll keep this straight. **[Participant 5]**?

00:09:36

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

Good morning. Thank you. Yes, I also am wearing a triple hat. I'm a patient. I'm an advocate representing patients with chronic disease and a family with many of us that have been both type 1 and type 2.

00:09:57

Moderator, RTI International

Great. Thank you. **[Participant 5]**. **[Participant 6]**?

00:10:01

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

Yes, hi, everybody. I'm Dr. **[Participant 6]**. I won't use my last name, although I'm not a patient, and I am not a prescriber either. My PhD is in public policy, and I have background in public health, as well, and 40 years of health services research. I work for an organization that has a health research group that has over 50 years of advocacy experience advocating for consumers, especially patients that have interests related to the safety and effectiveness of the nation's drug supply.

Having said that our organization, which is supported by over a half a million individuals, is a not-for-profit, we have no financial conflicts of interest today or in any way with regard to the broad pharmaceutical enterprise in the U.S. or globally. And today I'm not going to be talking about any PHI [protected health information] or any individual patients. It'll be a recounting of our evidence-based review of glycemic control, and especially Janumet as a glycemic control agent for type 2 diabetes, hoping, of course, that our remarks and our analysis can help inform consumers and CMS about what is a fair price for this particular drug combination. Thanks.

00:11:23

Moderator, RTI International

Great. Thank you, **[Participant 6]**, and then is it **[Participant 7]**? Am I doing that correctly?

00:11:28

Participant 7 (registered as a representative of a patient advocacy organization)

Yeah, my name's **[Participant 7]**. **[REDACTED]**. I am here representing a global, patient-led, patient advocacy organization made up of people with diabetes for people with diabetes and their allies. We work to make sure that everyone, no matter where they live, has access to, we primarily work on insulin, but on all of the diabetes drugs and supplies that they need to survive and to achieve their dreams. And we are also independent from pharmaceutical industry funding, and we fight for policies that center affordability and equitable access and the lived experience of the diabetes community.

I myself am a person living with type 1 diabetes. As you know, this drug is not approved for type 1, it's not indicated or studied or approved for type 1, because people with type 1 do require insulin

replacement therapy. I have not been prescribed this drug. I am also not a Medicare beneficiary. However, I have had a metformin prescription previously, personally, and many of our members and people that we serve are patients living with type 2 diabetes or other type of diabetes and have Janumet prescriptions. So, I'm here in more of that patient advocacy role.

00:12:39

Moderator, RTI International

Awesome. Thanks, **[Participant 7]**. So, it's great to hear that you all are coming from different perspectives and experiences, which will make today's discussion great. Thank you all for sharing that.

So, I first want to know a little bit more about whether or not you all have personal experiences taking the drug Janumet yourself, and if you could just put it in the chat window, have you or a loved one taken Janumet either currently, in the past, and in the chat window you can just put yes or no. We just want to understand where people are coming from.

Let's see mostly, so, a couple no's.

So, not with Janumet, **[Participant 2]** says. Okay, okay. So, it sounds like from what I've seen, no personal experience with Janumet. But, **[Participant 1]**, your husband is using it. Okay, that's helpful. Thank you.

One thing I want to talk about first, just beyond Janumet, is talk about diabetes. In general, how does diabetes affect your life, or your loved one's life, or your people that you serve? How does diabetes affect people's day-to-day lives?

Who wants to go first? Yeah, **[Participant 1]**, go ahead.

00:14:03

Participant 1 (registered as a caregiver)

Oh, well, it's affected because my husband has type 2 diabetes, so I am closely affected by that. I have to follow his blood sugar, his diet, and also financially, it affects us.

00:14:21

Moderator, RTI International

And then also **[Participant 1]**, how would you say it also affects his life?

00:14:28

Participant 1 (registered as a caregiver)

It affects his life because he's been hospitalized for uncontrollable blood sugars at times and he tries to do the right thing. But yet, his blood sugar controls him, so—

00:14:44

Moderator, RTI International

[Participant 2], go ahead.

00:14:48

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

So, my loved one, and it's, I guess I can say it's my father. Mostly he takes anywhere from 24 to 25 pills a day regularly because of the comorbidities associated with his type 2 diabetes. He has to check his blood sugar every morning to, as he puts it, see how bad he was yesterday. It's painful finger pricks. He does not have the glucose monitor. He has arthritis, so that adds to the challenges there.

But he also, wears around his neck nitroglycerin that, like carrying tic tacs, and has to use that when he has to, too, because the diabetes has affected his heart. Now he's 87. He's outlived both his parents and other family members who had diabetes. So, I think that's a testament to the ability that we have to control it better today than we did, for his parents and aunts and uncles, all of whom had type 2 diabetes. It's pretty scary sitting in the position I am right now, but I do think it affects everything. As **[Participant 1]** said, what you eat, how you eat, how you feel on a day-to-day basis, your heart, your eyesight, tingling sensation in your hands and feet. It really has a pretty profound impact on your life, particularly when it gets to more advanced stages.

00:16:18

Moderator, RTI International

Thank you, **[Participant 2]**. **[Participant 4]**?

00:16:20

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

Yeah. So, coming from my perspective, as a patient advocate, we represent health center patients, and health center patients are more likely to be lower income and obviously having a lower income that impacts a lot of their day-to-day life. And then in general, too, when they're having type 2 diabetes, as **[Participant 2]** was mentioning, lots more comorbidities. And then there's just a lot more barriers that they're facing to get the treatment that they're needing for type 2 diabetes. [O]ne thing that we really like about Janumet is that not only does it help treat type 2 diabetes. But then there's also many renal and cardiac benefits, that health centers, we're really trying to see that patient as a with whole person care. And so, I think that in general the patients that we see just have a lot of social drivers of health that really impact their ability to effectively manage their type 2 diabetes.

00:17:27

Moderator, RTI International

Yeah. **[Participant 7]**?

00:17:31

Participant 7 (registered as a representative of a patient advocacy organization)

Yeah, I think, as has just been said, managing diabetes is hard, no matter what, and it encompasses every part of your life from the moment you wake up to all through, when you go to through sleeping, and that we need medications all day, every day, often for the rest of our lives, making this also a really significant long-term cost burden, and that high medicine prices impact every part of our lives, as well. In addition to just being able, like having to manage what we're eating and what time

we're eating, and when we exercise, and not even just exercise, but just going up and down the stairs to go to the bathroom has an impact on your blood sugars, and so being able to—

And so then, also, having to manage all of the costs associated with living with diabetes. So, not just the lab work, the appointments to get your prescription. All of the things that are not covered by insurance, all of the testing the glucose snacks for lows or insoles for your shoes, things like that, but also all of the medications, and so that often leads to huge decisions on everything, from the career you take to staying in marriages to where you live to just every single aspect of my life is dictated effectively by living with diabetes.

And these high out-of-cost expenses have led to many of our community members staying in abusive relationships or staying in jobs that are not serving them, or in taking careers that are not in their best interest, all for the sake of managing their diabetes. And let me leave it there, for now.

00:19:42

Moderator, RTI International

Yeah, actually, **[Participant 7]**, can you tell me a little bit more about that? Like being careers and so forth, that aren't conducive for them?

00:19:50

Participant 7 (registered as a representative of a patient advocacy organization)

Just of being able to have access to health insurance. I recognize this is for Medicare beneficiaries, but having our health insurance relied on by our employer very often, and having—I've had ACA insurance, where I've paid $7,000 a year just for my prescriptions and regular appointments, with no significant complications or challenges. And so, having an employer-sponsored health insurance plan that is adequately covering your care is really critical.

