Transcript: Botox; Botox Cosmetic Roundtable Event, April 8, 2026, Medicare Drug Price Negotiation Program Public Engagement Events

This transcript was lightly edited for readability.

Introductory Remarks

Moderator, RTI International

Thank you everyone for coming today. I'm **[Moderator]** from RTI International, and I want to introduce my colleague, **[Secondary Moderator]**, and you may hear from her during the course of the conversation today. The Centers for Medicare & Medicaid Services, which we'll refer to as CMS, which is the acronym, throughout the conversation, is convening patient-focused roundtable events, like this and others, as part of the Medicare Drug Price Negotiation Program. The information shared during these roundtable events will help CMS understand patients' experience with the conditions and diseases treated by the selected drugs, patients' experiences with the selected drugs themselves, and patients' experience with other drugs that are used to treat the same conditions as the selected drug.

The information shared during these events will also help CMS identify other medications used to treat the conditions treated by the selected drug, what matters most to patients in managing their conditions, and other factors CMS may consider in negotiating Medicare pricing with manufacturers of the selected drugs. The purpose of our time here today is to hear from you all, and this includes a group of patients, caregivers, patient advocates. We want to hear about your experiences with the conditions and diseases treated by Botox, including chronic migraine, which I think is very well-represented today. We also want to hear about Botox itself and other medications for the same conditions.

I want to emphasize that our focus today will be on patient experiences, so if you want to share other topics related to the Drug Negotiation Program that aren't directly focused on the patient experience, we want to encourage you to send that input to the mailbox IRARebateAndNegotiation@cms.hhs.gov instead of sharing it during the conversation today.

The selected drug name “Botox; Botox Cosmetic” reflects the manufacturer's naming convention, and use of the manufacturer's assigned name when describing the selected drug Botox; Botox Cosmetic is not indicative of any change in the Medicare coverage or payment for the selected drug when used for cosmetic purposes. And I also want to clarify that today, when I say Botox during the discussion, I'm referring to Botox; Botox Cosmetic, and you are very welcome to refer to this drug however you would like to refer to it.

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

CMS Remarks

00:02:53

Dr. Mehmet Oz, Administrator for the Centers for Medicare & Medicaid Services

Hi, everyone. I’m Dr. Mehmet Oz.

I'm the Administrator for the Centers for Medicare & Medicaid Services, also known as CMS. CMS is the Federal agency that oversees Medicare, which provides health care coverage for more than 69 million older Americans and people with disabilities. We also oversee the Medicaid program and the Health Insurance Marketplaces.

I wish I could join you today in person, but I want you to know I am eager to hear your feedback and am deeply grateful for your participation in today's discussion.

It is a crucial conversation.

No one in America should have to choose between buying groceries or paying for their medications. But many are forced to make this choice. It's a choice that comes with a personal cost in addition to a financial cost. I started my health care career as a cardiothoracic surgeon. So I know firsthand what happens when people can't get their medicine, like the ones that lower their cholesterol or blood pressure. Left unmanaged, these conditions can be dangerous.

CMS is doing incredible work reigning in the skyrocketing cost of prescription medications, and we need all of you to help us make real, lasting change.

Right now, we're working on the latest cycle of Medicare drug price negotiation.

We announced the drugs selected for this round earlier this year. Some of them are covered under Medicare Part D, and others are payable under Medicare Part B. For every drug, our priority is to reach an agreement with the manufacturer on a fair price for Medicare.

We are committed to being fair and transparent throughout the negotiation process. And that's where you all come in.

It's my goal to get input from people across the health care ecosystem. We want to hear your perspective about the drugs selected for the current cycle of negotiation and renegotiation.

Your input makes a difference – a big one. Thank you for taking the time to join us today. I'll turn it over now to our event moderator.

00:04:44

Moderator, RTI International

Fantastic. I also want to make you all aware that staff from CMS will be sitting in on this event so that they can hear your experiences and opinions directly from you. Let me hand it over to them for a moment so they can say hello.

00:04:59

CMS Staff

Good morning, everyone. My name is **[CMS Staff]**, and I am with the CMS Drug Price Negotiation team, and we also have other CMS staff on the call today as well, and we all work on the policies for getting public input, as well as negotiating Medicare drug pricing. On behalf of CMS, I just want to thank you all for participating today. We're very much looking forward to hearing about your experiences during this roundtable discussion. And I will just note that we are going to go off camera now so that you all can focus on the discussion but just wanted to thank you. I'll go ahead and turn it back to you, **[Moderator]**.

Housekeeping

00:05:40

Moderator, RTI International

Thank you, **[CMS Staff]**. We have a few more housekeeping items before we begin, and some ground rules, so everyone knows what to expect. As **[Tech Support]** mentioned, if you get disconnected, please attempt to rejoin. If you can't connect, please reach out to the IRADAPStechsupport@telligen.com.

In terms of privacy, the discussion is not open to the press or to the public. We will use first names only during the discussion to protect your privacy, and we also ask that you don't share any unnecessary protected health information, such as your doctor's name or a medical facility where you've received care. Also, please don't share any personally identifying information, such as your employer's name, or a city you lived in, or the schools you may have attended, during the discussion. And then following the event, CMS will prepare transcripts that will have the participants' names and identifying information removed, and these transcripts will be made public.

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

And in terms of participation, we'll have a lot of questions, and we hope that you will contribute your perspectives throughout the call today. However, if there are questions that you don't feel like you want to answer, that's totally fine.

In terms of having the best conversation possible, we ask that folks minimize background noise by silencing your cell phone and other devices if you haven't already done so, and please mute yourself when you're not speaking. And we thank you in advance for keeping your video on during the discussion.

We have reserved two hours for the session today. However, it's possible we may not need the full two hours to discuss all the planned topics. If that happens, then we can let you all go a little bit early. I have a discussion guide right in front of me to keep us on track. We do have a lot of topics to cover, so there may be some points where I may need to redirect the conversation or cut a conversation short at times to make sure that we're able to cover everything and that all the participants have ample opportunities to share their perspectives.

In terms of breaks, since we have a long time together, if you need to step away briefly from the discussion, that's fine. Just turn your camera and microphone off and rejoin when you're able to. You don't need to tell me that, hey, I'm going to step away right now from the computer. Just turn everything off and return to the discussion when you're able to.

Okay, and then speaking. Please try to speak one at a time. I may need to occasionally interrupt folks, too, if two or more people are trying to talk at the same time. We want to be sure that everyone is heard and that we can get comments accurately recorded. Please use the raise hand feature in Zoom to indicate you would like to speak, and I think **[Tech Support]** had shown that to you. This will help us know when someone would like to contribute to the discussion. And then the chat, although we hope most of the activity will be in the oral conversation, you can also add your comments into the chat if you don't get a chance to share them orally. This may be the case, for instance, if we don't get to hear from you before we need to move on, or if you think of something later that you want to add to the conversation, just be sure to reference what question or topic you're covering when you use the chat function.

Unless anyone has any other questions, I'd like to just go ahead and get us underway with introductions.

Discussion

00:09:25

Moderator, RTI International

I'd like to start by going around the room and asking each individual to briefly introduce yourself. If you could tell us, first, your first name; whether you will be sharing experience as a patient, caregiver, and/or from the experience of a patient advocate; and the condition or conditions that Botox treats that you have experience with. **[Participant 1]**, you are the first box next to me, so I'm going to ask you to get us underway.

00:10:02

Participant 1 (registered as a patient)

Yes, I'm **[Participant 1]**, and I'm being treated with Botox for chronic migraines.

