Transcript: Ibrance Roundtable Event, April 17, 2025, Medicare Drug Price Negotiation Program Public Engagement Events

This transcript was lightly edited for readability.

Introductory Remarks

Moderator, RTI International

Thank you for everyone for coming today. I'm **[MODERATOR]**, and I'm from RTI International, and I also want to introduce my colleague, **[SECONDARY MODERATOR]**, who will be co-facilitating with me today, and you'll hear from him, maybe for a few points throughout our discussion. The Centers for Medicare & Medicaid, or CMS as it's known, is convening these patient-focused roundtable events and others as part of the Medicare Drug Price Negotiation Program.

The purpose of today's event is to hear from you all. And this group may include patients, caregivers, and patient advocates. And we'd like to hear about your experiences with the condition and diseases treated by Ibrance, as well as your experiences with the drug Ibrance itself, as well as other medications that treat breast cancer.

I wanted to emphasize that the focus of our conversation today is really to capture patient experiences. And so, if you have other really important information to share that maybe are not relevant to patient or caregiver experiences, we would encourage you to use the IRA mailbox, and we'll have that up on the screen at the end. So, if you have research studies or something that you would like to have CMS know about, you can use that mailbox to share those today.

Okay? And so, the information shared during these roundtable events will help CMS understand patients' experiences with the breast cancer treated by Ibrance, as well as patients' experiences with the selected drugs and patients' experiences with the drugs that are also used to treat the condition.

CMS may use this information in negotiating Medicare pricing with the manufacturers of selected drugs. And so, that makes your experience and perspectives very important to us. And we genuinely appreciate your time today.

So, to get us started, we have a brief video from CMS leadership so that you can hear directly from them how much they value your time and input.

CMS Remarks

00:01:28

Steph Carlton, Deputy Administrator and Chief of Staff, Centers for Medicare & Medicaid Services

Greetings, everyone. I'm Steph Carlton, the Deputy Administrator and Chief of Staff at the Centers for Medicare & Medicaid Services, or CMS. CMS administers Medicare, our country's federal insurance program, for more than 65 million older Americans and people with disabilities.

I deeply appreciate each one of you for taking the time to join us today. Lowering the cost of prescription drugs for Americans is a top priority of President Trump and his administration. As the second cycle of negotiations begins under the Trump administration, CMS is committed to engaging with stakeholders for ideas to improve the Negotiation Program.

In January 2025, CMS announced the 15 Medicare Part D drugs selected for the second cycle of price negotiations. Medicare's ability to negotiate directly with drug companies will improve access to some of the costliest drugs while fostering market competition and continuing innovation.

Our priority in negotiating with participating drug companies is to come to an agreement on a fair price for Medicare. Promoting transparency and engagement continues to be at the core of how we are implementing the Medicare Drug Price Negotiation Program. And that is why the process for negotiation engages you, the public.

This event is part of our effort to hear directly from a range of stakeholders and receive input that's relevant to the drugs selected for the second cycle of negotiations. Thank you again for joining us. Your input matters. And next, stay tuned to hear from the event moderator to give you more details on what to expect during this event.

00:04:01

Moderator, RTI International

Thank you for that video. So, in addition to the greeting from the CMS leadership, I also want to make you aware that there are staff from CMS who are sitting in on this event, so that they can hear directly from you about your experiences and your opinions. So, let me hand it over to our CMS colleagues to say hello.

00:04:20

CMS Staff

Thank you, **[MODERATOR]**. I want to welcome everyone on behalf of CMS. On the call today we have staff from the Medicare Drug Price Negotiation Group, which manages the Negotiation Program. We want to thank you for participating. And we're looking forward to hearing about your experiences during this roundtable discussion. We're going to go off camera for now, so, you can focus on the discussion. But we'll be here listening. We appreciate your input, thank you.

Housekeeping

00:04:49

Moderator, RTI International

Thank you, **[CMS STAFF]**. All right. So, we're just about ready to get underway. But we have a few housekeeping items. Just so we have a shared set of norms. So, we have some housekeeping items and ground rules. And so you know what to expect. So, first participation, we hope that everyone will contribute your own perspectives throughout the session. However, if there are questions that arise that you don't feel comfortable answering, you don't have to answer. That's okay.

Minimize background noise. So, please minimize background noise by silencing your phone or other devices. And if you can mute yourself when you're not speaking, that would be very helpful.

In terms of your privacy, this discussion is not open to the press or to the public. We're only using first names, as you see, during the discussion to protect your privacy. And so, we ask that you please do not share any unnecessary personally identifiable information or personal health information during that discussion.

We are audio and video recording today. But these recordings will not be shared publicly.

Following the event, CMS will prepare transcripts that have participant names and identifying information removed, and these will be, in fact, made available to the public.

