

This transcript was lightly edited for readability.

Introductory Remarks

Moderator, RTI International

I'm **[Moderator]**. I'm from RTI International, and I'd like to also introduce my colleague, **[Secondary Moderator]** from RTI, who you may hear from today during the discussion. The Centers for Medicare & Medicaid Services, which we'll refer to today by the acronym CMS, is convening this patient-focused roundtable event and others as part of the Medicare Drug Price Negotiation Program. The information shared during these roundtable events will help CMS understand patients' experiences with the conditions and diseases treated by the selected drugs, patients' experiences with the selected drugs, and patients' experiences with other drugs used to treat the same conditions. The information shared during these events will also help CMS identify other medications used to treat the conditions 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 the selected drugs.

The purpose of today's event is to hear from all of you, a group that may include patients, caregivers, and patient advocates, about your experiences with the types of breast cancers treated by Verzenio and other medications for breast cancer. I want to emphasize that our focus today will be on the patient experience, so if you wish to share other input on other topics related to the Drug Price Negotiation Program that are not about the patient experience, we ask that you send that input to the mailbox at IRAREbateAndNegotiation@cms.hhs.gov.

Again, your experiences and perspectives are so important, and we genuinely appreciate your time today. Along those lines, we're going to watch a brief video from CMS leadership so that you can hear from them about how much they value your time and input.

CMS Remarks

00:02:34

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.

00:04:25

Moderator, RTI International

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

00:04:41

CMS Staff

Thank you, **[Moderator]**, and welcome, everyone. I'm **[CMS Staff]** from the CMS Drug Price Negotiation team, and as **[Moderator]** said, there are other CMS staff on the call today as well. We work on the policies for getting public input and negotiating Medicare drug pricing. On behalf of CMS and my colleagues, 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 appreciate your time, taking the time today to share your experiences.

Housekeeping

00:05:17

Moderator, RTI International

Before we jump in and get started, I need to review some housekeeping items with you, which you'll see on the screen. Bear with me, there's a lot to go over. I'll go quickly.

First of all, if you get disconnected, please do try to rejoin the event today. If you cannot connect for some reason, if you could reach out to our IRADAPStechsupport@telligen.com.

Privacy. This discussion is not open to the press or the public. We will use first names only during the discussion to protect your privacy, so please don't share any unnecessary, protected health information, like your doctor's name or the name of a medical facility where you or somebody received care, or any personally identifying information, such as your employer's name or city

where you live, or any information that you could identify who you are. Following the event, CMS will prepare transcripts where the participant names and identifying information will have been removed, and these will be available to the public.

On a related note, we are recording today's event. These recordings will not be shared publicly. The 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 today, you consent to being recorded for these purposes.

We hope that you'll contribute your perspectives today. If there are any questions that arise you don't want to answer, you do not need to.

We are going to say to minimize any background noise and silence your cell phone and any other devices if you haven't already done so. And also, if you can mute yourself when you're not speaking. And we ask that you try to keep your video on during the discussion.

Today, we have reserved up to two hours for the session, although it is possible that we may not need that entire time, and if that happens we'll let everybody go a little early, and we started a little early, so I'll keep an eye on the clock today. We have a discussion guide, and I have that in front of me to keep us on track, and I have a lot of questions and topics to cover, so I may need to redirect or move us along at some point. But we will make sure that everyone's had plenty of opportunities to provide their insights.

If you need to step away during our discussion, that's okay, go ahead and turn off your camera and microphone and rejoin when you're able to. You don't need to tell me that you're stepping away, go ahead and silence that and come back to the discussion if you can.

I also ask that you speak one at a time, shouldn't be an issue. I believe **[Tech Support]** already walked through the raise hand feature that's available in Zoom. If you would like, you may use that feature to raise your hand to indicate that you would like to speak.

We hope that you will use this forum to speak and share your opinions, but if you also want to put some notes or other things that you've thought about in the chat, that is perfectly fine to do as well.

That's about all I have. Do you have any questions for me about the ground rules before we get started? Okay, wonderful. We're going to go ahead and get started.

I would like to begin today's discussion first by asking each of you to briefly introduce yourself. Tell us your first name and then whether you will be sharing experiences as a patient, or a caregiver, or from the perspective of a patient advocate, some of you may be wearing multiple hats, and that's great. And for patients, if you're comfortable sharing the specific type of breast cancer you have experience with, that's helpful too—if it's early stage or metastatic, etc. I'm going to go in the order that I see everyone on my screen. I'm going to start with **[Participant 1]**.

Discussion

00:11:09

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

Hey everybody, my name is **[Participant 1]**, and I'm here representing an advocacy organization.

00:11:15

Moderator, RTI International

Wonderful. Thank you for coming today, [Participant 1]. And [Participant 2]?

00:11:22

Participant 2 (registered as a patient)

Hi, I'm [Participant 2]. I am a patient. I was diagnosed Stage 2B lobular breast cancer [Stage 2B Invasive Lobular Carcinoma], and I finished my Verzenio treatment.

00:11:33

Moderator, RTI International

You'll have some really helpful insight and perspective on that drug and your experience overall, so thank you for making time to be here. And we have [Participant 3] next on the screen.