00:10:11

Moderator, RTI International

Thank you, and so you're speaking from the position as a patient today.

00:10:15

Participant 1 (registered as a patient)

Yes, a patient.

00:10:16

Moderator, RTI International

Thank you. Okay, just want to be extra sure. Okay, **[Participant 2]**, you're next on my screen, so I'll hand it to you.

00:10:23

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

Hi, my name is **[Participant 2]**, and I am a chronic migraine patient, and also a patient advocate, with the Alliance for Headache Disorders Advocacy. And I've been getting Botox for probably 13 years.

00:10:38

Moderator, RTI International

Thank you, **[Participant 2]**. **[Participant 3]**, you are next on my screen, so I'll ask you to take the next go.

00:10:46

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

Hi, I'm **[Participant 3]**. I am a chronic migraine patient. I have received Botox in the past personally, so I'm representing the patient perspective, and also on behalf of the National Headache Foundation community overall.

00:11:04

Moderator, RTI International

Thank you, **[Participant 3]**. And **[Participant 4]**, may I ask you to take the next turn?

00:11:09

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

Sure, my name is **[Participant 4]**. I guess you just said that. I am a patient. I have chronic migraine. I've lived with chronic migraine for over 30 years. I'm also the **[Redacted]** for the American Migraine Foundation, so thank you for including me today.

00:11:25

Moderator, RTI International

Thank you for being here, **[Participant 4]**. And **[Participant 5]**, you are next on my screen.

00:11:29

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

Hi there, I am **[Participant 5]**. Thank you for the opportunity to come on this call today. I'm the **[Redacted]** for the Coalition for Headache and Migraine Patients [CHAMP]. I am a patient. I've had migraine, chronic migraine, since I was a middle schooler, and I'm the caregiver to two teenage daughters with migraines. So, I think I'm, the trifecta, am I allowed to be all three?

00:11:53

Moderator, RTI International

You can, yes, absolutely, I love it. Great, thank you. And I think, **[Participant 6]**, we haven't heard from you yet.

00:12:01

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

Yeah, hi, my name's **[Participant 6]**. I'm a person living with chronic migraine. I am also the **[Redacted]** of a national advocacy organization, Miles for Migraine. I'm sharing both my personal experience living with chronic migraine as a former caregiver to my mother, and now to two daughters who also live with this disabling disease. Migraine has affected three generations in my family. If time would allow, I'd love to share some patient comments that we have collected here at our organization.

00:12:30

Moderator, RTI International

Great, thank you. Thank you so much. It sounds like we have a very broad array of perspectives, and I'm very grateful to have you all here. I'd like to start off by talking about patients' experiences with chronic migraine, treated by Botox. Thinking about the different ways that chronic migraine affects patients' lives, what would you say are the most important aspects of chronic migraine to have managed or treated?

00:13:06

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

I'll go first. Chronic migraine is not just a headache, it's a disabling neurologic disease that can take people out of their lives completely. I've lived through months where I couldn't function. I do actually receive Botox for chronic migraine, but before that time, I lived through those times, I've watched my daughter, **[Redacted]**, lose an entire year of her life in a dark room, missing school, friends, and major milestones, and what really matters is getting your life back, being able to function, to be in society, to work and contribute to society. It's not just about reducing pain, it's about restoring stability and predictability. I had to drop out of an MBA [Master of Business Administration] program and eventually stopped working because, before Botox was out on the market, I spent [time] in bed two to three times a week, so being able to restore my life is really what matters most.

00:14:08

Moderator, RTI International

Thank you, **[Participant 6]**. How about others? What matters most to have managed or treated in terms of chronic migraine?

00:14:18

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

I think **[Participant 6]** said it beautifully with being able to live your life. Prior to Botox, I was a teacher, taught for 24 years, had to look at retiring early. I think it's really important to know there's a story around the person with migraine and with these medications, and to look at their whole story when you treat, as well as **[Participant 6]** talking about how this is much more than head pain. I think it's important to really look at the whole person, all the symptoms, and I always say I feel that we should all get to live the life we feel called to live, and migraine should not steal that.

00:15:00

Moderator, RTI International

Folks have talked about rejoining life and thinking about the whole person's lives. Are there certain symptoms or complications due to the condition or mental health impacts that folks want to share? **[Participant 2]**, it looks like you came off [mute].

00:15:15

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

I was just going to say, in terms of the importance, I think reducing the frequency and the severity of migraine attacks is really important. Just knowing that there is no cure, but we're always in search of finding something, and for many of us here, Botox has been something that's helped reduce the frequency and severity, so we might possibly have more pain-free days, or more days where we're able to function, function more.

00:15:44

Moderator, RTI International

And **[Participant 6]**, I saw you come off mute, it looked like you had something to add.

00:15:49

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

I wanted to add that, myself, and I can speak for my daughters, we need a toolkit for migraine. We don't just survive with just one medication, and so we've got layers of medications that we have to use. But you mentioned other conditions. Migraine comes with a lot of comorbidities. Mental health is the biggest comorbid feature that migraine brings, the anxiety and depression. We have all experienced that, and it's not just about managing headaches, it's about managing multiple chronic conditions, and in fact, our organization has now taken on an initiative to start talking about all those other conditions because so many people are telling us [that] to manage their lives just with their headache disease is so time-consuming, and then to have to add that on top of it is very stressful.

00:16:55

Moderator, RTI International

[Participant 6], you mentioned depression, anxiety, stress. Do others have other comorbidities that they've experienced or have heard through your patient advocacy work?

00:17:07

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

I'd like to add in, I think that everyone's been stealing the words right out of my mouth. The biggest issue for me, though, I think, is that it's a very complex neurological disease that has so many different facets to it. While I might be able to find a medication that works for me, and I've had this for decades now, that sometimes shifts, and my disease is super complex. And I have to stay on it, and I have to have lifestyle adaptations, and I have to have regular check-ins with my doctor. And I think it's really important to remember that, and how that impacts life, and how, like **[Participant 6]** said, it's really a toolbox approach to this disease because as it shifts and moves—and you can become episodic to chronic—the comorbidities are going to shift with that, too, the depression, anxiety. I have sleep issues. It's very, very complex, and I do think that we need to talk about that and the relation to stigma with that disease because it's very stigmatized, because it's not just a headache, but all of these pieces play in. And actually, I'm having a migraine, day two of an attack, so if I'm a little foggy and my eyes are streaming, just bear with me today. I have taken my medication.

00:18:46

Moderator, RTI International

Thank you for being here, despite working through the pain. **[Participant 5]** raised a really great point, as well as **[Participant 6]**, the complexity of the disease and how it's constantly shifting. Would others like to comment, or be open to commenting on, what that shift looks like?

00:19:07

Participant 1 (registered as a patient)

I can speak to the complexity because [of] my migraines throughout my life, and I've had them since I was 13 years old, and I get the ones with aura, and sometimes, half my body would be falling asleep. Throughout my life, they have gone from episodic to chronic, back to episodic, and then I'm back in chronic. And I also wanted to mention that sometimes, the Botox, but I'm also taking the Vyepti infusion because my doctor felt that I needed both to control the chronic migraines, which were averaging 25 a month almost two years ago.

00:20:07

Moderator, RTI International

It gets back to taking over your life. 25 per month.

00:20:10

Participant 1 (registered as a patient)

Yes. Exactly.