00:20:22

Moderator, RTI International

Great thanks, **[Participant 7]**. **[Participant 3]**?

00:20:27

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

Thank you. **[Participant 7]**, I appreciated hearing what you had to say. I think the presence of type 2 in people over the age of 65 has increased morbidity, mortality, and a lot of diminished quality of life. And sometimes it's related to the type of coverage and access to health care that people have prior to being in the Medicare program. So, that's why I think we're all talking about a lot of other coexisting chronic conditions and multiple medications, and then a heightened risk of adverse drug events, most notably hypoglycemia with diabetes. And about a quarter of those over the age of 60 have diabetes, and it leads to increased cardiovascular, neurological, and higher rates of disability. There are huge disparities with racial and ethnic minorities. Lower socioeconomic groups and rural residents.

I serve **[REDACTED]** the Association of Black Cardiologists. This is an issue that's very close to them and their practices. So, there's a lot of care decision making among clinicians and beneficiaries. And I saw on CMS' fact sheet that there's close to a quarter of a million beneficiaries that take this particular drug. A lot of older adults need a significant reduction in blood sugar to achieve their glycemic goals, and this particular medication is oftentimes a good choice between

clinicians and their patients. For older adults who need two diabetes medications to reach their glycemic goals, and in particular, older adults that have kidney issues, it's been found to be particularly favorable in terms of tolerability and lower overall risk of hypoglycemia. So, that's part of why we're here today. Because combination therapies can really be helpful for older adults in particular. And you want to minimize that risk of hypoglycemia.

00:22:46

Moderator, RTI International

Great, **[Participant 3]**. And before I move on to the next question, **[Participant 5]**, do you want to give some final thoughts on how diabetes affects people's day-to-day lives?

[Participant 5], are you there? There we go.

00:23:05

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

Thank you. Well, I can speak for myself, and I can speak for others that I know very well, especially diabetes, is a big part of the work that we do within our chronic disease community. It affects you every day. It's how you feel from the moment you get out of bed, you put your feet on the ground, to the time you go to bed, and checking your blood sugar is critically important to know where you're at all the time, and it can fluctuate a lot. I mean, what you find out in the evening could be completely different than what it is after you fasted all night and slept all night, and it comes out completely different in the morning. I watched my mother with type 1 have significant issues. Had to be on the phone with emergency many times with her. The newer drugs that we have now didn't exist at that time. And I had a cousin that was riding a bicycle type 1 diabetes, and he just died. He was riding his bike, and he just died.

Other family members who have had amputations. I think amputations, we haven't talked about that at all. So, you want to get to glycemic control. Whatever we're trying to accomplish, we want glycemic control. And the way we do that is educating all the people that we know the best we can of, what does it mean? And how do you achieve that? I'm very lucky that my health plan has given me a pharmacist that checks on me every 30 to 60 days. We go over medication. We go over numbers, and then I do my HbA1c [hemoglobin A1c; glycated hemoglobin] every three months, and now they just put it out to five months because I was under control. And so, you do feel better when you're under control than when you're out of control.

00:25:14

Moderator, RTI International

Awesome thanks **[Participant 5]**. **[Participant 6]**, I'll let you finish [inaudible] us up about how diabetes affect people's day-to-day lives.

00:25:21

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

Yeah, so it's an interesting question for you to start on. And certainly, we've known for a long time, a very long time that diabetes is a major cause of morbidity and mortality, especially in developed countries like the United States. So, I say, it's an interesting question for you to begin on, because right now, I can tell you, the half a million supporters of my organization, and many people beyond that are nothing short of incensed by the scientific attacks that are coming from this administration right now, attacking things like university funding, NIH [National Institutes of Health] funding and so

forth, that would get at the roots of this particular disease, which is very complicated, and which has a number of different existing modalities of treatment, diet, and exercise, being sort of the very first line, but then at least nine to 11 different pharmacologic agents, including the two that we're talking about today because it is a combination drug.

And no disrespect at all to you, **[Participant 3]**, I mean, we understand the convenience potentially for patients of combination drugs. But we also, and medical professionals who have reviewed this, have two deep concerns about using a combination. The first is that it neglects titrating each drug individually and using them more precisely in serial or in parallel with the doctor, who makes sure they understand the side effects of both, and there are side effects for both these drugs. And number two, the gliptin component of Janumet is a drug that many expert commentators have said is not effective, is not worth use, should be a do not use drug, our organization included because of its safety profile and its effectiveness profile when you compare it to other existing therapies. So, these things should all be part of CMS' consideration. [W]e really think Janumet doesn't add much value. The willingness to pay by educated consumers should not be high, if anything at all for this particular drug. Thanks.

00:27:33

Moderator, RTI International

Thank you, **[Participant 6]**. I want to talk about also whether it's Janumet or another drug, and **[Participant 3]** [inaudible] I do need to go to the next question, but you can talk in a moment.

Whether it's Janumet or other drugs, when it comes to diabetes, what do you all think is most important to you or loved ones or patients to have managed or treatment? So, again, when it comes to diabetes type 2, what is the most important for it to be managed? What parts of it? And **[Participant 3]**, I don't know if you can answer that question, but I'll turn it over to you.

00:28:11

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

Well, I just since my name was invoked. I just wanted to say we work very closely with American Diabetes Association [ADA] and a number of the diabetes organizations and ADA guidelines talk about the benefits of choosing therapies that can minimize risk of hypoglycemia, and that it is considered a choice therapy because of the favorable safety and tolerability profile. And the folks that do the ADA guidelines or endocrinology, they're folks who work in the space. So, I don't think we have any diabetes clinicians on the call today, but hopefully, CMS is connecting with them and checking the ADA guidelines.

00:29:00

Moderator, RTI International

Thanks, **[Participant 3]**. So, again, what aspects of diabetes are most important to you or loved ones to have managed or treated. **[Participant 4]**?

00:29:11

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

So, I was gonna say that at health centers, we really try to have a whole person care. And one thing that our patients have seen I think a lot of benefits from is being able to see clinical pharmacists, because, as a lot of people have mentioned, there are oftentimes a lot of comorbidities with diabetes, a lot of different types of medications that need to be taken. And so clinical pharmacists

kind of have that whole person care approach where they help with medication management. They also can really spot some issues that maybe they need to raise to the doctor that they're working with. It can also help with education around healthy foods. And so, I think there have been a lot of health centers across the country that have tried to employ a clinical pharmacist to meet this need, because with health centers, a lot of patients are more likely to have diabetes compared to the rest of the American population. And so, we've seen a lot of positive benefits from that. And, it's something that needs to be covered, and that the patient should be able to easily access.

00:30:25

Moderator, RTI International

Great thanks, **[Participant 4]**. **[Participant 2]**?

00:30:29

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

Thank you. So, in terms of what the goals are, I think, from my perspective and that in dealing with my father's diabetes and others, it's just how can it minimize the impact of diabetes? How can I move on with my life and not have it affect—I mean, it's going to be present. And I think, particularly people with type 1 deal with it constantly during the day. But for my dad, and with our experience with type 2 diabetes, it is that, how do I minimize? How am I able to do all the things I want to do and not have type 2 diabetes interfere with it? So, is it medication and diet? Absolutely, and there are changes that have to happen on both sides of that.

