Transcript: Entyvio Roundtable Event, April 9, 2026, Medicare Drug Price Negotiation Program Public Engagement Events

MEDICARE DRUG PRICE NEGOTIATION PROGRAM
CENTERS FOR MEDICARE & MEDICAID SERVICES

This transcript was lightly edited for readability.

Introductory Remarks

Moderator, RTI International

Thank you so much for coming today. I'm **[Moderator]**, and I am with RTI International. I also want to introduce my colleague here, **[Secondary Moderator]**, who you may hear from today during the discussion. The Centers for Medicare & Medicaid Services, which we're going to refer to as CMS as an acronym, 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, and also patients' experiences with the selected drugs themselves, and patients' experiences with other drugs that are used to treat the selected conditions. The information shared during these events will also help CMS identify other medications used to treat the conditions treated by the selected drug and 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 all of you, so a group that may include patients, caregivers, and patient advocates about your experiences with the conditions and diseases treated by Entyvio. I want to emphasize that our focus today will be on the patient experience. If you wish to share other input on topics related to the Drug Negotiation Program that are not directly focused on the patient experience, we ask that you send that input to the mailbox that is in the chat, and that is IRARebateAndNegotiation@cms.hhs.gov instead of sharing that information today. Again, if you have extra input, you can send it to that email.

Your experience and perspectives are so very important to us. And we genuinely appreciate your time today. Along those lines, we're going to 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

00:02:46

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

Hi, everyone. I'm Dr. Mehmet Oz.

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

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

It is a crucial conversation.

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

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

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

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

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

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

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

00:04:38

Moderator, RTI International

I also want to make all of 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 **[CMS Staff]** from CMS from a moment, so they can say hello.

00:04:57

CMS Staff

Thank you, **[Moderator]**. Welcome, everyone. I'm **[CMS Staff]** from the CMS Drug Price Negotiation Team. As **[Moderator]** said, there are other CMS staff on the call today as well, and we work on the policies for getting public input and negotiating Medicare drug pricing. Now, on behalf of CMS, I want to thank you for participating today, and we look forward to hearing about your experiences during this roundtable discussion. We're going to go off camera now, so you can focus on the discussion, but thank you.

Housekeeping

00:05:35

Moderator, RTI International

All right, everyone, before we get started with the discussion, I do need to review some basic housekeeping items and ground rules, so everybody knows what to expect today. There's a lot here, bear with me.

First of all, if you do get disconnected, please attempt to rejoin. If you cannot connect, please reach out to IRADAPStechsupport@telligen.com and that email address would have appeared in some of the materials that you received from them.

This discussion is not open to the press or public, and we will use first name 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 the medical facility where you received care, or any personally identifying information, such as your employer's name, the city you live, names of schools you attended, etc., during this discussion. And then following the event, CMS will prepare transcripts where participants' names and identifying information will have been removed, and these transcripts will be available to the public.

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

We also hope that you will contribute your perspective throughout the session. However, if any questions arise that you don't want to answer, that is okay.

And also, please minimize background noise by silencing any cell phones and other devices if you haven't already done so. And also, if you can, just mute yourself when you're not speaking and unmute yourself when you're ready to jump in.

And thank you again for keeping your video on during this discussion. It's always helpful to see faces and engage with each other.

We have reserved today up to two hours for this discussion, but it is possible we may not need the full two hours. If that happens, we can let everyone go a bit early. I do have a discussion guide here in front of me, and that's going to help me stay on track, and we have a lot of topics to cover, so I may need to redirect our conversation, or at times cut a conversation short. And that's in order for us to have time to cover everything that we want to.

If we do go the full two hours, or even less, and you need a break, you may briefly step away during this discussion, and that is totally fine. Just turn off your camera and microphone if you need to do that, and rejoin when you are able. And you don't need to tell me or announce that you need to step away, you can just do that and return to the discussion when you're able.

And then, please try to speak one at a time. I may need to occasionally interrupt people so that everybody has a chance to speak. I believe that we already went over the raise hand feature that's available there in Zoom, so you can use that raise hand feature to indicate that you would like to speak, and that will help us know when somebody would like to add to the discussion.

And I think you were also made familiar with the chat feature. You may add some comments to the chat. We hope you will add the comments to the discussion, but if there's anything that you did not get a chance to say and want to put in the chat, you may do so.

Unless anyone has any other questions about what I've reviewed, we can get started. Any other questions on housekeeping? Let's go ahead and begin.

I would like to begin our discussion today by asking each of you to introduce yourselves briefly, and take a minute to do the following. We would love to know your first name, and then whether you are sharing your experience as a patient, as a caregiver, or as a patient advocate, so some of you may be wearing multiple hats. And then I'd also like to know the condition that Entyvio treats that you have experience with.

Let me go around the room in order that I see all of you on my screen. If it's okay, can we start with **[Participant 1]**?

Discussion

00:10:27

Participant 1 (registered as a patient)

Hello, I'm **[Participant 1]**, and I am a patient on Entyvio for Crohn's disease.

00:10:35

Moderator, RTI International

For Crohn's disease. Okay. Let's go next to **[Participant 2]**.

00:10:45

Participant 2 (registered as a patient))

Hi there, I'm **[Participant 2]**, and I'm also a patient on Entyvio for Crohn's disease as well.

00:10:52

Moderator, RTI International

Thank you, **[Participant 2]**, for being here. Hi, **[Participant 3]**.

00:11:00

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

Hello, I'm **[Participant 3]**. I'm an ulcerative colitis [UC] patient, and I'm also here representing the Crohn's & Colitis Foundation.

00:11:11

Moderator, RTI International

Okay. Thank you, **[Participant 3]**. And **[Participant 4]** .

00:11:19

Participant 4 (registered as a caregiver)

Hello, my name is **[Participant 4]**, and I'm a caregiver. My son is 12, he turns 12 next week, and he has Crohn's disease, and he is currently taking Entyvio.

00:11:31

Moderator, RTI International

Okay. Thank you for giving us that perspective today, **[Participant 4]**. Hi, **[Participant 5]**.

00:11:39

Participant 5 (registered as a patient)

Hello, my name's **[Participant 5]**, I have ulcerative colitis, and I'm on Entyvio as well.

00:11:44

Moderator, RTI International

Okay. Thank you, **[Participant 5]**. And is it okay if we refer to ulcerative colitis today as UC? Is there an acronym that you typically like to use?

00:11:53

Participant 5 (registered as a patient)

That's fine.

00:11:54

Moderator, RTI International

Okay. And **[Participant 6]**.

00:12:17

Participant 6 (registered as a patient)

I'm **[Participant 6]**, and I am a patient with ulcerative colitis on Entyvio.

00:12:22

Moderator, RTI International

Thank you so much for sharing that. As you all heard, we do have participants today with experiences related both to Crohn's, some of you, and others, UC. And, it will be really interesting today to tease apart some of those differences between those two conditions that are treated by Entyvio. If you wouldn't mind, when we speak today, if you could cue us or remind the group which condition you're referring to. For example, you might say, when I was considering treatment for my Crohn's, I thought about X, Y, and Z. That will help us keep track. Let's get started. We're going to start today by talking about patients' experiences with the conditions treated by Entyvio. We want to know about your experiences with Crohn's and UC. Thinking about the different ways that Crohn's and UC affects patients' lives, what would you say are the most important aspects of these conditions to have managed or treated? Again, what are the most important aspects of Crohn's and UC to have managed and treated. And if somebody wants to just jump in, that is just fine.