00:11:47

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

Hi, my name is [Participant 3]. I am a patient and a patient advocate. I was initially diagnosed with breast cancer in 2015, Stage 2, and then my cancer resurfaced in 2022, and I'm now metastatic breast cancer, hormone [receptor]-positive [HR+] HER2-negative [HER2-] and I have been on my first line of treatment since 2022, and that includes Verzenio.

00:12:17

Moderator, RTI International

You're going to also have some really helpful insights, so I appreciate you adding those today. And we have [Participant 4]. Hi, [Participant 4].

00:12:28

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

Hi, good afternoon. I'm [Participant 4]. I'm here representing the American Cancer Society Cancer Action Network. We advocate on behalf of patients, caregivers, families, and survivors.

00:12:42

Moderator, RTI International

I'm very familiar with that organization, they do great work, so thank you for being here today. We're going to get started with our talk on breast cancer, so let's dive in. We want to talk a little bit now about patients' experiences with these types of breast cancer that are treated by Verzenio or similar drugs. I first want to think about the different ways that breast cancer affects patients' lives. What would you say are the most important aspects of breast cancer to manage or treat? And these can refer to short-term or long-term aspects. Anyone can jump in to get us started. [Participant 2].

00:13:38

Participant 2 (registered as a patient)

I feel like the list is long. From my perspective, I'm a mother. I work full-time. From my lens, it is continuing to feel less pain and more energy, versus the fatigue and the joint pains and all the things that happen with the treatments, while also trying to treat the breast cancer. And to ensure those cells don't come back later. Trying to become normal again.

00:14:26

Moderator, RTI International

That all makes sense. Treating the breast cancer while also managing the pain and the fatigue. Who else would like to jump in and talk about what's most important to manage? **[Participant 3]**, hi.

00:14:41

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

Hi, I would have to agree with **[Participant 2]**. It's managing the treatment and the side effects while trying to still be functional. Taking care of my family, or the inability to do so. And the finances, it's extremely expensive to be sick. And I didn't know that. And the mental health.

00:15:14

Moderator, RTI International

Yep, that's a big one. I'm jotting down all these notes, we're going to come back to all of these. It's really helpful. Who else would like to jump in? Maybe some of the advocates? Is there anything else that you hear from the patients that you work alongside?

00:15:30

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

Yeah, absolutely. I think that my fellow panelists said it best. Other things that we hear from people who are dealing with breast cancers. Transportation issues, obviously understanding insurance coverage. It's not necessarily a Medicare program, it may not be necessarily intuitive for everyone, and dealing with things like prior authorization and all of that, as well as caregivers. Again, cancer does not discriminate, people have their lives, people have kids that they're raising and/or need caregiving support as well, and that's always a challenge to be able to manage all of that.

00:16:21

Moderator, RTI International

Absolutely, those are good additions. Thank you for those. Did I miss anybody? **[Participant 1]**.

00:16:33

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

Everything that we hear within our community of people who are diagnosed with breast cancer, surviving breast cancer, and those who are diagnosed with metastatic breast cancer are all the things that have already been discussed. I would add, the fear of recurrence. You're talking about the aspects of treating breast cancer, and then certainly I would add on that as you're treating the

breast cancer, you're always thinking about the fear of recurrence, and then, in **[Participant 3]**'s aspect, what happens then when you do have a recurrence?

00:17:08

Moderator, RTI International

You've touched on an excellent point, **[Participant 1]**. I'm glad you raised that. I wanted to delve a little bit into maybe some of the differences, if there are any when managing earlier-stage versus metastatic breast cancer. What types of differences do patients talk about in managing those two different types of breast cancer? **[Participant 3]**.

00:17:47

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

I guess because I've had the experience of both, I guess it depends. Each person is individual, because your care will be individual. But, as for me, the first time around, it was the physical aspect and the shock that was the most challenging for me to handle, and then my inability to continue to work because of how harsh the treatments were. My children were a lot younger then, and they needed more hands-on care, usually. I was diagnosed at the age of 35, and so the doctor told me, so to speak, they were going to "hit me hard" because I was younger, and so the physical toll that it had on me, it was a shock to my system, and I had to get used to the fact that I was going to have a new normal physically for my body. And then, of course, the financial aspect. You've got mounting medical bills and the inability to work. It was very traumatic. The second time around, it wasn't easy to hear the diagnosis, but I prepared myself, and now, because of some of the newer treatments, my cancer journey looks a little bit different. That's why I was so interested in talking today because the type of treatments that are available to patients and affordable to patients can really change how your cancer journey will look.

00:19:28

Moderator, RTI International

You're referring to the metastatic diagnosis?

00:19:31

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

Yes.

00:19:31

Moderator, RTI International

Thank you for sharing. I know this is not a easy topic to talk about, **[Participant 3]**, I appreciate you being so open and sharing with us. Anybody else have any perspective on maybe how managing the metastatic disease feels different than the earlier stage? **[Participant 1]**.

00:19:56

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

One of the things that I think we hear a lot is for patients to feel like they're sharing in the decision-making, especially with **[Participant 3]** saying that she was told they were going to hit it hard right away, and what that means. It sounds like she didn't know what that meant. Having that

conversation and saying, we're going to hit you hard, I know you have young children, you're going to need to make arrangements, whatever that whole conversation is, so that you can have a voice in what your treatment plan looks like.

00:20:33

Moderator, RTI International

Absolutely. Shared decision-making is so important. We're going to touch on treatments here in a little bit, so think about that, we're going to really delve into that here in a moment. Any other thoughts on the most important aspects of breast cancer to manage? I think we covered a lot there.

