Transcript: Anoro Ellipta Roundtable Event, April 6, 2026, Medicare Drug Price Negotiation Program Public Engagement Events

This transcript was lightly edited for readability.

Introductory Remarks

Moderator, RTI International

Great, let's get started. Thank you so much for coming today. I'm **[Moderator]**, and I'm from RTI International. I also want to introduce my colleague, **[Secondary Moderator]**, who you may also hear from during today's discussion. The Centers for Medicare & Medicaid Services, which I'll be referring to throughout today's event using the acronym CMS, is convening this Patient-Focused Roundtable Event and others as part of the Medicare Drug Price Negotiation Program. The information shared during these roundtable events will help CMS understand patients' experiences with the conditions and diseases treated by the selected drugs, patients' experiences with the selected drugs themselves, and patients' experiences with other drugs that are used to treat the same conditions as the selected drug. The information shared during these events will also help CMS identify other medications used to treat these conditions, what matters most to patients in managing their conditions, and other important factors CMS may consider in negotiating Medicare pricing with the manufacturers of selected drugs.

The purpose of today's event is to hear from you all—a group that may include patients, caregivers, and patient advocates—about your experiences with chronic obstructive pulmonary disease, with Anoro Ellipta, and with other medications for the same condition. I just want to flag that I'll typically refer to chronic obstructive pulmonary disease by the acronym of COPD during today's event. I want to emphasize that our focus today will be on the patient experience; if you wish to share input on other topics related to the Drug Price Negotiation Program that are not directly focused on the patient experience, we ask that you send that input to the mailbox at IRARebateAndNegotiation@cms.hhs.gov instead of sharing it during today's discussion.

Your experience and perspectives are very important to us, and we genuinely appreciate your time today. Along those lines, let's watch a brief welcome video from CMS leadership so that you can hear from them about how much they value your time and input.

CMS Remarks

00:02:29

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.

00:03:58

Moderator, RTI International

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

00:04:17

CMS Staff

Thank you. Welcome everyone. I'm **[CMS Staff]** from the CMS Drug Price Negotiation team. There are other CMS staff on the call today in addition to myself. We work on the policies for getting public input and negotiating Medicare drug pricing. On behalf of CMS, I want to thank you for participating today. We are looking forward to hearing about your experiences during this roundtable discussion. We are actually going to go off camera so you all can focus on the discussion, but we look forward to hearing from you. Thank you for being here.

Housekeeping

00:04:44

Moderator, RTI International

Great, thanks **[CMS Staff]**. Before we begin, I just want to review some housekeeping items and some ground rules, so that everyone knows what to expect throughout the event today.

First off, technical assistance. If you get disconnected, please attempt to rejoin. If you cannot connect, please reach out to IRADAPStechsupport@telligen.com, that address that was put into the chat when we were doing the pre-meeting.

In terms of privacy, the discussion today is not open to the press or the public. We will use first names only during the discussion to protect your privacy. Please do not share any unnecessary protected health information, such as your doctor's name, the name of a medical facility where you received care, or personally identifying information, such as your employer's name, the city you live in, and names of schools you attended, during today's discussion. Following the event, CMS will prepare transcripts that have participant names and identifying information removed, and these will be available to the public.

Video recording. On a related note, we are recording today's event. These recordings will not be shared publicly. Recordings will only be used for internal program documentation and to produce the redacted transcripts for public release, consistent with Federal privacy guidelines. By participating, you consent to being recorded for these purposes.

Participation. We hope that you will contribute your perspectives throughout the session. However, if questions arise that you do not want to answer, that's totally okay.

Background. Please minimize background noise by silencing your cell phone and any other devices you have nearby if you haven't already done so. Also, please mute yourself when you are not speaking.

Video. Thank you so much in advance for keeping your video on throughout the discussion to the extent possible.

In terms of timing, we have reserved up to two hours for this session. However, it's possible we may not need the full two hours to discuss all of the planned topics. If that happens, we can let everyone go just a little bit early. I have a discussion guide in front of me to help me keep on track. And 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're able to cover everything, and that all participants have ample opportunities to share their perspectives.

Breaks. If you need to step away briefly during our discussion, that's okay. Please just turn off your camera and microphone and rejoin when you're able to. You don't need to tell me that you'll be away from your computer. Please just return to the discussion when you're able to.

Speaking. Please try to speak one at a time. I may occasionally interrupt you if two or more people are talking to be sure that everyone can be heard and that everyone's comments are accurately recorded. Please use the raise hand feature in Zoom to indicate that you would like to speak. This will help us know when someone would like to add to the discussion. You can take a moment now to find this feature and see how it works.

Chat. While we're hoping for everyone to focus on the oral discussion, you can also add your comments into the chat if you don't get an opportunity 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 to the next discussion question, or if you think of something else that you'd like to add later on. Please just be sure to note what question or topic you are responding to and any chat comments.

Unless anyone has questions about the items I've just reviewed, let's go ahead and get started.

To warm up, I would like to begin our discussion today by asking each of you to introduce yourselves briefly. Please take a moment to tell us your first name and whether you'll be sharing experiences as a patient, caregiver, or from the perspective of a patient advocate. **[Participant 1]**, let's start with you.

Discussion

00:09:52

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

Sure, good morning. My name's **[Participant 1]**. I'm here as both a patient advocate and also a caregiver. I had a loved one with COPD.

00:10:08

Moderator, RTI International

Thank you, **[Participant 1]**. **[Participant 2]**?

00:10:11

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

Hey everyone, I'm **[Participant 2]**, and I am coming from the perspective as a patient advocate.

00:10:18

Moderator, RTI International

Great. Thank you, **[Participant 2]**. **[Participant 3]**?

00:10:21

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

Hi everyone, I'm **[Participant 3]**, and I'm coming from the perspective of caregiver for both of my parents who are currently living with COPD, as well as a patient advocate.

00:10:30

Moderator, RTI International

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

00:10:34

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

Hi, I'm **[Participant 4]**, and I'm here as a patient advocate.

00:10:38

Moderator, RTI International

Great. Thanks, everybody, for introducing yourselves and for telling us what experience you'll be drawing from today. I appreciate it.

Next, let's start talking about patients' experiences with COPD, the health condition treated by Anoro Ellipta. Thinking about the different ways that COPD affects patients' lives, what would you say are the most important aspects of the condition to have managed or treated? These important aspects of the condition to have managed or treated could be things that affect patients in the shorter term or in the longer term. And I'll wait to see if any hands go up. Great. **[Participant 3]**?

00:11:26

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

I think that from our lived experience, the most important thing has been the breathlessness and the fatigue. Certainly not being able to do the activities of daily living because you get out of breath, you're not able to go out as much … at one point, my mom wasn't even able to walk to the mailbox to get the mail, and literally, her life shrank to being confined to her house. From one room to the next when she was not well-controlled. And then, as things have gone on, and as exacerbations, flares have happened, it's definitely the fatigue and the decline in function post-exacerbation, post-flare, that has been most notable and most frustrating for both of my parents.

00:12:21

Moderator, RTI International

Thank you for sharing that, **[Participant 3]**. **[Participant 1]**?

00:12:39

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

I echo totally what **[Participant 3]** said. The other thing that I just wanted to mention is that, with my dad, he's dealing with multiple chronic conditions. I think most Medicare beneficiaries are, so not being out of breath affects his ability to get out for a walk, which is important for his heart health and his diabetes management as well. Also, just the mental health aspects of it, it is terrifying when you can't catch your breath, and then that panic sets in, and it makes it even worse, which is really important to factor in versus being able to manage it and have that control, and that sense of control, is also really important. And then, I love how **[Participant 3]** phrased it about your world gets smaller and smaller, and we know that that is so frustrating, and it also affects their mental health as well. When you can't go out, when you can't socialize, we know how important that is for all of us, but particularly as you get older. I just wanted to mention those things as well.

