

This transcript was lightly edited for readability.

Introductory Remarks

00:00:04

Moderator, RTI International

Welcome everyone, and thank you for coming today. Hi, I'm **[MODERATOR]** from RTI International, and I also want to introduce my colleague, **[SECONDARY MODERATOR]**, who you will hear from through a few points throughout the discussion today.

The Centers for Medicare & Medicaid Services, or CMS, is convening this patient-focused, roundtable event and others as part of the Medicaid Drug Price Negotiation Program. And the purpose of today's event is to hear from you all. And this group includes patients, caregivers, and patient advocates, and we want to learn your experiences with the conditions and diseases treated by Breo Ellipta, so asthma and COPD [chronic obstructive pulmonary disease]; your experiences with Breo Ellipta itself; as well as other medications for the same condition.

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

Now, CMS may use this information in negotiating Medicare pricing with the manufacturers of the selected drugs, and so your experiences and perspectives are very important to us. And we genuinely appreciate your time today. So, we have a brief video from CMS leadership so that you can hear from them about how much they value your time and input from this afternoon. All right. So, go to the video.

CMS Remarks

00:01:58

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.

00:03:35

Moderator, RTI International

Thank you. So, I also want to make folks aware that staff from CMS will be sitting in on this event this afternoon, so that they can hear your experiences and opinions directly from you. Let me hand it to them for just a moment, so that they can say hello. So, I think, **[CMS STAFF]**, you're greeting from CMS.

00:03:53

CMS Staff

Yes, hello, everyone. I am a member of the CMS Medicare Drug Pricing Negotiation Team, and we have a couple of other members from the team on this roundtable discussion as well. But we're going to stay off camera and kind of stay silent and listen to just the discussion going on. We will be here during the whole session, but we just kind of want to take a step back and listen in and let the discussion be fruitful, so thank you for having us. Thank you for being here.

Housekeeping

00:04:21

Moderator, RTI International

Well, thank you so much. So, before we begin, I want to review some housekeeping items and some ground rules, so folks know what to expect. First, participation. We hope that you will contribute your perspectives throughout the session. However, if there are questions you don't want to answer, that's totally fine.

Background. Please minimize background noise by finding a quiet location from other people and distractions. If you haven't already, please silence your cell phone or other devices, and please mute yourself when you're not speaking.

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

We are audio and video recording today. But these recordings will not be shared publicly. Following the event, CMS will prepare transcripts that have participant names and identifying information removed, and these will be available to the public.

I also want to highlight a few things to keep in mind for discussion. Thank you in advance for keeping your video on throughout the discussion. It helps with engagement. Timing. This session will last about 1 hour and 30 minutes. I have a discussion guide in front of me to help keep us on track. We

do have a lot of topics to cover, so I may need to redirect our conversation or cut a conversation short at times, just to make sure that we can cover everything.

And then technical assistance. If you get disconnected, just go ahead and try to rejoin. If you can't connect, please reach out to the mailbox you see here on the screen, the IRADAPSTechSupport@telligen.com.

And a break. If you need to step away briefly during our discussion, that's okay. Just turn your camera off and turn your microphone off and rejoin when you're able to. You don't need to tell me or tell **[SECONDARY MODERATOR]** that you'll be away from your computer. Just return to the discussion when you're able to.

And speaking. Please try to speak one at a time. I may occasionally interrupt you when two or more people are speaking, in order to make sure everyone has a chance to be heard, and that we can accurately record what folks are saying. If you need to, please feel free to use the raised hand function in Zoom. If you want to take a moment and find that function, please do so and see how it works. I'll give folks a second to do that.

This will help us know when someone would like to add to the discussion. Oh, **[Participant 3]**'s our test case. Thank you, **[Participant 3]**. This will help us know when someone would like to add to the discussion. You can also use the chat function to add comments into the discussion.

And finally, honest opinions. Everyone's opinions and experiences will differ, and we want to know what each of you honestly thinks about the topics that we discuss.

So with all of our housekeeping wrapped up, does anyone have any questions before we get underway?

Okay, then let's go ahead and get started. I would like to begin our discussion by asking each of you to introduce yourself. So, please take about 30 seconds and say your first name, the condition or conditions that Breo Ellipta treats that you have experience with or your loved one has experience with, and whether you will be sharing the personal experiences of yourself, those of a loved one, or whether you are sharing patient experiences from the perspectives of a patient advocate organization. All right. So, it looks like **[Participant 1]**, you're the first one on my screen. Do you mind kicking us off?

Discussion

00:08:14

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

Thank you. My name is **[Participant 1]**. I am here on behalf of a patient advocacy organization representing older adults. And that's really it. Thank you.

00:08:25

Moderator, RTI International

Okay, thank you, **[Participant 1]**. **[Participant 2]**, it looks like you're next on my screen.

00:08:32

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

Hi! My name is **[Participant 2]**. I am here today. I do represent a patient advocacy organization, but I'm here today representing my mother-in-law, who I was a caregiver for, who had COPD.

00:08:44

Moderator, RTI International

Thank you, **[Participant 2]**. And **[Participant 3]**, you're appearing next. So, if would you mind introducing yourself?

00:08:50

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

Hi, I'm **[Participant 3]**, **[REDACTED]** of Asthma Allergy Network, and I'm here as a patient advocacy organization representing a patient advocacy organization.

00:09:03

Moderator, RTI International

Thank you, **[Participant 3]**. And **[Participant 4]**, you look like you're next.

00:09:09

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

Hi, everyone! I'm **[Participant 4]**. I am coming today as a patient advocate, but also as a caregiver for multiple people in my family living with asthma and COPD over the last 25 years and have extensive personal experience with Breo.

00:09:24

Moderator, RTI International

Great. Thank you. **[Participant 5]**, you're next on my screen.

00:09:29

Participant 5 (registered as a patient)

Hi! I'm **[Participant 5]**. I have a few hats here, so I am a patient with asthma and take Breo myself. I also have been a caregiver for my now adult children, who both have asthma and also as a patient advocate.

00:09:44

Moderator, RTI International

Thank you, **[Participant 5]**. And **[Participant 6]**, how about you?

00:09:48

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

Hi, everyone. I'm **[Participant 6]** with the Asthma and Allergy Foundation of America. So, I am representing a patient advocacy organization.

00:09:57

Moderator, RTI International

Thank you, [Participant 6]. And it looks like [Participant 7], you may be our last one. Yes.

00:10:03

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

Hi, I'm [Participant 7] and I have asthma, but today I'm representing a patient advocacy organization.

00:10:14

Moderator, RTI International

Fantastic. Thank you, everyone. So, now that you've introduced yourself verbally, and I would like for you to use the chat feature to share some additional information that will be helpful for us to know. Have you or your loved one taken Breo Ellipta, whether currently or in the past? And please enter your responses in the chat.

So that would be for folks who are patients and caregivers primarily.

Okay, thank you. All right. Fantastic. Thank you everyone for using the chat. So, I think we are well underway. So, thanks for taking the time to introduce yourself and your experiences you'll be drawing from today. So, I'd like to start by talking about either yourself, your loved ones, or a patient's experience with the conditions treated by Breo Ellipta. There will be a lot to talk about with this question, so feel free to raise your hand, to share briefly or add comments to the chat throughout.

Because Breo Ellipta treats multiple conditions, I have a set of questions that I'm going to start with by asking about asthma, and then I'll do the same set of questions for COPD. So, I'd like to start with asthma. And first question is, in general, how does asthma affect you or your loved ones' or patients' day-to-day life?

And anyone can speak up.

00:11:49

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

Well, I'll pop in real quick. So...

00:11:51

Moderator, RTI International

Yes.