Let's shift to the next question. Next, I'd like to talk about patients' experiences with the types of medications used to treat these types of breast cancers. By medications, I'm referring more to these adjuvant therapies, such as Verzenio or other medications you may have taken, and not the other therapies and the chemo or the radiation. First, could you start off by finding the chat feature, and could you share with us in the chat any medications you or the patients you advocate for have used for these types of breast cancer? Don't worry about spelling if they're hard to spell, drop something in the chat.

Anastrozole, Verzenio, Lupron injection, Zometa infusions, yes, or Verzenio, Zometa, a lot of the same medications. Tamoxifen. The CDK4/6 inhibitors [Cyclin-Dependent Kinase 4 and 6 inhibitors], yep, and the hormone therapies, that all makes sense. **[Participant 3]**, I was curious too, could you tease apart for us which treatments were used for the early-stage breast cancer versus the metastatic, or did you use some of these medications both times?

00:22:49

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

The first time around I did IV [intravenous] chemotherapy and surgery, and then IV chemo, Herceptin, Perjeta, surgery, and I was on tamoxifen for a few years.

00:23:06

Moderator, RTI International

Okay, gotcha. And then the Verzenio would have been for the metastatic? Is that in addition to other hormonal treatments or are you taking that alone?

00:23:22

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

I do the Verzenio, letrozole. I don't do the Zoladex anymore because I had my ovaries removed. And then I do the Zometa infusions because I had metastasis to the bone.

00:23:36

Moderator, RTI International

It's helpful for us to get a roadmap of all these different medications that we could end up talking about because it's hard to tease apart what medication is causing what symptom. Any other medications? I think we got them all. This is helpful.

I want to talk a little bit now about the experiences with the medications that you all have offered up in the chat. Could you tell us what are the benefits to patients, or patients that you might advocate

for—what are the benefits of taking these medications? And if you can think about a specific medication, if there’s a specific benefit for one of those medications you can note that as well.

[Participant 2].

00:24:29

Participant 2 (registered as a patient)

I feel like if I’m going to list off benefits, it’s what the doctor says and what the brochures say. I have to trust in the systems. Because the medicine itself doesn’t feel good to take, but the quote-unquote research says it’s going to reduce your risk by this percentage because you fall in this category. The reason why I take it is in hopes that I fall in the group that it’s actually going to help. But outside of that, the benefits are, I will see my child graduate high school, I will hopefully see my child become a father. But outside of that, they suck.

00:25:17

Moderator, RTI International

But the benefit, I think you stated, is reducing the risk of recurrence, is what you were...

00:25:21

Participant 2 (registered as a patient)

Exactly.

00:25:24

Moderator, RTI International

Okay. And **[Participant 3]**, what benefits would you like to add to that?

00:25:29

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

I’d like to say, **[Participant 2]**, I share some of the same feelings. It does get worse. Honestly, when I heard that my cancer was back, if I had to go through chemo again, I wasn’t going to take treatment. That’s how bad I felt. It put me into heart failure. I had so many symptoms. I literally crawled around my home to take care of my children, and they thought I was playing a game, so they would get on my back like I was a horse, and I told myself I wouldn’t go through that again. So when I went to the doctor, and they told me the plan of care was going to be this drug called Verzenio, and it was a pill, I was so grateful. I too want to see my children hit those milestones in life, and this drug was an opportunity to do that, and not only to see them hit the milestones but not crawl around on the floor, or have to lay in the bed all day because I have no energy. The side effects do suck, but they aren’t as bad, and so Verzenio gives me the opportunity to live my life. I can go to ball games, parent-teacher conferences, I’m able to work, and I’m able to take care of my children. There are times when it catches up with me, but without this pill form, my life would be totally different. I might not even be here. Having Verzenio and letrozole—as soon as I started taking the medications, I could see immediate results because I had a tube in my lung because it kept filling up with fluid from the cancer. Immediately, I started to see these changes, and they were able to remove the PluerX [pleural catheter system] from my lung. The pain that I was going through started to improve. This pill was like magic for me, and I was so very grateful to have Verzenio and letrozole, and the fact that my providers took the time to not hit me hard again and they actually looked at the research

and the evidence and formed a treatment plan that would work for me. Having a pill—it gives you a life, it gives you autonomy.

00:28:02

Moderator, RTI International

That's wonderful to hear, **[Participant 3]**. And you mentioned the ease of taking a pill. Is that contrasted to—what kind of administration were you dealing with before? I'm assuming injections, or having to go to the hospital for injections, but can you speak to that a little?

00:28:22

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

Because of the chemotherapy, I could drive myself to the infusion center, but all of the medicines that they give you to combat the side effects, I was so drowsy I couldn't drive myself home. So not only could I not work, then I have to inconvenience someone else to take me to my appointments and take me home. Then I can't even take care of my kids for the next few days because I feel so bad. It was more costly to get the IV infusion as opposed to the pill form. You can't plan vacations or anything because you're tied to this infusion chair every so often. The side effects—because it goes directly into the bloodstream, the side effects hit you a lot harder than the pill form does currently for me now. It's a lot of cost, but not only financial cost. It costs you a lot of time, a lot of missed time, inconveniencing other people. With the pill, I can be anywhere. I went on vacation and I took my pill with me. And I was so excited because I didn't have to tell my children, "No, we can't do that because I have to be here." So it really is an improvement of life.