00:13:48

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

I'll break the ice. Crohn's and ulcerative colitis are degenerative, chronic diseases. There is not a cure and there's no way to prevent them that we know of today. The most important thing that can be done when treating patients with these diseases is to bring them into remission, and keep them there as long as possible, so that continued damage to the digestive tract does not happen, which will happen if you do not have the proper medication.

00:14:30

Moderator, RTI International

Okay. Thank you for sharing that, **[Participant 3]**. It sounds like remission is a key goal for you?

00:14:36

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

Right.

00:14:37

Moderator, RTI International

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

00:14:43

Participant 2 (registered as a patient)

One of the most pressing things that I have found helpful with any medication is, essentially, the changing of bowel habits, if possible. It's one of those diseases that's not always comfortable to talk about, but many patients with Crohn's and colitis suffer from a lot of urgency when using the bathroom. So, bathroom access or controlling the symptoms that lead to a lot of bathroom trips each day is important. I also have experienced fatigue as probably part of the disease, and I appreciate when that can be managed as well.

00:15:27

Moderator, RTI International

Okay, thank you, **[Participant 2]**, for sharing those. Are there any other key symptoms that these drugs need to manage for you? You mentioned some good ones.

00:15:37

Participant 1 (registered as a patient)

For me, I didn't start having symptoms until I started having bowel obstructions from Crohn's disease, and literally, in a ten-year span, I had 15 bowel obstructions in addition to multiple other things. And that's been a very critical part. It's been eight years since my last one. Still, if I have a coughing fit, my husband's knocking on the door saying, are we going to the ER [emergency room] again? But, getting my Crohn's under control, in addition to the stuff that was just mentioned with bowel habits and fatigue, but getting past having those. One time I had two obstructions four weeks apart, and getting past that has been really critical for us, because I couldn't do much of anything for a while there.

00:16:38

Moderator, RTI International

That's really helpful to hear, **[Participant 1]**. It sounds like this is a long-term problem that you're looking to prevent—the obstruction. What about any day-to-day symptoms? Are there any day-to-day symptoms that you hope to manage?

00:16:52

Participant 1 (registered as a patient)

The bowel habits are always a big part of anything for anybody who's got inflammatory bowel disease [IBD], and the fatigue, and also the cramping and the bloating that tends to go along with Crohn's disease. And, when you literally double over on the street because of the cramping being so bad hitting you, it's difficult. I was walking down the street in **[Redacted]** one time when it hit, and that wasn't good.

00:17:27

Moderator, RTI International

Thank you for sharing that. What about **[Participant 4]**?

00:17:33

Participant 4 (registered as a caregiver)

Again, I have the perspective as a parent of a pediatric Crohn's patient, and one of the biggest hurdles for us is growth. When your disease is not well controlled, one, it really lowers his appetite. And then whatever he does eat, his body literally has trouble absorbing the nutrients from what he eats, and so delayed growth is something that he has struggled with a lot. Obviously that's something that's particular to a pediatric patient because adults have already done their growing, but that's really a key factor for us. And then another thing that relates to all of these symptoms that other people have talked about, the mental and emotional health that goes along with having a chronic illness. And again, that may be more critical for an adolescent or somebody who's just trying to figure out who they are. But I think even though, obviously, a drug like Entyvio doesn't treat mental health, they're all interconnected and related, so if you're on a medicine that works for you, and can get your disease into remission, as **[Participant 3]** said, then your mental and emotional health will then benefit as well.

00:19:25

Moderator, RTI International

Thank you for sharing, **[Participant 4]**. I know it's not always easy talking about. I really appreciate your openness. Thank you. What about **[Participant 5]**?

00:19:34

Participant 5 (registered as a patient)

I can definitely echo some of what other people already said. Definitely symptom control, so pain, bowel movements, fatigue. Quality of life, it affects when you can leave the house, your work performance. I would also say depression as well, in terms of mental health, definitely echo you there, and then just overall remission as well, so endoscopic as well as in the pathology, I think. Something I've thought about more later in life, when you see something bad during a scope that could lead to cancer, so I think having a treatment that could prevent that as well.

00:20:10

Moderator, RTI International

Okay. You shared some great points there. I'd love to unpack a little bit with this group, and then, **[Participant 6]**, I'll get to your hand as well. I'll be sure not to miss you. I would love to unpack quality of life a little bit. Can you describe a little bit about how these medications benefit quality of life? Go into some detail or examples?

00:20:34

Participant 5 (registered as a patient)

I think if you're having symptoms, you have to think about where every single bathroom is. You might say, okay, you know what, I'm not going to go to do this activity, I'm not going to go on this hike because I just can't do that. I think in terms of work, when I had a flare four years ago, I was

consistently running to the bathroom every 20 minutes and I was trying to do time-lapse experiments, and that was really challenging. I would say those are two examples I have.

00:21:07

Moderator, RTI International

Okay. That's helpful, thank you. **[Participant 6]**, we'll get to your comment. Go ahead.

00:21:13

Participant 6 (registered as a patient)

Quality of life. Just being able to participate in my child's life, keeping the flares at bay and the symptoms at bay are super important.

00:21:52

Moderator, RTI International

[Participant 1], I see your hand as well. I think we've touched on something important that we would like to unpack more. **[Participant 1]**, why don't you get us started? Go ahead.

00:22:06

Participant 1 (registered as a patient))

I'm fortunate to have a very supportive husband, which makes a world of difference, but there are so many little things people don't think about. I've had to change what clothes I can wear because of the bloating and the abdominal pain. I can't wear jeans that zip up anymore. I can't wear anything that buttons at the waist because of nerve damage from my surgeries that I've had done. Now that I'm on Entyvio, I can be freer with my diet, but for a long time my diet was three-quarters liquids. I ate saltines and meat and very little solids. I was even juicing vegetables, just because I so craved anything that tasted fresh. But I couldn't eat the vegetables because I'd have another bowel obstruction if I did. And, traveling, my husband and I love to travel, and there have been some unpleasant experiences associated with that, including landing in the hospital twice. Fortunately, both times in this country. But, when you have to think about what you're eating and how it's going to affect you in the next 24 hours or so. I have literally traveled with, gone overseas, with foods that I know I can eat and with my packets of the shakes that I used to drink all the time because we knew I couldn't just eat whatever came up in Prague, Czechoslovakia. And there are trips we have not gone on. We currently live in an area that's well-known for the outdoors and all of the hiking, but I don't want to go hiking with anybody but my husband because he knows if I get hit with what I call a "Crohn's moment," he will guard the trail for me. And, you have to think about what you wear, what you eat, where you're going. It affects everything.

00:24:26

Moderator, RTI International

Thank you. Who else would like to add to that? **[Participant 3]**, would you like to share a little more?

