

*This transcript was lightly edited for readability.*

## Introductory Remarks

Moderator, RTI International

Hey, everyone! Thanks so much for coming. I'm **[Moderator]**, and I'm from RTI International, and 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 we'll refer 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 patient 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 the conditions treated by the selected drug, 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 the conditions and diseases treated by Lenvima, including differentiated thyroid cancer, endometrial cancer, hepatocellular carcinoma, and renal cell carcinoma, with Lenvima themselves, and with other medications for the same conditions. 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 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](mailto:IRARebateAndNegotiation@cms.hhs.gov) instead of sharing it in 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

00:02:19

**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.

00:04:11

Moderator, RTI International

I also want to make you aware that staff from CMS are sitting in on this event so they can hear your experiences and opinions directly from you, so I'm going to hand it over to them and let them take a moment so they can say hello.

00:04:38

CMS Staff

Hello, everyone, and welcome. I'm **[CMS Staff]** from the CMS Drug Price Negotiation Team. There are other CMS **[staff members]** on the call today as well. We work on the policies for getting public input and for 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're going to go off-camera now so you can focus on the discussion, but we greatly appreciate your time with us. Thanks.

## Housekeeping

00:05:09

Moderator, RTI International

Thank you, **[CMS Staff]** and team. Before we begin, I want to review some housekeeping items and ground rules so that everyone knows what to expect.

If you do get disconnected, please attempt to rejoin, and if you can't reconnect, please reach out to the email address shown on the screen. It's [IRADAPStechsupport@telligen.com](mailto:IRADAPStechsupport@telligen.com).

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

As you know, we are recording today's event, and 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.

As far as participation goes, we hope that you are comfortable and will contribute your perspectives throughout the session. However, if questions arise that you do not want to answer, that's okay.

We ask that you minimize background noise by silencing your cell phone and other devices if you haven't already done so.

We also ask that you mute yourself when you're not speaking, and we appreciate you keeping your video on throughout the discussion.

We've reserved up to two hours for this session. However, it's possible that we may not need the full two hours to discuss all of the planned topics. If that happens, we can let everyone go a little bit early. You can see I'm looking down occasionally. I have a discussion guide in front of me, and that's just to help me keep us on track. We have a lot of topics to cover, and I may need to redirect our conversation or cut our conversation short at times to make sure that we're able to cover everything, and that our participants have a lot of opportunity to share their perspectives.

We're going to be together for about two hours, and if you need to step away briefly during the discussion, that's also okay. Just turn your camera and microphone off and rejoin when you're able to. And you don't need to tell me that you're going to be away from your computer, just return to the discussion when you're able.

We ask that you try to speak one at a time, and I may occasionally interrupt you if there are two or more people talking in order to make sure everyone can be heard, and that everyone's comments are accurately recorded. You've tested out, I think, the raise hand feature. You can use that feature in Zoom to indicate that you'd like to speak, and that helps us know if someone would like to add to the discussion.

We're hoping that everyone would focus on the oral discussions. However, you can also add your comments into the chat if you don't get a chance to share them orally. This might be the case, for example, if we don't get to hear from you before we need to move on to the next question, or if you think of something else you want to add later on. If that's the case, just try and make sure that you note which question or topic you're responding to in any chat comments.

All right, any questions about any of that? We'll go ahead and get started. We're going to begin by asking each of you to introduce yourself briefly, and so we're going to go around our virtual room, and if you could take a minute to tell us, we see your first name, but just tell us your name, or if there's something else you'd like to be called, and whether you will be sharing your experiences as a patient, a caregiver, and or from the perspective of a patient advocate. And then also the condition or conditions that Lenvima treats that you have experience with. So, those three things: your name; whether you're a patient, a caregiver, or sharing a perspective as a patient advocate; and then the

condition or conditions that you have experience with. All right, **[Participant 1]**, you are first in my virtual room here.

## Discussion

00:09:14

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

No problem. Thank you for the opportunity to participate today. I am **[Participant 1]**. I am with the American Cancer Society Cancer Action Network, so I'm here on behalf of cancer patients and here to talk about the drug with respect to all of the four indications.

00:09:36

Moderator, RTI International

Thank you so much, **[Participant 1]**. All right, **[Participant 2]**.

00:09:42

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

Hi, I'm **[Participant 2]**. I am a **[Redacted]** with Cancer Support Community [CSC]. We're a nonprofit. We have over 200 support locations all over the country, and we provide psychosocial support to cancer survivors, patients, as well as caregivers, and I'm coming in as a patient advocate. We have a cancer experience registry where we draw a lot of data from thousands of cancer patients, survivors, caregivers. Endometrial cancer is my expertise, but I'll be speaking more to endometrial and kidney cancer today.

00:10:22

Moderator, RTI International

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

00:10:26

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

Hi there, I'm **[Participant 3]**, and I am here on behalf of Facing Our Risk of Cancer Empowered, also known as FORCE. We're a national nonprofit organization focused on people and families affected by hereditary cancers, and that includes endometrial and thyroid cancer, so I'm here as a patient advocate, but I'm also here as a patient. I am a three-year survivor of a type of differentiated thyroid cancer known as poorly differentiated thyroid cancer. Thank you.

00:10:56

Moderator, RTI International

Thanks so much, **[Participant 3]**. And **[Participant 4]**?

00:10:59

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

Hi, I'm **[Participant 4]**. I am the **[Redacted]** for the Community Liver Alliance, and I'm presenting on behalf of patients. I'm the patient advocate voice, and I'm focusing specifically on liver cancer. Thank you.