00:29:53

Moderator, RTI International

That's great. Thank you for sharing that. **[Participant 4]**, do you have anything to add about the benefits of these types of drugs?

00:30:00

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

Yeah. In anticipation of this opportunity, we had surveyed cancer patients taking this drug, and I'm pleased that our survey results match what **[Participant 3]** and **[Participant 2]** have talked about. In the survey, we found that 70% of respondents reported that the drug was important to their cancer care, and 30% said it was critically important. Ninety-seven percent of respondents said that this drug made their quality of life so much better, and I think that that follows very closely with what **[Participant 3]** had shared. And 100% of respondents had said that it had a very positive impact on their mental and emotional well-being, and I think that goes to the fact that this is a product that is available in a pill form, and that that does reduce some of the barriers that cancer patients often experience. The travel to and from treatment, and having to find a caregiver to help with all of that, and being able to have another option is very important to cancer patients, so that they can have some more control and can help to have a voice in their treatment, and what that means.

00:31:38

Moderator, RTI International

That's wonderful. What rich data, thank you so much for taking the time to survey some of the patients you work with. I would love to hear a little more about that, if you wouldn't mind, about how many people took your survey.

00:31:53

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

We had fielded a survey. As you know, with surveys, sometimes it's very challenging to find people who—It's like finding a needle in a haystack sometimes, to find people who are actually taking the drug. We had 33 respondents in total, 29 of whom were currently taking the drug, and four who had previously taken the drug. We're happy to follow up with CMS and provide all of this information as well. We have breakouts in terms of how long people were on the drug versus how long they were not. But most interesting is not necessarily what the data itself, the percentages of people who responded, X, Y, or Z, but we left open questions of "Just tell us what you think" and "Tell us what you mean" and we asked about what the drug meant in terms of patients' quality of life. We had one respondent who said, and I quote, that "the drug helped me maintain a normal lifestyle so that my life isn't completely disrupted by the illness." And another respondent reported that the drug "gives me hope for longer-term stability." Again, happy to follow up with all of the survey respondents, but I think it is important to have this option available for cancer patients as part of their treatment.

00:33:29

Moderator, RTI International

Fantastic, really helpful to hear those quotes from patients as well, so I'm glad that you all thought to let them open-endedly talk about some of this.

Before we move to drawbacks, we're going to talk about side effects and drawbacks here in a minute, but I don't want to move away from benefits too soon, but have we covered everything on benefits? Is there anything else you want to add to anything we've talked about so far? I'm hearing so far about this drug, how it's tolerated, increases quality of life, it appears to be effective.

[Participant 3], you gave a good example about having some tubes removed. Anything else?

Yes, **[Participant 1]**.

00:34:20

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

I might add here, thinking about the fact that it's an oral medication, that it's probably a more equitable opportunity for people who have those transportation issues, who have childcare issues, who have a caregiver, or who might not have a caregiver who can take them or pick them up from the appointment, so I do wonder, or think that it's important for a broader use of patients to have access to the drug.

00:34:58

Moderator, RTI International

Yep, I hear you. Easier to, in theory, access a pill than an infusion center.

00:35:04

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

If I could add something to that. **[Participant 1]**, that brings up a really great point, because one of the reasons I became a patient advocate is because I live in a rural area. And to get to my doctor's office, it takes me an hour and a half one way. And I don't know what those individuals who don't have transportation or the finances to do that—I don't know how they get it done. Now, instead of having to inconvenience someone, which could be an all-day event for my chemotherapy, I can get my medications delivered to my home. Think about all that time that's saved. That I could be doing, enjoying life, and doing other things, and being productive. I thank you for bringing that up.

00:36:02

Moderator, RTI International

Absolutely.

[Participant 2], do you want to share a little bit about some of the benefits you've encountered?

00:36:44

Participant 2 (registered as a patient)

I wasn't even thinking about the convenience factor because I didn't have a gap in treatment. I went straight from surgery to chemo to radiation to Verzenio to anastrozole. Mine was all part of the big plan, big picture. But thinking through that, Verzenio does offer that option, or anastrozole does offer the option not to have injections, if maybe that was another way that they administered that type of medicine. But I still have to go every month to the doctors for the injection. But it's nice not to have the port anymore to receive any medicines, and it's nice that no one knows what's going on, besides my circle. But the flip side is that there's a downside to that too.

00:37:59

Moderator, RTI International

Thanks for adding that. The convenience factor seems to be a recurring theme here, so that's an important note to make. I think we've covered a lot of benefits here.

I think you know what the next question is. I want to think now about some of the downsides to taking these medications, and whether it be Verzenio or similar medications that patients are taking. Does one of you want to start and talk about downsides? And it may be hard to tease apart which medication is causing the downsides, but to the extent you can comment on that, that would be helpful too.

[Participant 4], hi.

00:38:51

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

Hi. Again, going back to the survey that we had done, we had heard from respondents that cost was a factor, but almost half of respondents—not quite half of respondents—had also reported significant delays in prior authorizations and having to wait for approval from their insurance company in order to get access to the drug, which can have an emotional and mental weight on patients as well. So those were some barriers that we had heard about.

00:39:39

Moderator, RTI International

That's helpful. Thank you. **[Participant 3]**, what have been the downsides to these drugs for you?