But if there are other ways to minimize it, can I not be lightheaded? Can I not experience pain? How do I diminish those impacts? And then the other thing is, when you're dealing with someone who has multiple comorbidities is, and particularly on the medication side, but also on the diet side, especially with heart disease, there are so many dietary restrictions when it comes to medicines. There are so many contraindications when you're on multiple medicines that having the choices amongst different treatments having combination therapy that diminishes the pill burden, all of those things are so critically important.

And I know, I said my dad takes 25 pills a day. Anything that would cut down on that—you may think well 25, 23 is not going to make a difference. It does make a difference. It makes it easier for him to manage, to pick up prescriptions, to get to the pharmacy, to sit down and plan out his pills for the week.

But being able to not worry about the complications, being able to not have to worry about, I can't have orange juice with this, or I can, have to take this with food and this not with food. All of those things, anything that minimizes that impact is really important.

00:32:35

Moderator, RTI International

Great thanks, **[Participant 2]**. **[Participant 7]**, and then I'm gonna go to the next question. Go ahead, **[Participant 7]**.

00:32:40

Participant 7 (registered as a representative of a patient advocacy organization)

Yeah, I think, as we've been saying, accessible, consistently accessible access to essential medicines and diagnostic supplies is of most importance. And this includes medications, glucose

self-monitoring tools, and to ensure that they are truly affordable without cost barriers or stock outs and access to prescriptions and everything else, like having people having access to what works best for them.

I'll also just wanting to name that having culturally relevant, language-accessible, stigma-free diabetes education and care is also just so critical around having food security and access to healthy, culturally appropriate nutrition and care practices. And then also, as well, having that include the full community, right? So, the full person and the full community, so including mental health, peer support, community connection, fully addressing the emotional, social, psychological toll that diabetes has through fully accessible and wraparound support systems. Meeting people where they're at without blame and shame, and reflecting their actual lived experience and local realities.

00:33:52

Moderator, RTI International

Great, thanks **[Participant 7]**. I've got 30 seconds, and I'm gonna move on. I'll let you get a word in real quick.

00:33:58

Participant 1 (registered as a caregiver)

Talk fast.

00:33:59

Moderator, RTI International

Okay.

00:34:00

Participant 1 (registered as a caregiver)

Sorry, Dr. **[Participant 6]**, but I have to disagree with you, but this is what we're supposed to be here for right? To confer. But my husband was placed on metformin when he went in the hospital because they don't supply Janumet. His blood sugar went out of control. It also affected his magnesium. And that has not been brought up at all either.

So, without the Janumet, he is completely out of control. In fact, he went from having one tablet a day to two tablets a day, because of that. The important thing I think to look at is to stabilize the blood sugar so that it doesn't affect the other organs and also accessibility to medication without having to choose how to live. I think that's really important, and also, to take medication that doesn't cause a lot of ill effects, also, some side effects. But my husband has no problem taking a pill. He thinks it's magic. You take a pill, and I can eat a piece of pie. But of course, that's not true. So, nutrition is also a big concern with diabetes, and I think you have to take everything into consideration because it affects the total body, affects your vision, affects your muscles, it affects everything, all your systems. So, the important thing, I think, is to stay alive, to try to live a pretty decent life, and to stabilize the blood sugar.

00:35:37

Moderator, RTI International

Thanks, **[Participant 1]**. I appreciate everyone sharing those experiences that you've had. Now, I want to talk a little about your experience with Janumet, or maybe a loved one's experience, or someone that you served, their experience. And in addition to Janumet, I actually want to also talk about your experiences that you've had with other medications that are similar to Janumet for diabetes type 2. And these medications we call like therapeutic alternatives. So, this whole bucket of things that can treat type 2 diabetes. And then in a moment, we're gonna talk specifically about Janumet. But at the moment, we're talking broadly about all these drugs that can treat type 2 diabetes.

So, first, when considering the potential medications for type 2 diabetes, what matters the most to you or your loved ones, or the people you serve? Again, when it comes to potential medications for type 2 diabetes, what matters most to people?

And that could be how it works, how quickly it works, safety, a lot of different facets. **[Participant 6]**, did you want to answer that?

00:36:45

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

So, I wanted to just clarify something about what we've been going a little bit back and forth about combination versus monotherapy and, the proper choice of combinations, and it addresses your question as well, **[MODERATOR]**, because it does talk about alternatives.

And the first point I want to make out is, thanks, **[Participant 3]**, for pointing out ADA's recommendation. I'm not disagreeing with you that if hypoglycemia is a major concern that this particular combination has demonstrated some effectiveness in that regard. But there are still a number of safety concerns that have led many professional commentators, The Medical Letter, [inaudible], for example, our group, to still say that the benefits, that the risks outweigh the benefits with regard to adding the gliptin on. So, I think it's important that consumers understand that. I think it's important that CMS understand that this particular combination has a real problem when you add a gliptin, and you use a gliptin as glycemic control versus other things that you might use.

[Participant 1], for example, and your husband—It's great that it's working for your husband, happy for that. But overall, the data suggests that the gliptins aren't worth the additional a risk alone or in combination. So, that's one concern that we really want folks to know about. There are real concerns, pancreatitis, heart failure, severe skin reaction, vitamin B12 deficiency, severe joint pain—these are some of the adverse effects that go along with using Janumet, and in particular, with the gliptins. The other thing I think consumers should know is that when you combine drugs like this, drugs that have been approved and been on the market, it is a way for the industry to claim that they've innovated when arguably, they really haven't innovated, and they charge monopoly pricing. We know that. And that is not good for patients. And that's part of the reason, even if you think the drugs are working, why we should be concerned about this particular agent.

It hurts, we're arguing, it hurts patients doubly. Most patients, doubly with type 2 diabetes, **[Participant 1]**'s husband being an exception, perhaps. And it's both on the price side and on concerns about safety. So, I just want to make that clear. And when you compare it now, going back to your question, **[MODERATOR]**, you compare it to flozins, you compare it to adding insulin or other drugs to supplement metformin, if that isn't leading to proper hypoglycemic control, the

results in clinical trials have been better, and that, should speak to the fact that Janumet, when CMS goes to negotiate the prices, they shouldn't give the manufacturer free pass that they have some innovative drug that they should be able to gouge consumers for.

00:39:55

Moderator, RTI International

Thanks. Thanks for that perspective, **[Participant 6]**. One thing I want to note today is that we do wanna focus today on the patient's perspective on diabetes and Janumet, and not as much of a macro-level policy discussion, which is important, but at least for today's roundtable, this is more about understanding patient experiences, patients and perspectives, either you as a patient or caregiver or as a patient advocacy organization. So, I just want to set that context.

But again, I want to talk a little bit about—thinking about all the different medications that can treat type 2 diabetes, what do you all think matters most in these medications? And again, it can be things like how well it works, how frequently needs to be taken, those kind of things. What really matters to you or the people you serve the most in the medications that treat type 2 diabetes? Does that makes sense? Yeah, who wants to go? Yeah, **[Participant 2]**?