00:11:52

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

I actually represent an organization serving people with rare disease. So, people with EGPA [eosinophilic granulomatosis with polyangiitis], 99% of us have asthma. And, so asthma impacts people with this disease specifically in that it impacts their ability to even do everyday activities like grocery shopping. You know, grocery shopping becomes nearly impossible because of getting out of breath. I mean, that's kind of on one end of it. On the other end of it is it can result in pneumonia that lands them in the emergency room and hospitalized.

00:12:43

Moderator, RTI International

How about others? I think, **[Participant 5]**, you mentioned having experience with asthma for yourself and your children.

00:12:51

Participant 5 (registered as a patient)

Yeah, so I have what is termed as moderate, persistent asthma. So, I have asthma symptoms all the time. It's just worse at times than others, so you know it becomes very disruptive to have symptoms, even if it's like coughing, to be somewhere and you're coughing, right? So being able to control those symptoms prophylactically with the inhalers and other treatments is very important, so that you can go about your life as normally as possible and not be sitting on the sidelines, and worrying. Am I going to be able to do this? Am I going to be okay? Am I going to be able to walk to wherever or play with my kids, etc.?

00:13:45

Moderator, RTI International

How about others? Does anyone else have either personal experience or caregiver experience or patient advocate experience with asthma and want to comment on how it affects folks' lives?

00:13:56

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

Sure I'll jump in here. So, again, I represent a patient advocacy organization, and several years ago we actually did a survey called 'my life with asthma' to essentially answer this question. You know, how does asthma affect your daily life?

And some of the key findings were 97% reported that asthma limits their everyday tasks. So, really echoing what **[Participant 7]** mentioned. It also affects personal relationships. Seventy-eight percent, it's always on the back of your mind. It negatively impacts your emotional health.

We, you know, had about half of them say they're having symptoms more than once every day, and these to be clear, these were patients with more severe asthma. And probably the number one thing that we hear about, too, is the inability to afford their medication, which I know is partially why we're here today. So, I think it is really important to understand that asthma does impact people's lives so greatly. And there are good medications really play an important role in managing that asthma. So, I'll let **[Participant 3]** take over from here.

00:15:14

Moderator, RTI International

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

00:15:16

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

I know there's a few of us on here that could piggyback on each other. So, let's see.

So yeah, I was a mom of an adult child with asthma. So, I lived with it every day, but really a couple of points to add to what **[Participant 6]** and **[Participant 5]** have said, are the fact that there's

different asthma severities. So, people who have very mild asthma will have little impact, perhaps, on their quality of life or their day-to-day living, whereas people with some severe asthma or more moderate and severe asthma are going to be more greatly affected by it. I do want to make that point.

And then the other thing is that typically asthma is controlled in stepwise fashion, meaning that there's rescue or quick relief inhalers that are used that people usually carry with them all the time, and then there's maintenance inhalers that usually contain inhaled steroid to control inflammation so that people don't develop symptoms or exacerbation. So, it's important to be able to have both on hand for people. And it's very important for people who need the inflammatory controller medications that they don't rely on their quick relief inhaler because it doesn't control inflammation.

00:16:36

Moderator, RTI International

Thank you, **[Participant 3]**. It looks like **[Participant 4]**, you wanted to weigh in as well.

00:16:40

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

Yeah, I would just add, maybe a couple of things that I agree that there are different severities of asthma. And yet what we know is that across the board mild, moderate, and severe, over half of people are uncontrolled. And people normalize, adapt. They live lesser than, their lives sort of shrink over time as their disease gets worse, or as they're more uncontrolled.

And then the deaths, the mortality due to asthma is actually equal across all of those severities. So, I think that often surprises people. And in my own experience I know we've had some challenging times at different transitions of life, of, you know, realizing asthma is a chronic condition and needs to be treated as such, because many people see it more like intermittently, even at the moderate level. They think, well, I'm not as bad as, or I have good days or, like I said, they just normalize and adapt. So, I think my experience with my loved ones is that there's ebbs and flows in their asthma control. It's still a very unpredictable disease at times, and especially if one is not fully adherent or compliant with their baseline maintenance medication.

00:18:01

Moderator, RTI International

Oh, and **[Participant 1]**, it looks like you, we'll go with **[Participant 1]**. And then **[Participant 2]**. So, **[Participant 1]**?

00:18:05

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

Yeah, I just want to note that a very recent real-world evidence study, published in the January 2025 issue of the *Journal of Pulmonary Therapy*, and they looked at more than 15,000 older adults, and found that their asthma without COPD is often not well controlled with rescue inhalers alone. But these combination therapies that we're discussing today really help particularly older adults, not only manage their daily condition, but it also helps to give them the right dosage at the right amount at the right time, and make sure that they're not trying to make combinations on their own. It's just really very valuable for them to have these combination medications for basic maintenance of their condition. Thanks.

00:19:06

Moderator, RTI International

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

00:19:09

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

I just wanted to echo some of what **[Participant 4]** said, just as real-world experience, because I have asthma myself, and I have the mild asthma. So, I'm one of the worst offenders of, oh, this works great, and I'm just gonna have my rescue inhaler in every drawer, and I'll go get that when I need it, because I hardly ever have any attacks. And now I'm actually on a maintenance medication very similar to Breo Ellipta. It's not Breo Ellipta, but it's very similar. And all those inhalers still sit in those drawers, and it's probably been five or six years since I've even looked at one, just having my medication, and I don't really notice it because mine is really mild, but I do know from experience that if I go off of it I'll be back in that situation again, where I'm just at every drawer like all the time. So, I just wanted to, cause I have that experience.

00:19:56

Moderator, RTI International

Every drawer all the time. All right. So, I have one more question related to asthma, and then we'll do the same set of questions for COPD. What aspects of asthma are most important to you or your loved ones or patients to have treated or managed?

So what aspects of asthma are most important to you, your loved ones or patients to have managed or treated?

Yeah **[Participant 4]**, I was actually thinking, you would have some good...

00:20:29

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

Well, it has always been nighttime coughs. That is the thing that is most disruptive, that interrupts sleep. And then, unfortunately, my son would not, you know, perform well in school, and all of that as a result of that nighttime cough. So, I think that that's the most troublesome.

But we definitely hear a shortness of breath and the coughing, wheezing, all of those, even in daytime symptoms as well. But if I had to name one that has been most problematic in our experience, it's definitely that nighttime cough.

00:21:05

Moderator, RTI International

That's familiar.

How about others? Anyone else want to comment on the most important symptoms to have managed or treated?

00:21:13

Participant 5 (registered as a patient)

So, uh...

00:21:13

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

For me it is definitely short, oh...

00:21:16

Moderator, RTI International

Go ahead, **[Participant 5]**, and then we'll get to **[Participant 2]**.

00:21:19

Participant 5 (registered as a patient)

Sorry, definitely the nighttime cough is for me. But I do remember when my kids were little, it was just their ability to participate in sports, play with their friends, recess and stuff like that. So, it was just kind of that shortness of breath. I don't feel well. It was distracting for school because they'd be coughing, or they'd get sent to the nurse to get checked out to make sure that they're not sick. So, a lot of those kind of just the annoying symptoms.

00:21:52

Moderator, RTI International

Yeah.

00:21:53

Participant 5 (registered as a patient)

Was what we dealt with.

00:21:56

Moderator, RTI International

A thousand cuts. **[Participant 2]**, please.

00:21:59

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

Mine was definitely shortness of breath. My asthma was diagnosed actually in cold weather, the first time I ever moved from **[REDACTED]** to really cold, snowy weather, and that was debilitating for me. I just remember walking through a snowstorm, and for the first time, being short of breath and had to be rushed to the... You know, so that's always been the biggest issue for me.