00:11:18

Moderator, RTI International

All right, thank you all so much. As you heard, we have participants here with experience related to, I think, all four of the indications or the conditions. And we realize that the experiences with Lenvima and other drugs may vary, or may differ by condition. So, when you're speaking, it's helpful if you could please remind the group which condition you're discussing. For example, you might say, "when I was considering treatment options for liver cancer, I thought about XYZ." We realize some of you are representing multiple conditions, and if you could remind us of what those are, and if there are differences in the experience across those. All right, we're going to get started by talking about patients' experiences with the conditions treated by Lenvima. Thinking about the different ways that the conditions treated by Lenvima affect patients' lives, what would you say are the most important aspects of the conditions to have managed or treated? And these could be things that affect patients in the short term or the longer term.

00:12:30

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

I'm happy to start. We had actually surveyed cancer patients who were taking the drug, and found 34 respondents, 31 of which were currently taking the drug, and 3 respondents who had previously taken the drug. Happy to provide as follow-up all sorts of metrics. About 26 respondents had reported taking other treatment therapies before taking this particular drug. When we surveyed them, we found that overall, the most important factors as to why they were taking this particular drug was, number one, quality of life, number two, impact on survival, and number three was cost. We've gotten preliminary results back, haven't cross-walked it for respondents for the specific cancer type, so that's generally what the respondents said. Ninety-one percent, so 31 out of the 34 respondents, said that the drug was very important to their cancer care and treatment, and/or was critically essential as the only effective therapy for managing their care, and about half said that there was no other alternative treatment therapy. So, factors for CMS to consider, and we have other data. Happy to share.

00:14:14

Moderator, RTI International

Okay, and we might get into some of that a little bit more, **[Participant 1]**. As a follow-up, you are representing patients that have all four of these conditions, but that survey, we're not sure exactly what the representation is across conditions.

00:14:31

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

We haven't cut the survey based on condition, tracking respondents, we can do that, but for purposes of beating this deadline, we haven't done that yet.

00:14:43

Moderator, RTI International

No, of course, just making sure I'm recording that accurately. Yeah, **[Participant 3]**?

00:14:49

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

Yeah, when it comes to endometrial cancer, a lot of patients have had chemotherapy first before they start on this drug, and they start the drug because they've progressed in the face of chemotherapy. And we know from experience that chemotherapy causes a lot of burden and side effects. But in addition, when we're talking about endometrial cancer, there's a lot of hormonal effects, so people are worried about fatigue and weight gain and other issues that come from hormonal disruption. When we're talking about differentiated thyroid cancer that is radioiodine refractory, there really aren't many other options for patients. In general, they're going through cycles of looking for cancer, finding it, having it removed, or radiated, depending on where it spreads, but once it is no longer amenable to those types of treatments, then really, Lenvima is just about the only oral or the only systemic option other than chemotherapy, which, to my understanding, is not considered very effective in these cancers.

00:16:03

Moderator, RTI International

Okay. **[Participant 2]**, what would you say are the most important aspects of conditions to have managed or treated?

00:16:18

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

I wanted to speak a little bit to what **[Participant 1]** was talking about with financial. With the Cancer Experience Registry, the CER, we have about 170 of the four cancers represented. Endometrial makes up 100 of those, but one of my colleagues ran a query on financial toxicity with these cancers, and about a quarter of them reported moderate financial toxicity. Showing distress with insurance not covering it, or out-of-pocket expenses, and things like that. In addition to that, about half of them experience some degree of financial burden from cancer treatment, with all of the four represented. There was fewer of the liver, and thyroid represented there, but I think it is pretty much a universal thing that we've been seeing across all cancers, so I think that's something definitely to keep in mind. And I think that's why programs like these are so critical.

00:17:31

Moderator, RTI International

Okay. All right, anyone else? And again, we'll definitely dive into some of these other topics, but generally, when you're thinking about these conditions that are treated by Lenvima, what would you say are the most important aspects of the conditions to have managed or treated? We talked a little bit about quality of life, survival, the financial implications. Anything else that you wanted to share related to things like how the patient feels or functions. We talked a little bit about side effects.

**[Participant 4]**?

00:18:08

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

Yes, I'm going to talk about liver cancer, and it's not a one-size-fits-all disease, it's clinically complex, and a lot of times, patients are also managing other underlying liver diseases. For example, a metabolic liver disease or a virus. We think that not one single therapy is appropriate for every patient, and treatment decisions are obviously individualized, but as a disease progresses, patients often move through multiple lines of therapy, so cancer can recur, or patients may no longer tolerate a given treatment, so when that happens, we want to make sure that there's options, but, for liver cancer patients, I think the biggest benefit of lenvatinib would be that it isn't oral oncology therapy. Again, the benefit of that is to make sure that patients are tolerating it, but also that it reduces the need for frequent clinical visits, and it really helps for patients to stay on track with their medications as well, because they don't have to go and have an infusion. They could just take it orally, so it minimizes travel burden and decreases time spent in medical settings and really lets patients be more engaged in daily life and caregiving responsibilities. I think these are especially important for older adults and patients that are experiencing fatigue, or those who may face transportation or mobility challenges.

00:19:54

Moderator, RTI International

All right, **[Participant 4]**, I appreciate that. And we are going to talk about some of the benefits and drawbacks of the drug. To make sure we're staying on track, a little bit of a follow-up. As we wrap up this question, any other important aspects of the conditions to have managed or treated generally, whether it's by this drug or other drugs, what are the most-important things that you think affect patients in the short term or long term? **[Participant 3]**?

00:20:23

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

I wanted to point out, and I'm not sure if that goes under this, or we're going to be talking about it later, but, differentiated thyroid cancer, and especially, you know, radioiodine-resistant [radioiodine-refractory] thyroid cancer is really rare, so there's not a lot of research on it, there's not a lot of data, and for that reason, likely, there's not a lot of options happening. There's not a lot of pipeline going on. In many ways, this is a last hope for these patients.