00:13:47

Moderator, RTI International

Thank you, **[Participant 1]**. **[Participant 4]**, let's turn to you now.

00:13:50

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

Sure, most of what I'm saying is going to be reinforcing, like **[Participant 1]** and **[Participant 3]** said, it's to reduce the fear of living with that breathlessness, disruptions in daily life, the costs associated with exacerbations and just being in and out of the hospital or urgent care because of exacerbations, and maintaining an optimal quality of life.

00:14:14

Moderator, RTI International

Great. Thank you, **[Participant 4]**. **[Participant 2]**, did you have anything you wanted to add on this first question?

00:14:21

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

I think that everyone covered it quite nicely.

00:14:24

Moderator, RTI International

Great, thank you very much. I appreciate you all sharing those thoughts.

Now I want to turn our attention to patients' experiences with medications for COPD. What medications, if any, have your loved ones or patients that you advocate for taken, whether currently or in the past, for COPD? And for this question, I'm going to ask you to enter your responses into the chat. I realize that may take a moment because it may be a lengthy list, but if you could please just enter in the chat any medications that your loved ones or patients you advocate for have taken for their COPD, whether now or in the past. Thank you for clarifying that, **[Participant 4]**, that it could be any and all of the options available these days. If there are specific ones that you want to mention that you hear about in particular, please add those, but otherwise, I understand. Thanks, **[Participant 1]** and **[Participant 3]**, for giving us those lists, and I hear you, **[Participant 4]** and **[Participant 2]**, that it might be quite a long list of things that your different patients have experience with.

For the next few questions, I want to note that we want to hear about experiences that your loved ones or patients you advocate for have had with Anoro Ellipta or other medications used for COPD, so not limited just to Anora Ellipta. Please make sure that you specify which medications you're talking about as you share your experiences. What benefits have your loved ones or patients that you advocate for experienced with medications for COPD? As a reminder, please let me know which medications you're discussing. This question focuses on the benefits that your loved ones or patients experience from medications used for COPD. **[Participant 3]**?

00:17:03

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

Definitely for my parents, and I had one other person that I was a caregiver for that had COPD for over 10 years. My parents have been living with it, respectively, seven years and two years, my mom longer. I think that different medicines have worked at different times and stages. Number one, a lot of it has been teaching them to use it correctly, and teach and reteach and reteach, because that has definitely been a challenge, it's not a one and done, and as soon as a new medication is on board, we have to start all over with that training process. And I would say that initially, they were on an ICS/LABA [Inhaled Corticosteroids/Long-Acting Beta$_2$-Agonists], and that, I don't think, was the right medication or treatment for them. Then, as they moved to the Anoro with a LAMA/LABA [Long-Acting Muscarinic Antagonist/Long-Acting Beta$_2$-Agonist], it's been better. They've been able to sustain their lung function, their breathing. They've had more energy, more ability to live and do the things they want to do, whether that be travel, or go to their grandkids' activities, or family functions, or church, or whatever. I think that, when they've had flares, they've had to use OCS [oral corticosteroids], prednisone or antibiotics, and those have had their own pros in the short term, but also drawbacks and risk that they've expressed as well. I think it's not all on the upside when it comes to the hodgepodge of medicines that my loved ones have been on.

00:19:00

Moderator, RTI International

Thanks, **[Participant 3]**. You covered a lot of different benefits with that one. Can I ask, in terms of how easy the medications were to tolerate, how safe they were, how they were taken or administered, would you mind commenting on some of the benefits related to those different medications?

00:19:19

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

Again, for both of my parents, they would say that they prefer pills, oral medications, because they also have other comorbidities and take medicines in the morning and in the evening. So that fits better into their routine. The first few years, when it was just my mom taking her inhaler, it was probably 25, 30% of the time that she took it, because she just forgot. She didn't see it as the same type of medicine as her oral medicine, like her heart medicine, for example. That was frustrating for me as someone in lung health and who cares about her, for her to not see the same importance or significance of her inhaled medicines. Again, I think that recovering from a flare, there's an added level of intensity and desire to get over that hump, so they're probably a bit more adherent to taking those meds, the antibiotic or the prednisone, but probably not finishing them like they should, to be honest. And a lot of that does have to do with the side effects, not liking some of the side effects of both of those.

00:20:39

Moderator, RTI International

Would you mind talking more about the side effects of some of those specific drugs that you all encountered?

00:20:45

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

I think GI [gastrointestinal] side effects are pretty normal, and certainly both of my parents have experienced that. I think that, when on prednisone, that feeling of [being] amped up, they often will say, like a long-tailed cat in a room full of rocking chairs is the analogy, where they just feel jittery and edgy and not themselves, sleep disturbance, weight gain. That type of thing is common, but I don't know that they necessarily always equate it to the medicine. I'm always having to be sure … I'm asking these things because it's still not something that they're necessarily comfortable talking about. So I'm always prompting, "Are you having any of these symptoms? That could be the medicine," and helping them to understand that. I don't really think that they're always connecting those dots. I will say, as we talked about before, it's very different than the way they approach their heart medication or their diabetes medication, for sure. I don't know why that is, because I keep trying to tell them that lungs are equally as important, but for some reason, it doesn't seem to quite resonate.

00:22:19

Moderator, RTI International

Thank you for sharing that, **[Participant 3]**. Let's turn to you, **[Participant 2]**, to hear a little bit about the benefits that patients you advocate for have experienced with these different medications.

00:22:28

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

Yeah, definitely. Just a little bit of background, I represent health center patients who are four times more likely to have an income at or below the Federal poverty level, and then they're also twice as likely to have an income under 200% FPL [Federal poverty level] compared to the U.S. population, and they have a lot of non-clinical social risk factors that can impact their ability to get medication on a regular basis, or also, they have a lot of comorbidities, as **[Participant 3]** was mentioning. You're thinking about trying to take all of your different medications every day, having the Anoro Ellipta as a single step active, activation, dry powder inhaler [DPI] that you can just do once a day [is] really helpful for maintaining their COPD and trying to decrease some of the issues with breathing and such. It helps with adherence, which is really strongly associated with different socioeconomic factors like unemployment, and so I think that it's really helpful for managing multiple chronic conditions, so they're able to manage their COPD, it's not hurting them in other ways, and so I think it's been very beneficial in general.

00:23:50

Moderator, RTI International

Great, thanks, **[Participant 2]**. I heard symptom relief, as well as just taking the one medication once a day, that dosage and how it's taken or administered. What about any benefits related to safety, or how easy it is to tolerate, or quality of life?

00:24:07

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

I would say it definitely helps enhance quality of life. Again, as I mentioned, these folks are lower income, maybe financially strapped, and so this is one less worry that they have, to [not] worry about if [it] impacts their ability to get to work, or impacts their ability to take care of their families. I would say, I can't get into maybe as much of the clinical specifics, but I know that it's been really well-received at the pharmacies that we have with our patients.

00:24:39

Moderator, RTI International

Great, thank you. And in the chat, you indicated that you have experience with patients that have tried a number of different medications that are available. Could you comment on how the benefits of the medications differ, if at all?

00:24:56

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

I would say my area of expertise more is with this medication, and I know that just because, it's one of the medications that we're able to offer and get a discount through the 340B Drug Pricing Program and health centers. We are able to discount this medication at a very high rate. We want to meet patients where they are and not have any financial barriers, so I know, at least for this medication, it's been very well-received, and given the clinical trial, or, I mean, the political research, that it's been the best, one of the best for our patients.

00:25:40

Moderator, RTI International

Great. Thank you, **[Participant 2]**. **[Participant 1]**, let's turn to you to hear about some of the benefits that your loved ones or patients you advocate for have experienced.