00:20:12

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

I think the one thing that I would love to add when speaking about the complexity of the disease is that chronic migraine is a subsidy of migraine, so this is a highly impacted population. I think we all have either experienced or obviously know someone who's experienced a migraine attack. But when you're looking at chronic migraine, that's 15 days a month, so it is severely impacting people's lives, and the complexity of it is so layered. It becomes such a large part of your identity. I love that **[Participant 5]** was talking about stigma because with your family, your friends, your coworkers, you end up unintentionally becoming someone who's known for their illness, and that is so complex when it's interwoven in that, so having treatment options that help to prevent it before it can begin, and something that's within the toolbox, as **[Participant 6]** said, is just so critical for comorbid condition management on so many different levels.

00:21:30

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

With the complexity of the disease, also thinking about how, over time, both your triggers and your symptoms can change. I don't typically have an aura, but I do remember a while back, when I was trying to still teach, asking a question, and then realizing I couldn't count how many hands were up. That was a new experience, and one of the worst places to probably experience an aura, in a room full of 25 kids. But just realizing that as we deal with this disease, the way it impacts your life can change also, and I think that was also a really good point that **[Participant 3]** brought up with how complex it is and how disabling it is.

00:22:12

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

I think another thing to include as far as the complexity is how all-encompassing migraine is, and that's why all of us introduced ourselves saying, "I live with migraine." Because even in between attacks, when we're not in pain, we're still thinking about it, it still impacts every aspect of our lives, but we make a lot of choices every day about what we do and what we don't do, just based on, will this trigger an attack? When was the last one? A lot of anxiety and anticipation. Okay, when is the next attack going to happen? Do I have my medication? There's a lot to manage, even aside from just the pain, whatever is recognized as the headache, there's so many other issues that go along with it in your daily life.

00:22:55

Moderator, RTI International

Anyone else want to comment? Because I feel like we've started also trickling into the next set of questions about getting into the toolbox of treatment options, and I wanted to turn to talking about patients' experience with medications for the treatments.

00:23:14

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

I can speak to that a little bit because I'm the oldest one here, so I probably lived the longest without Botox. The toolkit I had back in my twenties when I first became chronic was a multitude of drugs that were prescribed to me that were not indicated for migraine, not developed for migraine. Antihypertensive, anti-epileptics, those drugs had so many side effects, I ended up having two car accidents within three months. Eventually, I had to leave my job, and I had to leave the MBA program I was in. During COVID [the coronavirus disease-19 pandemic], and I'm sure a lot of us have had this experience, I couldn't get Botox, and I became so sick, and I work from home. Luckily, this is why I went from working in a career where I was out in the workforce every day to then switching to the stay-at-home career as I aged. Without Botox, myself and my three daughters were spending countless days in bed, unable to function. My daughter dropped out of college. She was so sick from not getting her Botox. My other daughter, same thing. She had to go to part-time college, so I would just say that without that, if you know it works for you, and it's in your toolkit, it's mandatory. It's not an option. I'll let somebody else say something.

00:24:50

Moderator, RTI International

Before we move on to the specific medications, because you've raised a few, the antihypertensives, that had side effects, I wanted to take a moment to ask folks to go to the chat for a minute and enter what medications, if any, that you, your loved ones, or patients you advocate for have taken to treat the chronic migraines. And these can be medications taken currently or in the past. Take a moment to put that in the chat.

00:25:20

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

How much time do we have to do that?

00:25:23

Moderator, RTI International

Okay, you can take maybe the few most recent.

00:25:25

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

I've been on over 30 medications since I was diagnosed.

00:25:36

Moderator, RTI International

You don't have to enter 30, **[Participant 6]**.

00:25:38

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

Yeah, okay.

00:25:38

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

I would probably be around 15 different medications before I found them, but I'm happy to put that in.

00:25:45

Moderator, RTI International

Yeah, and you can think about the five, or three to five most-recent, because the next set of questions will ask about the benefits and drawbacks of each.

00:25:58

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

As we move into this conversation, there was just one point that I—putting on the advocate hat from CHAMP—what I found in my own life with my peers here, and with many of the patients that we work with, is that when we have someone who has chronic migraine, and they're moving into Botox as a treatment, they've tested, and they've gone through multiple medications, and I've found them—and correct me if I'm wrong, **[Participant 3]** or **[Participant 6]**—these are very educated patients by the time they're moving into this, and that is something that is sometimes overlooked or dismissed in this disease space that I think is really important.

00:26:50

Moderator, RTI International

And when you say that they're educated patients, can you say a little bit more? Is it educated about their disease and the medications?

00:26:59

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

I think that because migraine and headache diseases are so unique, and it's a neurologic piece.

I think that we don't have diagnostic testing, per se. I like to think that an individual, they know their history and their body the best, and they tend to—anecdotally, I can speak to patients that I've talked to—anecdotally, they tend to know what works and what does not work, and so when they're moving to a treatment—and again, this isn't episodic. This isn't new patients to having migraine. These are chronic patients who have been dealing with this illness for a long time, and I do think that that needs to be taken into consideration, that these patients, it needs to be patient-led, and that's why I think step therapy can be so problematic sometimes. When we're looking at patients who really understand their disease, my disease looks very different than **[Participant 6]**'s, it looks very different than **[Participant 3]**'s. I think that's part of the issue sometimes, and why physicians get frustrated diagnosing and caring for us is because it's a very complicated disease. Our comorbidities are different, our symptoms are different, and yet we all have migraine or chronic migraine.

00:28:32

Moderator, RTI International

I see some medications coming in. I'll give folks another moment or two to put in a few. CGRPs [calcitonin gene-related peptide], yep. Right. Thank you. All right, the hypertensives. I'm going to give another minute or two, as I have seen two, and many more. Again, just a handful. Okay. And then non-pharmacologic [treatments], I see, as well.

00:29:27

Moderator, RTI International

All right, let's do 30 more seconds, and then we'll talk about folks' experiences with these drugs. As **[Participant 1]**'s wrapping up her entries. Thank you for sharing these names.

For the next few questions, I want to note that we want to hear about your experiences or your loved ones' experiences, as I've seen moms and children mentioned here, what experiences you've had with Botox and these other medications that you've listed. And then, as we're going through, please be sure, if you're talking about a specific medication, to point us to that. Thinking about all these medications, what benefits have you, loved ones, or patients you advocate for experienced with these medications? What benefits have you experienced with these [conditions] treated by Botox and these other medications?

00:30:22

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

I experienced 15, 25 headache days per month, not migraine attacks, headache days with attacks thrown in there. Before I was in combination therapy of Botox and an anti-CGRP. At that time, I was only able to work part-time from home. For me, the only reason I can work full-time now is because I am on layered therapy, and it's not just Botox and anti-CGRP, it's neuromodulation, it's lifestyle, it's sleep, everything related to what a person living with migraine goes through. I will also say that I was a caregiver to my mother when I was a teenager. No child should have to do that. And living that life, she was taking opioids, this is back in the ‘60s and ‘70s, and the contrast of where we've come, I think, is really relevant, and I think that we don't want to use opioids anymore. I'm concerned that whatever happens to Botox, two things, people might have to revert back to opioids. Some patients still do, and it's completely appropriate for a certain group of patients. And right now, the access is important because when I get my Botox appointment, I know I'm going to be able to see my provider every 12 weeks. If that goes away, that benefit is taken away because less providers are going to prescribe Botox, or they're going to inject Botox because of the reduction in the reimbursement. I'll let somebody else talk. I could talk all day, so I'll stop.

00:32:23

Moderator, RTI International

Can others comment on the benefits of the medications that they have tried more recently or through the years, if there was something you want to pull from the past? **[Participant 3]**, it looks like you've come off, and then it looks like **[Participant 4]** also came off, so we'll start with **[Participant 3]** and then go to **[Participant 4]**.