00:24:35

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

I want to talk about some of the complications if IBD [inflammatory bowel disease] is not properly controlled, and these would be things like, in the pediatric population, we very much worry about cognitive development as well as growth. Kids who have IBD most often miss a lot of school and

end up having to skip grades or do other things to catch up with their peers in school. It definitely can impact your ability to work. And if not properly treated, IBD can lead to fistulas, which are when the bowel opens and there is basically a hole in the intestinal tract, which can be deadly. It can cause infections, as well as bowel obstructions can be deadly. Often when things like that happen, what you end up with are bowel resections. And most IBD patients will have bowel resections, and many will have multiple surgeries, and especially within colitis, you will see, if somebody has uncontrolled colitis, they will end up with a colostomy, where their colon is surgically removed. And then either they have a J-pouch [ileal pouch-anal anastomosis or IPAA], which is where colon is formed out of a part of the digestive tract, which works for some people, but also often has complications, or they have an ostomy, and they live the rest of their life with an ostomy, which definitely does impact the way that you live, in not only that you have to be careful that you have the ostomy properly sized and fitted and working, but it impacts your ability to interact with other people because people don't want to talk about it. You're walking around with a bag, it impacts interpersonal relations, and you have to be careful about where you go, that you have the ability to, I've heard this mainly from students, have access to your sterile supplies as needed. I'm sure I'm forgetting something, but the other patients, I'm sure, will think of them.

00:26:54

Moderator, RTI International

Thank you for sharing. What about **[Participant 2]**?

00:26:59

Participant 2 (registered as a patient)

About the quality of life, I thought of two things. One of them is just reliability. I feel like I'm not a reliable person all the time anymore, which, as a person, and a volunteer, and a mom, and a spouse, the list goes on. And thankfully, those who know me well know that I'm not a flaky person. I missed my daughter's, I went to her baptism when she was really little, and I had to lie down for the party that we had afterwards, and it was really hard. This was before I started on the right medication. And more recently, my son's 12th birthday, I had a little bit of a flare, so I didn't go to that. It's hard when you want to be reliable, and your body sort of does something that opposes that. That's quality of life. And the other thing that **[Participant 4]** touched on is the relationship with food that many patients develop. We often will find what we call a trigger food, and then we also know which foods, after a while of having the disease, are more nourishing and we can handle when we're in a flare. It changes our relationship with food. I know some people who are on NPO [nothing by mouth], and they can't eat, but they still will go out with friends and have a glass of water, maybe, but they have to explain to them and the server at the place, they sometimes will make up an excuse of, "Oh, I'm intermittent fasting," or something like that, so they don't have to go into a little spiel of having IBD.

00:28:46

Moderator, RTI International

Thank you for sharing that. I also wanted to go back to another topic, **[Participant 5]**, I believe that you touched on was the potential increased risk of colorectal cancer, with UC. Is there anything that anyone can elaborate on that, if that impairs your quality of life, or how you think about that?

00:29:11

Participant 1 (registered as a patient)

I wouldn't say it impairs my quality of life that much but I know even the one time I was declared in remission from Crohn's, and actually, technically, I'm in remission from Crohn's, but I've got other inflammation. Anyway, that's another complication. Even then, I have a colonoscopy every three years. I can't ever go to the ten years, or even five years. But even if I stay in remission, I have to face up to having a colonoscopy every three years. I scream at the TV when I see those Cologuard commercials, because we are never a candidate for those. I know that it's just something that's always in the back of your mind, oh yeah, I have to go through this again soon.

00:30:06

Moderator, RTI International

Thank you.

00:30:09

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

I'll jump in. The big thing is a whole heck of a lot of colonoscopies. A whole heck of a lot. I was at the five-year plan, then I was at the three-year plan, and now I'm at the one-year plan. And they're not fun. And you hear about the multi-cancer blood tests, that won't work for us. Cologuard, that won't work for us. We're at such high risk that none of those are even offered.

00:30:39

Moderator, RTI International

[Participant 4].

00:30:40

Participant 4 (registered as a caregiver)

Just to piggyback on that a little bit, colonoscopy is not fun for anybody, but think about being six and getting one. And related to that, doctor's appointments in general, and all the medical needs. My son is a great student, and he hates missing school. He's actually on spring break right now so tomorrow he's having an infusion, and a lot of other times we try to schedule things when he has a day off at school so that he doesn't have to miss school. But then you don't get to have fun on your days off, and your breaks, and your weekends, because you're going to get infusions, you're going to see the doctor, you're going to get your colonoscopy this summer. I think that's another aspect that maybe hasn't been mentioned as much, is just the time. And I don't know how much other people have to travel, but he goes to a children's hospital which is not where we live, so it's not just the appointment, but it's the travel time back and forth. Another aspect of quality of life and dealing with a disease.

00:31:57

Moderator, RTI International

That sounds challenging, yes.

00:32:00

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

I personally do not take Entyvio. I take nothing that is infused, but I think that other people on this call could speak to what it means to have to be able to go to an infusion center every four, six, or eight weeks, and it impacts whether you can travel and the way you live your life as well.

00:32:21

Moderator, RTI International

Thank you, and we're going to touch a lot on treatments for UC and Crohn's here in a minute, so we'll put a pin in that and come back to treatments here in a moment. Thank you. We'll have **[Participant 5]** and **[Participant 1]** make a few more comments about the experiences of living with these conditions. Go ahead, **[Participant 5]**.

00:32:42

Participant 5 (registered as a patient)

Just to directly answer your question before, I was just told by my doctor that if she sees any sign of anything that looks like cancer, I'm going to the surgeon immediately, just to directly answer that.

00:32:56

Moderator, RTI International

Okay. Thanks for clarifying that.

00:32:57

Participant 1 (registered as a patient)

I wanted to piggyback onto the traveling aspect because the last place we lived, my gastroenterologist lives 65 miles away. And that was in northern Michigan, and I had to go up there to get the infusions I was on at the time, and let me tell you, driving along Lake Michigan at eight o'clock in the morning when you've got a lake effect snowstorm coming in is not fun, and there were a couple of times that I just barely made it up there for the infusions, and you couldn't take the back roads that were further inland because they weren't plowed yet. And even now, my local GI [gastroenterologist] team is very attentive, but they've had to consult with a GI team and an academic center, so we've had to take several trips to an academic center, which is four hours away to see the GI doctor there, too. It interferes, we find ways, while we're going over there right now, what else can we make do with our time? But it even gets into your life for adults, although I can see it's worse for children.

00:34:25

Moderator, RTI International

Thank you for sharing, and I also see a comment from **[Participant 2]** here on the topic of colonoscopy, is when there is a polyp or something abnormal detected, it says it can be a worrisome finding, so thank you for sharing that as well. I can imagine so. Thank you for sharing so candidly and honestly these experiences of what it's like to live with Crohn's and UC. I appreciate your openness in sharing your stories, what it's like as a patient, and also as a parent, as a caregiver, so this has been really helpful for us to understand. We're going to shift gears just a little bit here and talk now about your experiences with medications to treat Crohn's or UC, so these conditions

that are treated by Entyvio. First of all, what medications have you personally, or your loved ones, or the patients you advocate for, what medications have you taken, either currently or in the past to treat Crohn's and colitis? And it might be easier just to put those names of the medications in the chat, because I'm sure there's a lot to say there, so if you wouldn't mind just taking a minute and naming those medications in the chat.