00:25:48

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

Well, I will say he doesn't take this medicine, and in prepping for this, I found out he's actually not taking the one he's supposed to be taking, so **[Participant 3]**, I feel you there. And I do agree that simplicity is so important, that once a day may seem like not a big deal, but when you're juggling—I think he takes 25 different medicines every day and multiple times a day, going from two to one is more than cutting it in half for him. It just makes it so much simpler. I do think that I've run into that two times. There's a barrier between, "I take my pills every day, why do I have to take this inhaler? I feel better." I've heard that one, too, and I'm like, "That's because it's working, it's not a one and done." Anything that can help them breathe easier, like, "I just have to remember to take my inhaler, and I can almost forget I have COPD." That really is the goal: remember to take your medicine, and then just relax and enjoy, and it's a progressive disease, we appreciate that, we know that there's not a cure, but just to take that one worry off the table is so valuable, and a huge benefit.

00:27:11

Moderator, RTI International

Thanks, **[Participant 1]**. And I hear you, that they're not currently on Anoro Ellipta, and maybe not the other medication that they should be taking. But could you comment on the benefits of that medication specifically that they should be taking? Is that the Wixela Inhub?

00:27:29

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

Yes, and what I found out from him was he just felt like it really wasn't making a huge difference. I'm going to explore whether he was on it long enough to really see a difference, but his goal, too, is to stay off oxygen. It's almost like, for people with diabetes, if I can stay off insulin, that's a goal. I grew up in, you probably hear it in my accent, in **[Redacted]**. I had a lot of relatives and a lot in his family who were smokers who carted around the oxygen tank. He really wants to avoid that. There are goals there, it's just more he didn't feel like that [medicine] was giving him the benefit, and so that's why he stopped taking it.

00:28:14

Moderator, RTI International

Thank you for that. **[Participant 4]**, let's turn to you now to hear about some of the benefits regarding COPD medications that you want to share.

00:28:22

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

Since we're talking about issues regarding the once-a-day and how that could be favorable, I just want to point out that DPI inhaler, like Anoro, it's different than a slow mist inhaler, or an HFA [hydrofluoroalkane] inhaler, like some of the therapeutic alternatives, so I just want to point out that that sometimes is easier for people to use who have COPD. It's worth mentioning.

00:28:47

Moderator, RTI International

Thank you, **[Participant 4]**, for pointing that out regarding ease of use. That's helpful to know. Are there specific medications that you think of in terms of differences between them and how easy they are to use?

00:28:59

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

My understanding … is that the slow mist inhalers may be harder to use for people with COPD. I don't have any personal experience with it, though.

00:29:11

Moderator, RTI International

Thank you for sharing that.

We've talked a little bit about this already, but let's talk about it more explicitly. What drawbacks or challenges have your loved ones or patients that you advocate for experienced with medications used for COPD? As another reminder, just make sure that you let us know which medications you're discussing. And **[Participant 3]**, I saw your hand go up for a moment, if you want to make that comment, as well as talk about the drug.

00:29:39

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

Yeah. It goes to what **[Participant 4]** was saying. Again, with a dry powder, you have to have a good inspiratory flow rate. You've got to be able to suck in to get that dry powder where it needs to go appropriately. And, especially when you're coughing or having a flare, it's almost impossible to use that in the right way. I've watched my parents literally as soon as they take it, cough, everything right back out. They're not really getting the medicine where it needs to go deep into their lungs. I think that that is a challenge. Another challenge, like I was saying before, is just not feeling the medicine working. Like albuterol, for example. My mom has had to use albuterol for acute symptoms. She's like, "Oh, I feel it. I feel the impact. I feel that I can breathe better." That's not always the case when she's using her controller med, whether that be Anoro or Trelegy. She's gone back and forth over time. I try to explain that those are two different things. They're doing different things, and that's why it's important to still maintain the controller medicine, whether that be Anoro or Trelegy, rather than just relying on that rescue medicine, or the thing that you feel you can immediately have relief and stop coughing or get a stronger breath. Again, I just don't think there's enough awareness or education about the disease and that chronic underlying process and the need to manage that versus the in-the-moment acute breathlessness or cough that you're trying to address with some of the rescue medicines.

00:31:48

Moderator, RTI International

Thanks, **[Participant 3]**. I heard that with these controller medications that lack of immediate relief is sometimes a drawback, and that patients really can't connect it to their immediate experience. You also talked a little bit about the type of inhaler and the way that it's administered, and I know you specifically called out DPI. Would you mind talking about some of the specific medications and the extent to which they were easier or more difficult to use from that standpoint?

00:32:18

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

The other person that I cared for was 87, and she lived with COPD for over 10 years, and as Ms. **[Redacted]** progressed, her dexterity, her hand-eye coordination, all of that was less and less. It made it much more challenging for her to use her medicines well, and to get the medicine where she needed it, that coordination. I think that it's why one size doesn't fit all, because DPIs tend to be a bit more complex for elderly patients to use, or to get that good breath in, that inspiratory flow in, as the disease progresses.

00:33:07

Moderator, RTI International

Great, thank you for that. Also, I wanted to follow up, I didn't hear, among the different drawbacks that you mentioned, any related to safety and tolerability or side effects. Would you mind sharing a little bit about that?

00:33:22

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

Thankfully, we've had very limited side effects from the inhaler specifically. At first, when my mom wasn't using the first one correctly, she did have some thrush, and then I taught her the importance of brushing her teeth right after and rinsing her mouth, that sort of thing. She also has some autoimmune issues, so she was prone to more oral thrush and issues orally. But I would say not as much side effects from the inhalers as much as the other medicines when experiencing a flare. When experiencing a flare, the oral steroid prednisone in higher doses really wreaks havoc on GI, sleep, weight, like, not feeling like yourself. My dad always says she's a raging, not-so-nice person when she's on them. And again, I think that it's one of those things, like, what else are we going to use? It's necessary, but it definitely disturbs a lot of other aspects of life, whether that be sleep, mood, interaction with your loved ones, and as many times as you say, "It's the medicine, Dad, it's medicine," it doesn't necessarily make that any easier to deal with.

00:35:07

Moderator, RTI International

And when you talked about thrush, you referenced the first medication they were on. Do you recall which medication that was?

00:35:13

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

That was an ICS/LABA that probably she never should have been on, to be honest, but I think that early on, her rural health care in Louisiana didn't get an appropriate diagnosis until about five years into the symptoms and journey.

00:35:30

Moderator, RTI International

Wow. Thank you for sharing that. **[Participant 1]**, let's turn to you to hear some drawbacks that you have heard about or have experienced.

00:35:39

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

I just was going to mention, in terms of having options, given the polypharmacy issue, my dad has a lot of heart health issues, and heartbeat regulation, that's the technical term. But that really limits his ability to take certain medicines. I haven't heard it as much with COPD specifically, but having options is so important because he does have those, I think he takes Pacerone, for example, and that's a very serious kind of medicine of last resort for heart failure and heart rhythm issues. That is contraindicated with so many things. I'm not as familiar about COPD, but I just wanted to mention that. That's why having different choices, these combination therapies that lower that interaction, but also just being able to have those choices.

The other thing, and **[Participant 3]** mentioned this as well, and I forgot to, is the use of antibiotics when they can't get that phlegm moving is really common, and it's just devastating. He just stopped a 10-day series of antibiotics for a respiratory infection, and it wiped him out. He also has issues with muscle loss from antibiotic use in the past and things like that, so I think that's also important to factor in. It's not directly COPD medicine, but it's a result of having COPD.

00:37:18

Moderator, RTI International

Thanks for that, **[Participant 1]**. And can I ask you, in terms of the different medications that you all have experience with, on the heart front, with those heart symptoms, can you comment on how those different medications compared for that?