00:32:39

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

Yeah. I have a unique experience. I had a head injury 11 years ago, and overnight, my world changed. I was biking home from work, I landed on my head, I flew off the bike, landed directly on my head, and I would wake up with a headache or a migraine. I would go to bed with a headache or a migraine. The medications that I used, as **[Participant 6]** had mentioned, many of them not indicated for migraine, and it took me about over a year, and I was seeing neurologists at the time to go through step therapy. I live in a major city, so taking even public transit to work, the screech of the train, the light, the sensitivity—the medication sometimes would help to bring it down slightly, but it wasn't until I was able to receive migraine-specific medications, I did inpatient program and received infusions, and was able to get on Botox. That was when I really started to see a significant change where I was able to get back to my life. One of the medications specifically, Topamax or topiramate, the brain fog was incredible. I felt like I could not function as an employee, as a friend. I was in a fog all the time. Some of the side effects, while maybe my head pain would have been slightly decreased, nothing like it was with Botox. It came with other symptoms, it came with other side effects that sometimes just didn't make it worth it, even, amitriptyline, I believe—and again, this was over a decade ago—there's side effects of birth defects if you're planning on having children. They come with a lot of risks. I'm really grateful that I was able to get to migraine-specific medication to be able to live a normal life again, but I needed to take short-term disability because of how sick I was and how depressed I had gotten because I was cycling through so many medications that weren't making enough of an impact. And again, for a chronic patient, 15 days or more, that's half of a month where you are disabled, that is a different level of need and care than folks who are episodic, who have maybe one a month or one a quarter. We're talking about a severely, highly impacted community, so medications, it's so important to have an ample toolbox, especially ones who are indicated for migraines specifically.

00:35:35

Moderator, RTI International

Thank you, **[Participant 3]**. And **[Participant 4]**, I know you came off and wanted to share. Would you mind sharing some of the benefits that you received, either from Botox or other medications that you've used over the years?

00:35:45

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

Sure, like **[Participant 3]**, I've tried some of those off-label meds that we work, or that are sometimes prescribed, like Topamax and propranolol, as well as all the other ones listed, but I think the biggest thing for me was that some of them did improve the severity, or more likely the frequency. However, the improvement was short-lived, and that is something I think a lot of us experience as well. And I was going to the hospital every month, and being admitted, and every time I would go, then the hospital doctors would either up the Topamax or address that, but nothing was making me better. I finally got to try Botox, and I said I wasn't going to cry today, but at the end of 12 weeks, I realized I had not been in the hospital for three months, and that had never happened for me. Sorry, this probably isn't very professional.

00:36:41

Moderator, RTI International

No, this is a safe space.

00:36:43

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

Yeah, thanks. Too bad it's recorded, though, right? But anyways, that is life-changing, and to think about having that pulled away is terrifying, and I think that's why we need to be here today.

00:36:58

Moderator, RTI International

Thank you, **[Participant 4]**, for sharing and opening your heart to all of us today. Both **[Participant 3]** and **[Participant 4]** have mentioned a reduction in severity in symptoms, and then the longer-term elimination of symptoms. Do others have benefits that they want to share? Or compare and contrast?

00:37:22

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

As others have talked about, I think a lot of us are on CGRP medication and Botox together, and like what **[Participant 5]** was saying, to get to that point where you're able to take Botox and a CGRP together, you have to have gone through lots of step therapy, lots of talking with the insurance company, prior authorizations to get to that point, but the combination of the both together is what helps me to have fewer migraine days and have more days where I'm able to function. I did have to go through a period of time in order to get insurance approval to have just Botox for six months, and then just the CGRP medication for six months to prove that I had to have both layered in order to be functioning, and not be where I'm at 20, 30 days a month. It's been helpful to have the combination.

00:38:15

Moderator, RTI International

Thank you, **[Participant 2]**. And **[Participant 5]**, I saw you come off as well.

00:38:19

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

In relation to not only the medication and the benefits of the medication itself, I think there's something to be said about the ability to receive the medication. I live in a rural area, **[Participant 3]** brought up living in a more metropolitan area. There are significant barriers to people who live in rural areas. There are also significant barriers to people, where they are on the economic scale. And I think that's important, especially in relation to a medication like Botox where they might only need transportation to go get that medication every 12 weeks as opposed to monthly. If it's something quarterly, I think that's of value to the patient, and I think that's important. I also think the availability of Botox and the ease by which it can be given to patients, where maybe it's not an infusion, I think that's a key point that we should probably remember. And I live it because I'm in a rural space, but I know a lot of patients who are also in my same boat.

00:39:38

Moderator, RTI International

You mentioned, the kind of administration, infusion versus a Botox, or other, could you say a little bit more about that as a benefit for the folks you advocate for or for yourself?

00:39:52

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

Yeah, jump in anyone else, but I think that there are so many barriers in the patient journey, even my own personal thoughts on, oh, does an infusion feel different to me than a Botox shot, but also taking out even what's available through my insurance, my availability to get there, my downtime to get there. Fortunately, I am able to work, and I have a very flexible job who understands when I'm down with an attack, it is what it is, and they power through it with me. A lot of people do not have that. If you look at, from health care workers to people who are in retail and food service industries, they do not have flexibility in their schedule, and I think that it's very important for us to remember that. And to understand that if they have to take a bus or public transportation to get to their medication, that's a factor in what they're going to choose. It's not all about, when we're choosing medications, yes, our ability to return to life is one of the biggest pieces, the impact of that on side effects is really big, the cost is really big, but our ability to adhere to the schedule of it is very important, and I think that Botox, I am not personally on Botox right now, but from the patients that I speak to, from my friends who are on it who use it for chronic migraine, it's a very easy schedule to adhere to, and it's a really important and easy part of their toolkit, if that makes sense.

00:41:50

Moderator, RTI International

Makes a lot of sense. Thank you, **[Participant 5]**. **[Participant 1]**, it looks like you wanted to say something?

00:41:57

Participant 1 (registered as a patient)

Yes, I wanted to say something. You know, for me, the combination of Botox and the infusion has been really helpful. I went down from 25 headaches a month to four or five a month. I find that incredible. But I also want to give a shout out to Medicare because I'm on Medicare. And I have a whole list. I only wrote, a few of the medications that I use, but I've been through probably the entire pharmacy. And Medicare has been very helpful in approving my Botox and the infusion. And previously, when I was working, I ended up working the last five years part-time because my headaches were getting worse. And I was also a teacher and a school counselor, so I had a lot of stress. But, you know what? For me, just to keep going and hope for the best has kept me going and doing things that I'd like to do.

00:43:19

Moderator, RTI International

Thank you, **[Participant 1]**. We talked about benefits, and **[Participant 3]** and **[Participant 5]**, you've mentioned some of the drawbacks as part of that conversation, so I'd like to turn to those drawbacks. What drawbacks or challenges have you or others experienced with the medications used for chronic migraine?

00:43:41

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

The drawback isn't the medication itself. It's not the challenge, it's the access. It requires consistent scheduled treatment, so any disruption can lead to rapid decline, which both my daughters and I first experienced firsthand during COVID. And also, there is a little bit of a wearing-off effect for some patients. That has happened to me in cycles. It doesn't always happen to me, but right around 10 weeks, as it begins to wear off, I become more disabled. I would just say those declines, again, from not having it during COVID, and once it starts to wear off, you really feel it, and the disability is huge.