00:39:49

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

I'm going to let **[Participant 2]** talk about the downside of people not knowing you're sick, because I already know what she's going to say. But, for me, the biggest thing that I struggle with Verzenio is the cost. I work two jobs and I have two children, and I currently can't afford my medicine, and I'm not taking my medicine because I have to decide whether or not I'm going to pay my mortgage or take this pill. I've chosen to pay my mortgage and feed my children. I think it's ridiculous, the cost of the medication. For me, finance. Next, I would say the side effects. They're not as harsh, but they are there. There's a lot of GI [gastrointestinal] upset, nausea, and a lot of diarrhea, and I'm sorry to be graphic.

00:40:55

Moderator, RTI International

Please do.

00:40:56

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

And it's a lot of fatigue, also, that goes with that. I think those are the two biggest issues for me.

00:41:15

Moderator, RTI International

I'm sorry to hear you're going through that.

Anybody else? Any advocates here, similar downsides? **[Participant 2]**, do you have something?

00:41:25

Participant 2 (registered as a patient)

To the point of trying to tease out side effects, or the downsides of fatigue. That is pretty hard to tease out, because for me, from diagnosis until now, it's a large mental load, all of the things. I will say that the hormone treatments, because I'm premenopausal, is going from basically childbearing years right into being 75 years old and your body's in shock, and what that does to your personal relationships, like my husband and I. There's not enough support around those areas for people that are younger. I will say that I had some neuropathy during my last few rounds of chemotherapy and it disappeared, and then I started Verzenio, and it showed up and it's never gone away. And it's hard to tease that out, because everyone who's on Verzenio most likely has done all the stuff I've done. To know where the damage is done. And then when I ended Verzenio, I had all this hope that my fatigue would disappear, and my neuropathy would disappear, and none of that has happened.

And Verzenio—I was always confused about the cost, because it was super expensive, yet then I didn't spend one dollar on it due to the pharmacy and my doctor doing the savings programs, but I would read a lot about people who could not get that to work, and I wasn't fully aware of how it

worked, but one time I was fighting about the cost and I was blown away how expensive it was. And then it's also treated—there's a lot of misinformation to even doctors and pharmacists. Some pharmacists will label it as chemotherapy. Now, it has very similar effects, I had to get blood work. My liver wasn't working correctly, and then you fear them dropping the dose and thinking it's not going to work. And over and over again, the research through the doctor says any dose level, they see the same results of it—and that's something that doesn't compute, why someone has a lower dose, and yet their survival outcomes should be the same as me with a higher dose. There's a lot of fear of that, I think, with all that misinformation to maybe have trust enough in the research of the drug itself and what's being shared, and how it's being shared.

And then, to what **[Participant 3]** was saying, yeah. It gets delivered with Imodium A-D, that's your first experience receiving it. And I got to work from home, so I was lucky in that, but then you create a survival plan in order to go out to your kids' sporting events, or go out to eat without pooping your pants, to be honest. And then you go in, and then you find out your liver is failing because of the drug, and then they tell you, you should have heart disease, and you might have this, and bone density issues. It's the gift that keeps on giving. That's what I feel like cancer can be. Or at least breast cancer is.

00:45:33

Moderator, RTI International

[Participant 3], I saw your head nod several times. GI issues, liver disease, having to go back for blood work often. Can you relate to this?

00:45:44

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

Absolutely. Thank you also for bringing up the mental, psychological, emotional impact of going from childbearing to menopause, not having support for your family. To be completely transparent, my husband of 20 years—we're now separated because the cancer and all the issues and the side effects that come along with these medications. It not only impacts the patient, but it impacts their family as well. There's not enough support behind the impact on the caregivers and the families, and it's very difficult to be in menopause when I don't feel like I should be. Your body completely changes, you gain weight, and all these new issues, and then you hate to say anything because you're alive, and you feel guilty saying anything because the alternative is to not be here. But it is a struggle.

00:47:00

Moderator, RTI International

Yeah, it is, you've been through a lot, and here you are today speaking with us, and how grateful we are for this, so...

00:47:08

Participant 2 (registered as a patient)

I agree with you, **[Participant 3]**. I was thinking, all those side effects—it goes into you. With the Zometa infusions, you go to the dentist and you have to tell them because they could break your jaw because you're on Zometa. You could fall skiing and crush your bones. It's to the point that you're doing all this stuff to survive, because that's what you're told you're supposed to do, and

you're supposed to be grateful that you're still alive, but so many things are being broken down inside of you, and then even the relationships around you, because of that. You're not the same person anymore at all, both physically and mentally. And you have to put your faith into this research that, so often, I'm not represented in—people my age, or my type of breast cancer, lobular, is not represented, race isn't always represented properly. And the research can be old. So you have to go, "Well, I hope they know what they're doing." And then you spend all the money to do it.

00:48:31

Moderator, RTI International

Absolutely.

Anybody else want to—**[Participant 4]** or **[Participant 1]**—add on to some of these downsides? I think, **[Participant 4]**, you already shared your survey results. **[Participant 1]**, did you have anything else to add about downsides?

00:48:45

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

No, everything that's already been said is what we hear from our community. It's that cumulative effect of all the treatments and what that does long-term to your body. Yeah, those are the things that we—and the cost, of course—that's what we hear loud and clear from our community.