00:20:59

Moderator, RTI International

I appreciate that additional context, **[Participant 3]**, for sure. I might touch back on that again as we continue the conversation. I think we've touched on some of the stuff that's going to be upcoming, too, so we'll dive more into that. Right now, I'd like to turn your attention to the experiences with the medications for the conditions that are treated by Lenvima. For this question, I'm going to ask you actually to put your responses in the chat. What I'd ask you to do is list or indicate which medications, if any—and in your case, I think you all are patient advocates—but have you, your loved ones, or patients you advocate for taken, whether currently [or] in the past, for the conditions treated by Lenvima? I know there's a lot of them, probably, that are possible, so if you think about the most frequent or the most recent, I ask you to, again, let us know what the condition is, and then what those medications are, in addition to Lenvima. Yeah, **[Participant 1]**?

00:22:15

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

I'm sorry, I don't know that I understand. You're looking for what other drugs, in addition to Lenvima, patients are taking?

00:22:24

Moderator, RTI International

That's what I'm saying, I know there's so many options, especially when you're representing a large population of patients, so if you think about those that are the most frequent, or the most recent, that's what we're really looking at, to get a sense of what other medications you're thinking of when you're thinking of therapies for these conditions.

00:22:51

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

Okay, I think that may be challenging, again, given that obviously everybody on the call is looking at this in terms of the cancer perspective, but we also have to remember that we're also dealing with people who may have comorbid conditions as well, so I'm assuming that you're only looking for the drugs [for] cancer treatments.

00:23:12

Moderator, RTI International

That's right. For those same four conditions that we talked about.

00:23:27

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

Just speaking for my organization, if we would be happy to provide that information, I would want to talk to our clinicians to get a sense of what other drugs are routinely prescribed. I'm not a clinician by training, so don't have that information, and wondering if it's possible to provide that as a follow-up.

00:23:53

Moderator, RTI International

Yeah, we might be able to get that from you, **[Participant 1]**, but if there's even general classes of medications, if you don't have the brand names or all of the specifics, that's okay. We're just trying to get a general sense, in today's discussion, of what those other medications or drugs might be used to treat these specific conditions.

00:24:19

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

Got it. Thank you.

00:26:23

Moderator, RTI International

Yes, **[Participant 2]**?

00:28:55

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

I was going to add that, I've commented really quickly about the oral drug, and one thing that we found is that having an oral treatment can reduce the patient as well as the caregiver burden. I don't know if we'll have time to talk about the caregiver burden, but that's something that we see a lot from caregivers, but also patients, it can be a little bit of a little bit tricky to navigate, because, of course, the patient's the one going through all these treatments and everything, but that can also be a huge emotional and sometimes even physical toll on the caregiver, so anything that can make the process more simple can make the overall experience better.

00:29:34

Moderator, RTI International

Thank you for sharing that, **[Participant 2]**. I think **[Participant 4]**'s still working on hers, but I'm going to ask some follow-up questions, and you all can share, and **[Participant 4]**, certainly feel free to jump in when you're able to. For the next couple of questions, we want to hear about any experiences that you, if you're a patient, your loved ones, or the patients you advocate for have had with Lenvima and with other medications used for the conditions that are treated by Lenvima. Again, I would ask that you specify which medications you're talking about when you're sharing these experiences. **[Participant 2]**, some of what you just shared would fall into that category for sure. We touched on benefits a little bit earlier, but now diving into that a little bit more, which benefits have you, your loved ones, or patients you advocate for experienced with medications used for the conditions treated by Lenvima? And as a reminder, that could be Lenvima, but it also could be other medications. We're looking for those benefits, and they could be related to the effectiveness, I think we talked a little bit about dosage and administration, safety, how easy it is to be tolerated, and even if you've talked about it a little bit earlier, this is really where we want to get into that discussion. **[Participant 1]**.

00:30:59

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

Yep, happy to start, thank you. Going back to our survey, we heard from respondents that the drug works effectively to manage their cancers when other therapies had stopped working. And we also received some individual responses, which I'll run through by cancer type. We had one kidney cancer respondent who said, and I quote, "it's been effective where other treatments have failed." A different kidney cancer respondent, one with advanced kidney cancer, said that the drug shrunk their tumor by half. And a patient with liver cancer had shared that it delayed their cancer progression and, quote, "gives them more time, with stable disease." We also heard from respondents that it impacted their quality of life, improving their quality of life. One respondent with kidney cancer said, quote, "it's given me an extended and better quality of life." Another cancer patient with kidney cancer shared, quote, "it's effective and helps me to live a normal daily life." Going back to some of the issues that were raised on the fact that it's an oral medication, a number of respondents also talked about the fact that it was an oral therapy option, and how that led to

improved quality of life. One patient with kidney cancer said, quote, “given that the medication is an oral medication, it's helpful so that I don't have to keep going to the hospital.” Again, I think that goes back to some things that other respondents had talked about in terms of not having to go back to the hospital and get infusions. Transportation, as you well know, is a big issue for cancer patients, so the fact that this is an oral treatment is incredibly helpful. And finally, a patient with liver cancer had reported, quote, “the once-daily oral medication was incredibly easy with dosing.” Again, happy to share more as a follow-up, but, throughout the survey, we were hearing from respondents about how the fact that it's an oral medication does cut down on other costs, transportation, out-of-pocket costs going to the hospital, and the like, and improvement in the quality of life and ease of administration.

00:33:33

Moderator, RTI International

Thank you for sharing those, **[Participant 1]**. That's really helpful. **[Participant 3]**?