00:44:28

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

I think that step therapy is a huge drawback. We've touched on that also, but when we speak about access—and I heard someone else say it took me over a year— it took me years to get to Botox as well, and I believe that that lack of access to care helped change me from episodic to severely chronic. I'm told all the time how severe—I'm thinking, it’s nice to sit in the room with you ladies, so to speak, because often at your clinician's office, you may hear, “you're just so severe,” and you feel like you're the only one. It's great to be hearing this, but that access to care is huge, and that step therapy just holds a lot of people back.

00:45:13

Moderator, RTI International

Go ahead, **[Participant 2]**.

00:45:15

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

I was going to say, like **[Participant 6]** mentioned, I definitely experienced the wearing off. About a couple weeks before my Botox appointment, my attacks increased quite drastically, and I wish that there was a way to get more, but, yeah, I definitely experienced that, and my Botox appointment is the most important appointment that I have. I'll drop everything, and sometimes getting in, where I live, there's not very many neurologists and headache specialists that do Botox, so sometimes, they'll schedule me past my 12 weeks, and I have to call and say, “have you had any cancellations so that I can get in?” And it's very stressful trying to make sure that I get my appointment as close to 12 weeks as I can. So, that's another issue with access, is not having enough providers that administer Botox for migraine.

00:46:04

Moderator, RTI International

And I know, **[Participant 3]**, you had mentioned the brain fog, that the severity improved, but it was short-lived. Are there other drawbacks that you experience with using any of these medications, Botox or others?

00:46:18

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

Yeah, for other medications, I had some, numbness, impacts to sleep, and there's a lot of anxiety even in between attacks, fearing the next big attack, and if you're going to be able to—for me, I almost missed my sister's dress shopping for her wedding. I was in the middle of an attack, I had to take a medication, and I couldn't drive. And I had to call around and find someone who would be able to come into the city to drive me to the suburbs, and that is an emotional and psychological impact that is so real for many patients. I would also say a really big barrier when we're talking about access is prior auth [authorization] process. I was talking to two providers yesterday, and it's so cumbersome on the administrative side, but then on the patient side, they might not understand what's going on, and if you're not educated and pushing your provider's office, there could be delays in treatment. But also, as other people have mentioned, you could be becoming more disabled before you can feel it when you're getting ready for your next dose of it, and brain fog and your symptoms could be coming back, so then even navigating trying to get access, navigating prior auths and step therapy, and following up at doctors’ offices. It's a luxury to be able to sit on a phone call on hold for X amount of time. Some patients do not get that when they have really restrictive jobs or lives or kids. They can't sit on hold for an hour or two to try to navigate what's going on with it. So, that access piece of it is just so critical.

00:48:18

Moderator, RTI International

And **[Participant 3]**, when you mentioned the brain fog and the sleeplessness, do you recall which medications those were that had those side effects for you?

00:48:26

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

Yeah, I was on some older medications. Definitely Topamax. I was prescribed some narcotics in the trazodone area, and those had inability to drive or do some things. I can't remember all of the different side effects. I bet other folks on the call could speak more to that, just because my experience was a little bit further ago.

00:48:56

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

I can share that, I was put on amitriptyline, and I had suicide ideation.

I talked with a number of other patients in our community, and I told people up front because I wanted them to know this happened to me, and this could happen to you. And they have all said that there has been one time in their life where they've all experienced suicide ideation.

00:49:24

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

I actually, **[Participant 6]** saying that right now, I had a lot of suicidal ideation and suicidal thoughts, and I was on that medication. That could likely be the reason, which was why I ended up having to take short-term disability. I also entered a mental health program because I was in such chronic pain at the time. And again, cycling through medications that, while they can decrease severity, it still was not enough to be able to get me back to my daily life.

00:50:01

Moderator, RTI International

And **[Participant 4]**, you've come off, too. Do you want to share a little bit about some of the drawbacks of different medications in your history?

00:50:09

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

Sure, I did experience some of the side effects with Topamax, and also a big one for me was propranolol. Again, a blood pressure medication used off-label, and my blood pressure dropped so much—I was still teaching at the time—that my school nurse said, “you have two options, I'm going to call an ambulance, or I'm taking you to the ER [emergency room].” Again, just being scared with having that impact and not expecting it, you're willing to try anything, but that was a definite drawback for me.

00:50:43

Moderator, RTI International

We've talked about some of the drawbacks of individual drugs. How do those drawbacks differ by the various medications? Could you compare and contrast the drawbacks of the medications that you've tried?

00:50:59

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

They had the older medications, the anti-seizure medications. I had a lot of numbness and tingling with those, had some different antidepressants that cause weight gain. Those older medications that are not migraine-specific have a lot more side effects than these new CGRP medications. I would say overall have much fewer side effects that are much less severe. That's what I've experienced.

00:51:25

Moderator, RTI International

And **[Participant 5]**, I see you put in the chat, side effects more recent, depression and horrible fatigue. What medication is creating that for you?

00:51:33

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

I'm on the off-label blood pressure, which [has] just made me so exhausted. Prior to that, I was on Fioricet as a young person, which, again, I don't think that's something that is actively prescribed now, but I had a really bad time with that—depression, severe depression, suicidal ideation—thankfully, there are so many more treatments out now.

00:52:03

Moderator, RTI International

And **[Participant 6]**, or **[Participant 4]**, I see that they also didn't work, no efficacy. Do you want to say a little bit more about that?

00:52:11

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

Yeah, I would say, if you look at the list of preventive medications that are barred from other disease classes, there's a whole list of them. I would have to go and pull it up for you, there's got to be more than 20. I was on all of those. And the reason I got switched was either I had side effects or they didn't work. Like I said before, I had two car accidents, so I was completely, I don't know even how to describe that. You know, I was brain fogged, I guess. And certainly, topiramate, the nickname is “dopamax,” because I remember sitting in a meeting, and I couldn't do simple math, and there was a neurologist there, and he's like, “You're having trouble.” It was so obvious. But I would just say that it's either mental disability, physical, and every medication, there’s not one that worked for me except for Botox layered with a CGRP, neuromodulation for me, and, also lifestyle. I'm like a baby, I’m on a very strict schedule, eat, drink, sleep. And meditation, and yoga, everything that I have to do.

00:53:31

Moderator, RTI International

And **[Participant 4]** or **[Participant 1]**, did you want to add a little bit more to the conversation?

00:53:37

Participant 1 (registered as a patient)

Yes, in the past, because I was on the topiramate for 20 years, but I only took it at night. I didn't take it during the day. I did have some of that brain fog or whatever, but I was still getting eight migraines a month at that time. Or between six and eight. The new CGRP meds are so much better. I had constipation with the Aimovig. But then the Emgality was great, but they only lasted two years. I took Aimovig for two years, and the migraines got worse. And then I took the Aimovig, and then two years later, migraines got worse. Then I fell off the cliff, almost two years ago, and that's when I ended up back at the headache center. I've been going there for 27 years, and they've been incredibly great in treating my very complex migraines. Now I'm on the Botox and the infusion Vyepti, and I think I wrote it wrong in the chat, and it's really helped. I'm still having four or five, but they're not as severe, and I can function. I feel really, really happy and excited that these newer medications are out, and they're helpful.

00:55:06

Moderator, RTI International

[Participant 3], it looks like you came off, too. Did you want to share, add something?

00:55:10

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

Yes, I wanted to share, I was speaking with a chronic migraine patient yesterday who has tried a number of different meds as well, and one thing that she also talked about was self-administering shots, and the discomfort of that. I understand Botox also is shots, but quarterly versus giving it to yourself. There is a barrier there for some patients who don't feel comfortable with that option, so it's not necessarily a side effect, but the way that it's administered, I think, for some other medications, is notable from a preference perspective of patients, and their ability to do it, or feel comfortable doing it, things like that.