00:49:05

Moderator, RTI International

Okay. And **[Participant 1]**, I think you hit on a good word there, it's the cumulative effect. This is where it's more than just one symptom, it's the accumulation of all of them.

A few more questions on benefits and downsides. For those that have experience with more than one medication—and this is for the advocates as well—how would you say the benefits differ, or the drawbacks differ? When thinking about different options of medications, how would you say the benefits or drawbacks have differed?

We'll start with you, **[Participant 1]**.

00:50:00

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

We've talked about this before, but I'll bring it up again. Certainly, the option of the oral medication is definitely a benefit versus the infusions and other things where you have to be going to the hospital. And it's not even the fact of going in and having the transportation, all the other issues that we talked about, but it's going into that type of a facility where you're being reminded all the time, every day or every week, that you're sick and that you have to go and do this, so that also wears on that mental health aspect.

00:50:38

Moderator, RTI International

That's a good addition. **[Participant 3]**, I think I saw your hand up earlier. Did you have any thoughts on how beneficial...

00:50:49

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

I had a question before I responded. Do you mean in comparison to any other type of medication we take, like for blood pressure, etc., or...?

00:50:59

Moderator, RTI International

In any different type of breast cancer medication you take. We've touched on this a little bit, but how would you summarize how the benefits differ for these different medications?

00:51:13

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

I'd have to think about that some more.

00:51:15

Moderator, RTI International

Yeah, that's okay. We've already talked about the administration as a pill as one benefit. Anybody else want to summarize what some of these key benefits are?

00:51:25

Participant 2 (registered as a patient)

I would say, for me as an early breast cancer patient, that outside of anastrozole and Lupron, every medicine had an end date for me. My chemo, radiation, Zometa, Verzenio—all had an end date, so there was definitely this celebration that would come with completing something. And then there was anastrozole, it's—we don't know how long I'll be on it. Because research keeps changing. There's a new drug out there called SERDs [selective estrogen receptor degrader]. If I did the traditional years, I most likely won't be out of menopause. I feel like that's a key thing I just thought of—that other drugs, they had an end date to them.

00:52:23

Moderator, RTI International

That's a great one. I like that. Thanks. Okay.

00:52:29

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

And I can comment, as for later-stage cancer, when it's metastatic, there is no end date. It's either you die, or it stops working and then you need another option. I guess it depends on where you are on that cancer spectrum.

00:52:49

Moderator, RTI International

Okay. And then, anything about the drawbacks? When you're comparing different medications or similar medications, how would you say the drawbacks have differed?

00:53:17

Participant 2 (registered as a patient)

I didn't actually compare. I did what the doctor suggested, and it was—at least for the anastrozole, the thought around that was, "Let's do this and see how your body tolerates it, and then we'll discuss if we need to shift to a different option."

00:53:41

Moderator, RTI International

Okay, yeah.

00:53:43

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

I agree with that. I didn't really compare. At a certain point, it became—I was so afraid to make a decision. You don't want to make the wrong decision. And so I relied on the providers to help guide that. Once you find something that works, you want to stick with it, because if you switch to something else, who's to say that it will? I didn't do a lot of comparison.

00:54:16

Moderator, RTI International

Okay. How would you say, in general, your experiences with Verzenio has compared to the anastrozole that you've both taken? As far as the symptoms go.

00:54:32

Participant 2 (registered as a patient)

I feel like the GI symptoms were overarching the largest problem with Verzenio.

00:54:44

Moderator, RTI International

And did the anastrozole yield those types of side effects at all, or to a lesser extent?

00:54:50

Participant 2 (registered as a patient)

No, not at all. That medicine created joint pain, so no matter how long or how short I sat, I stood up like I was 85 years old and had to shake it out. Like I was like the Tin Man. Verzenio probably exacerbated it a little bit, but it's still very similar, now that I've been off Verzenio.

00:55:19

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

And the hot flashes and the weight gain. [laughs]

00:55:23

Moderator, RTI International

And that's with the anastrozole, is that right? Okay.



00:55:27

Participant 2 (registered as a patient)

Yep.

00:55:28

Moderator, RTI International

And then, Verzenio, have you experienced any of that? Flashes, weight gain, any of that? Okay, so that's unique to the anastrozole.

00:55:36

Participant 2 (registered as a patient)

I will say Verzenio kept the weight off. When I ended Verzenio, I gained 20 pounds, because I didn't have GI issues, so yeah. [laughs]

00:55:50

Moderator, RTI International

This has been a lot of good information on the benefits of these drugs, and definitely some drawbacks I'm hearing, and that's unfortunate that you have to deal with. My last question on this topic before we shift gears is, overall, when considering a therapy for breast cancer, what factors matter most to patients? How would you answer that? Overall, when considering a therapy for breast cancer, what factors matter most to patients?

Hi, **[Participant 4]**.

00:56:30

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

Hi, I would say, in our survey, definitely quality of life, and that's going to vary depending, from patient to patient. But, that was the number-one factor that they considered in whether or not to take this drug. Some focused on long-term survival and reduced chance of recurrence. Other people focus on the fact, again, it was an oral option, which I think we've discussed, and the lifestyle of how this drug fit into their lifestyle, side effects that we've heard notwithstanding. But those are some of the things that we had heard about in our survey.