00:40:57

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

Sure, I'm happy to start. For us, it really is a lack of side effects. Diabetes, type 2 diabetes was the first condition my dad was diagnosed with, unfortunately, probably because he didn't control it well enough. The complications added on heart disease and the like, with kidney issues as well. So, I think, again, pill burden is hugely important, cost, access, hugely important. But from a health perspective, it really is—how do I minimize? How do I get the most benefit with the least side effects and least burden on me as an individual? Maybe not in that order, but certainly those are definitely the top three, the best benefit at the less impact on my life. And co-protective effects, if you will, when you're dealing with minimal side effects, minimal contraindications and the like.

00:41:58

Moderator, RTI International

And **[Participant 2]**, you touched on this, but when you say, lessen, lessening burdens, can you speak more to that?

00:42:05

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

Well, sure. Some of it is how do I feel after I take the medicine? How often do I have to take it? Are there restrictions on how I take it? When I take it? Is it with food, without food? Do I have to space out my medicines? Other medicines that I'm taking? All of that can create challenges for people, and especially in my circumstances, an 87-year-old, very independent, extraordinarily stubborn, honestly, and wanting to be in control. I think sometimes when people are diagnosed with a chronic condition, especially one like diabetes that affects so many aspects of your life, you feel a little loss of control. And being able to have treatments that really help you regain some of that control are really important, and know that you're protecting your health, and you're feeling better. And the medicines will make you feel worse if you will, from side effects and the like.

00:43:10

Moderator, RTI International

Great. Thanks, **[Participant 2]**. Oh, **[Participant 5]**?

00:43:15

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

Thank you so much. This is a great conversation that's going on. So, I have done both mono and combined. My husband does combined. I actually felt better when I was on combined. But I had side effects and had to make a change. I think what's really important here is access, coverage, and reducing the fear that people have when they get the diagnosis of type 2 diabetes.

I remember, one of the things that was offered to me through my health plan was going to class, so I could learn more about diabetes. And there were people in there that had just been diagnosed. So, I've been working in the chronic disease community, the chair of our group, 30-year diabetes nurse expert, took care of the classes. So, I had a lot of education in diabetes, and they would just break down and start to cry. They think that they had a death sentence, just getting that. And then they had to stay and have the nurses in the room explain to them that it isn't a death sentence. It's just you have to learn how to live with it. So, instead of saying, I'm going to die with it, you have to learn to live with it. Well, what makes our lives better? What do we need to do to make the quality of our life better?

Well, education, I think, is key in understanding type 2 diabetes. And I think you've heard from so many others here that I can totally agree with, how often you take it. Where a shot you take it once a week. That is so nice compared to having to take medicine every single day, or think about the time, or is it with dinner? Is it with breakfast, is it—Oh, my gosh, I forgot to take my meds. [T]hings like that. So, it makes it easier.

I also want to say that therapeutic alternatives. We need to have them. We need to have the doctor that's working with the patient, understand the needs of that patient. And what's best for them. So, I'm on my third round to one that I found that actually works for me and has got my HbA1c under control. But it took three different types of medicine to get me to this point, so I think all of them. What works for one may not work for another, and we just need to keep that in mind.

00:45:44

Moderator, RTI International

[Participant 5], I want to follow up on one of their points. You mentioned a shot. When thinking about treatments for diabetes, does it matter if it's a shot versus a pill, and if so, why? Why is that important?

00:45:58

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

Well for me, it's easier because of my lifestyle. I just have to go do a shot, and off I go. I don't have to think about taking the pills. When I did take a one-a-day pill, I mean, I was okay with that. I just had to figure out when I wanted to take it every day, and then do it, and not forget to take it with me, or have it with me if I wasn't going to be home. But I think what, it's whatever is going to give you better control of your diabetes. That's gonna work the best for you and so, that's why choice is also an important part of all this.

00:46:34

Moderator, RTI International

Great. Thanks, **[Participant 5]**. **[Participant 1]**?

00:46:37

Participant 1 (registered as a caregiver)

[Participant 5], I totally agree about the educational portion of it. I think it's really important to educate yourself, or if a loved one will help to educate them. The other, also **[Participant 2]**, I do agree with when they start having the comorbidities, and they're taking so many medications. What I found helpful are those pre-filled containers, and because the vision can be affected also, and the dexterity because of neuropathy, it's very helpful for them just to open up a little portion of the pre-filled container to take their medications. The other part I wanted to bring up is the cost of the medication, and I actually do, I call all the pharmacies up to see what the price is for the medication, because my husband has to take a 60-day supply. [I]t's double. So, I found out that Merck charges $726 a month for a 60-day supply. If he has his insurance, it can be anywhere from $324 to $631. But if you, if you take that and what Medicare takes out per month, $185 a month, and his Social Security is only $14,000 a year, it doesn't leave much to live on. If you subtract everything, he has $10,000 a year to live.

And I think that's something that's really important. Do people need to choose? Do I take my medications today? Do I eat today? Do I pay my bills today? Now, there are so many people that are making that decision. And why should we, in a country that we live in right now, why should we have to be deciding that? Why can't these drugs be eligible for people? That's about all I want to say right now.

00:48:40

Moderator, RTI International

Thanks, **[Participant 1]**. **[Participant 3]**?

00:48:45

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

I mean, you asked about what's important to people. And again, we work a lot with the diabetes organizations across the board, across T1 [Type 1] and T2 [Type 2], and I would say, we also have a network of patients and family caregivers and what they primarily identify with may not be diabetes, but many of them have diabetes in addition to Alzheimer's or heart valve disease, other conditions. And I just want to say that the whole issue of I think sometimes convenience is said in a kind of a paternalistic way, and, to everyone's points here, when you are taking multiple medications, adherence is really important.

And I think the benefits of having new types of therapies that do combine are beneficial for older adults. If you can combine things in a safe way, and I was just looking back at some of the research. I just really hope, I just don't like hearing all this stuff sort of thrown out when the major clinician organizations are in favor of these medications, which is what we rely on when we're looking at sort of fact-based information.

And then the one last thing I just, want to talk about is just the other thing that I think patients really value is the ability to have dialogue with their clinicians. And I just want to remind CMS that the first section in the Medicare Act, Section 1801 prevents the agency from interfering in clinical care.

And I do think that what's of primary value to our organization and the people we serve is that they're able to make decisions with their clinicians and with their family caregivers about what works best for them. And I think, really, that's where you know this discussion, this is the core of the discussion, and we need to keep it at the center.

00:51:00

Moderator, RTI International

Yeah, thanks, **[Participant 3]**. I see three people have their hands up. I only have time for one more person for this question. So, **[Participant 7]**, I'm gonna go... No? Okay, **[Participant 4]**, you?

00:51:12

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

Oh, **[Participant 7]**, that's nice of you. I'll keep this quick. So, just going back to what **[Participant 1]** said, the cost of the medication is huge for health center patients, as I was mentioning, especially thinking about Medicare patients, a lot of them are dually eligible. So, having both Medicare and Medicaid coverage and something that we try to do is make medications affordable for patients participating in the 340B program where this drug is sold to health centers at a discounted price, and in order to meet the patients where they are, we offer a lot of copay assistance programs to help lower the copay patients see depending on their income. Because obviously, we don't wanna have patients have to choose what medication that, or, choose between getting medication and choose between rent, food, things like that. And so, I think, as we're thinking about this, making sure that it is not just, I think Janumet, but other alternatives that might work better for other people, are also affordable as well. So, then, the clinician can make that decision of like, okay, cost is not going to be a barrier for us to maybe switch you to another medication that will be more beneficial to your type 2 diabetes.

00:52:36

Moderator, RTI International

Great thanks, **[Participant 4]**.