00:55:56

Moderator, RTI International

Thank you, **[Participant 3]**. Thinking overall, when considering a potential medication for chronic migraine, what factors matter most to patients? **[Participant 3]**, you mentioned that administration, do others have other factors that matter most to patients?

00:56:16

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

I would say the effectiveness of the drug, the side effect profile, and the ability to function, that's what we're talking about here.

You know, a treatment is only as meaningful as it allows you to live your life. And also consistency. Delayed treatment causes more anxiety because people living with this disease never know when the next attack is coming. I've been doing this for my entire life, starting with my mother, it seems so unfair to me that here we are, we've been waiting, I've been waiting my entire life for a preventive to come that's actually researched and developed for migraine. Now, Botox is not that therapy, but it works. The CGRP medications is what I'm talking about. The point I'm trying to make is, we have so few therapies to begin with that are actually researched and developed for our disease, for prevention. And if you take away Botox that works for us, the damage that it's going to cause, to me, is scary. What matters is treatments that work and the ability to access those treatments.

00:57:37

Moderator, RTI International

How about others? I know **[Participant 6]** had a very comprehensive list, the effectiveness, ability to function, side effect profile, access, other factors that matter most to patients.

00:57:49

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

[Participant 6] did an amazing job of capturing a lot of that. I've been in conversations both with patients and clinicians, and defining that okay or better is not good enough. I think when **[Participant 6]**'s talking about being able to live your life, that's a conversation for patients because maybe I didn't go to the hospital every month, but how many attacks did you still have? We have to be significantly better where you can work, where you can take care of your family, where it doesn't impact. I feel like all parts of my health have been impacted by my migraine disease, so I think it's really important to look at that quality of life.

00:58:30

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

CHAMP actually did a focus group with some patients, two or three years ago now, that talked about this, and the side effect profile, dosing, the frequency of administration, out-of-pocket costs were the top, but the real focus, I just pulled it up really quick, it was unanimously cost and coverage, and the side effect profile, and how fast a medication works were some of the top pieces that we saw in that focus group.

00:59:05

Moderator, RTI International

Thank you, **[Participant 5]**.

00:59:08

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

Yeah, as far as that access, and then also, like she was saying, the amount of time that it takes to work, because often, you have to jump through so many hoops just to get to try the medication, and then, is it going to work? And then you have to try at least three months, maybe six months, and if it doesn't work, then you have to jump through more hoops to try the next medication. So, I think the speed at which it works and even getting to access that medication in the first place.

00:59:37

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

I would also add to the list fewer ER visits, hospitalizations. Again, for chronic specifically, that is a real outcome of not having the right toolkit and treatment options, and Botox, I think, really keeps people out of ERs and hospitals.

01:00:01

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

Yeah, I agree. Before I was on combination therapy, I was in the hospital multiple times. And what that costs the health care system is huge. So, now I haven't been in the hospital probably since going on combination therapy.

01:00:22

Moderator, RTI International

Anyone else? Go ahead, **[Participant 5]**.

01:00:34

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

I think that's a really good point in relation to the ER, and I would also say, walk-in care as well. When I talk to walk-in care physicians, they see a lot of migraine patients, and they have one option to give them in that environment, or they're sending them to the ER. When we talk about the cost of care, if you have someone going to an urgent care, and then they're being referred to [the] ER, it's a lot.

01:00:56

Moderator, RTI International

Yeah. Okay, so a lot of considerations when selecting a medication. I have a section on medical needs, and thank you so much for the input so far. I'd like to talk about how well Botox and other treatments for chronic migraine meet patients' needs. We asked you earlier to reflect on the most important aspects of chronic migraines to have managed or treated. I think we've covered a very comprehensive list, but aside from those aspects you've already shared, what other medical needs related to chronic migraines are important to you, your loved ones, or the patients that you work with?

01:01:35

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

When you say medical needs, can you be more specific what you're referring to?

01:01:41

Moderator, RTI International

Like symptom management, for example, things that affect your ability to live your life in the fullest way possible.

01:01:49

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

I'd like to say that we're still in the dark ages of migraine treatment, unfortunately. A lot of clinicians will tell you, “Oh my gosh, this is great, we finally have combination therapies that are working for patients.” I work with a lot of patients that don't have that luxury. The combination therapies have not worked for them. They're still disabled, and so they are on Medicare disability. Taking one more thing away from them is, I can't even imagine. Again, I can't stress enough the anxiety that comes with living with a chronic illness, not knowing when the next attack is going to come, the stigma that we are living with because we're not understood, and then to not be able to have the medical care that we need to take care of ourselves. That psychological burden adds to the disability burden that myself and patients that I know are living with. Does that answer your question?

01:03:05

Moderator, RTI International

Yeah, and **[Participant 6]**, I wanted to clarify, when you said combination therapies, are you referencing the layered therapies of the CGRP and Botox?

01:03:14

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

Yes, the CGRPs are only as effective as—the research, I think, is showing—between 50 and maybe 60%, correct me if anybody knows the exact number. But the bottom line is, these drugs don't work for everyone, and why can't we do better if there's one billion people in the world with migraine? And they're not all chronic, of course. But we need more therapies, not less.

01:03:48

Moderator, RTI International

I see some folks shaking their head. Would someone like to chime in about needs that are not currently met by existing treatments?

01:04:01

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

I think with Botox, I notice I don't have side effects compared to some of the other medications. For me, it's affected gut health, and we've talked about mental health, And someone was just asking me that I hadn't seen in a while, how is this affecting your fitness, or your health in that way? And thinking about me getting older, which, **[Participant 6]**, you are young. you did not have to say that about yourself.

01:04:33

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

I'm going to be on Medicare in a few months.

01:04:37

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

Still young, I'm probably not that far away. But yeah, I think it encompasses everything, your whole body, with migraine, and so I think it's really important we have that conversation. It is truly not just head pain. Some people don't even have head pain. That is not me, but there are so many other pieces of this disease to consider, and how it affects your life.

01:05:03

Moderator, RTI International

And to what extent are the existing treatments able to meet those medical needs for you all?

01:05:12

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

What I did was, we have support groups at our organization because most of the people that come to our support groups are on disability, and they are telling me—one person said, even with coverage, getting Botox is complicated and stressful between prior auths, timing, specialty pharmacy delivery. The process often offsets the relief it provides. We all want relief, that's the end, to me, that's the end game, we're not talking cures here. We're talking relief so there is a reduction in pain. Before Botox, this woman says, “my pain was a nine or ten out of ten. Now it's around a five, still daily, but finally at a level where I can function.” Again, we're not talking about perfection, we're talking about just the ability to function.

01:06:15

Moderator, RTI International

Go ahead, **[Participant 3]**.

01:06:17

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

Yeah, I'd love to build off of that, what **[Participant 6]** was saying. Inherently with step therapy, patients are required to fail. The other medications that they're taking are not working. They're seeking something to even get to the prior auth for Botox. The other medications, they're not effective in the way that they need in order to be able to functionally live their life. If they're at that stage of it, it is it is something that's needed in their toolbox to try because they are disabled in some capacity, where the other medications are not working for them.

01:06:59

Moderator, RTI International

Thank you, **[Participant 3]**. We've talked about the CGRPs and Botox being effective for some of you all. Do you feel that certain medications or treatments address the medical needs to a greater or lesser extent than others?

01:07:15

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

Address the needs of, say that again?

01:07:19

Moderator, RTI International

Do you feel certain medications or treatments address the medical needs to a greater or lesser extent compared to other medications or treatments?