00:37:33

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

Well, again, it's a work in progress in terms of getting him on the right COPD medicine and making sure he's adhering to it. But I know that, on a number of different fronts, every time there's an adjustment that needs to be made when you're taking so many medicines, you've got so many chronic conditions, it is a conference in terms of collaborating amongst providers and trying to figure out what's going to work, because you, and sometimes, unfortunately, patients, have to choose. Do you want to manage your diabetes, or do you want to manage your COPD, or do you want to get it good enough here to have it much better in another area? And it's a shame that we are facing those kind of trade-offs, but I think that's reality for a lot of people dealing with multiple chronic conditions.

00:38:25

Moderator, RTI International

I hear you. And also navigating those contraindications, as you were saying, are there specific drugs where that was easier to navigate than others, or not so much?

00:38:38

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

I'm sure there are, I don't have that expertise, unfortunately, but we, candidly, have had challenges with the primary care provider who's trying to help him with his COPD versus his cardiologist wanting to refer him to a pulmonologist, and then convincing your parent, hey, you really do need to see the specialist here, even though you love the guy you see in your primary care practice all the time, they may not be as up to speed, and I see **[Participant 3]** laughing, that's part of the caregiver journey as well.

00:39:15

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

I think we're living parallel lives, **[Participant 1]**.

00:39:21

Moderator, RTI International

All right. Thank you all. When considering a potential medication for COPD, could we talk a little bit about what factors matter to patients the most? **[Participant 4]**?

00:39:44

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

Well, costs, we haven't talked about costs and trade-offs, when people can't afford medications, how they will be choosing medications that may not be the one that they want for them, but the one that they can afford. I know I'm going to open up a conversation here from all of us on this issue, and how sometimes we know that patients are not doing as well on a given medicine, but they don't have a choice because of lack of affordability.

00:40:14

Moderator, RTI International

Cost, I know, can be a big issue. Any other factors that are key considerations when considering a potential medication for COPD, aside from cost?

00:40:27

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

I would say convenience, and then how easy is it to get. Again, in rural health care , my parents really love their primary care doctor. He's not always up to date on the latest, greatest, so that's been a real challenge for us as well. Their pharmacist is a lovely person. He does such a great job of looking at all of their meds, knowing all the different conditions. But he's not an expert in COPD, and if it saves them $10 here, $10 there, sometimes my parents will [say], "The pharmacist said that this will save us whatever," I'm like, "Oh my gosh, Mom, no, no, no, you don't understand that." It's worth paying the $10 extra a month, and I understand on a fixed income how trying that is, but it is [worth it], definitely. And then the convenience of navigating every single year that the plan changes. Oh my goodness, every year, it's hours and hours on the phone. Thankfully, again, a great pharmacist who sits with them and says, "Okay, this is the best plan for you to either stay on or to move to, given what your medications are today." But, my dad was diagnosed with lung cancer in addition to his COPD, and one plan may be better for one condition versus the other, and making those decisions, the whole navigating of that decision each year, has been really, really challenging for them.

00:42:14

Moderator, RTI International

Got it. In addition to cost considerations, there's also coverage considerations, and going through that process every year with those. I hear you, that that can be really challenging.

And **[Participant 4]**, I saw that you mentioned, in addition to access issues and ease of use, which I know we've talked about a bit, efficacy. Would you mind sharing more about the way in which efficacy is a consideration when thinking about COPD medications?

00:42:43

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

Well, "therapeutic equivalent" does not necessarily mean that it'll work for each patient, and so we need to make sure that the patient preferences and the patient needs and responses to the drug will be the same, will be right for them. So that's specifically why I was referring to efficacy, because I want to make sure everybody, knows that it's really important that patients do need choices and options because although it might have that therapeutic equivalence, it might not work as well for them. And then we already touched on ease of use in terms of the actual use of the inhaler itself.

00:43:25

Moderator, RTI International

Thanks, **[Participant 4]**. And I know, **[Participant 3]**, your comments got at this a little bit, dealing with different health care providers that may have different experiences, or maybe that was **[Participant 1]**, I'm sorry. What about the extent to which a medication is recommended by a health care provider? Is that an important consideration for choosing a medication?

00:43:53

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

I can chime in. Yes, absolutely. Coming from someone they trust, but ... there are guidelines, and we would love to see more providers aware of those guidelines and following those guidelines, and

CMS probably has a role to play there. I know that may be getting us too far afield, but that's the only thing I would say is, absolutely, recommendations are important, and I know a lot of providers look at, and it sounds like **[Participant 2]** works directly in this field, they look at affordability as a big [goal], get them the best and the most affordable, and balancing that can be a challenge for everyone. I've had many conversations, like **[Participant 3]** has talked about, too, where it's literally $10 or $15 a month different, and I'm like come on, this is this is your breathing. I get $5, I'll give you the $5 if that's what it takes, but, sometimes, those choices are really hard. I do think, again, cutting down on the number of doses where it's one and done is really, really important. And the combination therapies are super helpful, too, because I do think they're greater than the sum of their parts, and having to juggle multiple medicines versus one, one dose, if you will, and having that combination therapy is really important, too, and a great benefit.

00:45:21

Moderator, RTI International

Thanks, and I want to follow up on something regarding that. We've talked a little bit about adherence to treatment regimens and how that can be affected by cost, or coverage issues, as well as ease of use. Can I ask, do any of your loved ones or the patients you advocate for feel there's a difference in taking an inhaler for one puff twice a day versus two puffs once a day? Are those kinds of things playing into it in a meaningful way? **[Participant 2]**?

00:45:56

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

Yeah, **[Moderator]**, I made a similar comment earlier that when I'm thinking about the patients that we're advocating for, a lot of them have to juggle, obviously, maybe other comorbidities, and then just dealing with everyday life, that can get very busy. Having an inhaler that you only have to think about once a day is so helpful for adherence. And then that improves their quality of life in so many ways, as I know a lot of other folks have talked about on this call. I've heard very high marks from our pharmacists that have been working with our patients.

00:46:38

Moderator, RTI International

So maybe it's less critical how many puffs it is, [it's] once a day that is important to your patients?

00:46:46

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

Yeah, the frequency is a big issue.

00:46:49

Moderator, RTI International

Okay, frequency. That's helpful to hear. And along similar lines, still talking about adherence, have you all had any experience with interventions used to improve adherence with drugs for COPD, and how did those work? **[Participant 2]**?

00:47:11

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

I'll jump in again. As I mentioned our health centers have a lot of pharmacies in the communities, either, in-house at the health center, or they contract with community pharmacies, want to make sure that they're close to patients that have those trusted relationships. What we do a lot of is making sure that our pharmacists are training, and providing education around, inhaler usage, and just being a trusted voice to provide that education, even if it's not at the time that they're picking up their inhaler, maybe they need to come back or even call. Just continuing to have that relationship has been, I think, helpful in knowing that there is no wrong question, and we'd rather them call, or make an appointment, or whatever, so that they can really help that COPD and restrain the symptoms.

00:48:14

Moderator, RTI International

So in terms of interventions, it sounds like that greater role of the community pharmacist and the relationship with them, and making sure that these things are getting used right, and that they're fully understood. That's really helpful to know. Any other interventions to improve adherence? They could also be things like using a spacer device, actual mechanical interventions. **[Participant 1]**?

00:48:43

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

I was just going to say, I've used the spacer devices with my children on asthma. They were so helpful, super helpful. My dad has not [used them], but I did find those to be incredibly helpful, especially with the mist-type inhalers.