00:52:37

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

Can I just briefly add one thing about affordability? Just quick, **[MODERATOR]**, because one thing that didn't come up and we hear from consumers all the time is consumers want lower prices, of course, but they want fair prices, and when they look at international pricing for the same medicine, they get very upset, reasonably so, that they have to travel to Canada or Europe to fill their prescription for these medicines. Just wanted to make that point, we hear that a lot from consumers about a variety of drugs, including this one. Thanks.

00:53:07

Moderator, RTI International

Thanks, **[Participant 6]**. So, we've been talking about treatments broadly for diabetes. And now I want us to focus in specifically on Janumet. And I want to talk about some of the benefits of Janumet, and also some of the challenges and drawbacks. But first, what do you all see as some of the main benefits that you or your loved ones, or people you know have experienced in taking Janumet? Again, some of the benefits that people have experienced with Janumet? **[Participant 1]**?

00:53:45

Participant 1 (registered as a caregiver)

Well, the benefit is that they only have to take the one combination pill, and the other benefit is that it stabilizes their blood sugar.

00:53:56

Moderator, RTI International

Okay, how about others? What are some of the benefits of Janumet? **[Participant 2]**?

00:54:08

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

Well, some people have mentioned, too, chronic kidney disease is a common comorbidity along with type 2 diabetes, and my understanding is that Janumet also has protective benefits there. And the other thing I just would mention is that we talked a lot about the pill burden and comorbidities, having treatment options that don't have a lot of contraindications with other medicines are a really important part of having those treatment options because there's so many medicines that are contraindicated, that when you're living with multiple chronic conditions it can be hard to figure out one, something that works well, but then also works with everything else you're taking.

00:54:53

Moderator, RTI International

And **[Participant 1]**, I still see your hand up. That may have been just from previously, when you spoke.

Okay, all right.

Now on the flip side, I also want to talk about some of the drawbacks. What are some of the main drawbacks or challenges that you or people you serve have faced with Janumet?

[Participant 1]?

00:55:19

Participant 1 (registered as a caregiver)

I seem to be the chatty one. The drawback for my husband's case, I told you when he went, when his blood sugar became uncontrollable, and he ended up in the hospital, they put him on metformin, and metformin really made his blood sugars crazy. So, that was the drawback. Once they put him back on Janumet, but they had to double the dose, he takes it twice a day, that he became stabilized. He went from a blood sugar of 340, and he's now running between 91 and 110. So, I think that's a major factor.

00:55:57

Moderator, RTI International

Thank you. And **[Participant 7]**?

00:56:00

Participant 7 (registered as a representative of a patient advocacy organization)

Yeah, if I could take a pill and stay between 90 and 110, that would be incredible **[REDACTED]** But I think, overall we work to really make sure that everyone has options. We know that not every drug is going to work for everyone, and that having choice in the market, and not having a ton of patent evergreen like, making sure that this choice is actually affordable and accessible is so critical.

And that one of the biggest limitations I think for this drug and others is not necessarily like it not being quite as potent at like A1C reductions or some of the other potential complications or other reasons, but that the cost just can be really, really high. My metformin prescription was like $3 copay, it was like really, really affordable as a generic and just not having those generic options, and it's just really limiting for folks, and means that it's just not an option. You know it's not available because of the high cost. And so, I think there are, I'm sure, other limitations and considerations. And just because of the work that we do we just hear about the high cost as the most significant consideration when looking at this compared to other drugs.

00:57:33

Moderator, RTI International

Thanks, **[Participant 7]**. So, there's many drugs—sorry, **[Participant 6]**. Go ahead.

00:57:38

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

Thanks. So, just specifically, I already went over a list of adverse effects that we're concerned about, especially with the gliptins. The metformin, too, is imperfect. In particular, there's concerns about actually kidney toxicity or lactic acidosis, which is rare, but can be fatal. And the drug metformin currently carries a box warning because of that. So, like with all drugs, there are issues.

And, I mentioned that in particular, because the issue of sort of safety for kidney illnesses for Janumet has been expressed. And, that's what I just described, that box warning, is one of the reasons why even using Janumet for people with kidney ailments could be risky. And then, again, I wanted to just be clear about our concern and about what's recommended by professionals, so I'm not a physician, but I work with physicians, and I consult physician documents like UpToDate, and The Medical Letter, and [inaudible], and the literature. And I again, I'm not disagreeing with you, **[Participant 1]**, for hypoglycemia, if it's a principal concern, this drug has demonstrated efficacy. But there's still the safety concerns. But overall, and The Medical Letter is very clear and [inaudible] has been very clear. I'll quote, I can even quote for you from [inaudible], gliptins overall, including sitagliptin, which is what we're talking about right now, have not proven efficacy, making them drugs to avoid. That was in May 2023 by physicians in Europe reviewing this sort of thing, physicians sending advice to other physicians, so thanks.

00:59:35

Moderator, RTI International

Great. Thanks, **[Participant 6]**. **[Participant 3]**?

00:59:41

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

I just wanna bring up the point that you made earlier, if we're not going to be focused as much on like the policy aspects. Because I just feel like comparing ourselves to single-payer countries where they try to ration care is not really the topic of discussion here.

01:00:00

Moderator, RTI International

I do want to focus more on the patient experiences today. So, beyond Janumet, there's obviously other medications that are available for type 2 diabetes. What are some of the more common ones that you're familiar with, that you or people you know, take?

01:00:22

Participant 7 (registered as a representative of a patient advocacy organization)

I'm sorry. Can you repeat the question?

01:00:24

Moderator, RTI International

Yeah. So, beyond Janumet, what are some of the other drugs that you're familiar with, that people take? **[Participant 1]**?

01:00:32

Participant 1 (registered as a caregiver)

Glipizide.

01:00:33

Moderator, RTI International

Glipizide. Okay.

And you don't have to raise your hand, just blurt it out. **[Participant 2]**?

01:00:41

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

My dad's on Jardiance, and he also takes glipizide and metformin.

01:00:51

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

Ozempic.

01:00:53

Moderator, RTI International

Ozempic? Okay.

So, those, and there's many more, of course, those are what I would call the therapeutic alternatives, that term I used before. I want to talk about how these therapeutic alternatives, compared to Janumet, or kind of compare and contrast them.

First, how do the benefits of the therapeutic alternatives differ from Janumet? So, how do the benefits of therapeutic alternatives differ from Janumet? **[Participant 1]**?

01:01:28

Participant 1 (registered as a caregiver)

I know, with the Ozempic, my husband did try that for a little while, and he did lose weight on it, so there was some weight control with that, so that did help him in that regard. But for some reason, it made him confused, the medication, so we took him off of that.

01:01:47

Moderator, RTI International

Okay? So, one of the benefits, that there was a weight loss. But one drawback was it created confusion. And we'll talk about drawbacks, too. Okay. What are, again, some other benefits of therapeutic alternatives over Janumet? **[Participant 2]**?

01:02:05

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

In my experience we didn't have the head-to-head comparison. So, I think **[Participant 1]** had that more with Janumet, and others potentially. But I know with the Jardiance, my dad was given the option of going on insulin or Jardiance, and that was how it was put to him by his health care providers. So, he opted for the pill and it did help dramatically lower his A1C. I do know, I believe with Jardiance and I believe with others in that class, it flushes the sugar from your body so potential, and this can be Janumet, as well. But it increases his risk of UTIs [urinary tract infections], which he has experienced.