00:33:38

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

When we're talking about endometrial cancer, mostly we're talking about chemotherapy. There was a recent survey where patients said that the burden of chemotherapy was as bad, if not worse, than the burden of the disease itself. And for every progressive line of treatment, the chemotherapy gets harder. There's a lot of side effects that you have to manage, including the fear of immunosuppression, and being at really high risk for any kind of infection or disease, like food poisoning, that type of thing. And then what other people talked about, the burden of having to go and get your blood drawn, wait and see, you know. Are your counts okay? Can you get the chemotherapy? And actually having to make multiple trips to an infusion center in order to get treatment vs. being able to be on an oral agent.

00:34:35

Moderator, RTI International

Okay, thank you, **[Participant 3]**. So, some of the burdens, of some of those different therapies. And, are those alleviated or are there benefits from this drug that they find over those other options?

00:34:52

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

Yeah, the side effect spectrum is different, but also, it's oral, so they don't have to go in and make multiple trips to the hospital and find out if they can get treatment or not based on what their blood counts are like. There's a lot of inconvenience, a lot of out-of-pocket costs associated with the travel. And the feeling that you're a patient, because you're constantly in a hospital and attached to chemotherapy. There's a lot of mental health side effects, or benefits to not being on chemotherapy, from the mental health perspective as well.

00:35:33

Moderator, RTI International

Okay. That's really helpful. Any other specific benefits to this drug, or to other drugs used to treat these conditions that you wanted to highlight? I think we've talked a little bit about the effectiveness, the impact on quality of life around various aspects, the administration, the route of administration, it being an oral medication, I think fewer side effects. I heard the convenience, some cost-related benefits. **[Participant 3]**.

00:36:12

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

Just to say one more time for the thyroid cancer. It is a rare cancer, and there are very few other options available for people who are no longer amenable to having their metastatic disease radiated or surgically removed. There really isn't other choices for them.

00:36:33

Moderator, RTI International

Okay, yeah, that's important. For sure.

00:36:41

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

I don't know if it was mentioned, but because of the experience with this therapy, there is an established safety profile, so it's well-characterized and established with clinicians who have experience managing the side effects. This predictability supports better patient counseling, safer long-term use, and more-informed treatment decisions, I think.

00:37:07

Moderator, RTI International

No, I don't think that had been mentioned, **[Participant 4]**, so that's an important addition, for sure. Okay, any others? We've talked a little bit about this, but shifting to the other side of that, what drawbacks or challenges have you, your loved ones, or the patients you advocate for experienced with medications used for the conditions that are treated by Lenvima. That could include Lenvima again, and it could include some of these other medications. **[Participant 3]** talked about the burden of chemotherapy, I think, specifically for endometrial cancer. I want to make sure we've captured that. But, really opening it up to the other conditions and, again, for Lenvima or any other treatments for these conditions, the challenges or drawbacks that the patients experience. **[Participant 1]**?

00:38:05

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

Going back to our survey, we actually found that a number of respondents reported delays in accessing the drug because of prior authorization and other utilization management tools that had been imposed. Utilization management tools, not their words, those would be ours, but we did hear, from, again, one respondent with kidney cancer who reported having to wait three weeks for

prior authorization in order to obtain the drug, so a lot of the drawbacks that we heard was related to prior authorization, and cost as well, as **[Participant 2]** had talked about earlier.

00:38:47

Moderator, RTI International

I appreciate you bringing that back up. And that's specific for Lenvima, **[Participant 1]**?

00:39:01

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

Yes, specifically for Lenvima, yes.

00:39:04

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

We echo that it's important, the access, making it easily accessible, and that there are coverage policies that really allow patients to start treatment as soon as possible, as soon as they can, and to stay on the treatment as long as they need to. And prior auth [authorization] is always an issue, but there's also cost-sharing barriers as well as formulary restrictions. These practices, utilization management practices, can delay care, [cause] treatment interruptions, and [lead to] worse outcomes, quite frankly. Access barriers are not administrative, they're clinical.

00:39:47

Moderator, RTI International

Okay. Thank you. **[Participant 2]**.

00:39:51

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

This isn't specific to Lenvima, but just had to plug a little bit. We just presented at NCCN [National Comprehensive Cancer Network] an endometrial cancer study, looking at people that had delays, barriers to care, and whether or not their social, their symptom burden and functioning differed between people that didn't have these issues, and majority were due to insurance delays to care, as well as not being able to get time off of work, authorization issues in general, and they tend to have higher sleep disturbance, as well as fatigue and pain. And I spoke to a woman who, I presented the poster, who was a psychologist for oncology patients, and she said a lot of the sleep disturbance tends to be around anxiety about cancer in general, but also, even if the treatment is working, not being able to get it covered. We thought that was very interesting. And then they tend to have people that have barriers to care, lower social functioning, so being able to feel comfortable spending time with family, or being isolated. That can also impact ability to get treatment. This is for endometrial cancer patients that the study was done on with the Cancer Experience Registry.

00:41:15

Moderator, RTI International

I appreciate you sharing that. It sounds like there's some cascading effects, maybe, from some of these issues, sure.

00:41:23

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

Yes.

00:41:24

Moderator, RTI International

That's really helpful. And **[Participant 3]**, you shared something in the comment, and I see you have your hand up, so tell us a little bit more about what you were thinking.

00:41:31

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

I wanted to echo what was just said by **[Participant 2]**, but also true for thyroid cancer as well. There is anxiety that goes along with uncertainty, and across the board, regardless of where that uncertainty is coming from. Whether it's uncertainty about access to the drugs, what they will cost, do you have to battle your insurance company to get it covered? Any of those things. They all add to the patient burden and lead to disruption in sleep, in mental health, inability to engage, inability to work, all of the above.