And if you've also taken Entyvio, if you can mention that in the chat as well. Some of you may have, some may not. Thank you for putting all that in there, and it looks like some of you have experience with multiple medications. For the next few questions, I want to note that you may have used multiple medications, so, please make sure to specify which medication you're talking about. Some of you have taken multiple medications, so if you could just cue us into saying, when I took medication X versus medication Y, that will help us remember where we are and keep track. Let me ask this question. What benefits have you or your loved ones or patients you advocate for experienced with medications for Crohn's and colitis? As a reminder, just let us know what medication you're talking about, and let us know what the benefits to those medications are. **[Participant 5]**, you want to kick us off?

00:38:15

Participant 5 (registered as a patient)

When I was first diagnosed I was on Asacol for three years. I think the benefit at the time is that I had a mild case, and it was an easy-to-take pill for a child, and there were no real side effects other than burping, I think. Other than controlling my symptoms, I cannot really say anything positive about 6-MP [mercaptopurine] or prednisone, both severely impacted my quality of life. And I would say Entyvio has been great, it's gut selective, therefore it does not affect the rest of your immune system very much, which is definitely different than a lot of other biologics, so I think that's been way different than, the 6-MP or the prednisone.

00:39:08

Moderator, RTI International

Really helpful. Thanks for teasing apart the different benefits for the different drugs, that's really helpful to hear. Let's turn to **[Participant 2]**, if you could just walk us through some of these medications and the benefits to these medications.

00:39:21

Participant 2 (registered as a patient)

I agree that prednisone is not great. It can be good for short-term relief maybe while you're getting used to another medication, but the side effects are severe and known. I had moon face, emotional volatility, smelled like a barnyard animal at night all of a sudden, so they're not pleasant side effects. I was on Cimzia for a while, in addition, and that was an injectable, in addition to it being a vicious jab, which I really didn't like, I ended up actually paying the copay at my doctor's office so that a nurse would inject me, because it was so painful. I got bruising, a really bad bruising, and when I did it in my stomach it, to what **[Participant 1]** alluded, I couldn't wear jeans, I had to change my midriff section clothing because I had pretty bad sensitive bruising. I was on Remicade for a while, and that was helpful for me for a long time. It is a two-hour infusion, plus you might have pre-meds or labs or whatever, so for me, I ended up having to take about a half a day off of work to go to my university center to have the infusions. And I built up an immunity to that, unfortunately, so I was not able to continue on that. And then I switched to Entyvio, and I agree with **[Participant 5]** that I

like that it's gut specific. It's also a faster infusion and now there is an injectable available. I haven't had that, I've only had the infusion.

00:41:03

Moderator, RTI International

Okay, I was going to ask that, so you have the infusions, and is that an injectable that you would do at home, or a self-administered?

00:41:12

Participant 2 (registered as a patient))

Yeah.

00:41:13

Moderator, RTI International

Great, thank you for walking us through those. How about **[Participant 6]**? Could you walk us through the benefits to the medications you've taken?

00:41:23

Participant 6 (registered as a patient)

I was diagnosed about 20 years ago, 23 years ago, so I started on Asacol, with high doses of prednisone, so Asacol was something that I had to go through, and go through many flares, and then be treated with prednisone because it was step therapy, so I had to prove failure to one thing to then move on to the next. Then it was azathioprine, and the benefits at times, they would control the symptoms, but I had several flares and lots of prednisone use during those, so finally got to a point where we were able to prove that I needed something additional, and a long hospital stay led to Remicade and through Remicade, I was able to be on that for quite a few years, but for me, it started at eight weeks, and then quickly went to six weeks, and then that was for a couple years, and then the dose increased each time, and the length shortened. By the time I finished Remicade, I was at every five weeks, which really gives your immune system no time to recover in taking that, and finally, it actually just stopped working. I didn't actually build up immunity, I just got a really bad flare and because I've had so much prednisone, unfortunately, prednisone isn't an option. It's not really safe any longer for me to treat the flares with, and so we tried for the Remicade to keep kicking in, and unfortunately lived in a flare for about six months, leading up to deciding to go on Entyvio. And even with Remicade, I was getting very sleepy with it. It started with one-day recovery, then it started to increase to three-day recovery, and then it'd be about a week, a week and a half of severe fatigue that would happen. So we added IVs [intravenous], and so now, even with the Entyvio, which I've been on for about a year and a half, I do not get the tiredness, which is really great. It kicked in really quick for me. I know for some people, it doesn't always do that, but for me the flare was able to be reduced, and I do still get the fluids, just as an additional treatment with it, but the infusion is short, so I'll take the fluids with it, and we're able to give it both together at the same time, and so I've really benefited from the Entyvio option, being some of my other options are limited, especially during flares because of the additional diagnoses I've had from having to be on prednisone for the wrong drug not [being] quick enough.

00:44:21

Moderator, RTI International

That's helpful to hear. And **[Participant 6]**, you mentioned you take the infusions of Entyvio?

00:44:29

Participant 6 (registered as a patient)

Yep, I receive an infusion every eight weeks.

00:44:30

Moderator, RTI International

Every eight weeks? Okay. What about **[Participant 4]**? Do you want to give us the perspective as a parent, a caregiver?

00:44:39

Participant 4 (registered as a caregiver))

[Redacted] was diagnosed when he was six, which I had no idea. I haven't mentioned yet, but my husband also has UC, so we were not totally unfamiliar with IBD, but I had no idea that children that young get it, and since I have met others who get it even younger. We started, I think on Pentasa, knowing that it was a long shot for it to work, but we thought we'd try with the least invasive. That did not work. He also had prednisone to just get things under control. The next medicine that he tried was Humira, and that worked really well for a couple of years, so that was awesome. I never thought that I would be giving my own kids shots. I learned to do that, but in retrospect, I miss it a lot because you could do it, you were done in five minutes, you could take it on vacation with you, you didn't have to schedule your life around when you were going to need your next dose as we do with infusions. So Humira was good, but after a couple of years, its effectiveness started waning, and at first we increased, I can't remember the order of things, but we increased both frequency and the dosage. And after maybe six more months of trying that, it was like, okay, this isn't working anymore. One thing that's interesting about kids is, you would think, or at least I would think, small bodies, smaller doses, but that's not always true because their bodies just metabolize the drugs so quickly. After Humira he tried Stelara for a bit, which was also an injectable at home. That didn't seem to work for him. Somewhere along the line, we also had methotrexate, on top of the other things. That wasn't helpful. And then he's been on Entyvio for six months or so. It's infusion, has been every eight weeks, but we're going to be shifting to every four weeks because it seems like he needs more. He also has been taking Rinvoq, which is a once-daily pill that he can take at home, but that was not doing enough, so currently he's on both Rinvoq and Entyvio. We love the idea of Entyvio being gut-specific, but unfortunately since he's also on Rinvoq he does still have the whole-body immune suppression, which is hard when you're a kid who goes to school and there's sickness constantly. I think I covered most of it.

00:47:58

Moderator, RTI International

Yes, thank you, those are great additions, **[Participant 4]**. And **[Participant 1]**, do you want to talk about some of the benefits to these medications?