01:02:53

Moderator, RTI International

Janumet increased his UTIs?

01:02:55

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

No, he's on Jardiance.

01:02:57

Moderator, RTI International

Jardiance.

01:02:58

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

But yeah, and I believe that may be a factor. It may be a factor with drugs in the class. It's in a different class. I'm not sure, but I know that UTI infection with diabetes in general is a risk. But some of these drugs flush the system, flush the blood, the sugar out, and so that increases that risk as well. Okay.

01:03:21

Moderator, RTI International

Oh, **[Participant 1]**, you're muted. **[Participant 1]**?

01:03:34

Participant 1 (registered as a caregiver)

Can you hear me now?

01:03:35

Moderator, RTI International

Yeah, there we go.

01:03:36

Participant 1 (registered as a caregiver)

Okay. My husband was, when he was first diagnosed, was put on Jardiance, and it put him in the hospital. He had every side effect. If, when they went on the TV ad, every side effect on the bottom my husband had. He started with vertigo. He started with vomiting. He went into electrolyte imbalance. He ended up with atrial fib, rapid atrial fib from the electrolyte imbalance. So, it horrible. So, of course he can't take that anymore.

01:04:11

Moderator, RTI International

Was that Jardiance, **[Participant 1]**?

01:04:12

Participant 1 (registered as a caregiver)

Yeah, that was Jardiance, yeah.

01:04:16

Moderator, RTI International

So, I want to talk about the other side, which is, how do other drugs have drawbacks compared to Janumet? So, again, how do these therapeutic alternatives have downsides as compared to Janumet?

[Participant 5]?

01:04:38

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

Yeah, it's interesting in this discussion, because it looks like **[Participant 1]** is the one that has the true experience on Janumet with her husband, and he's done really well on it, right? Now that we're hearing controversy, that we shouldn't even have it on the market. Yet her husband is doing really, really well, goes back to the use of the doctor needs to work with the patient to find out the right medicine at the right time, the right dose.

I've had side effects from different medicines that they tried on me. My husband has had side effects, but the value of the medicine, the control of the HbA1cs, that value and return on the

investment to better my quality of life override some of the—I can live with some of these side effects that I have or he has. I went on two totally different medicines. And yeah, the way that they are, the sugar is, it gets out of your system is also interesting because they're also different, and how they reduce that. But for me to finally get my HbA1c under control was a big deal. I also lost 20 pounds. And the other thing we haven't talked about here is the effect of obesity on diabetes, which is also huge. But I think that just from my point of view of not ever taking Janumet, but listening to what **[Participant 1]** has had to say about her husband, that has been the best medicine for him, and where other medicines are better for others. So, it still comes back to the discussion with the provider.

01:06:29

Moderator, RTI International

Thanks, **[Participant 5]**. **[Participant 6]**?

01:06:32

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

Yeah, just a quick follow-up comment. So, the CMS called for this information when they asked for comments. So, we took a look for comparative effectiveness trials, which I think is the essence of your question, **[MODERATOR]**. Right? So, how does this particular drug, and it's two drugs, right? How does it do compared to others? **[Participant 1]**'s experience is important, I mean, it seems like her husband didn't do well on Jardiance. It's a flozin drug, but he did do better on this combination.

The few comparative trials and one of the key comparative trials that we found the opposite result, in particular with gallbladder-related illness. So the importance of—it seems like two points are being made, right? One is the importance of working with your clinician to find the right medicine, and the other is the importance of generating real data that could give us a sense of whether or not this or any drug is actually an innovation, an advance over other drugs and in what scenarios that happens. So, thanks.

01:07:51

Moderator, RTI International

Thanks, **[Participant 6]**. Now, I've actually heard this a little bit today where someone has switched medications. And I want to talk a little bit more about, if you or a loved one has tried multiple medications for diabetes, what were some of the reasons for changing medications? **[Participant 1]**, I thought you would be a good person to talk about this.

01:08:21

Participant 1 (registered as a caregiver)

I feel like I already answered this question, but I'll repeat it again. There's many reasons. The reason was, first of all, it controls blood sugar. He felt better on it. It was easy to take. It was a two to one medication. He understood the effectiveness of the drug. He felt good on the drug. The only problem was the cost of the drug. That was the biggest problem. But I would say it's because it brought his A1C from 8.3 down to, I think he's at 5.7 right now. So, it was a gradual, wasn't right away. It was a gradual decrease. But that's with diet control and checking his blood sugars every day, and I guess that's all I have to say with that.

01:09:23

Moderator, RTI International

It's helpful. And also, for this question, it doesn't have to be switching to or from Janumet. It's just about reasons why people switch their medications. **[Participant 2]**?

01:09:39

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

First of all, congratulations, **[Participant 1]**. That's pretty amazing results and good for him. And you. I'm sure you're changing the diet at home, too. For us, we did have to make changes. Anytime there was a change—when you're dealing with multiple chronic conditions, if there's a change in medicine for one condition, that can be a cascading effect across, where there's contraindications and the like. And again, that just reemphasizes the importance of therapeutic alternatives and choice and access to a wide range of treatments. I think it's over half of Medicare beneficiaries have five or more chronic conditions. So, this is a very common issue, and particularly people dealing with cardiovascular disease and diabetes and obesity-related diseases that all kind of go hand-in-hand and commonly co-occur, that a change in one can factor in a change for multiple.

01:10:39

Moderator, RTI International

Okay, thanks, **[Participant 2]**. So, a little bit of a different question. What would it be like for someone who has diabetes if Janumet or other medications were not available for treatment? So, what would it be like for someone who has diabetes if treatments were not available for it? What would it be like? Oh, **[Participant 1]**.

01:11:07

Participant 1 (registered as a caregiver)

It's incurable disease, and they would die. They would die without the correct medication. Or they would also develop further complications. And the other problem is, they'd be shopping around for medications that probably didn't work, and it would cause more problems for them. I'm well aware of dealing with chronic illness. I have a blood cancer called multiple myeloma and I had to take Revlimid, which was $800 a capsule. And I took that every day. So, I'm well aware of trying to find the right medication for the chronic disease. One thing I wanted to bring up to **[Participant 6]** also is that not every medication works the same for everyone. Every illness could be the same diagnosis, but every person will not always have the same effect. So, I just wanted to say that.

01:12:16

Moderator, RTI International

And then, **[Participant 2]**, what would people's lives be like if medications and treatments weren't available for type 2 diabetes?

01:12:24

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

I think **[Participant 1]** stated it very well, is that we're looking at, people would die, but unfortunately, it would entail a lot of suffering leading into that as well. My great uncle, my dad's uncle, had type 2 diabetes, I mentioned it tends to be unfortunately pretty prevalent in my family,

and growing up in the diabetes belt. Many people can relate to that, but he, literally, we watched him go from losing toes to his foot, to his leg below the knee, to his leg above the knee before he lost his life, and the disability and pain that he experienced as a result of that. That's what you're talking about without the availability of treatments to control this disease.

01:13:14

Moderator, RTI International

Oh, **[Participant 5]**?

01:13:17

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

Yeah, I don't know if I could say anything better than what **[Participant 2]** and **[Participant 1]** have already said. Having access to choice is key, and building in that better quality of your life for people. If we, let's say, one type does not fit all. We have a very diverse population of people that have diverse chronic conditions and everything affects them differently. So, there's no one-size-fits-all. I think that's been really clear in the conversation that we've had today, and that it would not be the road to take to lessen access to the medicines that are available today, and the research and innovation that needs to continue to make it better. So, they can work on lessening side effects, and they can make it better down the road for the next generations that are coming.