00:42:11

Moderator, RTI International

For **[Participant 3]** and **[Participant 2]** and all of you, these challenges, or drawbacks when considering these medications, is it specific to Lenvima, or do you see differences between this drug and other medications? In terms of some of those challenges.

00:42:28

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

I would say a lot of the targeted therapies, and ones that need prior authorization, for sure, we see it. It's not just Lenvima.

00:42:44

Moderator, RTI International

Sure, okay.

00:42:44

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

Yeah, agreed.

00:42:47

Moderator, RTI International

**[Participant 1]**?

00:42:47

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

Yeah, I guess I would also add, if you have a patient who's tried another treatment before, and then moves on to this particular drug, all of that is compounded. I know you're focused on this particular drug for a stated purpose, but looking at it from the cancer patient lens, it is an exhaustive process to go through, particularly when you have to switch treatment therapies and go to a different treatment therapy, and when you have additional roadblocks, it's compounded, and whether those roadblocks are transportation issues, whether those roadblocks are utilization management, whatever those roadblocks are, it's an exhaustive process, so whatever can be done to eliminate roadblocks, I think all my fellow panelists would agree that would be a good thing for cancer patients.

00:43:47

Moderator, RTI International

Sure, yeah, it sounds like you're in agreement there. How about any other challenges related to the medication in terms of side effects? And I think, **[Participant 3]**, you talked about some of those side effects, particularly with chemotherapies. But as far as Lenvima or alternate therapies, are there any challenges that come to mind about effectiveness, safety, side effects, ease of use, route of administration, frequency, anything like that that you wanted to make sure we recorded? **[Participant 3]**?

00:44:22

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

All of these drugs usually—at least for thyroid, but endometrial, too—at some point, these drugs do become ineffective. So, we also need to make sure that there's a pipeline of other medications behind it that people will have as options. And maybe this is a little bit off-topic, but if there are restrictions to access to these medications, especially the newer medications, then there may not be more newer medications coming down the pike. Something to consider. Patients need hope, and they want to know that even as each subsequent line gets more difficult, there may be other options for them.

00:45:19

Moderator, RTI International

Okay. **[Participant 4]**?

00:45:23

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

I agree with everything she said, and in addition, for liver cancer, as the disease progresses, there may be need for multiple lines of therapy, and I've been in this liver space as a patient advocate for 21 years this year, and for so long, I saw nothing for liver patients at all. The innovation is amazing, and we want to keep the innovation going, but liver cancer often is progressive and recurrent, and patients often move through multiple lines of therapy over time, so when it progresses or recurs, having other options, it's critical, because without access to multiple therapies, patients could run out of options, as mentioned earlier, or treatment gaps may occur, which worsens the outcome. So, I think having multiple therapies is not redundant. It's really important for liver cancer patients.

00:46:26

Moderator, RTI International

I saw **[Participant 3]** was agreeing with you in the comments there, too, so it sounds like you all have a similar perspective on that. Thank you so much for sharing that.

00:46:34

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

There's also combination therapy and sequencing strategy, so oftentimes in real-world care for liver patients, liver cancer patients, it's one after another as the disease progresses, or sometimes there's a combination approach where, in certain settings, using two or more drugs is better for the patient. It's an exciting time to understand that there are options when there weren't any options for such a long time, and that they're really effective, especially when it can be individualized to patients.

00:47:13

Moderator, RTI International

**[Participant 4]**, I think that's a great segue to the next question, which is going to ask you to think about these benefits and challenges and drawbacks together. And thinking about when considering the potential medication, or I guess medications for these conditions that are treated by Lenvima, which factors matter to patients the most? What are the things that would matter the most to them? Thinking holistically. Sure, that makes sense, **[Participant 3]**. **[Participant 3]** in the comments said it varies by person, and **[Participant 1]**, I'm going to get to you, but **[Participant 3]**, you want to expand on that a little bit?

00:47:54

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

It depends on how well they feel, how many lines of treatment they've been through, their financial situation, their support system. There's so many factors. People want to live longer, but they also want to live well. And they recognize that there's trade-offs. Oftentimes, people are willing to tolerate side effects if they feel like they'll still be able to live a good quality of life, and it will extend their life. But at some point, there is a trade-off, and people may choose quality of life over quantity of life, and there's so many different factors that can play a role in that, that I think it's hard to encapsulate it with one statement.

00:48:48

Moderator, RTI International

Sure, sure. **[Participant 1]**, and then I might go back to the statements that you just talked about a little bit, **[Participant 3]**, but, **[Participant 1]**?

00:48:58

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

Yeah, **[Participant 3]** is exactly right. It's very different, just as cancer is not just one disease, but several hundred diseases, each individual cancer patient is a patient, is a human being, and they have different priorities and approach things differently. That being said, we did, in our survey, ask

respondents, generally, what should CMS consider as it's going through this process, and we had two respondents. One, a patient with liver cancer said, and I quote, "how well the drug works in controlling cancer should be the priority." And we had another patient, again, with liver cancer, who reported that the drug provides improved survival and quality of life. Those are things from respondents' own thoughts that should be taken into account.

00:49:59

Moderator, RTI International

For sure. So, quality of life and effectiveness, I think, very well wrapped up in those two comments. **[Participant 2]**?

00:50:08

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

Yes, something I wanted to add, a little bit to the previous question, is for endometrial cancer patients especially, there's been a lot of stagnation with any sort of treatments available until the past few years, and so they're definitely somewhat unique in that, this could be an exciting period, but it also could be a lot of years, or however long they've been with the disease, of disappointment, and so managing those expectations too is something to be mindful of for those for that population.

00:50:40

Moderator, RTI International

That is very important context, **[Participant 2]**. **[Participant 3]**?