00:22:23

Moderator, RTI International

All right, **[Participant 7]**. I see your hand up. Thank you.

00:22:26

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

Yeah, I would definitely echo what people said about the shortness of breath. For the people that we work with, the asthma shortness of breath is probably the most impactful and challenging part. And then tied to that, and I think **[Participant 5]** mentioned this, tied to that is the impact that the shortness of breath has on the ability to just do your everyday ADLs [activities of daily living]. People talking about, I can't, I don't even have the energy to shower. I don't even have the ability to, because shortness of breath takes so much energy away, I don't have the ability to make myself lunch. So, those really basic things that I think we take for granted so easily, if we can breathe, are really the things that are the most problematic, and say emotionally painful for people. I would echo that personally, too. But that's what we hear from the people that we serve.

00:23:43

Moderator, RTI International

Thank you, **[Participant 7]**, for sharing that. I could hear it in your in your heart and voice.

So, thank you for sharing about asthma. I'd like to circle back for COPD if there's folks who can comment on the experience from the perspective of COPD. So, in general, how does COPD affect either yours, your loved ones, or the patients that you work with, their day-to-day life and experiences?

00:24:13

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

I'll start if you want.

00:24:15

Moderator, RTI International

Yes, please, **[Participant 2]**.

00:24:17

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

My mother-in-law lived with us. She just passed away in January, but she lived with us for six years, and she didn't have asthma or COPD when she moved in with us. It was something that developed when she was in her eighties, and I have to say the most debilitating thing initially of the COPD was getting actually the right diagnosis.

We went through nine million things before we finally settled on what in the world she had. First it was regular asthma. They had her on all these inhalers that weren't really working, and it didn't really treat her underlying condition. And so the initial phase... and then it was getting through the phase of wow, she's wheezing all the time and getting that under control. And the coughing all the time, oh, the coughing and just getting that whole thing under control was so hard, and especially at her age, because she had never experienced this before, or had it so that was our initial experience with COPD was just getting told, knowing we what we had to work with, what we were dealing with.

00:25:21

Moderator, RTI International

How did you finally get that diagnosis and get the condition managed?

00:25:26

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

Well, it was several doctors, it was a whole process. So, finally we went to a, so somebody kept saying she had asthma. They were treating asthma and treating asthma, one of her doctors, and she was also very stubborn, and so I didn't really start taking over her care until she had a stroke fully. She didn't let me until like last year right before she had her first stroke. But she... We finally got a doctor who was like, oh, you don't have asthma.

00:25:53

Moderator, RTI International

Wow!

00:25:54

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

Oh, yeah, no. He looked at the thing, he just like, so it was a doctor right in the same area, I mean, he, we finally went to another one, and he was just really run of the mill, and he took her off all the stuff she was on, and was like, no, no, you just need to do this. And the first medication they gave us was like, it was a complete, it was really difficult to do, and neither she nor I could, I was like this is not working because I can't get this in her on a daily basis, like we can't figure this contraption out. And so, I know we'll get to more conversations about that later. But we did finally get the right diagnosis, and we did get it under control for that with just a second opinion, I guess.

00:26:35

Moderator, RTI International

Thank you for mentioning that ease of use, because we definitely will be circling back to that, **[Participant 4]**. Thank you so much for...

00:26:43

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

Yeah, this is a journey that no one ever chooses, to be honest. I've been on it for 10 years with a dear woman that I lived with part time, and now I still go as her caregiver one week out of the month, and stay and support her 10 years into the journey, and she's now in hospice palliative care with late-stage COPD. And then both of my parents have been diagnosed with COPD, my mom about seven years ago and my dad in the last year. And I would echo what **[Participant 2]** said. It took us, even as an advocate in the space, even knowing what we were dealing with, they live in rural America without the best health care. They have other comorbidities, and it took us years and multiple providers before we got that accurate diagnosis.

And then it has taken us even longer to get on medication that's actually controlling the symptoms and the slowing the progression of disease.

I think, so that diagnosis and treatment journey is very hard to see someone that you love in their life just continue to shrink and shrink and shrink from a very full, active ability to function and be a part of their family and society in those golden years to being sitting on the couch, and really, very limited in their life. And then, unfortunately, in the case, like I said, with [REDACTED], my friend, she's now oxygen-dependent. She can't leave her apartment. And so, the lack of independence, and how that has impacted other aspects of her health and her mental health, her financial well-being, I mean, every single bit of her nest egg has been sucked away from her out-of-pocket expense, even though she is a Medicare recipient.

And same thing with my parents. You know, you've got multiple comorbidities with multiple drugs, each of them costing on average, close to a hundred dollars out-of-pocket a month on a fixed income. And so, the financial burden of COPD and it's, sister diseases that it tends to run in comorbidities with, it's just really unfortunate.

And then the final thing I'll say, is the stigma around this disease. Everyone thinks this is a smoker's disease. Two of the three people I'm talking about never smoked, never, no smoking history. And yet the very first thing that is asked every single visit is, do you smoke? And they've had the conversation with their primary care and their pulmonologist. No, don't smoke, didn't smoke, but there is still that belief, unfortunately, that this is a smoker's disease, and somehow that therefore someone brought it upon themselves.

00:29:42

Moderator, RTI International

Yeah, thank you for bringing that into the discussion. So, last question, and then we'll move on to another set of questions. Same thing, what aspects of COPD are most important to you, your loved ones, patients that you work with, to have managed or treated?

00:30:06

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

I'll just add, just trying to prevent exacerbations is just so important for this population. There's a lot of poor outcomes when people start to have exacerbations. And just a comment on [Participant 4] mentioning about oxygen, the risk of being on oxygen that actually adds additional challenges. Although my mother didn't have COPD, she was on oxygen at the end of her life, and she died really because she tripped over her oxygen cord and had a broken hip as a result of it. So, just the activities of daily living when you're challenged with not being able to breathe properly and being on oxygen are just real challenges for this population.

00:30:53

Moderator, RTI International

Thank you everyone for bringing in these different perspectives and the complexity of what we're talking about here today. So, [SECONDARY MODERATOR], before I move on, did any other questions come up for others?

00:31:06

Secondary Moderator, RTI International

No other...

00:31:06

Moderator, RTI International

Did I miss anything?

00:31:07

Secondary Moderator, RTI International

That's all. Thanks, **[MODERATOR]**.

00:31:08

Moderator, RTI International

Thank you. All right. So, thank you for sharing your experiences. Now I want to talk about your experiences with Breo Ellipta itself. In addition to Breo itself, I would like to also hear about any experiences you've had with other medications, for example, like Symbicort, which is also part of one of the options for asthma and COPD. For those folks on the phone, we sometimes refer to these drugs used to create, to treat the same conditions or the same set of symptoms as therapeutic alternatives. So, if you hear me say therapeutic alternatives, basically just saying other drugs to use to treat the same conditions or symptoms.

Okay, so again, we'll have the questions for asthma and for COPD. And so, when considering potential medications for asthma, what matters most to you or your loved ones or the patients you've served? And go ahead, **[Participant 5]**. Looks like you're [the] first hands up.

00:32:14

Participant 5 (registered as a patient)

So, for me, it's side effects, because that was how I wound up on Breo, because we were going through all of the other therapeutic alternatives, and I wound up trying one that I hadn't tried before, still wasn't getting the asthma relief, but it was causing issues with my vocal cords, and it was the type of inhaled corticosteroid, like the class of that, that was known to kind of irritate vocal cords, and I picked the short straw and had that side effect. So, we had to jump through a whole bunch of hoops to get Breo approved. And then, you know, because it was new, it was not on formulary. It had the copay card, but then, when they stopped the copay card, then we had to go through all of that again to try and get it approved. So, for me, it's the side effects. And being able to really just find the one that works and doesn't create more problems than it's trying to solve.