But to echo what **[Participant 2]** said, we've often relied on pharmacists, and a good pharmacist can make a world of difference, because they're just willing to sit, even if it's repetitive. I've sat down with my dad and reminded him … he's like, "I don't even know what all these pills are for." And so we've done that multiple times about, "Okay, well, this one, this one, this one." And his physicians [have] as well, in terms of, "Why am I taking this? I have side effects with it," not the inhaler, but other medicines. And just having those conversations to understand what side effects you should expect, what side effects are indication of a problem, adjusting dosages, things like that, making adjustments, [it is] so important to have that open line of communication. But even to sit down and have the conversation about, this is what you're taking and this is why, it's been really, really helpful in terms of adherence, and now I understand why I'm doing this, why I need to continue doing this, or, in some instances, maybe I don't need to continue, that's usually more of a supplement than prescription medicine, but those are part of the mix as well.

00:50:19

Moderator, RTI International

I hear you. So these close relationships with community pharmacists, as well as the doctor being involved in making sure that there's a good understanding of the importance of the drugs, side effects to expect, et cetera.

I know we've talked about a number of different factors that matter to patients when considering a potential medication. We've heard about efficacy, we've heard about access, ease of use, frequency. Are there any other factors when considering a potential medication for COPD that you haven't heard about yet that come into play in those decisions that we should talk about?

00:51:03

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

I was going to say one thing, **[Moderator]**. Yeah, we had a period of a lot of hospitalizations, back to back to back, unfortunately, in 2024 and 2025. And every time that we came out of hospital, and came home, the decision about what medicines and when to take and how to take it, it was like, what can we get them to do? It was my mom and my dad, so it was back and forth, so, sorry, I'm speaking in the plural, but it was like, what can we physically get them to do in those immediate days after and encouraging them, like, "this will keep you out or keep you from going back." Even when they didn't really want to take it, or didn't feel it was making a difference, or whatever. And so, I just thought I would call that out, because we really haven't talked about post-hospital, and discharge, and, those immediate days after. You're just you're in survival mode of what can you get them to do and help to start building that strength back? To **[Participant 1]**'s point earlier about frailty, my mom ended up losing 50 pounds in that year and a half, and now she's basically just skin and bones. And her ability to really get up and do anything, cook, clean, go to an event, whatever the case may be, has been significantly impaired because of the frailty issue. And I think that that is, again, something that is not often fully appreciated, or discussed with COPD patients. How do you keep this from happening? Or at least prevent the progression as much as possible. And it was too little, too late in her situation, where it was so quick and so far gone in that in and out of the hospital multiple times in a 12- to 18-month period. [Because of that], I don't know that she'll ever regain that function or strength back.

00:53:43

Moderator, RTI International

I'm sorry to hear that, **[Participant 3]**, and [there are] a lot of important considerations in what you said there, it sounds like. Not only is adherence an issue, just in general, but that adherence and the use of the medications directly following an exacerbation or a hospitalization sounds like it's particularly important. And I also heard that preventing progression, and some activities of daily living, in terms of quality of life, that frailty sounds like it's really impacted quality of life. Thank you for sharing about those considerations. **[Participant 1]**, did you also have something to add about important considerations for choosing a medication?

00:54:23

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

Yeah, the one thing, to add on to, what **[Participant 3]** was saying, I was going to mention that post-discharge and the brouhaha, it's unsettling, to say the least. And I heard someone describe it to me this way, too. It's like, aging, when you're young, you think aging is this gentle decline, and then it's air pockets, and it is dramatic. Being able to appreciate that it is a progressive disease, but slowing, avoiding those air pockets, it's expensive for CMS, it's devastating for the patient and the family, so building that in is so critically important, and that's why I think I just wanted to mention that, that it's hard to recover when you lose 50 pounds. Now you're in kidney failure because this happened, and now you're juggling another chronic condition. But to be able to [slow disease progression], that's an important thing for the patient, the caregiver, of course that is a benefit to these long-acting medicines and management, continued access and coverage, and those types of things.

00:55:36

Moderator, RTI International

Thank you for sharing that. Not only prevention of progression, but also prevention of complications associated with that progression. Thank you for sharing all of that, I appreciate it.

Let's move on to the next topic. You all have provided a lot of really helpful input so far, and I really appreciate that. Now let's talk about how well Anoro Ellipta and other treatments for COPD meet patients' needs. At the beginning of our discussion and throughout, we asked you to reflect on some of the most important aspects of COPD to have managed or treated. Aside from the aspects that you've already shared, what are other medical needs related to this condition that are important to your loved ones or patients you advocate for? Other important medical needs related to COPD. And it's okay if you want to reiterate something that you already said. We just want to get a good understanding of the different medical needs involved.

00:56:43

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

Well, I'll talk a minute about lung function. That's a term that, quite honestly, neither of my parents knew or appreciated, and it was far too long and too late before they really, number one, even knew what that term was, because spirometry wasn't done until five years into the journey, but then how much what their baseline was, and then how much that changes over time, and understanding that the disease is getting worse, but also it's so interconnected to heart disease. Again, with both of them, they have congestive heart disease, and sometimes it's hard to know, is it the heart, is it the lung? Is it the lung? Is it the heart? What is causing that breathlessness? What is causing the fatigue? My dad lives with AFib [atrial fibrillation], as **[Participant 1]** was talking about before, and so it's in those very notable AFib bouts, he knows dramatically, he can feel the difference of his heart racing and when it's out of rhythm. It's much harder for him to realize when his breathing is worsening.

And so, I've tried to have these conversations, and it's more of a slow fade than a "I realize it happening." And again, a lot of times, it's been in those moments where I push to see a pulmonologist, or when I say, "Your controller medicine is clearly no longer taking care of this," or they've had a viral infection or a respiratory infection that has put them in the hospital, where I've been like, "You have to do more. We've got to step up to something else." And, again, because I am an advocate, I think sometimes they're like, "you're just so pushy with the doctor." Well, I don't know what else to do to make sure that you're getting the care that you need. They both really want to be there for one another, and for their great-grandchildren, and all of that. But it's also a weird matter of respect, I think, with your parents specifically. I didn't have the same level of attention when I was a caregiver for just a friend who invited me into that role versus with my parents. And to them, I'll always just be their little girl versus the patient advocate. It's definitely a different thing, I would say. But for us, it was me pushing to say, "we have to increase your medicine. We have to go to a different medicine along the way," specifically increasing to triple therapy for my mom after the second hospitalization where I was like, there's no reason why she shouldn't be on triple anymore.

01:00:10

Moderator, RTI International

I heard a number of different things in there. It sounds like the monitoring of lung function and awareness of lung function that you all unfortunately didn't benefit from early on, but the way that the symptoms are entangled with other comorbid conditions, and managing those comorbid conditions and understanding what is related to what, it sounds like is really a major struggle. In terms of advocating for changes in medication or changes in dosage and such, you specifically mentioned infections, respiratory infections, and I was wondering if you could talk a little bit more about that as a medical need for patients with COPD to deal with that sort of thing.

01:00:57

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

We have this debate about vaccinations, and again, I hope I'm not trying to be political, but my goodness, has it become a political topic in our extended family and home about the importance of vaccination for my mom and dad, whether that be COVID, flu, pneumonia, shingles, all of the above, RSV [respiratory syncytial virus]. We've gone round and round over the last few years about how important it is prior to the peak of season, especially if they're going to be around the grandchildren and great-grandchildren, to have those vaccines and to prevent infection and virus, but it's not always been well received. They've not always done it, even though I've harped on it. And, again, in that 18 months that we were in and out of the hospital, it was largely due to infection.

01:01:57

Moderator, RTI International

Thank you for sharing that, **[Participant 3]**. The importance of avoiding infection, preventing them, whether through vaccines or other methods. What other medical needs can you all share that patients experience related to COPD? **[Participant 4]**?

01:02:18

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

I'll just give you a quick one. Prevention of exacerbations. There's new medications now that can actually help with that, and once again, making sure patients have the right information about escalating care and talking to their doctor about new treatments, and making sure that they can benefit from them. I was going to mention vaccinations, too, but **[Participant 3]** covered that.