01:14:17

Moderator, RTI International

[Participant 7], if you want to finish off on the question and then I have another one.

01:14:21

Participant 7 (registered as a representative of a patient advocacy organization)

Yeah, **[Participant 3]** was saying, we shouldn't compare ourselves to countries with universal health care. But I think, just to answer this question, we can look to a lot of countries where they just don't have access to these drugs, like so many countries around the world just do not have access to these drugs, and people cannot get the care that they need because they can't afford it. They can't access it.

And right here in the United States, so many people cannot get access to the drugs and the care that they need for a lot of different issues. Right? It could be mental health issues or stopping people from going to the doctor, could be fear from citizenship issues or fear to being burdened with significant debt is scaring people from going to get preventative care to getting prescriptions. And even if you can, if you know that you need to get access to this care, you might not be able to afford it, right? And so, there are these social issues and significant affordability issues, influence drug adherence. And for this and so many other drugs that lead to really significant health consequences.

We've said some here, too, but we haven't mentioned, vision issues and blindness, nerve damage causing pain. You know these things lead to hospitalizations, but also long term takes people out of the workforce, takes people out of taking care of kids, other means of supporting our economy and supporting our communities by not being able to be there because they're dealing with their health issues. Maybe they're not able to drive. Maybe they're not able to walk, whatever it is.

And just, specifically, financially, a lot of these disability cost long-term disability care that can cause significant strain on our public health resources. Just to say, I think we really want to make sure that everyone has access to the care that they need, regardless of their complications and their disability. That disability is not a burden on our society. But that it does cost more for these, treating people in DKA [diabetic ketoacidosis], in the hospital, in the ER, than it does for providing people access to drugs, especially if we can negotiate those prices to be affordable and accessible to all.

01:16:53

Moderator, RTI International

Thanks, **[Participant 7]**. And **[Participant 3]**, I see your hand up, I do want to ask another question which you can address, or you can go back to the previous point, which is—so we do have these drugs like Janumet and other alternatives that do treat diabetes but there, but it doesn't address everything. So, what aspects of diabetes, if any, are Janumet or other medications unable to address?

01:17:25

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

Interestingly, I was kind of wanting to make a point about hypoglycemia, because I do think sometimes it's minimized in these kinds of conversations sometimes. And I just want to emphasize that having low blood glucose levels is not a minor thing, and especially for older adults. You can get disoriented. You can have seizures, difficulty speaking, loss of consciousness, you fall, which is a huge cost to the health care system, and it can go all the way to coma and death. So, I know we talked about things like amputation and all of that. But I think sometimes hypoglycemia is really, oh, it's just low blood sugar, and it can be a really big deal for people. So, it's not something that this drug doesn't address. It does address it. But I just want to emphasize it's important. And it shouldn't be minimized.

01:18:29

Moderator, RTI International

[Participant 5]?

01:18:31

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

Yeah, thank you. One of the things I see is they get better with innovation is that, we haven't talked about, we've talked about chronic kidney disease and protective there, but we also have cardio protective. We have weight loss, all coming, stemming out of some of these newer medicines, and that's a real plus. Because if we can get after weight, we know that weight has a great impact on the body. We know it has great impact on cancer and on diabetes and heart disease. And so, as we see these medicines come out, and discussing how we make them affordable, how we get coverage, so people have coverage that they can afford. How they can get information about patient assistance programs. Very important, is the access. But I think we're seeing some really substantial gains in other areas that one medicine is helping to protect other chronic conditions.

01:19:44

Moderator, RTI International

[Participant 2]?

01:19:46

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

Just to respond to your question about I think it was kind of like, what would we love to see that we aren't seeing yet?

01:19:55

Moderator, RTI International

Yes.

01:19:56

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

Okay—is just reversal. These drugs are providing protective effects. They are minimizing the impact of diabetes. But they're not reversing type 2 diabetes, and who wouldn't love to see that? And then, also on the preventative side, we are seeing more on the preventative side, and I know that's not necessarily the topic for today. But given, I know you're looking at obesity and drugs that treat obesity as well. If we can minimize the impacts of obesity and prevent obesity and reverse obesity, that will have profound impacts on type 2 diabetes and a number of other obesity-related conditions.

01:20:43

Moderator, RTI International

And **[Participant 1]**?

01:20:44

Participant 1 (registered as a caregiver)

Just make it a point on what you said, not you, forget which one said about the patient assistance programs that could be available. The only problem I have seen with those is that they base everything on poverty level and incomes, and they really need to adjust that. Because, after paying very high amounts for your drugs per year, it almost puts people into the poverty level, but they don't look at it that way. More assistance would be helpful.

01:21:25

Moderator, RTI International

So, those are all the questions I have.

But I did want to take a moment to pause to see if there's anything else that wasn't covered in our discussion today that some, you feel is important to share with CMS. So, I'll open up the floor to you. **[Participant 5]**?

01:21:48

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

Yeah, thank you, **[MODERATOR]**. I was on the first round of CMS discussions. I love this new format. This new format is so helpful. We're actually listening. What a listening session is all about is really hearing from the people, the stakeholders, the advocates, and so, kudos to CMS. We really love to see you continue this, these types of discussions. I think they're really important, and hold a lot of value to hear all these sides.

01:22:18

Moderator, RTI International

Great. Thanks, **[Participant 5]**. And tell me why this format works better than the previous format.

01:22:25

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

We don't have anything prepared. We're just talking to you about our personal experiences. And I think that you're talking to us from our hearts and from what we see and from the work that we do, and from the horror that chronic disease and chronic conditions, especially diabetes, bring to families and bring to our communities.

And when we can talk through that, I always say we're better together, and when we could talk through things together, and even hear different sides. Coming from a different place is really important, because you don't always get that opportunity to hear all those different sides and say, no, I don't believe in that, or yes, I believe in that, or thank you for discussing that, and that is completely different than what we did the first round.

01:23:21

Moderator, RTI International

Thanks, **[Participant 5]**. **[Participant 2]**?

01:23:24

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

A hundred percent agree with **[Participant 5]** that this was better. And I think you hear a lot of common themes and common areas of agreement which I think is great, too. One thing that we've heard a lot about access and price and those are really important and cost to the patient, in particular. And this is one question I had, and I know that you don't have to answer it. But factoring in, how much impact these drug price negotiations will have on generic entry. I think it may impact biosimilars more than these small molecule medicines. But that was one question that I had and concern I had about, because we know that a lot of the drugs that are under consideration will have generic competition.

Some of them before 2027, when these negotiated prices would take effect, and I wondered and had concerns about how that might impact patient costs and access in the long run. Thank you.

01:24:25

Moderator, RTI International

Thanks, **[Participant 2]**. **[Participant 3]**?