00:33:24

Moderator, RTI International

Okay, thank you, **[Participant 5]**. **[Participant 3]**, looks like you wanted to chime in next.

00:33:29

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

I spoke with a number of patients who were on Breo in anticipation of this call, and the overriding thing was similar to what **[Participant 5]** was saying. That is, being able to afford the medication that works best for you. And if Breo is that drug, to be able to afford Breo.

I spoke with patients who really wanted to be on Breo, but it was so cost prohibitive that they couldn't, and they were on another choice, like Symbicort, that worked, but not as well as Breo did.

So, the important message that I was hearing repeatedly was that even though they might be therapeutically equivalent, they may not work exactly the best for each patient, and so patients need to have the choice of being able to afford and obtain the medication that works best for them.

00:34:21

Moderator, RTI International

And **[Participant 3]**, if you wouldn't mind saying, and kind of unpacking that 'what works best' for you or for the patients that you spoke with? Was it like ease of use? Is it clinically effective? What does that mean to them?

00:34:33

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

Yeah, it was clinical effectiveness and being able to control their symptoms so they could lead the best life possible. That was the main overriding statement to me when I was talking with them. Also, the convenience of Breo being a combination inhaler, so they didn't have to use two separate inhalers, or they didn't have to use twice daily dosing, that was really attractive to a lot of them.

00:34:58

Moderator, RTI International

Great. Thank you for unpacking that a little bit for me. **[Participant 6]**, thank you.

00:35:04

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

Yeah, I was really just going to echo what **[Participant 3]** was mentioning and emphasizing that asthma is a heterogeneous disease, so exactly that. There are many different phenotypes. The way one medication works for one asthma patient is exactly that. That's the way it works for one asthma patient. So, ensuring that, even with the existence of therapeutic alternatives, patients need to be able to access the medication that works best for them. You know, as they work through this with their medical provider. And so really, ensuring that whatever comes out of this is not negatively impacting access issues, because ultimately access and affordability is the most important.

00:35:55

Moderator, RTI International

And before we move on, **[Participant 6]**, you had said that what comes out of this does not negatively affect access. Could you say a little bit more about what you mean?

00:36:04

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

Sure. So, one of the concerns that we have is simply that, the way our drug pricing system works, we know that all of the negotiated drugs must be covered. But where they're covered, those hoops that you may have to go through, where they're placed on formularies. I know that's not up to this part of CMS. But considering where MDBG [Medicare Drug Benefit and C&D Data Group] is looking at potential negative consequences of actually having a potentially cheaper alternative, but for whom? We want to make sure it's the patients who are experiencing the benefits of these negotiated prices.

00:36:49

Moderator, RTI International

Thank you, **[Participant 6]**. **[Participant 4]**, please go ahead. What matters most, for you or your loved ones, in terms when you're considering potential medications for asthma?

00:36:59

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

Well, I would echo a lot of what's already been said. But I think that there's a couple of things that are unique with Breo, specifically. As you said, that fixed dose combination of ICS [inhaled corticosteroid]/LABA [long-acting beta2-agonist] in a dry powder inhaler, that is unique. And there are some patients who prefer that dry powder inhaler, right? It's easier for them to take. On the other hand, there are others who can't take it, and who don't have the ability for the coordination difference that it takes between a pMDI [pressurized metered dose inhaler] versus a DPI [dry powdered inhaler].

The once daily dosing, a huge thing. The side effect profile has been a huge issue with my own loved ones. The out-of-pocket cost has been the major driver honestly, in both of the situations that I talked about earlier.

But the other thing I would say about the therapeutic alternative discussion, is that we know inhalers are not interchangeable. Right? So when we see someone, what we call 'non-medically switched,' right, forced to go from one inhaler to another without a medical reason, solely because of a formulary change, that adherence drops to that inhaler, and that, in fact, it takes greater than 30 min in a clinical encounter to retrain and effectively address why that switch is happening.

And so, I think that this notion of the interchangeability of inhalers a false idea, false concept that should not be touted or recommended by the decisions that CMS makes in this area.

00:38:49

Moderator, RTI International

Thank you. **[Participant 4]**.

We'll do... **[Participant 7]**, did you wanna weigh in? Okay, yeah, because I had you next. And then you've dropped from my screen. Please go ahead, **[Participant 7]**, and then we'll get to **[Participant 1]**.

00:38:59

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

Okay, thanks. I echo the interchangeability, that there is a perception of interchangeability, and absolutely, it is not interchangeable. For people with, you know the rare disease, EGPA, who have asthma, that asthma is so complicated, and being able to actually address the asthma and effectively manage that asthma becomes even more complicated. And so, Breo Ellipta is one of the few medications that overall, the patients who have this disease state is really, is really helpful in managing the everyday aspect of asthma. Part of it is, for whatever reason, it's the clinical effectiveness of it, it really does seem to help the shortness of breath. And of course, people with this disease end up taking usually an average of 15 to 22 medications a day to manage the disease. And so anytime there's any medication that reduces the number of doses that medication burden is really important. So, this being a once a day and being effective for the whole day, is significant.

And then I would say, too, that also makes it more able for people to, if they're going on vacation, if they're going traveling, there's less they have to deal with. The fact that it's a blended medication, but it has, a combination dual action is also really effective. People talk regularly about having to use their emergency inhaler much less when they have this. In fact, some of them have said they haven't used their emergency inhaler in years, because this is managing their medication so well.

Many of them do talk about the challenges of the prior authorizations, and or where they fit in the formulary. Quite a few people are not even offered this medication, even though it actually has been pretty effective for this population and the asthma within this population. They're not, unless they're at a center of excellence or someone who really understands asthma in a very deep manner, a lot of times, they're not even offered this medication. So, I think one of our biggest fears from a patient advocacy perspective is that that would drop even lower in terms of that being offered to patients. Because, you know, there's the challenges that are created, the unintended consequences that are created by having things taken off of formulary and or not available to patients, as we're seeing, with some sometimes depending on the Medicare negotiation. Yep, I think that's it.

00:42:16

Moderator, RTI International

There, and **[Participant 1]**, we'll let you close us off with this particular question.

00:42:20

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

Yeah, thank you. And I think I'm just echoing something that's already been stated several times. But number one, yes, totally agree that patients should have access to the drug that's right for them, that they and their health provider think is best for their particular situation. But I think ease of use, particularly with the medication that we're discussing today, is very, very important, particularly for older adults who may have multiple chronic conditions, who may be on other medications. It's very convenient not to have to combine other therapies that may be confusing, or people may not get right and not administered correctly, and therefore may not have the outcome that they desire.

That is the benefit of the combined therapy medication for those for which it's right. And then, additionally, since it's come up, we do have some concerns about the perverse incentives of the price negotiation process, and I believe, unintended consequences for plans to shift costs by putting these drugs on, just through utilization management, limiting access to these drugs by excluding them from formularies or requiring step therapy or prior authorization for their use. So, we know that CMS and appreciate that you haven't passed award some of these planned sponsors to ensure access and not place drugs on non-formulary tiers without clinical justification. We hope that you will take a hard look at that in this process, in this new cycle, and how you can crack down on that and certainly help provide some transparency around which drugs are being placed on formularies, so that people have that information and can respond accordingly. Thanks.