01:02:41

Moderator, RTI International

Thank you. So preventing exacerbations, that's helpful to know as another important medical need. **[Participant 1]**, I saw your hand up, and then we'll get to you in a minute, **[Participant 4]**.

01:02:54

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

The other thing I was just going to mention, vaccinations, obviously, that's a big one in our household as well, but also the ability to be independent. My parents still live independently, they take care of each other. Being breathless greatly limits that. Being able to do just basic household things ... they are getting to the point where they're having to let things go. That is extremely challenging. And I'm not just talking about driving, but household things. I can't walk to the mailbox. I mentioned being able to stay off oxygen, that is a big one for him, on full-time oxygen in particular, he may need it on occasion, coming out of the hospital or things like that, but to avoid that is a big deal for him. So those types of things as well, but independence is probably the number one.

01:03:56

Moderator, RTI International

Yeah, thank you for sharing that, for sure. And in terms of independence, I know that can be very closely intertwined with quality of life. Could any of you speak on medical needs related to quality of life and maintaining independence? Or **[Participant 1]**, would you share a little bit more about independence and how that's played a role?

01:04:18

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

Yeah, I can start with that, but being able to do the things that you want to do, and your world gets smaller and smaller, but being able to pick up a grandchild. With my dad, sometimes when he's having a bad episode, he can't bend over and tie his own shoes. He doesn't want someone else to come and put his shoes on for him. I mean, that is just, it's just emotionally devastating. None of us mind doing it, but [to] not be able to do something so simple ... it's just devastating, emotionally. Getting out of breath walking to the mailbox. [He] worked in construction all his life, and so was used to being very physical and strong, and not being able to do something, like having to stop walking upstairs and hold onto the rail and catch his breath for a minute or more, and then finish. That really affects his mental state, his quality of life, and his interest in getting out. If I'm going out for lunch with friends, are there stairs? Am I going to be embarrassed, or am I going to be able to do it? Am I going to be able to walk from the car to the entrance and go in and sit down without having to stop and catch my breath? All of those types of quality of life things that often we take for granted, other people without COPD take for granted. When it's well-managed, you can take it for granted too, which is great, but if it's affecting you, it really can have a dramatic impact.

01:05:56

Moderator, RTI International

I hear you. So not only the importance of independence for quality of life, but also I hear, avoiding embarrassment is a big one. **[Participant 3]**, let me get to you in just one minute. **[Participant 3]**?

01:06:16

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

Yeah, I was just going to echo exactly what **[Participant 1]** was saying. It's been very much a shared experience of the pride, the embarrassment, the mental health, and, just being very anxious, they stopped traveling. The grocery shopping, for example—thankfully, again, now you can get your groceries delivered, but they live in a rural area, and that was fairly recently, and even being able to run out and get whatever my mom needed for the day, or at the grocery store—he wasn't able to do those sorts of things. The embarrassment of friends, the embarrassment with his own family of asking for help to mow the lawn, or the things he's always done. He completely gave up his hobbies of fishing and all of that because he was so out of breath by the time he got the boat in the water that he didn't feel comfortable actually going out on the lake. It's those kinds of things that, again, it should be the time of your life where you're fully enjoying retirement and family and I would say it's certainly had a negative impact overall on their ability to do that in the last five to ten years significantly.

01:07:50

Moderator, RTI International

Thanks, **[Participant 3]**. In addition to being able to do those really important activities of daily living and being able to grocery shop and those sorts of critical things, I hear from you that being able to just do hobbies and the things you enjoy during that time of your life is a really big impact of this condition. Thank you for sharing that. And **[Participant 3]**.

01:08:16

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

Can I say one other thing, **[Moderator]**, that I realize we haven't talked about at all? My dad smoked for about ten years of his entire life. My mom never smoked. But she lived in a household with smokers growing up, and she then lived with my dad in young adulthood as a smoker. And yet, they still, almost every single time they encounter a new provider, have to address their smoking history, and are they currently smoking? It's still a question almost at every visit, and every hospitalization, "are you smoking?" And it is the most annoying thing to both of them. I mean, it really gets them fired up. And it gets me fired up, to be honest, because we don't ask people, did you have a cheeseburger yesterday? When they have heart disease or present with diabetes, and harp on, are you eating healthy, and all of this in the same way? And yet it still has such a stigma associated with this condition, even to the point where, for a while, my mom refused to believe she had COPD because she didn't smoke. And it was several years before I could convince her to believe you can have COPD and never have smoked a cigarette a day in your life.

01:09:55

Moderator, RTI International

Thanks for sharing that, **[Participant 3]**. Dealing with this stigma and having to keep and cover the same ground over and over again about what the risk factors were that may have led to this. I hear you, that sounds like it would get really frustrating over time. Also, **[Participant 3]**, while I'm talking to you, you had mentioned earlier, and I just wanted to go back and clarify, it sounded like maybe your parents were on triple therapy, LABA, LAMA, and ICS, and then they backed down to Anoro Ellipta. Can I—

01:10:28

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

No, actually, it was the opposite. My mom stepped up to triple, not backed down.

01:10:35

Moderator, RTI International

Got it. I was wondering if there were side effects involved in that decision-making, or...

01:10:45

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

Sorry, post-exacerbation and actually multiple exacerbations, when we were able to get her approved, and stepped up.

01:10:55

Moderator, RTI International

So maybe avoiding future exacerbations, or at least reducing them, was the key thing there?

01:11:03

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

Yep.

01:11:04

Moderator, RTI International

Thank you for that. Before we move on, any other medical needs that are important to, to share related to living with COPD that we haven't already talked about?

01:11:18

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

My point about the smoking was that a lot of people do still have a smoking history or are current smokers, and so as an advocate, I often hear the access to nicotine replacement therapy is less than optimal. Treating that as a disease with actual treatment and care and multi approaches to managing that addiction, I think, is a real need in this community as well.

01:11:50

Moderator, RTI International

Got it, thank you. I don't think we had talked about that previously. Tobacco cessation, counseling, advice, other supports, that's definitely helpful to add to the picture. **[Participant 2]**?

01:12:04

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

Yeah, just to add a little bit more onto that, and great point, **[Participant 3]**, thanks for bringing that up, that I think getting access to affordable tobacco uses and cessation interventions, and being able to get connected to a bronchodilator therapy, really complement cessation efforts by controlling symptoms that might otherwise discourage quitting attempts, again, if you are an active smoker, which, as people were mentioning, that is not always the case. But I think that patients who COPD symptoms are well controlled, they may be more receptive to and successful in tobacco cessation programs that a lot of health centers are doing, again, with those clinical pharmacists.

01:12:57

Moderator, RTI International

Thanks, **[Participant 2]**, for sharing that. The medication benefits are also entwined with the level of success that might be expected with tobacco cessation efforts. Thank you for that. **[Participant 3]**, did you have another thing—

01:13:10

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

I'm sorry, I forgot to also mention about outside of treatment, the need for pulmonary rehabilitation and access to oxygen. Both of those two things have been, supplemental oxygen [has] been, barriers in my journey, especially with my friend who I cared for until she passed away last year. And pulmonary rehab, in and out of the hospital, like I said, five times in 18 months, no one ever mentioned pulmonary rehab. And that would never, ever happen if we were dealing with someone with a spinal cord injury, or a TBI [traumatic brain injury], even perhaps cardiac rehab. But with pulmonary rehab, it was like, oh, that's a thing, you should actually do that. Just thinking about, again, the holistic care of the COPD community. And then with **[Redacted]** on supplemental oxygen, it was unbelievable what we had to go through to get her a portable oxygen tank and concentrator. And again, she was a Medicare beneficiary and living independently up until the very end when we had her in hospice care. It's just surprising that, again, that holistic COPD care at every stage is not really fully, supported or appreciated.