00:48:12

Participant 1 (registered as a patient)

I'm a little more complicated because I also have psoriatic arthritis, and I did not have to go through the same degree of step therapy to get to biologics, because I'd already been on one for the psoriatic arthritis. But, at one point, I was on, in 2011, Humira and methotrexate together. And was actually doing pretty well for both illnesses, but then we had to pause it twice for my first surgery, and then I got a bad facial cellulitis. And after that, it never worked that well again. No matter what they did and we had to move on, and I didn't really have significant response to, what was it? Just a couple of other biologics, to Remicade or to Simponi, they helped a little bit, but never enough. I was still having the obstructions. When we got me on Stelara, that worked fairly well but not well enough, both according to me and according to my GIs, and that was when they added Entyvio to Stelara. I was on both of those, as well as methotrexate. And, I was doing well with that for several years. And then, a year and a half ago, everything started going bad again. Both my gut and my joints. And we went through a variety of things, and ended up, I'm still on Entyvio and methotrexate, but taking Rinvoq with it. And I'm actually doing pretty well right now and a few weeks ago, started having the most energy I've had in quite a while. But even so, both of the last two falls, I've been anemic enough that they've had to do infusions, which appears to just be from the inflammation where my surgeries happen, not from Crohn's. So it's complicated, but I'm definitely doing much better now than I have. I did well with the Stelara and Entyvio, but I'm doing even better with the Rinvoq and Entyvio.

00:50:59

Moderator, RTI International

Before we turn away, this has been a wonderful discussion on the benefits, we're going to talk a little bit about the drawbacks to medications as well, but before we turn away from talking about the benefits, I would love to hear just a quick summary statement of, for those of you who've been on multiple medications, how the benefits differ. How would you summarize that in a sentence?

00:51:33

Participant 2 (registered as a patient)

I realized, as I was talking that I didn't do any of what I was telling you about, the bad side effects of everything, so I don't have to go for the next question. But I think, for me, that prednisone, and any steroid, but prednisone in particular, seems to be a quick fix. That is often, for me at least, it's a benefit, it starts to work very quickly. And then the other I like, Remicade, because it was more gut-specific, so some of the other biologics can be gut-specific, and that's a benefit.

00:52:08

Moderator, RTI International

That's helpful to know how these benefits differ. And anybody else on how these benefits differ.

00:52:17

Participant 1 (registered as a patient)

That's obvious. It's been touched on the difference between, for the Rinvoq I'm on now is a pill, which is very convenient. Entyvio infusion, I just got mine earlier today, in fact. Methotrexate is easy to travel with because I inject it, but it doesn't have to be refrigerated or anything. Others have touched on steroids. I've been on a lot of steroids in the past because of all the obstructions, they

put me on high doses in the hospital, you don't want to go there. Anyway, I put on 40 pounds with those, which I have finally taken most of it off. And most of the side effects of those are well-known.

00:53:08

Moderator, RTI International

Think about how the benefits differ for these medicines.

00:53:11

Participant 1 (registered as a patient)

The benefits differ. And different lengths of time, like Stelara, I'm blanking on how far apart those were, but some of the infusions are further apart so you don't have to worry. It's not as difficult to schedule it into your life. If you're doing it weekly then you have to especially if it's a medication that has to be refrigerated, you have to worry about it. If it's every six weeks, you might be able to take a pretty good trip in between infusions, and things like that. There are many things we end up balancing. But what you want more than anything else is one that works.

00:53:48

Moderator, RTI International

Efficacy. I'll just go in order. Let's start with **[Participant 5]**, **[Participant 3]**, and **[Participant 6]** and **[Participant 4]** to round out the benefits of how these medications compare. **[Participant 5]**, what are your thoughts on that?

00:54:05

Participant 5 (registered as a patient)

I think whatever brings you to remission would be beneficial, and that has definitely happened with Entyvio. I have maybe a somewhat different experience with getting on an infused medication. I had been taking pills since I was nine, and I went on it when I was 29, 28, and I was actually excited to not take pills daily for the first time in my life that I could remember. I think there is sometimes a benefit to something that does not happen as frequently.

00:54:38

Moderator, RTI International

I was curious, your perception is it's more beneficial to be not having to take or remember to take a pill every day?

00:54:46

Participant 5 (registered as a patient)

That's how I felt at the time. I can see both sides.

00:54:51

Moderator, RTI International

Absolutely. Thank you. What about **[Participant 3]**? How the benefits differ?

00:54:56

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

I can speak from experience, not only does prednisone suck, I think everybody on here understands that. For me, it caused sleeplessness, emotional volatility, balloon face. And long term, it can cause much cardiovascular damage, osteoporosis. But also, I took methotrexate, which sucks just as bad. It's basically chemotherapy. I had low energy, hair loss, and nausea with that. Which I would like to avoid.

00:55:33

Moderator, RTI International

Oh, yes. **[Participant 6]**, tell us a little bit about the how the benefits to these different drugs differ for you.

00:55:42

Participant 6 (registered as a patient)

Prednisone was always a quick fix to a flare, but has long-term trade-offs that are not beneficial that now I end up taking something else for, so it's a quick fix. Usually works pretty efficiently for that short period of time, with long-term effects. Remicade was good, and it worked well, until it started to build up the different things. And with Entyvio, the benefit is I get my time back, it's very quick. It worked fast for me. It is not creating the fatigue that I had with the other drugs that I was on that built up over time, so even after a year and a half, I'm not seeing that fatigue. And again, I got time back, and I have not had a flare in that year and a half, so that's success.

00:56:42

Moderator, RTI International

Wonderful. Thank you. **[Participant 4]**? We're talking about how the benefits to the medications compare.

00:56:53

Participant 4 (registered as a caregiver)

I don't know if this is exactly answering the question, but I think the way I would summarize it is that there are pros and cons to all of them, and as somebody said, the efficacy is the bottom line, whether it works for you or not. And that's so unpredictable from person to person. There's no way to say XYZ is the best IBD medication, because it might work for some and completely be useless for another person. Just having a large selection of possibilities out there to try is super key, especially when one worked for you for a while, and then it doesn't anymore. You have to have new things to try.

00:57:46

Moderator, RTI International

Thank you so much for this really valuable input on these drugs' benefits, but also on some of these drawbacks, so we've heard a little bit about that. And let's just take a few minutes to flesh out this idea of the drawbacks, and hear more about that one. What types of challenges, have you, your loved ones, the other patients experienced with these medications? And I think you've already touched on a lot of these, but how would you summarize what the key drawbacks are? And if you

could also, if you've had experience with more than one medication, talk about how these drawbacks differ between the medications. **[Participant 6]**, do you want to start by talking about some of these drawbacks?

00:58:30

Participant 6 (registered as a patient)

I think prednisone, the biggest one, and **[Participant 3]** just touched on it, diagnosed with cardiovascular disease, osteoporosis, broken hip, need a hip replacement. I'm not at an age where any of that should really be in the realm of what I'm thinking, and unfortunately, due to the long-term prednisone use, and I still get continual diagnosis where they're like, "It's likely your long-term prednisone use." Unfortunately, had I had the biologics sooner and less prednisone and high doses of prednisone for long-term use, I wouldn't be seeing some of those things. And also, the drawback with the Remicade, and again, I think I talked about that, having to increase the frequency, and it really crushing the immune system, there was never a time for recovery. The amount of different illnesses that I had to go through, and the length of those illnesses, on top of the flares that would happen, or the hospitalization because again, even with the drug and having to change the amount, I'd still end up in the hospital, I'd end up with ischemic colitis. Different things that were pretty severe. Just being sick all the time, also, I'm not seeing that with Entyvio, so I feel blessed that that is not happening, because I'm not having to call the doctor and be like, "I need an appointment, I need to be checked for this," and I really appreciate that piece of it.