00:44:28

Moderator, RTI International

Thank you, **[Participant 1]**, all right. So, to keep us moving, because we're going through all these for COPD too, I wanted to kind of combine a question for those of you, or either through caregivers

or patient experience with Breo for asthma. What would you say are your benefits, and what are the drawbacks for Breo, for your asthma?

00:44:56

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

I'll speak up. So, I think benefit, again, the two in one, the ease of use. And drawback, definitely, the out-of-pocket cost. And again, I would say, just the benefit of the once daily dosing would be the other thing that definitely is important.

00:45:23

Moderator, RTI International

Anyone else want to weigh in on benefits or drawbacks and challenges for use of Breo that we hadn't discussed? **[Participant 3]**, go ahead, please.

00:45:31

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

I'll just mention that when I was speaking to one patient she brought to my attention that for someone who has arthritis that they might have more difficulty using Breo, as opposed to an HFA [inaudible] inhaler. So, I just wanted to mention that even though we're here for Breo, that some people may not be able to use that and might have to opt for something else.

00:45:56

Moderator, RTI International

Yeah, that sliding thing is that you're referring to on the inhaler. Yeah. And oh, some more hands. So, oh, **[Participant 3]**, are you? Did you wrap up? Could we go to **[Participant 5]**? Okay, thank you, **[Participant 5]**. Please go ahead.

00:46:11

Participant 5 (registered as a patient)

So, I would echo that some of the benefits are the one-time dosing. And that's really convenient. For people who do have a harder time breathing in, doing that kind of sharp inhale, the dry powder can be a hindrance for that, right? As opposed to a DPI with a chamber where you can just press it, and then breathe that as you can, although there is an arthritis and you know, grip strength issue with the MDIs as well.

00:44:47

Moderator, RTI International

Yeah, thank you for bringing that in, both **[Participant 3]** and **[Participant 5]**. **[Participant 7]**, looks like you had something to add for benefits or drawbacks.

00:46:56

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

I echo, of course, the same things about the once daily dosing. I think that, in terms of drawbacks, primarily is awareness. And again, I just want to bring up the potential unintended consequences as we look at moving forward with the negotiations. You know, I think the biggest drawback that we hear is just people aren't aware of it, which means their doctors, their local kind of community-

based pulmonologist is not aware of it as a treatment, a good treatment option for people with asthma related to EGPA, and so I would hate for that to fall even lower in the awareness as potential unintended consequences with utilization management.

00:47:43

Moderator, RTI International

Thank you. All right. So, now we'll go to the therapeutic alternatives. So, aside from Breo Ellipta, what medications, if any, have you or your loved ones taken, whether currently or in the past, to treat asthma. And **[Participant 2]**, I think you may have actually alluded to that a little earlier in your experience if you wouldn't mind kicking us off.

00:48:05

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

Yes, the initial asthma medication that was prescribed was actually a twice-a-day. This was for my mother-in-law, when she was thought to have had asthma. We ended up in COPD, but initially, for a long time she had asthma, and she went around telling everybody 'I can't believe I developed asthma at **[REDACTED]** years old,' but the initial asthma medication, first she couldn't use the contraption. She didn't have enough force to be able to put it all together and use it.

And then, the second asthma medication was a twice-a-day asthma medication, and like, my grandfather before her, if you can take something, if somebody tells you to take something twice a day, they may only take it once at that age, because they think they're saving money. You know what I mean? Like he would, there would be like a pill that he would have to take twice a day, and sometimes he would cut them in half, like my dad and I just used to be like, what are you doing? But it's the same thing with if, oh, I have, this is an expensive medication. I should probably only do it once a day. I'm feeling fine, so I think that's the issue. And getting to a once-a-day medication was great at her age that she could use by herself. I mean I was helping her. I make it sound... she was very stubborn, so I helped her whenever she would let me as much as she would let me. But yeah.

00:49:30

Moderator, RTI International

Thank you. **[Participant 4]**, how about you? You've noted a number of experiences with other therapeutic alternatives.

00:49:38

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

Yeah, I mean, I still say that probably the most used inhaler is albuterol. I mean, that's the reality, right? I wish that we were in a different day and time. But that's the truth, and even for my own loved ones, who still refuse to always accept that this is a chronic condition that you need to address both the broncho constriction and the inflammation, although I keep trying to educate them, and had that conversation. As far as other alternatives, Symbicort, Advair, you know, through the years those have been the standards of care and treatment options in asthma specifically. Maybe when we get to COPD I'll talk about other things.

00:50:23

Moderator, RTI International

Okay.

00:50:23

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

The other thing I'll say, you know, other alternative that I wish wasn't an alternative, but it's the reality is that some people manage just by systemic steroids. So, you know, when they have a flare they turn to a burst of systemic steroids and or whether that be oral or intravenous, and then they manage, and I use that term very loosely, manage their asthma in that really putting out the fire way.

00:50:58

Moderator, RTI International

Yeah, thank you for bringing that forward, **[Participant 4]**. And **[Participant 3]** looks like you'll wrap us up on that one.

00:51:05

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

Yeah. When I was talking to the patients about what they were using, it was Dulera, Advair, and Symbicort, especially the generics, Advair and Symbicort, because it was cheaper for them, especially if they were on Medicare. Again, they were all saying, it wasn't working as well as Breo, but that was what they could afford. So, that's what they were using.

00:51:29

Moderator, RTI International

Yeah. And, **[Participant 7]**, you're nodding, so go ahead and take it away.

00:51:33

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

Yeah. So, for the people that we serve, absolutely, the Symbicort and Advair are generally ones that are tried, and Spiriva also has come up occasionally. All three of those have been noted to be less effective with asthma if they have EGPA, and then I thought that was a great point about the systemic steroids.

The use of prednisone, I think, can be overutilized as a way to compensate when the inhaler is not working properly, and that's a whole other conversation, I know, but I think that that's a really important consideration, as you think about this, CMS thinks about this moving forward because there are clearly, really, really serious potential complications to overusing steroids. So, and I do believe that it's utilized frequently.

00:52:46

Moderator, RTI International

[Participant 3], did you have something to add? Okay, just very enthusiastic with the hands up. Okay, so I'm going to combine benefits of using these therapeutic alternatives and drawbacks. If anyone would like to comment on what are the benefits of using these other drugs, and what are the drawbacks? If any...

00:53:10

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

I mean, I would say, slightly redundant from what we've already said in that, for some people the pMDI is just easier to maneuver than DPI. So that's true. And then, for some people, for some reason, we don't really know why, their body responds better. And then, of course, the financial considerations that have already been outlined well, here. I think those are the pros and cons depending on which side of the coin you're on.

00:53:41

Moderator, RTI International

Yeah, anyone else want to add a benefit or a drawback to a therapeutic alternative?

00:53:49

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

I'm just gonna echo what **[Participant 4]** just said, which is, emphasizing that the benefits and drawbacks will be patient-specific. You know, depending.

00:54:00

Moderator, RTI International

Okay. All right. So, now we could go through all this for COPD. So, put your COPD hats on. So, when considering potential medications for COPD, what matters most to you, your loved ones, or the patients that you work with?

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

00:54:26

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

I would say, I think I've kind of already said this, but the number one issue obviously was getting it under control. But once it was, once we figured out that she had COPD, the most important thing became the cough. And because the cough was the scariest, especially at that age. For her, it was the wheezing. She hated the wheezing because we'd be sitting at dinner, and there would just be wheezing the whole time. So, those two things were the most prevalent, and the things that we worried about the most for her, and were the most important to her.

00:55:01

Moderator, RTI International

Thank you, **[Participant 2]**. And **[Participant 4]**, thank you.

Go ahead.