00:57:21

Moderator, RTI International

Yep, absolutely, and I see **[Participant 3]** in the chat—you said it's quality of life, so piggybacking on what **[Participant 4]** just shared, it's the lifestyle that you can continue.

Any other factors that matter most? Okay. I think we have got about a half hour left, so if you need to roll your shoulders, stretch, or anything, that is fine, and we will dive into these last set of questions.

I now want to focus on the extent to which the treatments we've been discussing for these types of breast cancer meet or do not meet patients' needs. Throughout this discussion so far, we've asked you to reflect on these most important aspects of breast cancer to manage, and we've already talked a lot about what those aspects are, and I have so many here, I don't think we've left any out, but there are many aspects to think about. Would you say that these needs are sufficiently

addressed by the existing treatments available? Would you say that patients' needs are being sufficiently addressed?

00:59:00

Participant 2 (registered as a patient)

Can you clarify a little bit? You mean needs of quality of life? Those needs? Or did I miss...

00:59:08

Moderator, RTI International

Yeah, I'll rephrase that a little bit. When we're thinking about some of these aspects to manage, like quality of life or recurrence, do you feel like the available drugs, the available treatments to you are meeting these needs?

00:59:29

Participant 2 (registered as a patient)

I have faith in that they are, and I have a good care team, and then funny enough, Facebook is a great support community.

Could it always get better? Of course. Yeah, thanks.

00:59:55

Moderator, RTI International

I think I'm hearing—these treatments are largely meeting your needs but could be better.

[Participant 2], is that what I heard you say?

01:00:05

Participant 2 (registered as a patient)

Sure, they're meeting my needs. My need is for survivorship. So I could answer that in 40 years. Quality of life—they could totally be improved.

01:00:30

Moderator, RTI International

Yep, some improvement there, it sounds like, could be helpful. **[Participant 3]**, do you have any thoughts on how well these treatments are meeting needs?

01:00:41

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

I'd like to speak on a broader view. It depends on whether or not you have access. And what you have in place to support the patient in their survivorship. But also, I can't fully say that it's meeting the need when African American women are dying at twice the rate. Why? If we have these medications, is it because of access? Is it because of cost? I really can't say it's meeting the need until everyone's on the same level to access and cost. And that's just my opinion.

01:01:44

Moderator, RTI International

Yep. That's an excellent point. Thank you for sharing that.

01:01:49

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

I think **[Participant 3]** raises a very good point, and **[Participant 2]** as well. That, while this drug is a great option, we also need to make sure that we're investing in cancer research to make sure that we can improve upon the therapies that are in existence today, and even make better therapies and more options for cancer patients in the future, and also make sure that we have evidence-based research that addresses some of the causes of cancer and why it affects certain populations over another. I do think that as CMS undertakes this very important project, that thought is given to make sure that we don't curtail access to innovative therapies in the future. We've seen how far cancer treatment has come in decade over decade, and we want to make sure that that's preserved for future generations as well.

01:03:01

Moderator, RTI International

Thanks for sharing that. All right, any other thoughts on these treatments meeting needs? Okay.

Let's shift perspective slightly to the other side of that coin. And we've touched on this, but which important needs of having breast cancer would you say are not being addressed by existing treatments? In other words, are there major gaps in the available treatments? Any gaps that remain with the available treatments? And **[Participant 3]**, you had mentioned already a very large gap about access to care, so that was a really important one. But any other gaps, whether they be symptoms or...

01:04:01

Participant 2 (registered as a patient)

Honestly, the first thing I think about—and I don't think it's a treatment, so it probably doesn't fall—it's that those blood tests out there that look for tumor markers. It's not a treatment, but it's because there is no, there is no playbook for it yet. If they can't find it on a scan, the doctors can't do anything about the results they get from that test. I don't know if there's treatment that needs to be created for when you get a positive on those tests.

Like, the gap.

01:04:43

Moderator, RTI International

You're talking about blood tests. Are these screening or diagnostic tests that you're referring to?

01:04:52

Participant 2 (registered as a patient)

I can't think of the name. Maybe one of the patient advocates know what I'm talking about?

01:04:58

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

Are you talking about ctDNA [circulating tumor DNA] or biomarker testing?

01:05:02

Participant 2 (registered as a patient)

Maybe more of a biomarker testing. There's a few companies out there that do it. And some doctors are in on it, they are like, "Yes, you should do that every three months," and some are like, "Don't waste your time and money because if we can't find it on a scan, we can't do anything about the results that we get."

01:05:27

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

But I think that [Participant 2] raises a really good point in terms of making sure that people have access. First, making sure that people have education and access to screening and early detection as soon as possible. That's a major gap that we see that cancer patients have, and we want to make sure that when a person has cancer, that the cancer is detected as soon as possible, because you have a greater likelihood of a successful outcome. And part of that is education, and making sure that people know what screening is available, and making sure that people are armed to be able to have a frank conversation with their doctor, and raise their hand and say, "Even though I'm below the screening age, something doesn't feel right." And making sure that you can have that conversation and get diagnosed as soon as possible.

01:06:31

Moderator, RTI International

Great, and that links back, I believe, [Participant 2], to what you were talking about—these blood tests, that they could be better, to serve as a screening tool. I hear you, a good addition.

Anybody else want to comment on some of the gaps in treatments? Okay.