01:14:46

Moderator, RTI International

Thank you, **[Participant 3]**. And that's actually a great segue to my next question, which is, we've talked about a lot of different medical needs and important aspects of the condition to have addressed, including relief of symptoms, preventing progression and complications, preventing or reducing exacerbations, and then some of these other things, like other interventions such as oxygen, pulmonary rehab, tobacco cessation.

I want to talk a little bit about the extent to which these various medical needs are being addressed, or not addressed, by existing treatment options and care. When I say treatments, I want to open it up. That could include Anoro Ellipta, other medications used for COPD, or other types of available treatments for this condition. Could you all comment on the extent to which these different medical needs are being addressed, or not addressed, by current treatment options? **[Participant 1]**?

01:16:04

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

I'll just chime in a little bit. I think that there are two things. One is the medicine, and then one that I haven't seen as much is that coordination that you see in other disease states—I'm sure a lot of people may push back and say not so much, there's room for growth [improved coordination] there everywhere—but to **[Participant 3]**'s point, when she was talking about pulmonary rehab, how important that is, and it shouldn't just be, here's a prescription for medicine, it's like, here's some exercises you can do, here's some other things that you can do, here's what to look out for. That communication between the pulmonologist and the cardiologist and the primary care physician, that really helped to surround the patient and help them slow the progression and achieve that quality of life and reduce those medical symptoms and challenges. That does not happen, or at least in my experience, maybe it does in pockets, but not necessarily everywhere, and that drives up costs for everybody and reduces health for everybody. In terms of the medicine itself, I think there are a lot of ways that we can optimize the benefits that we get out of these medicines by helping to create that surround that really is supportive. And right now, it falls on caregivers a lot to try to navigate that. Many of us, it sounds like **[Participant 3]**'s doing it from a distance, I'm doing it from a distance, and that it's not necessarily helping the patient, it's not helping the caregiver, and certainly not helping Medicare in terms of saving money and reducing the poor outcomes for these beneficiaries.

01:18:03

Moderator, RTI International

Thanks, **[Participant 1]**. The coordination of care is another important medical need that we have maybe skirted around, but haven't talked about directly until now, and it sounds like, from your perspective, that medical need of coordination of care has not been addressed in your experiences, or would be, you wish it were more optimal, at least. Can I follow up on one thing? I know you had mentioned pulmonary rehab a few times. Is that something that your parents did, and if so, was it successful?

01:18:37

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

My dad got cardio rehab, which is and was super helpful. It was a post-hospitalization. It helped with his breathing, too, because exercise is helpful. But yes, he went through, I think it was 12 weeks of cardio rehab after a heart failure hospitalization, and he was up to walking a mile and a half on a treadmill. I mean, it was remarkable. So that type of thing really can be helpful. He felt great, he was impressed by his progress, they track progress, so in terms of helping the patient see, it's not just "I'm able to walk up the stairs," but there are milestones. So that type of stuff is really, really helpful. And even if it's not rehab, I know sometimes that's important because it shows them what they can do, and they're in a setting where they feel comfortable and not at risk. If I just went to the Y and got on a treadmill, I may not feel comfortable, but in a rehab setting where I know where my limits are, they're monitoring me, that is really helpful. It did really help him a lot.

01:19:51

Moderator, RTI International

Thank you for that, **[Participant 1]**. And so back to the question of the extent to which medical needs are being addressed, or not addressed, by existing treatments, let's talk about symptoms and relief of symptoms. I know breathlessness, that's one that we talked about quite a lot, actually, towards the beginning. To what extent are medications that are available at this point addressing or not addressing symptoms? **[Participant 3]**?

01:20:33

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

I would say that, for patients who, number one, are diagnosed, which is only about half of all COPD patients, who, number two, are appropriately managed, which I would say is even half of the group that's diagnosed, and then for those that actually take the medicine as prescribed, which is probably half of those, so we're talking approximately, if I do my math right, less than one in four, are getting the medicine that they should be getting to stay well-controlled. For those that are, and that are taking it routinely and well, I would say they're—and I'm thankful in that there's been periods of that with all the people that I've been involved with in managing their condition. The thing that happens, though, is that, as we talked about early on when they have a period of stability, it's like, I'm doing better, I'm going to go off my medicine. And I'm like, no, that's not the way this works. You have to keep taking your medicine. But there is this sort of pushback. Again, what I want to say is that when people take the medicines correctly, they work. They really do, for most people. It's a matter of having access to them, knowing the importance of taking them consistently, and controlling the things that could cause a flare that are the key to COPD management. And that prevention, diagnosis, treatment, and long-term management, all four key pillars of COPD that I think, unfortunately, are not fully appreciated or are reinforced.

01:22:33

Moderator, RTI International

Thank you for that point, **[Participant 3]**. So there's a big caveat on this question that is to be able to address these medical needs, the medications have to be taken, and taken properly, and such. There's a big asterisk by this one. **[Participant 1]**, what do you have to add about the extent to which medical needs are or are not being addressed by existing treatment options?

01:22:57

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

Yeah, no, I agree with **[Participant 3]** from what I've seen from others dealing with this illness, is that when you are taking the medicine, you're on the right medicine for you, that works for you, you avoid those air pockets. It's like I was saying, it is a progressive disease, so maybe you're progressing, but it's not as noticeable. It's not interfering with your daily life. You're able to go ahead and move forward. And you're on that slower decline, if you will. But it's more gradual. You're avoiding the hospitalizations, you're not having to cut back as dramatically on your life, and what you want to do, and what you enjoy doing, so you aren't seeing that that decline, and when you hit those, you have an exacerbation, maybe you end up in the hospital, maybe you don't, but it affects everything. For my dad, when he goes on antibiotics, his diabetes flares because his blood sugar increases. Those tranquil periods where everything's going well are so precious, and that's when they're taking the medicine, they're on the right medicine, they're taking it as prescribed, that's what you get, and that's really valuable.

01:24:17

Moderator, RTI International

Thank you for that, **[Participant 1]**. Again, another plug for the importance of taking these medications and taking them properly to really realize the benefits of them in terms of addressing these medical needs. What about preventing and reducing exacerbations? That was an important medical need that we talked about quite a bit at the beginning. To what extent do existing treatments address the need of reducing and preventing exacerbations?

01:24:54

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

Again, I think it's a combination of the medicine and the adherence to the medicine, the ease of use, that really helps. That combination is the secret sauce, if you will, to reducing those urgent situations.

01:25:11

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

Yeah, and the prevention piece that we talked about seasonally, and exposures. But there's still breakthrough. This is part of the disease, being chronic, being progressive. We definitely don't have all the answers, and I also am not sure that COPD is a single disease, to be honest. I think that we are learning more and more as the science evolves, that there are likely different types of COPD that are more responsive to different types of medicines. So as science evolves, I'm hoping that we get better at the treatment side of this disease as well. But we don't have it all figured out. And again, it's been an area with pretty low prioritization and investment, and if you look again at the data, half of all patients have a flare each year of those that are diagnosed. It's certainly still a lot of unmet need.

01:26:24

Moderator, RTI International

Thank you, **[Participant 3]**. And I know, collectively, you all have experience with a number of different medications, whether it's the folks that you advocate for or the folks that you're taking care of. Do you feel that certain medications or treatments address these different medical needs to a greater or lesser extent than others? I know that's a big question, since there are a lot of different medications that you all know folks who have experience with, but are any of those doing a better or worse job of addressing?

01:27:04

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

I think the data's clear about triple therapy, to be honest. Triple therapy definitely has better outcomes in the more moderate to severe category. I hear that anecdotally from people living with the condition and from their caregivers as well, so I would definitely say that, and that's what the guidelines say. We need to be moving people to triple, especially in light of exacerbations and flares.