00:55:05

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

Yeah, I would say, I agree with what **[Participant 2]** said here and in the control of the cough, the sputum production. That's a big thing with my mom. I think the one that, again, slows the progression of disease, in having been in the journey for so long now, that is easy for them to use, is,

that they will use because of the mindset of how costly the medication is. I mean, I definitely can empathize with the thought of like taking half the dose because you think you're going to stretch it out longer. And you know, we've had those conversations. So, there's just a lot of things that I think play into both the reason why people take that medicine, and adhere in the way that there, it's prescribed versus perhaps some of the reasons why they don't.

00:56:07

Moderator, RTI International

Okay, thank you, **[Participant 2]**. So, we're going to have some deja vu here.

So, considering you, your loved ones or patients that you work with, the experience with Breo for COPD. What are the main benefits, and what are the main drawbacks that you've observed?

00:56:26

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

Once-daily-dosing, fixed combination, you know, it really is. And, and again, for some people the DPI is easier. It, it just is, so it works better.

00:56:40

Moderator, RTI International

Anyone else want to comment on COPD of benefits and drawbacks of Breo for COPD?

00:56:48

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

I mean that, I'll say that the biggest drawback which, I mean, it's somewhat echoing what some other people have said here, were, it was great, and she took it well, and it worked, and she was once a day, and all of those things. But the biggest issue was the inconsistency of whether or not it was going to be covered, and what the exact copay was gonna be, which I know isn't here today, but that, I have to echo that somewhat, because that was always, you think about this when we're talking about our loved ones and our own health. We look at our health as a continuum of beyond 12 months, and coverage looks at things in a 12-month cycle, and so that was always a little bit bumpy, was whether or not we were going to get the next dose or we were going to have to switch, and there was a switching which maybe I'll talk about later. But we did have to, and we ended up going back. But yeah.

00:57:42

Moderator, RTI International

Okay, that's very important. Thank you.

So, we talked about the Breo itself. So, turning to the therapeutic alternatives, what medications, if any, have you, your loved ones or patients that you work with used to treat COPD, whether it's currently or in the past?

So other medications that you've used.

00:58:08

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

Spiriva, Trelegy, some of the others. Yeah.

00:58:11

Moderator, RTI International

And **[Participant 2]**, did you have any other experiences with your mother-in-law's COPD? Other medications?

00:58:19

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

There was, I think, the other. There was another one called Atrovent, that we used. I can't remember the exact name, but she was on another one, too, that didn't work. We ended up switching to Breo Ellipta, and then she was... We had to go off of Breo Ellipta for a little bit, and we went on to, that's when we went on Symbicort. Symbicort did not work for her because of the twice a day thing like I said. She just didn't do it twice a day. I mean, she just didn't do it. So, we ended up back in the hospital at one point. So, those were the various ones that we were on.

00:58:57

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

I would also just remind us about the management of exacerbations, and COPD and echo the OCS [oral corticosteroids] concern and antibiotic use of in those exacerbation periods.

00:59:11

Moderator, RTI International

You want to say a little bit more about that, **[Participant 4]**?

00:59:14

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

Well, yes and no, because...

00:59:17

Moderator, RTI International

Okay.

00:59:18

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

For me to be honest, living with it, living this day in, day out, because we know that oftentimes OCS do not work for COPD patients if they don't have that eosinophilic phenotype. And yet they're prescribed. If you're having an exacerbation, you're going to get more times than not antibiotic and a burst of steroids, and there seems to be no concern for the side effect profile that **[Participant 7]** was talking about before, and I think it is really harmful, to be honest, that just because these are inexpensive medications, that we think we could hand them out like candy without really thinking about downstream the risk that it's presenting, and in my loved one's case that has resulted in

osteoporosis, it has resulted in a significant weight gain, that then has other complications and health issues, sleep disturbance, mood disturbance...

Yeah. My dad says, he's been married to my mom for and been with my mom for 65 years, and he says every time she takes that medicine he thinks they're finally going to get divorced. So, I mean, it's legitimate. The side effects of those drugs, but they're used all the time.

01:00:45

Moderator, RTI International

And when you said, every time she takes that medicine, are you referring to the antibiotic steroid combination...

01:00:51

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

The burst of prednisone specifically.

01:00:53

Moderator, RTI International

Okay, thank you.

01:00:54

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

Yeah.

01:00:56

Moderator, RTI International

All right. And then, just like we did with asthma.

What are the benefits and drawbacks of these therapeutic alternatives to Breo for treatment of COPD?

01:01:16

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

Well, definitely, the side effect profile, I think, is better with Breo than a lot of the other things that we talked about, and I think that again that once daily dosing is a huge thing, as we've heard.

The drawback is the out-of-pocket expense, and I didn't say no one has mentioned this, but I mean my friend **[REDACTED]** actually started getting her medications from Canada and you know, just for solely for the expense, the out-of-pocket expense piece and she was afraid that someone was going to come knocking on her door to carry her away because she was importing drugs. So, I mean, it's just all of these things that are unintended consequences of the current, perverse incentives that **[Participant 1]** mentioned earlier of the system.

01:02:10

Moderator, RTI International

Anyone else have benefits or drawbacks to the other therapeutic alternatives?

All right, I know we've been here for an hour. And I've gone through a lot of questions. Okay, I'm gonna go ahead and move to another section. So, we'll get, so we can stay on time.

So now I'd like to talk about how well Breo and other medications for asthma or COPD meet patients' needs. Again, I'll start with asthma. Then I'll ask the same questions about COPD.

What would it be like for someone who has asthma if Breo or other medications for this condition were not available? So, another way of saying that, what needs of people with asthma does the Breo Ellipta or other medications for this condition meet?

[Participant 7], please go, take it away.

01:03:17

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

Yeah, if Breo was not available on a personal level for many of the people that we serve, they would not be able to do their everyday ADLs. They would not be able to shower, do their everyday cooking and meal preparation, housekeeping things that again are things we take for granted if we can breathe, that would be one of the things.

The other is that, truly, this medication is impactful enough that it could potentially be life threatening. The people with this disease would be likely to end up in the emergency room and hospitalized, likely to end up with pneumonia. And I can say that for people with EGPA, 30% are hospitalized because of their asthma. And with that the average stay of a hospital stay for a person with EGPA asthma, again, I know this is specific asthma. It's not tied to EGPA, but the general asthma that happens with EGPA, the average length of stay in the hospital is 11 days versus a person who has asthma unrelated to EGPA, and that is three to five days stay. So, it's almost triple the amount of time spent in the hospital.

01:04:50

Moderator, RTI International

Thank you, **[Participant 7]**. **[Participant 5]**, did you want to comment?

01:04:54

Participant 5 (registered as a patient)

Yeah. So, for me, personally, I would be trying to control my symptoms or manage my symptoms, not control them, but manage them kind of after the fact with other medications. And I know that I would wind up with the antibiotics and steroids constantly, because that was what was happening before we got the right combination with the Breo plus some other things to get things under control. So, you know, you're constantly taking over-the-counter medications or other prescriptions that are not addressing the root cause of the symptoms. They're just masking it, it's putting a Bandaid on a gaping wound, and it's not gonna be sufficient. You're not going to be able to manage your daily tasks. You're going to be miserable, not wanting to go do things, not wanting to commit to future events and stuff like that. So, it just tanks your entire life.

01:06:04

Moderator, RTI International

Thank you, **[Participant 5]**. That was very profound. **[Participant 2]**, go ahead and share.