01:24:34

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

I wanted to also agree with **[Participant 5]**. I love this format. The only thing that I, to me would be even better is to be able to have some back-and-forth dialogue with the CMS staff. It's great that they're listening. But I think, when we talked about the patient-focused drug development meetings at FDA, there's a little bit of back and forth between the staff and the community. And you're lovely, **[MODERATOR]**, but talking to actual CMS staff would be great. And then I just wanted to add, we work a lot with the pharmacy community, and there was a survey that the National Community Pharmacists Association did. They're very concerned about stocking ability of the negotiated drugs, because, they're worried about cash flow problems. And I think this has been brought up with CMS. But it would be great if they could kind of use their muscle a little bit more on this issue, as well as issues around how Part D plans are dealing with increases in utilization management to kind of offset the restructuring of the Part D liability for them. Because we've heard countless stories of people's plans changing and UM [utilization management], and all of that, so that worries us too. And I know that is veering more towards the policy side of things. But that's where CMS could do a lot. So, we feel like these drugs should just not be able to be moved on the formularies. You're driving the prices down. The whole point is to increase accessibility and CMS doesn't seem to be using its authority up to the statute level. Thanks.

01:26:29

Moderator, RTI International

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

01:26:32

Participant 1 (registered as a caregiver)

I just want to make a couple little statements. I just want to state that when they're negotiating prices to always remember there's a human factor behind it. Sometimes that's forgotten. And also, I would like big pharma price gouging to stop. I think it's time, and we really need to lower the prices now. The patients deserve better.

01:27:00

Moderator, RTI International

Thank you, **[Participant 1]**. And **[Participant 6]**.

01:27:03

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

Yeah, I agree with lots, certainly a lot of common themes and common ground. We all agree, diabetes is a highly impactful health concern in this country. It's one where we've got some good therapies, but they are expensive unfortunately. We lowered the cost of insulin recently, at least for Medicare beneficiaries, and continuing to sort of fight those access battles are key. And new innovations, too. I think what, per your question, **[MODERATOR]**, what could add to this discourse, which is great, might be some presentation to, because really the focus here is, how do you come up with a fair price for a given product? In this case, a product that's widely demanded because of the because of the disease we're talking about principally. Of course, we have some concerns about its efficacy overall, as I've expressed. But we're talking about how do you get to a fair price? If somehow you could, in a forum like this, display for people what the drug costs, we know now from,

thanks to **[Participant 1]**, it's like $700 a month. I mean, that's just outrageous, but compare it to manufacturing costs. Compare it to what it's priced in other countries, as well. Reference pricing is one way to go also, and then have people sort of do the thought experiment as a group and talk about what it means, in terms of their monthly budget to be able to survive an illness that you can't not treat, right? It's so important. So, I think that would add to the discourse, and it came out some here, and I appreciate everybody expressing that from a personal perspective, a lot, thanks.

01:28:48

Moderator, RTI International

Great. Thank you. Thank you, **[Participant 6]**. And then my last person is **[Participant 4]**. Go ahead, **[Participant 4]**.

01:28:53

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

Thanks, **[MODERATOR]**. And what **[Participant 3]** brought up about the cash flow issues, with NCPA, the National Community Pharmacist Association, right? Health centers, we work very closely with NCPA and have a lot of entity-owned pharmacies and contract pharmacies, and I did want to bring up that, our one concern that we also have is cash flow issues. Because health centers provide people care regardless of their ability to pay. We have a lot of uncompensated care, and we're happy to do that because we get government funding to provide everyone care. But when we were thinking about cash flow issues and how we might not be getting, we might have to pay a higher upfront cost to get Janumet, to stock our shelves and wait for the rebate on the back-end manufacturers. It's definitely a concern. For example, one of our health centers back in 2024, purchased about 274 packages of Janumet, which is almost 25,000 units. For the 340B cost, getting that discounted cost at $2,288. That's great. If we would have had to wait for a rebate and purchase it upfront, that health center would have had to pay $188,000 and wait for that rebate. And so, more than half of health centers operate with margins below 5%, and 11 million patients were served by health centers operating with negative margins a couple years ago. And so, and I know that this is not a policy discussion, but obviously health centers, we want to make these drugs available for our patients. But we also want to keep our doors open, too. And so, we are very big community hubs. And so, I just wanted to bring that up, that it is a concern for us.

01:30:48

Moderator, RTI International

Thank you so much, **[Participant 4]**. So, thank you all for being in today's group. And I really appreciate your time and sharing your experiences today. Your experiences and input were really important and really helpful and valuable and will help CMS inform their negotiations for each drug. CMS staff have been listening in, like I mentioned, to the roundtable, and will be able to bring your perspectives back to their team. **[CMS STAFF]**, did you want to add anything else?

01:31:15

CMS Staff

I think, **[MODERATOR]**, you covered most of it. But again, I wanna just say on the CMS side, we thank you for sharing your experiences with us. Thank you for giving us the comments that you appreciated this format, and we're really grateful for just hearing all your thoughts for everything. So, thank you all for coming and being able to openly share.

01:31:35

Moderator, RTI International

Thank you. **[Participant 1]**, I saw your comment. If you could email that to the email address that we're gonna present, which is on the screen now. Thank you, **[Tech Staff]**.

Thank you. Oh, let me find my spot here. So, if you have any questions regarding today's session, you can submit them to this email address. It is IRARebateAndNegotiation@CMS.hhs.gov, and you can put in the subject line 'public engagement events.' And again, I'll leave this on here just for a moment for you all to scribble this down. But again, thank you all so much. I really appreciate your opinions, and that's all I have for today. Thank you all.

01:32:24

Participant 1 (registered as a caregiver)

Thank you.

01:32:25

Moderator, RTI International

Thank you.

=== END OF TRANSCRIPT ===

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

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

Appendix

Participant 1: Registered as a caregiver for an individual who has experience with the selected drug, the condition(s) treated by the selected drug, or other treatment(s) similar to the selected drug for those condition(s)

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

Participant 2: Registered as a representative of a patient advocacy organization; a caregiver for an individual who has experience with the selected drug, the condition(s) treated by the selected drug, or other treatment(s) similar to the selected drug for those condition(s)

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

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

Declared Conflicts of Interest	
Yes	Receipt of financial payments (e.g., gifts, funding, research support, honoraria, travel, or other expenses) from a company with direct/indirect interest in the Negotiation Program, in excess of $10,000 by you, your spouse, or an immediate family member
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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

Declared Conflicts of Interest	
No	Receipt of financial payments (e.g., gifts, funding, research support, honoraria, travel, or other expenses) from a company with direct/indirect interest in the Negotiation Program, in excess of $10,000 by you, your spouse, or an immediate family member
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No	Any other personal or professional relationship or interaction with a company or related association with direct or indirect interest in the Negotiation Program that may be considered a financial conflict of interest

Participant 5: Registered as a patient who has experience with the selected drug; a representative of a patient advocacy organization

Declared Conflicts of Interest	
No	Receipt of financial payments (e.g., gifts, funding, research support, honoraria, travel, or other expenses) from a company with direct/indirect interest in the Negotiation Program, in excess of $10,000 by you, your spouse, or an immediate family member
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Yes	Any other personal or professional relationship or interaction with a company or related association with direct or indirect interest in the Negotiation Program that may be considered a financial conflict of interest

Participant 6: Registered as a representative of a patient advocacy organization

Declared Conflicts of Interest	
No	Receipt of financial payments (e.g., gifts, funding, research support, honoraria, travel, or other expenses) from a company with direct/indirect interest in the Negotiation Program, in excess of $10,000 by you, your spouse, or an immediate family member
No	Direct assistance preparing your remarks from someone who is NOT a family member, caregiver, friend, or your healthcare provider
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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 7: Registered as a representative of a patient advocacy organization

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