01:07:28

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

You're talking about Botox addressing the needs, or you're saying what other drugs are you talking about?

01:07:36

Moderator, RTI International

Any of the medications or treatments.

01:07:38

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

I would say, to me, it's a joke that we only have one preventive that was R&D [research and development] for migraine, and that's the CGRPs. Botox was discovered by accident to work, just like some of the other drugs were. But it works without side effects. All the other drugs that we've talked about that I put in the chat with that list have all caused side effects, well-documented in the research. I would say that in this day and age, we've got two classes [of drugs], and that's it. And that seems really unfair. We're talking about migraine, if we look at it as a women's disease because it affects more women than men. 70% of people with migraine are women. Look at this crew, we're all women!

And so, I think this disease is stigmatized. People don't understand it. Women are seen as complainers. We're just trying to get out of our obligations, back in the Victorian era, where now, these days, we're just seen as lazy. And doctors don't want to treat us. That should tell you so much about why we don't have the R&D for this disease. Now we've got two classes that work, and we've got neuromodulation, so let's put that in there, too, so three, and all the other drugs are terrible. I don't think there's one person on this panel that will say to you, “oh yeah, I'm still on one of the anti-epileptics”—maybe they are, because some people still need that, because these drugs are not working for everyone. We can't discount those people that are not being helped, even by the few classes that we have. I would say it's almost impossible to compare because the old drugs are so bad with so many side effects, and we need to keep going. We can't take this away, we need more, and we need to keep going.

01:09:58

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

I would agree. The older drugs are terrible, and the step therapy just keeps people in pain longer, going through the side effects, going through all the different trials. The old drugs, there's really no comparison, and having the CGRP medications has been game-changing, but I agree, it's still not enough, and there's still a lot of issues with access. But as far as comparison, there's no comparison between the old ones and the CGRP meds.

01:10:28

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

I would add to that, too, we keep talking about access, and the big thing also is we want to prevent people, if we can, from being episodic to chronic, or so far into chronic that it's hard for any medication to work. That's a sense of urgency that we should have to keep Botox available, and to really look at what actually helps patients. **[Participant 6]**'s right, the others were terrible. I was in a window of “let's up the dose,” and you're upping something that's not working. It was just like beating, well, I wouldn't want to hit the wall with my head, but it's just maddening. So, absolutely, we need more.

01:11:10

Participant 1 (registered as a patient)

I also wanted to add that I think access to doctors, at least in my state I went to quite a few doctors and I really wasn't getting really good results. I had to go out of state to a headache clinic to find the help that I needed. But not everyone can afford to do that or have the insurance coverage to be able to do that. That's another consideration, that at least where I live, there's not that many doctors that treat migraines.

01:11:51

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

And it's not just you, it's around the country, it's well-documented that for the number of people living with migraine, there are less than about 800 UCNS [United Council for Neurologic Subspecialties] certified. Now, **[Participant 3]**'s organization, amazingly, is doing such a great job at training other clinicians to treat headache and migraine. But we have such a shortage, the wait times are a year in some of these academic centers, and if we make it more complicated for them to prescribe Botox, then patients are going to lose out on one of the most vital therapies. Botox is a no-brainer for so many people.

01:12:31

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

I want to add to that, **[Participant 6]**. We have one headache specialist for our entire state. I don't know if I can tell you my state, but we have an estimated 200,000 people living with migraine. That's one headache provider, so **[Participant 3]**, keep going. We need them trained.

01:12:59

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

We're trying, I promise. One other thing that I wanted to add, **[Moderator]**, to your question about the effectiveness of certain meds is [that] every migraine attack is different from person to person. But even within a person, you can have multiple different attacks. One attack might not look the same, and the therapies and the treatment options may have worked for one attack that you have, but not another. And CGRPs have had effectiveness, but this is adding another layer to that to help patients who are so severely disabled.

01:13:43

Moderator, RTI International

Thank you, and I know **[Participant 6]** and **[Participant 3]**, and I think, **[Participant 2]**, you mentioned we have all these medication, we have these existing medications, but they're not enough. Is there anything else in that “not enough” category that we haven’t discussed?

01:13:58

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

I would add, there's not enough understanding. Our organization puts [on] races all around the country to bring more awareness to the disability that migraine causes. Our patient advocates have a really hard time fundraising. You know why? Because they say, “I'm fundraising for migraine, I'm going to a walk-run for migraine," and people are like, "Migraine? I get headaches, too." So, the stigma that our patients are facing, I'm used to it, I can handle it, but we did a research project on stigma that patients were facing, and what we did not know in this community is the amount of internalized stigma that our patients are facing when they go to advocate, even at their clinicians—we don't even have enough clinicians that understand the complexity of headache diseases—so they're left to not talk about their disease. We already know that there are millions of people who are undiagnosed, who are using OTC [over-the-counter] medications that actually can make them worse, but they don't know that because they're not looking into this on their own. We need more treatments, we need more understanding that this is a very serious neurologic disease. It is the most disabling disease in the world for people under the age of 50. Why is it that we don't have more treatments? I can tell you why. Because it mostly affects women. And so, we get a drop of research relative to the disability. The drop of research we get from the NIH [National Institutes of Health] budget is not in line with how much disability this disease causes. We need more research, more treatments, and we need less stigma [so] people finally understand, oh yeah, migraine is serious, my friend **[Participant 6]**, her daughter had to drop out of high school, and you know what? She had to give her mom injections of opioids when she was 16 years old, and a doctor had to show her how to do that. Who has to do this? This should not be happening. I think we have a long way to go, so I appreciate you asking this question.

01:16:24

Moderator, RTI International

Are there any other gaps in treatment or concerns that remain despite what is available?

01:16:31

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

I think one gap, if we take the ideal for somebody who's chronic, is to really look at your preventative plan, and what gap we create if we're not giving people what they need—for this purpose, Botox—then you're going to increase the amount of abortive medications they're going to take. There's going to be a greater burden on the workforce. We start seeing all of those things affect every other area of life. The question is, why not get this down? And if we know that it helps and can alleviate some of the other medications necessary, it just seems ridiculous not to think it's a good idea to keep. We need to keep what works.

01:17:10

Moderator, RTI International

Anyone else want to talk about gaps or observations they've had with themselves or the patients that you advocate for?

01:17:19

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

In terms of not enough, I'd say there's not enough mental health recognition. Like we talk about a lot, people living with migraine are more likely to have anxiety and depression. And we say that, but as far as how did they get treated, how much does this impact their quality of life, how much does this impact their ability to work, and that extra burden of having these mental health conditions on top of all the other physical issues that go along with migraine.

01:17:47

Moderator, RTI International

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

01:17:50

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

I would also say a gap, we've talked about the lack of headache specialists, but also just education on the primary care level, where folks are initially going. If there's more education on that front, and getting them started on something earlier, and trying different medications, starting to go through the process of step therapy, there could be less progression, there could be less disability in your lifetime. But it does start at that primary care office, unfortunately, and right now, our understanding is it's about two to three hours of training in headache medicine in med school, and so any support on that end, and even getting people started on something, I think then you can see the efficacy of what works and what doesn't work, but right now, we're not even there.

01:18:45

Participant 1 (registered as a patient)

I think we also need to address medication overuse, because if you're not being treated properly, and you start taking whatever is available over-the-counter because you're so desperate and in so much pain, this can lead to other worse things instead of being treated properly.