01:00:11

Moderator, RTI International

Thank you. **[Participant 5]**, what are your thoughts on drawbacks of different medications?

01:00:16

Participant 5 (registered as a patient)

I can echo what pretty much everyone said about prednisone, weight gain, moon face. I had a lot of shakes, so could not get through school presentations, I ran D3 cross-country and track, and it affected that. 6-MP, I mentioned in the chat, I had mono [infectious mononucleosis] for four weeks, and it wouldn't go away unless they pulled me off of it. And maybe more of a quality of life thing, but I couldn't drink alcohol, which, as a college kid, was maybe not the most fun. I didn't mind it that much, but having to continue to explain every single Saturday night why I wasn't drinking was not ideal. That one also predisposes you to skin cancer and lymphoma, so that was something that was not really told to me as a child. I think probably not the fault of my parents, they wanted to keep a lot of things, to not freak me out, but something I wish I had known, I would have been probably a lot more careful about wearing sunscreen as a young adult.

01:01:26

Moderator, RTI International

Thank you. **[Participant 2]**, did you want to share about the drawbacks?

01:01:35

Participant 2 (registered as a patient)

One more I thought of that was more medication-specific rather than just because of Crohn's disease was, when I had been on methotrexate, after prednisone for a while, I developed carcinoma

in situ, and I had to have a cold cone biopsy [cold knife cone biopsy], and there were some sort of gynecological issues that happened. My OB/GYN [Obstetrician-Gynecologist] was pretty sure it was because of the methotrexate.

01:02:01

Moderator, RTI International

And **[Participant 1]**, do you want to round us out in thinking about how the drawbacks differ for these medications?

01:02:10

Participant 1 (registered as a patient)

Others touched on it, but I was thinking about susceptibility to other infections, which is common with the medications that are not gut-specific. I was on Enbrel for arthritis before I developed Crohn's, and I had several oddball bouts of cellulitis on it, and then I had cellulitis when I was on Humira. When I was on Remicade, I got shingles. And this was before Shingrix was out. When you're on a biologic, or anything that suppresses the immune system, you can't have anything that's a live virus vaccine, so I couldn't have had the old vaccine. And that also delayed a Remicade infusion by six weeks because I was so ill from that. I haven't had a lot of side effects from the other medications, but the susceptibility to infections and viruses can be really big. Luckily, we were mostly living in **[Redacted]** then, so I didn't have as wide an array of people to run into, but still, it's a big issue.

01:03:32

Moderator, RTI International

Wonderful. Thank you all for sharing those drawbacks so openly. Let me gently move us to our next question. Overall, when considering a potential medication for Crohn's or UC, what factors would you say matter to patients the most? What matters the most? **[Participant 5]**.

01:04:02

Participant 5 (registered as a patient)

Four years ago when I was having the flare and considering medication, I was very ill and I fully trust my doctor. I think getting to remission the fastest just matters the most. She presented me with various biologic options, but was very clear, and said, "Entyvio, this is the clinical trial data from the VARSITY trial." It is clearly better than the other options, and you should go with that. And I'm a scientist as well, but I'm not a clinician, so I fully trust her. I think quality of life matters as well, and side effects too, people have other complications, but I think living in a world where we can trust our physicians and go with their recommendation and not have to do step therapy or deal with insurance issues is really important.

01:04:57

Moderator, RTI International

Right, it sounds like I heard you say quality of life and evidence were important there. **[Participant 6]**, what matters most when deciding on medications?

01:05:08

Participant 6 (registered as a patient)

I would say doctors' experience, patients' experience, and just the knowledge of it. Being able to take the drug that your doctor knows and has seen to be effective in similar cases to you, I think is important, and being able to get the drug in a quick time frame. Getting the right drug at the right time is so key to quality of life, and also the drug that is going to allow you to stay in remission the longest. A lot of times the longer we're out of remission, the harder it is to get back into, and then the frequency of non-remission increases, so making sure that we get the right drug at the right time to reduce the length of flares and the reduction of remission times.

01:06:05

Moderator, RTI International

That's an interesting point. Thanks for raising that, **[Participant 6]**. Could you elaborate a little bit about talking about the right drug at the right time? Is there a delay that could occur? Could you just elaborate on that a little?

01:06:16

Participant 6 (registered as a patient)

I was diagnosed a long time ago, and it was more about management drugs versus treatment drugs at that time, and there was a lot of steps to go through, to prove failure that we can't manage it with just pred[nisone]. The Asacol, Azathioprine, I had to have failure to get to those drugs, or else be in a dire situation to prove that I needed the drug. And even then, there was insurance denial and having to put all the history together and have the doctor go on a call, and luckily, my doctor was great, and was like, "We need her to have this drug. She's been on so much prednisone, this is becoming unsafe, we need her to have this drug." But again, had I had that drug earlier and not had to go through the steps and prove failure, the long-term side effects of what I had to be treated with quickly, which prednisone, unfortunately, I know we keep bringing it up, but that was the option, and the high-dose, long-term use, I possibly wouldn't have some of the additional diagnosis that now affect my quality of life, on top of ulcerative colitis.

01:07:43

Moderator, RTI International

Thank you for explaining that. **[Participant 3]**, do you want to talk about what matters most when deciding on treatments.

01:07:52

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

I want to echo access to the proper medication at the proper time. The position of the Crohn's and Colitis Foundation is that medications that are subjected to Medicare price negotiation should be exempted from all utilization management. The fear being that once the price for these medications is lowered the spread to the Medicare Advantage programs or to the insurance companies that manage Part D goes away. And at that point, this drug, because it's cheap, is no longer preferred by the insurance program, and therefore, they could decide to institute utilization management to slow down patients' access to those medications. And we would like to not see that happen.

01:08:44

Moderator, RTI International

Thank you for sharing that, **[Participant 3]**. **[Participant 2]**, I think your hand is up, what matters most when deciding on treatments?

01:08:55

Participant 2 (registered as a patient)

I wrote down four things. First, ability to curb symptoms and disease state. Second is convenience or access for patients, although it's not always convenient to go get an infusion, it is still better than being in the hospital for a week. Three, as few side effects as possible. And four, and I think that **[Participant 6]** mentioned this, but a longer, a long-ish, track record of being okay for a patient, that we have long-term studies saying that it's effective and that there aren't horrendous side effects.

01:09:54

Moderator, RTI International

That's been a really valuable discussion on some of the benefits and the drawbacks, and how you consider these both when making decisions, and thank you for giving us this this input so far. We're going to shift to the next part of our conversation. **[Participant 4]**, did you have something you wanted to add?

01:10:31

Participant 4 (registered as a caregiver)

I just had a thought arise, and this is maybe touched on, but I agree with other people that having a doctor you can trust, and if our doctor says this is what we think we should try, that's what we're going to do. But there have been times, and if he says, we could try this, or we could try this, and we think this is going to be more likely to be approved quicker by insurance without a fight, that's also a factor that has been part of our considerations.