01:06:10

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

Hi. Yes, I mean, I would just say from where I sit, having worked with my mother-in-law, if we had.... I wish I could remember the name of the one that had a dose release button that she couldn't do. But there was one that had this dose release button that we had to put together, and we went, like I said, we went through several things before she ended up with the medication that she could take, and when she passed away at the beginning of this year, on [REDACTED], it had nothing to do with her asthma or COPD. Actually, it was her AFib. That's a whole other story. But it was her, it wasn't that. And so, I would argue that that came before the AFib and all the struggles there, so I would say we probably had her longer because we got her asthma under control, like she was... or not her asthma, her COPD, which it was eventually diagnosed correctly, as under control. So, that's my perspective.

01:07:09

Moderator, RTI International

Thank you, [Participant 2].

And [Participant 3], could you share a little bit about what it would be like for someone who has asthma if Breo or other medications weren't available?

01:07:18

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

Asthma management is all about control, and not only symptom control, but inflammation control. And that's how Breo serves the patient best by controlling both the inflammation and the symptoms of asthma. So, if this drug were not available or the therapeutic alternatives, then there's going to be more symptoms. There's going to be more healthcare utilization, hospitalizations, and deaths. And that's why these innovative medicines are so important so that people get the medication that works for them.

01:07:51

Moderator, RTI International

Thank you, [Participant 3]. Anyone else want to say what it would be like for folks who have asthma if these medications weren't available? All right.

So, then, a second question related to asthma, what aspects of asthma, if any, are Breo or other medications for this condition, unable to currently address?

01:08:20

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

Repeat the question, please.

01:08:21

Moderator, RTI International

Yeah, what aspects of asthma are... is Breo or other medications unable to address?

What are the kind of shortcomings? Looks like, [Participant 3], you might have some thoughts here.

01:08:38

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

I'm gonna state the obvious... affordability. It's so expensive. It puts it out of reach for so many people. And that's the biggest challenge with, I'm hearing from patients who use Breo, that they can't afford it.

01:08:51

Moderator, RTI International

Thank you. And **[Participant 4]**, so I think you wanted to come in before. Sorry about that.

01:08:57

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

No, it's fine. I mean, I wanted to make sure I understood the question first. So I mean, we still know that there's five to 10% of the population, you know, that even when they do take their combination medications, have severe asthma and remain uncontrolled. Right? So I do still think there is a subset of the population that no matter if Breo was available or not, they're not going to get the relief that they need from the current therapies, and they'll need to escalate those therapies. So, I think that we're getting better at understanding what those underlying different endotypes and phenotypes are, and personalizing treatment accordingly. But I don't think we've got it all figured out. I always say asthma is not a single disease. It's a spectrum of diseases, and I think the science is bearing that out now.

01:09:53

Moderator, RTI International

So. Thank you, **[Participant 4]**. **[Participant 5]**?

01:09:57

Participant 5 (registered as a patient)

Yeah, sometimes it's only part of the treatment regimen. So, for me, the ICS LABA is only one part. If I didn't have that along with some other things, it wouldn't be controlled. But if you take the Breo out, it's not controlled. If you take any one of them out, I lose the control. So, it's not one or the other. It sometimes needs to be a combination, and that is very individual per patient.

01:10:30

Moderator, RTI International

Okay. Thank you, **[Participant 5]**. That's a constellation of things.

Okay, so I'm going to circle back and do the same questions for COPD. Thanks everyone for your patience. I know with the time it can be very fatiguing.

What would it be like for someone who has COPD if Breo or other medications for this condition were not available?

Okay, **[Participant 1]**, please weigh in.

01:10:59

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

Thanks, and I really didn't come here with the intention of a personal story share, but I will because of this great question. My maternal grandmother passed several decades ago from COPD. And where a lot of these medications weren't really available, in particular, not in the form they're in now. I saw her quickly devolve from an oxygen tank to a skilled nursing facility to a, a funeral home in a very short space of time. I mean, the great thing about some of these therapies we're discussing is they can dramatically improve the quality of life for people.

I mean the bottom line, they may not forego inevitable consequences of these illnesses, but it's not just about quality of life, but I think in many cases they can actually improve the quality of life. So, just thought I would share that. It's really wonderful that we're in a place where we're having this discussion about some of these therapies, that we've made this progress. So, thanks.

01:12:09

Moderator, RTI International

Thank you, **[Participant 1]**. **[Participant 4]**?

01:12:13

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

Yeah, thanks, **[Participant 1]**. People will die. People will die. I mean, that's the truth. Without these kinds of treatments, people will die.

COPD exacerbations will rise. Hospitalizations will rise. Cardiovascular risk associated with COPD will rise. We know that once a person has an exacerbation, they're two times more likely to have a CV event within the next 12 months, so I mean, it will be deadly.

01:12:46

Moderator, RTI International

That very much that sums up a very strong outcome. Thank you, **[Participant 4]**.

And then, what aspects of COPD is Breo or other medications unable to currently address?

That same question. Go ahead, **[Participant 1]**. Oh, **[Participant 1]**, and then, **[Participant 2]**, I think.

01:13:10

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

Just again on the affordability issue. And I again, I understand that's not exactly what this form is for, but in addition to the formulary issue which we've discussed. I know that there are some anomalies in the way that community pharmacists are reimbursed, and I think we're particularly concerned about a recent survey that the community pharmacist just conducted. It's saying that 61% of their members may not stock some of these drugs because they're losing money, or inadequate or delayed reimbursements. So, I think it's access is what we're talking about here, is it's great to have a better price on these drugs, but if it's at the price of access, it's not much of a gain. So, if any steps can be taken to address some of these unintended consequences of the process that's as it's currently designed, I think it's gotta go hand in hand with the process that we're in right now. So, thanks.

01:14:13

Moderator, RTI International

And then, **[Participant 2]**, I think you had something else you wanted to add.

01:14:17

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

Well, yes, I mean, I guess the biggest challenge that the medications do not address, and this is why we have innovation, is that these drugs control the symptoms, and they reduce outbreaks or exacerbations, but they don't halt or reverse the progression of the disease. I remember being in the appointment with my mother-in-law, and we were looking at her scans, and he was telling her, oh, you have COPD, and you know the root damage done to the lungs, that continues. And so that's not a negative of the medications. In my opinion, it's just like it's where we need to go next. Like, what is that? What does that look like?

Also just a lack of real training. I felt like, I was glad when my mother-in-law finally let me start going to appointments with her. But prior to that I just thought of all the seniors out there who maybe don't have anyone to go with them to their appointment, and they're sort of lost. And is there enough training and monitoring and oversight of, even if they're using everything properly? I just felt even I got overwhelmed, and I am a patient advocate. I run a patient advocacy organization. It's not that, you know. And I thought, wow, I'm even challenged a little bit with this and so those are the two things I think about.

01:15:41

Moderator, RTI International

Thank you, **[Participant 2]**. **[Participant 4]**, please go ahead.

01:15:44

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

Well, I think in COPD, again, we're probably a decade or more behind where we are, even in asthma, and understanding the disease and getting the appropriate innovation and attention and prioritization. And so, we know it's about one in four people living with COPD, that need triple therapy, that have to move up to a triple. And so, I think that again that complicates the whole treatment regimen, the more inhalers you have, the more inhaler confusion you have, and the less likely they are to use it correctly. So, all of that.

And then we still know that again, there's a five to 10% of population that isn't even going to maintain control on that triple therapy and may need some of the more advanced therapies. So, I definitely think that we still have so much room to go when it comes to COPD. And it's an exciting time, because the science is evolving. But we're not there yet.

01:16:52

Moderator, RTI International

Thank you.

Right, and so kind of one more question remaining that's kind of more specific to the conversation. I want to just wrap up by talking about your perceptions of the overall importance of Breo to patients.

So, just kind of thinking broadly about everything you heard today. How would you summarize the importance of Breo for people with either asthma or COPD, you can talk from either or both perspectives.