00:50:46

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

Yeah, and I would say true for both endometrial and thyroid, and probably the others as well. If you don't have a lot of options, something that can help you live longer may help you live [until] the next therapy is available for you as well. If you know there's something coming down the pike, or something that might be available, you may be more likely to tolerate some of the side effects, knowing that there may be hope for something else, down the road. And when you don't have that, I mean. Hope is a big motivator for people to keep moving on.

00:51:26

Moderator, RTI International

For sure. And **[Participant 4]**, I see that you added something in the chat here about improvements in liver cancer detection. You want to tell us a little bit about that?

00:51:41

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

Sure. The liver doesn't have any nerve endings, so it's a silent organ. By the time you're yellow, or you're having ascites, you're really circling the drain. So, it's really important to find this cancer early, liver cancer, and we know that there are risk factors for certain people that need to be screened more often. Depending on the type of liver disease they have, because all roads will lead to liver cancer if it's not treated, or taken care of, or diagnosed earlier. Just being able to identify it earlier makes all the difference in the world because, you know, enhanced imaging, like CT

[computed tomography] protocols or MRI [magnetic resonance imaging], and again, looking at biomarkers and blood-based tools to monitor and to survey all this is really important. As we're finding the cancer earlier and it can be treated and be more effective, it's even more critical to make sure not only the therapies are covered and accessible, but that the screening is too.

00:52:55

Moderator, RTI International

Okay. So, even prior to treatment, at that screening point, which it sounds like would be related to effectiveness. **[Participant 3]**?

00:53:08

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

I know at least with endometrial and with thyroid cancer, we're talking about advanced cancers. And I don't know about the other indications, but I do think that it really is a good point about moving these therapies to earlier stages where they actually can be curative, and so that does require, if we are making these drugs unavailable, it makes it harder to move it along the research continuum to get to a point where we're actually able to provide it to people when they can be cured.

00:53:45

Moderator, RTI International

So, more available earlier, it sounds like, during this process, yeah, okay. Anything else? So, when you're considering the potential medications for these conditions, what are those factors that matter to patients the most? And we definitely have talked about this as a very individual situation. There's a huge spectrum of what we're talking about, not only across conditions, but even within conditions. In terms of that. Anything else that comes to mind? I wanted to touch on one thing. **[Participant 3]**, you were talking about quality of life and effectiveness, or quantity, living longer, but then also the quality of life and how that can be a balance, I think, for some people. Do you mind expanding on that a little bit?

00:54:39

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

For example, chemotherapy is harsh, it's hard to tolerate, but there's usually a point where you're going to end it, and so you can see a finish line, and that's one of the things where you're balancing "how long am I going to have to be on this" versus "how bad it makes me feel while I'm on it." And some of those are daily decisions. When you're feeling really, really bad, you're getting bone-crunching fatigue, and you can't get out of bed, it's really hard to make decisions about, "do I want to do this for another day or another round?" But if, at the end of that, you can see a finish line that may allow you some time where you don't have to be on the treatment, or where there might be another drug down the road if you complete this line of therapy, then you may be willing to do those trade-offs. That's just one example, and there are so many. Because drugs have a lot of side effects, and they have side effects that are very individual, and some of the worst side effects are the rarest side effects. It's not like people are always going to experience every side effect in order to make a decision. It's always this risk-benefit, and that benefit can be longer term, or it can be next week, or next month, or next year. I was really trying to speak to the complexity of it, and I'm not sure that I'm articulating it as well as I could be.

00:56:23

Moderator, RTI International

No, I think that's extraordinarily helpful, and I think you've explained it very well, that individual decision that has to be made based on some complex factors. Anyone else? All right, we're going to move into the next section, and reiterating, if I haven't said it before, the information you're providing is super helpful, and we appreciate it. So, we're going to talk a little bit more about some of the specific medical needs related to these conditions and how well Lenvima, and other treatments for the conditions that Lenvima treats, meet patients' needs. As you might remember, at the beginning of the discussion, I asked you to think about the most important aspects of those conditions to have managed or treated. The aspects of the conditions themselves. You've shared some things about effectiveness, quality of life, and I think we talked about cost and how that could impact it. Aside from those aspects that you already shared, what other medical needs related to these conditions are important to you (if you're a patient), your loved ones, or the patients you advocate for? As an example, are there important medical needs related to specific symptoms for those conditions? The side effects, which we've talked a little bit about, but the side effects of available treatments, other things related to quality of life, which I know we've touched on, or managing some of those other conditions or comorbidities that the patient has. **[Participant 1]**?

00:58:16

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

I guess I'll reiterate what my fellow panelists have also talked about. The fact that it is an oral medication really is tremendously important to patients, because it does have such an impact on quality of life, and the fact that it's a once-daily oral is even better, because then that helps patients better manage their conditions.

00:58:45

Moderator, RTI International

Okay, thank you, **[Participant 1]**. That's related, I guess, to the quality of life that in the treatment. **[Participant 3]**?

00:58:54

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

I think a lot of that varies when we're talking about advanced cancers with endometrial cancer and with thyroid cancer. A lot of it depends on where the cancer has spread. That has a direct effect on the symptoms that people are experiencing, things like bowel obstruction in the case of endometrial cancer, or bone metastasis and pain associated with it, with thyroid cancer. So, I think that a lot of that is going to be condition-related, depending on the individual and their cancer burden at the time.

00:59:29

Moderator, RTI International

Again, going back to that kind of individual, yeah, completely understand that. For any of you, what medical needs do you think—and again, understanding it could be a very individual decision—but generally, what medical needs do you think patients are hoping treatments for this condition would address? **[Participant 4]**, I see [you're] back to typing, feel free to come off mute.