01:11:05

Moderator, RTI International

Thank you for noting that one. We're going to shift gears a little bit and talk about the extent to which the treatments that we've been discussing meet or do not meet patients' needs. Throughout this discussion, we've talked a lot about the most important aspects of UC and Crohn's to be able to manage and you've shared a lot on this already, and thank you so much. Are there any other medical needs that are important to manage that we may not have touched on?

01:11:45

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

One thing I have on the top of my head is that this is the first time Medicare has negotiated a medication that can be infused. And Entyvio is even more complicated because it can be infused or injected and because the payment streams through Medicare for those two are completely separate, you're talking Part B versus Part D. There, we believe that the form of the medication, whether it is infused or injected, that decision needs to be made by the patient and their physician. There are good reasons why people might need to have it infused. Because they're on higher doses, because they're not able to do the injections, and there are good reasons why people would want to

do the injections, because they're traveling and lots of other things. What we fear is that both programs are going to be incentivized to send patients to the other in order to save money, and Part B is going to try it to send everybody to D, and D is going to try to send everybody to B, in which case patients could be ping-ponged back and forth, not because of their medical condition, or the desire, or medical necessity, but just because of the payment mechanisms. In addition, for the infused medications, it's important to note that the reimbursement from Medicare not only covers the cost of the medication itself, it also covers the cost of administering the medication, and this has become very important in the IBD space. When the price that is paid for Entyvio goes down, so will the reimbursement for the administration, because it's 6% of the price. However, the cost of administering that drug for the infusion center to get it, to store it, to go through the process of billing it, to actually infusing it, remains the same. And the reimbursement goes down because the price goes down, and we've seen this happen with Remicade, which has had a number of biosimilars come onto the market very quickly. And the price keeps dropping, which theoretically is fabulous, but now it has dropped to the point where the infusion centers cannot cover the administration, and they're refusing to accept our patients, and they're sending them all to the hospital. And we don't want to see that happen here.

01:14:23

Moderator, RTI International

Thank you for sharing those, **[Participant 3]**. We're going to shift a little bit and talk about the extent to which the treatments that we've been discussing either meet or do not meet patient needs. Let me rephrase a little bit. Which medical needs would you say are sufficiently, or even partially, addressed by the existing treatment options? Which needs are being addressed? Or somewhat addressed.

01:15:12

Participant 5 (registered as a patient)

By the medication we're on, by Entyvio, or by other ones?

01:15:17

Moderator, RTI International

By any of them. What needs would you say are being sufficiently addressed?

01:15:24

Participant 5 (registered as a patient)

I'm on Entyvio now, so I can do that. I'm currently in endoscopic remission, so I would say the needs of the disease are being, treated. I would say almost all of my symptoms are in remission as well.

01:15:41

Moderator, RTI International

Good. **[Participant 1]**, you want to comment on what needs are being addressed?

01:15:48

Participant 1 (registered as a patient)

The overall overwhelming need is just to get the symptoms under control as much as possible which, as I said, I've still got inflammation because of the surgery that apparently does not get

addressed by Entyvio, but it's still a lot better than it was. And for me, every year that I make it without another obstruction, it's a major win. I have fantasies of going the rest of my life without having another NG [nasogastric tube] in me. Even if I have to have surgery again, it's better than having that blasted NG-tube. Entyvio definitely does that, we're not sure to what extent since we added it on to Stelara, and since then we've changed my Stelara to Rinvoq. We're not entirely sure how much comes from which medication, but neither my rheumatologist nor my gastroenterologist is willing to stop either one of those. We're just [happy to] have symptoms under control after years.

01:17:05

Moderator, RTI International

Under control.

01:17:06

Participant 1 (registered as a patient)

That's huge.

01:17:08

Moderator, RTI International

Thank you, **[Participant 1]**. **[Participant 6]**, what about you? What needs would you say are sufficiently or partially addressed by your treatments?

01:17:16

Participant 6 (registered as a patient)

I've been in remission for about a year and a half. Most symptoms have been reduced. The severe fatigue that I was experiencing with a previous drug has been reduced, and I'm not seeing that side effect. With the infusion, I am still able to get the additional fluids that I need, so that's great that they can go hand in hand. Again, time back into life with a shorter infusion from two and a half hours to a half hour, is great as well. And then, I think it's just it's been beneficial. And for the first time in 15 years I've actually gained weight. I would say it does feel like the nutrient absorption has increased for me, and I know that's been brought up previously, which is also a big side effect of UC, so that's also exciting, I guess.

01:18:26

Moderator, RTI International

Thank you. **[Participant 4]**, do you want to comment on what needs you would say are being sufficiently addressed, or partially addressed?

01:18:36

Participant 4 (registered as a caregiver)

I would just say treating the disease, treating the symptoms, trying to get the gut into remission without the whole body, immune system suppression. Reiterating that it really targets the gut, Entyvio, speaking about Entyvio and Crohn's disease, that selective targeting instead of suppressing everything.

01:19:08

Moderator, RTI International

Any other thoughts on what needs are being sufficiently or partially addressed? Let's go to the flip side of that coin now, is what important aspects of having UC or Crohn's disease are not being addressed by existing treatment options that you've talked about? In other words, are there any major gaps that remain despite the treatments available? **[Participant 4]**, you want to kick us off on that question?

01:19:48

Participant 4 (registered as a caregiver)

This is so pie in the sky, but they're just treating. They're not curing. That would be amazing. If you could take something that actually got rid of it forever, and it wasn't something you were still going to deal with for the rest of your life.

01:20:12

Moderator, RTI International

Thank you for sharing that one. **[Participant 3]**, do you have thoughts.

01:20:16

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

That's exactly what I was going to say. These are disease-modifying, but not curative. In addition, what would be great is to have a test that would tell us what medication will work for what patient so people didn't have to cycle through all of these different medications to bring their disease cycle under control, and I believe that's coming, that biotesting is in development, and when it is finally developed, we would really like for Medicare to cover it.

01:20:50

Moderator, RTI International

That's a great one, thank you for sharing that. **[Participant 2]**, what are your thoughts on what those gaps might be?

01:20:56

Participant 2 (registered as a patient)

This is also sort of pie in the sky, like **[Participant 4]**'s cure, which is great. I also think that if there can ever be some sort of mental health, either benefit or recommendations, formal recommendations from GIs, for example, about support groups or something like that, so that patients don't feel so isolated. I know, depending on where you are geographically, if you don't physically see people, you can connect online, but I think connection with other patients has been a really helpful thing. I know that's not part of medication, but just had to say that.

01:21:31

Moderator, RTI International

Thank you, and **[Participant 1]**, what about some gaps that aren't being addressed with these treatments for you?

01:21:42

Participant 1 (registered as a patient)

It's not as much the treatments as it is our system that I was thinking about. I've been fortunate because of my husband's last career had very good health insurance, and we've got very good Medicare plan through them. But, so many people have to go through the step therapy, and you can't just, there are a lot of these medications that people have to work their way through that we know don't really work that well, and are not that good even at treating the disease, much less getting you anywhere near a medicated remission. And being able to jump into biologics, and being able to take the medications they know work well these days, makes a huge difference in the regulations forcing, There's been some improvement on step requiring step therapy, but there are still too many insurers who do, and too many places that allow it.