01:17:34

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

If I was...

01:17:35

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

I feel like I've been repeating myself. You know, I think we've pretty much covered...

01:17:41

Moderator, RTI International

Okay.

01:17:41

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

The value of this and, and why it's important and why it be affordable, but also available. So, thanks.

01:17:49

Moderator, RTI International

Okay.

I'm glad we're getting like consistency and coherence. And so, **[Participant 4]**. And then **[Participant 5]**. And then, **[Participant 7]**, I know you tried to chime in. Great. Okay, great. So, **[Participant 4]**, go ahead.

01:17:59

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

Yeah, I mean, I think that we've sat here for an hour and a half, and throughout this day we will breathe 20,000 times, right? We won't think twice about it. It's automatic. We do it.

But from living with people that are living with these conditions and taking this medication, what I can tell you is that there are days where every single breath, it's conscious. They think about it. It's a struggle.

And without this medication, more people will struggle.

And so, my last thing is just, I don't envy, I know the challenge of trying to reduce prescription drug spend, of trying to manage all of the PBM [pharmacy benefit manager] reform and the affordability and accessibility issues that we are discussing here today. But this is a product that is changing people's lives and saving people's lives. And I hope that we will maintain a level of access that is reasonable.

01:19:04

Moderator, RTI International

Thank you, **[Participant 4]**. And **[Participant 5]**?

01:19:07

Participant 5 (registered as a patient)

So, you know, as everybody else has talked about access for Breo, but I think we have to also remember that it's not one or the other, that choice needs to be there, so that it's the right match for the patient. You know Breo is important, but it's not more important than a different medication that might be the right one for another person.

So, I think, what I'm trying to say is that we don't want to value one over the other. And so, I think making sure that they're all available is important.

01:19:46

Moderator, RTI International

Thanks, **[Participant 5]**.

And then **[Participant 7]**?

01:19:53

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

I would say, if I had to pull the primary pieces that are most important, as it relates to Breo, I would think I say one is that it gives people their everyday life back. Again, that the things that we all take for granted, just participating in living, taking a shower, making food, going to a grocery store, everyday things that we just take for granted. This allows people to participate in life.

And the second is, it actually reduces hospitalizations, and of course, hospitalizations have a higher cost burden, not just for patients, but also for insurance and Medicare. So, while it might be pricey, it is way cheaper than the alternative of ending up in the hospital and ending up with hospitalizations because of it.

01:20:50

Moderator, RTI International

Thank you, **[Participant 7]**. And **[Participant 6]**, did you want to say kind of what's most important or special about Breo from the perspective of your organization?

01:20:58

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

Well, I think you know, this harkens back to what everyone was talking about with access and access to the right medication for each patient and not considering the asthma population as this, homogeneous, like something the therapeutic alternatives are going to work just as well. We need to maintain the right access at affordable prices. And, this is, to **[Participant 7]**'s point, this keeps people healthy, which is also cost savings. You know, not only is it positive health outcomes, but we are really just worried that the, I just wanna echo that we're just worried that these cost savings are not gonna translate to the patient. And so, we hope that CMS is committed to monitoring how this impacts patient access to ensure that it's not, because, you know, we do know that the reason people don't take their medications as prescribed is largely related to cost. So, we hope that CMS is able to minimize the unintended consequences, many of which that have been mentioned today. But ultimately access to the right medication changes lives.

01:22:20

Moderator, RTI International

Thank you, **[Participant 6]**. And **[Participant 3]**, would you have any final thoughts of what's most important to the folks that you spoke with?

01:22:29

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

I didn't know if you wanted to go to **[Participant 7]** first, because she had her hand raised.

01:22:33

Moderator, RTI International

Oh, did she? Oh, I'm sorry I was, I'm trying to make sure I capture everyone before we close. And so, **[Participant 7]**, please.

01:22:41

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

I was just going to add, I think the other piece is that it really opens up an entire universe. So, by being able to access these kind of medications, people can be a better mother, a better daughter, a better sister, a better spouse, a better employee. So, it actually has ripple effects in terms of the benefit that this kind of medication has on people and the people that they love and interact with.

01:23:07

Moderator, RTI International

Thank you, **[Participant 7]**. Better people in general. And then, **[Participant 3]**, now please wrap us up.

01:23:13

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

I would just be restating what everybody else says. But I always think about the American Lung Association statement that if you can't breathe, nothing else matters. And for the people living with these conditions, breathing is a really every day, important thing that, like **[Participant 4]** said, we take for granted, but for these people, getting on the right treatment makes all the difference.

01:23:37

Moderator, RTI International

Thank you, all right. So, that was my last question. But I did want to wrap up by just asking if there's anything that we didn't talk about today that you just really wanted to be sure that CMS knows about. So, I'll open the floor for that.

01:23:54

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

I would just like to say, thank you for hosting these roundtables. I think this is a very positive experience, and both personally as a person who utilizes this medication, but also with the hat of an advocacy organization, it is invaluable that we get to share these real stories with you about the

impact of this medication. So, thank you for taking the time to, you know, host these and the town halls.

01:24:26

Moderator, RTI International

Thank you, **[Participant 7]**.

Anyone... oh, go ahead, **[Participant 2]**.

01:24:30

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

I just wanted to echo that and say, thank you. As an, our organization, I'll put my organization hat on right now, we did some discussions with advocates, that prior to this getting, encouraging them to sign up for doing roundtables, and we had advocates who participated in the first sessions, kind of do some coaching, and I have to say I was a little bit really nervous about today. And I feel like this is a really great format, because they were like, oh, no, you just speak for three minutes, and then you're done. You don't know if you did anything good, nobody responds, and this was nothing like that, and I just want to say it was very enjoyable to be on this call today and discuss all this.

01:25:12

Moderator, RTI International

Thank you, **[Participant 2]**. Thank you. And thank you all for participating in today's group. I know it's kind of a marathon, but we appreciate you taking the time to talk with us. Your experience and input is more valuable than you may know, and it will help CMS inform CMS' negotiations for the drugs.

So, CMS have been listening to the roundtable, and we'll be able to bring those perspectives forward. So, that's really a nice advantage to all coming together today. So, **[CMS STAFF]**, did you want to wrap us up with any closing remarks?

Closing Remarks

01:25:46

CMS Staff

I feel like you touched on it all. Thank you guys for all sharing your insights. We really appreciate this opportunity to hear you guys' perspectives. So again, thank you for everything. And we'll take this and work with it. Thank you.

01:25:59

Moderator, RTI International

Great, all right. And I think we have a final slide to put up. So, if you have any questions following today's session, you can submit it to the mailbox here you see on the screen. If you want to take a photo with your phone or take a screenshot so that you can have that for later, you are welcome to do so. So, you can submit the questions to this mailbox at the

IRARebateAndNegotiations@cms.hhs.gov with the subject line, public engagement events. So,

that's public engagement events for the subject line. All right, I think then, we have... give you all a few minutes to grab this information and thank you, everyone.

01:26:39

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

Thank you. Good day, bye.

Thank you. Bye, bye, thank you.

01:26:44

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

Bye.

===== 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 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
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
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 condition(s) treated by the selected drug; a patient with experience with other treatment(s) similar to the selected drug for those condition(s); 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); 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
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
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 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
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 4: 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); 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 5: Registered as a patient who has experience with the selected drug; a patient who has experience with the condition(s) treated by the selected drug

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

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

Declared Conflicts of Interest	
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 7: Registered as a patient who has experience with the selected drug; a patient who has experience with the condition(s) treated by the selected drug; a patient with experience with other treatment(s) similar to the selected drug for those condition(s); a representative of a patient advocacy organization.

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