01:00:07

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

I was thinking that so many times, the cancer's not resectable, so they need this medication, and I think that the depression, the mental health for patients, dealing with chronic diseases and liver cancer, it's very difficult, and it's also hard for the caregivers as well, is dealing with the behavioral health aspect of it. And again, individualized, right? Everybody approaches these things differently, so I hope that helps. But we have to think about the whole person and whole-person care, not just an organ or a disease, but the whole person.

01:00:53

Moderator, RTI International

Yeah, that's really helpful and an important addition. For sure. Anyone else? What other medical needs related to these conditions are important for those patients? Anything related to managing other conditions, those comorbidities? I think, **[Participant 1]**, you brought that up early on, that a lot of these patients have other health challenges. All right, so we're going to move on from that, and for the next couple of questions, we've done a little bit of this, but I'd like for you to reflect on your experiences with treatments for those conditions that are treated by Lenvima. Again, those treatments could include Lenvima, other medications for conditions treated by Lenvima, and other types of available treatments for these conditions that maybe are not medications, so, other kinds of treatment. Which important aspects or needs of the condition are being addressed, or at least partially addressed, by the existing treatment options? **[Participant 1]**?

01:02:30

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

Again, I'll go back to what we've all talked about before, about how this is another tool in the arsenal. It is another oral medication as opposed to IV [intravenous]. Also, I can appreciate that you have set questions. It is hard to parse that out. Flagging again, I don't know that we talked about this enough, but this is a unique product because it does have the four indications, and so that may be challenging in terms of CMS having to do what CMS needs to do with respect to the negotiation of the product. But, again, flagging that for cancer patients, the ones that we spoke to, having this product as an option, and having a choice between products that they can weigh in terms of what works better for their life, and having a conversation with their doctor, even just having options in general can be so important for cancer patients. We would urge that that be taken into account.

01:03:41

Moderator, RTI International

Okay. Thanks. **[Participant 3]**?

01:03:44

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

My understanding with endometrial cancer and with thyroid cancer is that this drug is used after people have progressed from the other available treatments, and that there aren't many other options, maybe more with endometrial, fewer with thyroid. I guess my point is this: when other therapies stop working and they aren't controlling it, and the cancer is growing and spreading, then people have no other choice. Maybe I'm misunderstanding what you're asking, but these drugs are

used or this drug is used when the other treatments aren't controlling the disease. I'm not sure if I'm addressing your question or not, sorry.

01:04:45

Moderator, RTI International

No, you definitely are, **[Participant 3]**. If I were to try and rephrase this, I would say, considering the various aspects or the needs of the condition, in terms of all of the available treatments that are out there, what are those aspects or the needs of the condition that are being treated, or that there are options to treat? I think you just said one thing, the control of the cancer, right? Keeping it from growing, if there are available treatments that are effective at doing that, that might be a need.

01:05:27

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

It seems to me it's THE need.

01:05:30

Moderator, RTI International

Right, the most important.

01:05:31

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

The symptoms come from the fact that the cancer is growing into organs that your body needs, and so whether it's metastasized to your liver, or your lungs, or your bone, or your brain, your body needs that, and so, it's progressing. So, if the other drugs are no longer controlling the disease, then you need a drug that can control the disease, because the symptoms and what leads to death in metastatic disease is the fact that it's taking over organs that can no longer function.

01:06:07

Moderator, RTI International

Right, perfect. On the flip side of that, to shift it a little bit, the opposite of that is to ask what important aspects or needs of the condition are not being addressed by the existing available treatment options. You shared that there are these options, these therapies that can help control the cancer, which then can affect symptoms, as you just mentioned. But are there gaps in treatment? Are there concerns that remain despite the available treatment options? Are there still things that are that are missing? **[Participant 3]**?

01:06:49

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

So, there's no Stage V cancer. People's cancers progress, even in the face of this. We're not curing people, for the most part, who have advanced disease. So, there are huge gaps, because until we can cure these cancers, there's going to be a gap for people. Their cancer's going to progress, and eventually it will lead to their death. So, we do need more drugs to the next line, and the next line, and hopefully something better. And immunotherapies have worked great in some instances where people have gone from Stage 4 metastatic to completely no evidence of disease, and we need more of those.

01:07:39

Moderator, RTI International

Yeah, that's important. And I think particularly for those specific cancers that you've been talking about. What else? What are the gaps in treatment or the concerns that patients might have that remain despite the currently available treatment options? **[Participant 4]**?

01:08:06

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

I think access to quality care, you know, particularly for people who live in rural areas or health care deserts, that could even be inside of an urban area. I think social determinants of health really intersect with a lot of this, too. Is English your second language? You have a higher propensity for liver cancer if you have hepatitis B, which is primarily an Asian immigrant, African immigrant population, and thinking about, are people worrying about their health when they're worrying about immigration? There's so many other factors out there that affect [people] that are societal, so I think that, too, is a problem. You know, providers understanding the need for screening or enhanced screening for certain populations. I think thinking about that that aspect of it is really important also, outside of having access to the drugs.

01:09:19

Moderator, RTI International

Yeah, absolutely, that makes sense, for sure. Thanks, **[Participant 4]**. **[Participant 2]**?

01:09:27

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

Yeah, piggybacking on what **[Participant 4]** was saying, at CSC, we've done a few studies looking at the difference across cancer types between academic oncology centers and community oncology centers, and sometimes there's a huge disparity even with what they're able to provide for treatment, let alone training their staff. Sometimes the cancer patients end up needing to do some research on their own time, because the providers are not as knowledgeable about certain things, and that can be overwhelming. You may be closer to an academic center, but maybe your insurance doesn't cover [it]. You have to go to a community center that's farther away, and so that impacts a lot of what you're able to get access to.