01:22:44

Moderator, RTI International

[Participant 4], you want to talk about any gaps with his treatment.

01:22:48

Participant 4 (registered as a caregiver)

I'm not sure if I would call this a gap exactly, but even with the choices that are available, how many of them take a long time to take effect, or for you to be able to tell if they're effective. I think a couple others alluded to that, but as I mentioned, my husband also has UC, and it was years and years of trying different medications, and, some it might say, it'll take three to six months before we'll see if it's working, and six months he would still be unhealthy, but we would just stick with it, ridiculously hoping, maybe at nine months it'll work, or maybe at 12 months it'll work. And so, the time just passes, and you've gone through years and years, and I guess I would say it's a gap that the treatments aren't quick to take effect, a lot of them, and you spend a lot of time waiting either for them to take effect, or to decide that they aren't working.

01:23:47

Moderator, RTI International

Thank you for sharing that, **[Participant 4]**. You actually touched on a little bit of another question I wanted to circle back to. How do you all feel that certain medications or treatments address these needs better or worse than others? Do you feel that certain medications are addressing some of these needs to a greater or lesser extent than others. **[Participant 1]**.

01:24:34

Participant 1 (registered as a patient)

For me, Entyvio is so great because of being gut-specific, but also addressing a lot of the symptoms without having the same range of side effects and complications.

01:25:01

Moderator, RTI International

Thank you, I'm glad to hear it's working well for you. And then others, do you feel that certain medications are working greater or to a lesser extent than others? And I know we've touched on this already.

01:25:27

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

That sounds like a broken record. You just don't know. Until you try them. I can say that all of these are better than prednisone and methotrexate.

01:25:42

Moderator, RTI International

That's helpful, thank you. **[Participant 5]**, do you have thoughts on that as well?

01:25:46

Participant 5 (registered as a patient)

Yeah, I flared once a year when I was on Asacol, I flared once a year when I was on 6-MP until the end. I have not flared on Entyvio. That's my data.

01:26:07

Moderator, RTI International

Good to hear. Thank you all for sharing all this information about how these treatments are working for you. I am going to turn to my chat to see if members or our observers have any other questions. And I don't believe that they do. Before we wrap up today, and part ways, I just want to give you an opportunity to summarize any thoughts on the importance of Entyvio and to raise any other topics that you don't feel like we weren't able to cover today. But do you have any final thoughts to summarize your thoughts on the importance of these drugs? You already shared so much, but feel free to summarize or not.

01:26:57

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

I've got one. I've already talked about utilization management, but I'm going to talk about it again. We're acutely aware that Medicare has put in reforms to utilization management for medical procedures, and that's great for colonoscopies, because believe me nobody wants to get a colonoscopy, and then having insurance stand in your way is no fun. But we believe it is about time that this also be extended to medications because this is where our patients see the biggest problem is access to the biologics that they're prescribed.

01:27:32

Moderator, RTI International

Thank you for sharing that. **[Participant 5]** and **[Participant 2]**, any final thoughts?

01:27:38

Participant 5 (registered as a patient)

I think the only thing I haven't shared is that I did have to go through the insurance waiting period for Entyvio, and because of that I flared a second time and because of that, I had to get a second medication, which one wasn't good for me, and probably caused more damage to my intestine, but also cost the insurance company another medication, so they might be able to reduce costs if they don't do this as well.

01:28:07

Moderator, RTI International

Thank you. **[Participant 2]**, any final thoughts that you haven't shared?

01:28:10

Participant 2 (registered as a patient)

I didn't share this either, but I'm going through something similar to **[Participant 5]**. My insurance all of a sudden is not interested in covering Entyvio after six years of being on the same insurance, so I'm five weeks overdue, and I had to miss a day of work last week, so I'm starting to get symptomatic, and I'm really hoping that things go through soon. But I was just going to say that my tenure with Entyvio is the longest of any medication that I've been on for Crohn's, and that, to me, is a sign that I've been I've been doing well on it, compared to other medications I've taken in the past.

01:28:48

Moderator, RTI International

Okay. Great. **[Participant 1]**, what about you? Any final thoughts as we wrap up?

01:28:54

Participant 1 (registered as a patient)

I was just thinking with the people talking about having to deal with insurance. I'm fortunate now because where we live, the GI practice actually has somebody who specifically deals with insurance and pharmacies, and they are so good. They send every bit of information in at the beginning, and they almost never get anybody denied. But it is a big problem for patients. I know so many people who keep getting their medications denied. I've got friends with my kind of arthritis who can't get on medications they need, and it's just a huge problem, and it really infuriates me, because, when I was on Stelara, I know the price for it in the EU [European Union] was one-fifth the price for it in the U.S., and even since Stelara went on the program, was it last year, the year before? It is still much more expensive here than it is in the EU. And that's just ridiculous. It does not need to be this way. I'll get off my soapbox.

Closing Remarks

01:30:09

Moderator, RTI International

No, that's okay, it's why you're here. Thank you all. This has been so helpful and thank you for participating and taking your time to be with us today, and your experiences were valuable, and they're going to help inform CMS negotiation with Medicare pricing for Entyvio. CMS staff have been listening to this roundtable, they've been listening to you, and they will be able to bring your perspective back to their teams. With that, I'm going to turn it back to **[CMS Staff]**, if they are on camera.

01:30:44

CMS Staff

Yes. Thank you, **[Moderator]**. Here I am and thank you all very much for taking the time to share your experiences with us. You've given us a lot of valuable information to think about, and I just want to say that we are genuinely grateful for it. Thank you.

01:31:03

Moderator, RTI International

Wonderful. Before we go, if you have any other questions following today's session, or any other thoughts that you wanted to submit, there's a mailbox address here, so again, just go ahead and put those notes into a message to IRARebateAndNegotiation@cms.hhs.gov, and please put in the subject line Public Engagement Events, and they will receive those messages. Thank you all again, and I hope you have a nice rest of your day and take care.

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

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

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

Appendix

Participant 1: Registered as a patient who has experience with the selected drug or the conditions 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 health care provider
No	You, your spouse, or an immediate family member is employed by or holds equity interest (stock or ownership interest) in excess of $10,000 in a company or related association with direct or indirect interest in the Negotiation Program
No	Any other personal or professional relationship or interaction with a company or related association with direct or indirect interest in the Negotiation Program that may be considered a financial conflict of interest

Participant 2: Registered as a patient who has experience with the selected drug, the conditions treated by the selected drug, or other treatment(s) or drug(s) similar to the selected drug for those conditions

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 patient who has experience with other treatment(s) or drug(s) similar to the selected drug for those conditions; representative of a patient advocacy organization

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

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

Participant 5: Registered as a patient who has experience with the selected drug, the conditions treated by the selected drug, or other treatment(s) or drug(s) similar to the selected drug for those conditions

Declared Conflicts of Interest	
No	Receipt of financial payments (e.g., gifts, funding, research support, honoraria, travel, or other expenses) from a company with direct/indirect interest in the Negotiation Program, in excess of $10,000 by you, your spouse, or an immediate family member
No	Direct assistance preparing your remarks from someone who is NOT a family member, caregiver, friend, or your health care provider
Yes	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 patient who has experience with the selected drug, the conditions treated by the selected drug, or other treatment(s) or drug(s) similar to the selected drug for those conditions

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