01:27:36

Moderator, RTI International

And in terms of the different triple therapy options, do you hear better or worse things about one versus the other? I believe off the top of my head, that's Trelegy and Breztri.

01:27:53

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

I hear positive things about both, to be honest. I can't say that one more than the other, from my perspective.

01:28:01

Moderator, RTI International

Got it. Any other comments on that, the extent to which certain medications or treatments are addressing medical needs to a greater or less extent than others? And are there major gaps beyond the ones that we've already talked about in treatment or concerns that remain despite currently available treatment options? What types of needs remain despite currently available treatment options? **[Participant 1]**?

01:28:41

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

Sorry, I needed to step away. I would just say there's not a cure. I mean, that's the ultimate, or even greater slowing of progression, or the ability to intervene really early and stop the damage.

01:29:00

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

Yeah, and I would say, we've had an introduction of biologics in the COPD space very recently, and we're learning more about other pathways that may help to slow that progression of disease if intervened earlier. Again, I think it's a little early to say because these are pretty novel treatments with very few patients, but in the clinical trials, at least, they look like that they definitely help to slow that progression, keep people out of hospital, reduce steroid use for those oral steroid patients, and again, that's probably a very specific phenotype of COPD patient.

01:29:52

Moderator, RTI International

Thanks to both of you. A cure, or at least early intervention, to more successfully reduce the progression of the disease, or to slow it down. Any other major gaps in treatment or concerns that remain despite what's available today?

Well, the event is nearly over. Before we part ways, I want to give you an opportunity to summarize your thoughts on the importance of Anoro Ellipta for patients or raise any topics that you feel were not adequately covered by our discussion today. Do you all have any final thoughts about Anoro Ellipta, COPD, or other medications that treat COPD, that you feel are important to share with CMS before we part ways? **[Participant 4]**?

01:30:51

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

Yeah, we're here representing patients or patient advocacy groups, but the one thing is, [how] are the results of what we're doing going to impact the price negotiations? And the one thing that I worry about is price negotiations to the point where it becomes unavailable to patients, or it is not affordable for patients. Because we know a lot of patients rely on Medicare Advantage plans, and there's formularies, and the drug may or may not get on there. So how [is] that going to ultimately impact that? And so, I just wanted to make the point that we want drugs to be affordable, but we also want to make sure that they're available.

01:31:36

Moderator, RTI International

Thank you, **[Participant 4]**. The importance of availability of different options and minimizing unintended impact.

01:31:43

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

Yeah, and we went through this with Flovent, which is another GSK drug a few years, a couple years ago, and ultimately, patients who really needed that important drug just couldn't get it. Different circumstances, but it was ultimately something that really concerned our community.

01:32:03

Moderator, RTI International

Thank you for sharing, **[Participant 4]**. Other final thoughts about Anoro Ellipta, or COPD, or other medications that treat COPD?

01:32:12

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

Yeah, **[Moderator]**, I think it's important for CMS to really step back and think about, we're talking about the third leading cause of death and disability in the U.S. And yet, we are considering limiting access to the life-saving treatments in a space where there's been limited options for so long. It just doesn't even make sense to me that this is a disease area of consideration at this point, to be honest. COPD is under-prioritized, under-recognized, under-diagnosed, under-managed across the board in the U.S. And it is our most vulnerable populations. And yes, I'm passionate about this because it is my parents, it is my loved ones. I've watched someone die from COPD. And so, yeah, I'm passionate about it. And I cannot, I can hardly fathom the thought that we would limit access to this treatment or have a consideration that would force people to change medication when they were well managed.

01:33:29

Moderator, RTI International

Thank you, **[Participant 3]**. And I just want to put, I know I mentioned it at the beginning, and we'll show it again at the end, but for comments about the drug price negotiation and policy and such, there is that mailbox that you can submit that sort of input to. I would, I wanted to put another plug in for that. Any other closing, final thoughts that you want to share with CMS about these medications or this condition? **[Participant 1]**?

01:33:56

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

Yes, I would, the other thing I would just add is that I have concerns that oftentimes, we're just looking at focusing in, and so I appreciate these sessions because you get a more holistic view of what the patient experience is, but your focus is really on how do we make this, how do we pay less for this medicine, and I just want to make sure that you're considering the landscape of impact on choice, on access, on diagnosis, reducing stigma, you've got a population where well over half have multiple chronic conditions. I think over 50% have three or more, so they're juggling a lot. For the individual patient, for the individual, for the caregiver, we're looking at a whole host of things, so upsetting the apple cart or upsetting access on one end has a huge ripple effect, and please consider that as you're looking at this, to look at it holistically and not narrowly at one drug, one price, that type of thing.

01:35:05

Moderator, RTI International

I'm hearing a big theme of the importance of having lots of different options for this, for this patient population. **[Participant 4]**?

01:35:13

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

Yeah, I took some notes during our session, and these were my big things, were making sure it's affordable and accessible. Therapeutic alternatives are not necessarily equal or equivalent. Therapeutic alternatives may not work well for one patient versus another. Once-daily dosing versus twice-daily dosing is really important. Combination devices are preferred over individual devices because of ease of use and convenience for the patient, and there's a difference between DPI versus slow mist versus MDI [metered-dose inhalers], and those need to be based on patient ability to use those devices the way they're intended.

01:35:55

Moderator, RTI International

Thank you, **[Participant 4]**. You started doing some of our analysis work for us. I appreciate it. Those are definitely some of the key points that I heard as well, and I appreciate everybody's input on those. Any other closing thoughts for CMS before we call it a day? **[Participant 1]**?

01:36:10

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

Yeah, just one other thing, and I mentioned this before, when you're dealing with combination therapy, I think it's really important that they are greater than the sum of their parts, and **[Participant 4]** mentioned this, is that ease of use is important. I think with a number of combination therapies, there's some synergy there in terms of the medications themselves working together. For the patient, that ease of use is hugely important as well, and an adherence standpoint, it's so important to encourage those combination therapies. I mean, as **[Participant 3]** mentioned too, triple therapy has become the gold standard or guideline treatment for people at the severe end of the disease, and that's so important in terms of going forward for this medicine, but for us.

01:37:02

Moderator, RTI International

Thanks, **[Participant 1]**. It sounds like there are really some unique benefits associated with combination therapies, not only in ease of use, but in other respects as well.

Closing Remarks

01:37:17

Moderator, RTI International

Okay, everybody, that is it for me. I want to invite my CMS colleagues back to say goodbye here. **[CMS Staff]**?

01:37:31

CMS Staff

Thank you, **[Moderator]**, and thank you, everyone, very much for sharing your experiences and the experiences of your loved ones with us today. As **[Moderator]** said, the input you provided is incredibly valuable to CMS, and you've given us a lot to think about, and we are very grateful for your time today. Thank you.

01:37:52

Moderator, RTI International

Thank you, **[CMS Staff]**. And thanks to you all, again, for participating in today's event. We really appreciate you all taking the time to talk with us today, and your experiences and input were, like **[CMS Staff]** said, extremely valuable, and they'll help inform CMS' negotiations for Medicare pricing for Anoro Ellipta. And if you all have any questions following today's session, you can submit them to that mailbox that we mentioned. That's IRARebateAndNegotiation@cms.hhs.gov with the subject line "Public Engagement Events." Thank you so much again for your time today. I hope that all of you take care. Again, I really appreciate your input.

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

Participant 3: Registered as a caregiver who has experience caring for an individual who is treated by the selected drug, with the conditions treated by the selected drug, or other treatment(s) or drug(s) similar to the selected drug for those condition(s); representative of a patient advocacy organization

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

Participant 4: Registered as a representative of a patient advocacy organization

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