01:10:19

Moderator, RTI International

That's a great follow up, for sure. And **[Participant 3]**, I saw you mentioned the mental health care.

01:10:29

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

Yeah, for sure. There's a lot of anxiety with advanced cancers, and there aren't a lot of, not enough mental health care professionals to address it. Many don't really specialize in working with cancer patients, and, what **[Participant 2]** was saying about access to the academic centers, you may live near one, and your insurance may not cover it, but also, there are a lot of barriers to becoming established as a patient and even getting a second opinion that make it really hard to access some

of those care centers that do have wraparound services, like mental health care support and palliative care.

01:11:13

Moderator, RTI International

That's really helpful, and I think brings us back to some of the things you had talked about earlier, or many of you had talked about earlier. Anything else? Things that maybe the patients that you advocate for wish were addressed by the existing treatment options, and we've certainly touched on quite a few things, and the fatigue. It sounds like that's one of those cascading effects, too. Anything else? Okay. We're going to have a few wrap-up comments here, but I wanted to give you each the opportunity to summarize your thoughts on the importance of Lenvima for patients, and to raise any topics that you feel weren't adequately covered by the discussion today. I know you all mentioned we are limited to this structure, so, if there are things that you wanted to address, this is the opportunity to do that. My final question is, do you have any final thoughts about Lenvima, conditions treated by Lenvima, or any other medications that treat the same conditions that you feel are important to share with CMS? **[Participant 4]**?

01:12:44

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

I want to say thank you for this opportunity to have this dialogue, and I appreciate my colleagues around the virtual room also sharing their experiences, but what I want to say in closing is that for liver cancer, it requires flexibility and continuity and access. Negotiation efforts should support affordability, but also preserve patient choice and really timely access to clinically appropriate therapies, including oral options like Lenvima. Because patients' access options are not theoretical. It's what allows them to continue treatment and maintain a quality of life. I want to leave that in closing. Thank you so much.

01:13:32

Moderator, RTI International

Appreciate it, **[Participant 4]**. **[Participant 3]**?

01:13:35

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

Yes, I echo what was just said. Thank you for the opportunity to share. I think access is everything, and making sure that you're not limiting choices for people who already have limited choices. Access to oral therapies can really help people live a more normal life, rather than being tethered to a hospital and chemotherapy or other medications that require infusion. I hope that you guys will continue to consider the patient voice. And thank you for inviting us here.

01:14:18

Moderator, RTI International

Thanks so much for coming, **[Participant 3]**, and for sharing your insights and perspectives. **[Participant 2]**?

01:14:25

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

Yes, echoing everyone else's comments about being grateful for the opportunity. And I think a huge thing that a lot of people brought up today is the fact that this is an oral medication, and how this can really have trickle-down effects of making this easier. Even just reducing the need to take a bus to go somewhere to get immunotherapy is huge, not needing to schedule childcare or any other things that may get in the way of getting able to get treatment. And also, one thing I wanted to emphasize was, this can also reduce the reliance on caregivers, and although you still may need a caregiver, taking a pill and monitoring that is a lot less arduous than needing to go to a center, and there's a lot more moving pieces sometimes with immunotherapy, and so it's another reason why I think this is so important for more people to have access to.

01:15:25

Moderator, RTI International

I appreciate that, [Participant 2]. And [Participant 1]?

01:15:29

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

And I'll echo, again, what my fellow panelists had said. Thank you for the opportunity to participate today. We want to make sure that cancer patients have as many tools in their arsenal [as possible] to be able to address their cancer needs. A couple important things, and we've all talked about this, the importance of making sure that we're supporting research into new cancer therapies, making sure that we have oral products available for cancer patients, and wanted to echo what [Participant 2] had said, because I think we may not have talked about this enough, the caregiver burden. The cancer patient is, of course, front and center when dealing with the disease, but there is a significant burden on cancer patients' caregivers, as well, and not everybody has caregivers available to them. So, whatever we can do to make sure that we minimize barriers to care, it will certainly help cancer patients and help us to, fortunately, one day eradicate this disease. And that's what I think that we're all fighting for every day.

## Closing Remarks

01:16:53

Moderator, RTI International

Yeah, for sure, and I think you got some agreement in the comments there. All of you did, agreement in the comments, so very supportive group, and [I] appreciate you all leaning on each other for information as well. I am going to see if my CMS colleagues could come back on video. There's [CMS Staff]. And we've got some others here, too, so you can see the folks behind the scenes that have been listening and learning from your experiences and insights. I want to, again, thank you for participating in today's event. We appreciate you taking the time to talk with us, and your experiences and input were, again, I personally appreciate it, and I think we all do from this research perspective. It's extremely valuable and will help inform CMS' negotiation for Medicare pricing for Lenvima. [CMS Staff], I'm going to turn it over to you for our final thought.

01:17:52

CMS Staff

Thank you, [**Moderator**]. On behalf of CMS and my colleagues you see here, I want to thank you very much for taking time to share your perspectives and your experiences with us. Each of you have given us a lot of valuable information to consider, and for that, we are genuinely grateful.

01:18:12

Moderator, RTI International

And I think our tech team is going to share the mailbox information. If you have any questions following today's session, you can submit them to the mailbox, again, that's shown on that screen. It's [IRARebateAndNegotiation@cms.hhs.gov](mailto:IRARebateAndNegotiation@cms.hhs.gov), with the subject line Public Engagement Events. It's also in the chat. Thank you all for your time today. 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 representative of a patient advocacy organization

<b>Declared Conflicts of Interest</b>	
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

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

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

<b>Declared Conflicts of Interest</b>	
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

<b>Declared Conflicts of Interest</b>	
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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