We have covered a lot of ground today, you all have been so helpful. We're going to wrap up with a few closing questions, if you don't mind. Before we close, I'm going to go to the back channel and see if CMS has any other questions for us. And it looks like they don't have any questions. You all have provided so much information, they have nothing more to share. But, before we wrap up, are there any other additional questions or comments that you want to share, to close out your thinking on where we are with breast cancer treatment, or on Verzenio or other treatments?

01:07:55

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

I have a question first, and that is, how do the pharmaceutical companies give back? Yes, they provide a medication, but how do they give back? What they're profiting, are they mandated to give back in any way? And then my last comment is, I think that this is a great step in the right direction to have these negotiations between CMS and the pharmaceutical companies, we have to rein them in a little bit. But some of us are not on Medicare and Medicaid, and I'm one of them. I hope that this will set a precedence that in the future, there will be negotiations with private insurance companies as well, or maybe a sliding scale based on what your income is, but I am grateful for the fact that,

there is going to be some type of mandate to control the prices of these medications. I would hate to think that I'm not important enough to be alive because I don't have money to afford the medication. So they need to keep that in mind—that we're people. I pray that the people on this call understand that I'm not just a face, I'm a person. Thank you for your work in trying to get these negotiations going. The medication—it works for most people. I don't know the statistics, but it's a good medication, but it doesn't do much good if only a select few people have access to it. I think that's it. Thank you all for having me.

01:10:23

Moderator, RTI International

That's a wonderful closing remark. **[Participant 2]**, do you want to round out any final thoughts?

01:10:30

Participant 2 (registered as a patient)

Yeah, one to **[Participant 3]**, I don't know if you have looked into it, but if you have not, I urge you to look into the Eli Lilly Cares program and ask your oncologist's office, because like I said, there's two ways that people have been getting Verzenio for low to no cost. And I didn't have to submit anything about what I make, and so there's definitely a way to do it without them basing it on your salary, if that's something that would exclude people, so if you've not looked into that, please look into that, because it was all over the Facebook pages, and so I know it exists, and I know people have used it. The second piece was—and it spurred when **[Participant 3]** was asking about how they give back—I know there's time periods with these drugs that they can then be allowed to make generic versions. And I would, as a patient who's on anastrozole, I read people talking about, "You have to be careful about the formulation of your anastrozole because it can come from different labs, or different companies." So my statement is with Verzenio, I don't believe there's a generic version out yet, but if that's something that is coming down the pike because it's been out long enough that the patent's off, or whatever that process is. The research isn't on new formulations with the same guarantees that people think it might have if I'm making any sense on that, that's the direction that this drug is going towards.

01:12:32

Moderator, RTI International

No. Yeah, generic would be great. **[Participant 4]** or **[Participant 1]**, do you have any other closing thoughts that you'd like...

01:12:40

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

In closing thoughts, first of all, thank you to CMS for all the work that you're doing with this negotiation process and for including patient voices. This panel had two amazing patient advocates and want to thank you both for all that you do. We have tremendous volunteers and, again, we had survey recipients who helped us to hopefully add and contribute to this process, and wrap up a lot of things that we've heard, both in terms of today and from our survey as well, that for this particular product, having the oral option is helpful in terms of quality of life. We'll share our survey results with CMS and happy to answer questions on that. But I really do think that the quality of life and the fact that this particular drug allows people to continue to live and do their daily life, and not that

there's no interruption, but that you're not having as much interruption as you may have on other drugs is really important for CMS to consider, so thank you again.

01:14:06

Moderator, RTI International

That's very well said. Thank you for summarizing that so eloquently, **[Participant 4]**. **[Participant 1]**, do you have any further thoughts you'd like to add?

01:14:16

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

I really don't have anything additional. Everybody's covered all the bases from our community's perspective, but I do want to thank you for including the patient voice because it's so important for people to be heard, so thank you for inviting us here today.

Closing Remarks

01:14:34

Moderator, RTI International

Wonderful. Before you all go, again, so appreciative of your time, and this information that you're providing us today will help inform CMS' negotiations for Medicare pricing, so thank you so much. CMS staff have been listening to this roundtable and will be able to bring your perspectives back to their teams and to the table. Before you go, I want to go ahead and let them close out with some final thoughts and remarks.

01:15:04

CMS Staff

Thanks, **[Moderator]**, and I will heap on the praise too. Thank you all on behalf of CMS and my colleagues attending this roundtable event. Thank you very much for taking the time to share your experiences and perspectives with us, and I especially want to thank **[Participant 3]** and **[Participant 2]**, we really greatly appreciate you sharing your personal stories. Each of you has given us a lot of valuable information to consider, and for that, we are genuinely grateful. Thank you.

01:15:32

Moderator, RTI International

We definitely are, and if you have any questions about today's session, or if you want to follow up—**[Participant 4]**, I know you had some survey results, anything that you would like to provide—you can submit them to a mailbox, and we're going to drop that on the chat. It's IRAREbateAndNegotiation@cms.hhs.gov. Any of you are welcome to provide any other thoughts, input, a write-up. And in the subject line, if you could please put "Public Engagement Events" so they know where to route that information.

I'll give **[Participant 4]** a second to write that all down before we log off. And thank you all again. Very appreciative of you. Have a lovely rest of your afternoon.

===== 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

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
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 2: Registered as a patient who has experience with 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 3: Registered as a patient who has experience with the selected drug or the conditions treated by the selected drug; representative of a patient advocacy organization

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

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

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