01:19:13

Moderator, RTI International

All right, those are wrapping up the questions, but before we part ways, I wanted to give everyone an opportunity to summarize your thoughts on the importance of Botox for patients, or to raise any other topics that you feel that we didn't have a chance to discuss or didn't come up today. So, final question, do you have any final thoughts on Botox, conditions treated by Botox, or other medications that treat chronic migraine that are important to share with CMS? **[Participant 1]**, I'll go ahead and give it to you since you've just come off, but I'll make sure to cover everybody.

01:19:45

Participant 1 (registered as a patient)

Okay, for me, Botox and the combination with the VYEPTI® has been life-changing because going from two years ago—and I've always had episodic, worse, better, for my whole life. But for me, Botox and the combination has been life-changing. And I really would hope that it keeps being available, especially for me as a Medicare patient, because it's really helping me a lot to live and to enjoy life.

01:20:23

Moderator, RTI International

Good. Thank you, **[Participant 1]**. Would someone else like to have any closing thoughts or something they would like to add to the conversation?

01:20:33

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

I'll go next. I just, again, want to thank you for the opportunity to be here this afternoon. I just would ask that CMS recognize that chronic migraine is a disabling neurologic disease, and that we preserve access to Botox for the patients who rely on it. I think that for many patients, in my experience, both personally and through the organization that I work for, Botox is not elective, it's not interchangeable. It's really a preventive treatment that reduces headache days enough to give many patients the ability to work, be caregivers, and have back as much of a normal daily life as they can with this disease. And again, thank you so much for having us on here and let us give our input.

01:21:36

Moderator, RTI International

Thank you, **[Participant 5]**. **[Participant 6]**, I remember at the beginning of the call, you said you had some other patient experiences you wanted to share, if you want to share them here or send them to the mailbox if it's a longer list.

01:21:50

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

I actually, yeah, I emailed them.

01:21:53

Moderator, RTI International

Oh, fantastic.

01:21:54

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

Because I do have some patients on Medicare right now. You know, I would also add, and I echo everything that was just said, and again, thank you for spending this much time with us, it's invaluable. I want to say that the burden that patients are already experiencing getting appointments [the] first time, even when they have to go to a headache specialist, is overwhelming. We don't have enough doctors. The wait times are too long. It's making people revert from episodic to chronic. To take away another therapy, and then to put the burden also on clinicians, not just patients, but the inability then to want to prescribe these drugs, is going to have a huge effect on our community, and it just scares me.

There's not a lot of procedures that neurologists do to begin with. They're one of the lower-paid clinicians in the medical field. And I know because my daughter's a dermatologist, she makes a lot more money than her neurology friends do. I know they're not in it for the money, but I'm just saying, the academic institutions are going to look at that and say, we can't do this because we'll lose money if you reduce the cost. Hopefully they'll take this into consideration and understand it's going to affect millions and millions of people. It's not a rare disease, I will say that.

01:23:46

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

Absolutely, **[Participant 6]**. And I think it comes down to what's most important and where do we want to spend our money. If Medicare pulls Botox, then I would say be prepared for a lot more abortive medications to be filled. Be prepared, potentially, for that medication overuse headache because every day you're in pain, sometimes it's a game, or you're trying to rotate medications so that you don't have that, but that's a lot to put in a patient's hands who is debilitated due to this disease. My hope is that we can keep what's working for people because that makes the most sense and continue the research as well. Thank you again for this opportunity.

01:24:25

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

Yeah, and **[Moderator]**, just to be clear, medication overuse is a condition when patients are taking too many abortives. That's what drives the health care system higher in reimbursements because that drives a patient into the ER and into an inpatient status.

01:24:45

Moderator, RTI International

Thank you, **[Participant 6]**, for that clarification. **[Participant 2]** or **[Participant 3]**, is there anything that you wanted to add to close us out?

01:24:53

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

I just would like to thank you for putting this on and for listening to us. I would just reiterate that access to Botox is critical. It's been life-changing for me, and I know many, many other people it's been life-changing for. Just to summarize what we have said before, having access to Botox not only is your quality of life, being able to work, spend time with family, caregive, but also the financial aspect of not having access to it, resulting in ER visits, medication overuse accessing more of the urgent care. There's just a lot of different aspects, and so many reasons to keep it accessible.

01:25:34

Moderator, RTI International

Yeah. And **[Participant 3]**, would you like to close this out?

01:25:38

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

Yeah, absolutely. I echo everything that fellow patient advocates have said. They said it so eloquently, so thank you for the ability for us to be able to speak to you. I guess I would like to say that when looking at the statistics, really thinking about each individual person that's impacted, yes, we talked a lot about symptoms and pain, but one of the first things that we all talked about was being able to get back to your life, and having a full, rich life. And, to end on a patient story, another patient that I spoke with yesterday was talking about how if she didn't have Botox, she didn't know if she was willing to be open to having a family and having kids. These are very real decisions that people have to make on their life, on their jobs, based off of their capacity to do things because of such a highly disabling disease. And the access to Botox is critical for functioning, so if someone is actively using it, they could have a totally different trajectory of their life, their economic impacts, financial impacts, but that individual impact for one person to be able to go dress shopping with your sister, to be able to go to your kid's school performance, to go and be able to start a family without the anxiety of thinking if you could handle it. Those are all the real people impacted by it, so we're so grateful for being able to speak on behalf of all of those folks.

Closing Remarks

01:27:17

Moderator, RTI International

You all have thanked me, but I think I really need to be thanking all of you for coming and participating in today's events and trusting us with your stories and experiences. I appreciate you taking the time to talk with us today, and your input was extremely valuable and will help inform CMS' negotiations for Medicare pricing for Botox. CMS staff have been listening today to the roundtable and will be able to take your perspectives and what you shared back to their teams. I think CMS folks have some closing remarks.

01:27:51

CMS Staff

Yes, I just want to take a moment to thank you all so much for sharing your experiences and your knowledge with us today. This has been such a rich discussion, and you've just given us a lot to think about and consider, and I just want to emphasize how grateful we are for your participation today, so thank you.

01:28:11

Moderator, RTI International

Great. In closing, if you have any questions or something you wanted to add but didn't have the opportunity to share today, you can submit them to the mailbox at IRARebateAndNegotiation@cms.hhs.gov with the subject line “Public Engagement Events.” Thank you, everyone, for being here and giving us an hour and a half of your day today. And you all take good care.

===== END OF TRANSCRIPT =====

For a list of the drugs selected for the current cycle of the Medicare Drug Price Negotiation Program, click on the following link: https://www.cms.gov/files/document/factsheet-medicare-negotiation-selected-drug-list-ipay-2028.pdf

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

Appendix

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

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 health care provider
No	You, your spouse, or an immediate family member is employed by or holds equity interest (stock or ownership interest) in excess of $10,000 in a company or related association with direct or indirect interest in the Negotiation Program
No	Any other personal or professional relationship or interaction with a company or related association with direct or indirect interest in the Negotiation Program that may be considered a financial conflict of interest

Participant 2: Registered as a patient who has experience with the selected drug or the conditions treated by the selected drug; 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 3: Registered as a patient who has experience with the selected drug and other treatment(s) or drug(s) similar to the selected drug for those conditions; 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	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 4: Registered as a patient who has experience with the selected drug, the conditions treated by the selected drug, or other treatment(s) or drug(s) similar to the selected drug for those conditions; representative of a patient advocacy organization

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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Participant 5: Registered as a representative of a patient advocacy organization

Declared Conflicts of Interest	
No	Receipt of financial payments (e.g., gifts, funding, research support, honoraria, travel, or other expenses) from a company with direct/indirect interest in the Negotiation Program, in excess of $10,000 by you, your spouse, or an immediate family member
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Participant 6: Registered as a patient who has experience with the selected drug or the conditions treated by the selected drug; 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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