Okay. So, I wanted to highlight a few other things to keep in mind during our discussion. We would really appreciate if folks who are participating in the discussion would keep their video on so that we can have a nice kind of warm discussion, and have that rapport. Timing. The session will last about one hour and 30 minutes. I have a discussion guide in front of me to help us stay on track. We have a lot of topics to cover, so I may need to redirect the conversation or say, okay, we need to move on or cut somebody short a little bit time, just to make sure we can cover everything.

Technical assistance, if you get disconnected, please attempt to rejoin. If you cannot, please reach out to the mailbox here on the screen that IRADAPStechsupport@cms.hhs.gov, you see, in that first item.

And in terms of breaks. If you need to step away briefly from the discussion. That's totally fine. Just turn off your camera, turn your microphone off and then rejoin when you're able. You don't have to flag me down or say, hey, I need to leave. You can just step away, turn off those features and come back as soon as you can.

Speaking, just as always, good manners. Try to speak one at a time. I may occasionally interrupt when two or more people are trying to speak at the same time, and just so we can get a talking order in place, because I want to make sure that everyone has a chance to talk, and that everyone's comments are accurately recorded.

And then please feel free to use that raise hand feature in Zoom. I know, **[Participant 6]**, you said. That's a little small for you. So, if you wave or put your hand up, I'll try to keep an eye out for that, and I also have **[SECONDARY MODERATOR]** to also help me keep an eye out for hand waves.

Okay? And so final item is honest opinions. Everyone's experiences and opinions may differ, and we just want to make, we want to know that what each of you honestly thinks about this topic that we discuss.

All right. I think we've gone through all our housekeeping items. Any questions before we begin?

Okay, then let's go ahead and get underway. So, I'd like to go around the virtual room and start the discussion by asking everyone to introduce themselves. So, please take about 30 seconds, if you would say your first name, and whether you will be sharing personal experiences from yourself, those of a loved one, or whether you're sharing patient experiences from the perspective of a patient advocacy organization. Or if you're wearing multiple hats today. That's also valuable to know, **[Participant 1]**, you are first on my screen. So, if you wouldn't mind kicking us off, I would really appreciate that.

Discussion

00:08:44

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

Of course. Well, good afternoon, everyone, or good morning for any of you situated in the West Coast. My name is **[Participant 1]**, and I'll be speaking from a patient advocacy organization experience in the work that I do with patients through a helpline program.

00:09:00

Moderator, RTI International

Thank you, **[Participant 1]**. **[Participant 2]**, you appear next. Do you mind going next?

00:09:06

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

Absolutely not. Thank you. Hi, my name is **[Participant 2]**. I am with Cancer Support Community. We are a nonprofit that supports people impacted by cancer. And so it is through that lens that I'll be participating as a patient advocacy organization sharing the insights of cancer patients and caregivers. We've gathered through our supportive services we provide as well as through our psychosocial research that's called our cancer experience registry.

00:09:35

Moderator, RTI International

Thank you, **[Participant 2]**. And **[Participant 3]** looks like you're next on my screen. Okay.

00:09:40

Participant 3 (registered as a patient)

My name is **[Participant 3]**. I'm a breast cancer patient. I'm the 4th generation on my paternal side of the family who's had breast cancer. So, I will be speaking also on behalf of the 14 women in my family who have also had breast cancer, and I'm also the **[REDACTED]**, where tens of thousands of women all over the world have downloaded it and used it, and I'll be speaking from their perspectives as an advocate for them, as well.

00:10:08

Moderator, RTI International

Thank you, **[Participant 3]**. And, **[Participant 4]**? And **[Participant 4]**, you may need to come off mute.

00:10:21

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

I've only been doing Zoom for five years. So, good afternoon, everyone. I'm really honored to be here with you guys, learning, looking forward to learning about your experiences and hearing your stories. My name is **[Participant 4]**, as she said. **[REDACTED]** the patient advocacy group called Survivors for Solutions. I've been living with a chronic illness **[REDACTED]**, I give credit to innovative medical development that has allowed me to live my life for the last 35 years. And so, I'm curious to hear how you all have done with this drug and how we're going to work together to keep the pipeline going.

00:11:07

Moderator, RTI International

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

00:11:12

Participant 5 (registered as a representative of a patient advocacy organization)

Thank you. My name is **[Participant 5]**. I'm here representing the American Cancer Society, Cancer Action Network [ACS CAN]. For those who do don't know, ACS CAN is an organization affiliated with the American Cancer Society that advocates on behalf of cancer patients, caregivers, and survivors of cancer. I will be representing the point of view of cancer patients. We did, just so people know, we did a survey of cancer patients who've taken the drug Ibrance to try to get a broad perspective on what people's experience has been. It's not meant to be statistically significant, but it is methodologically good, and gave us the experience of people on Medicare who are taking Ibrance or have in the last 18 months, to speak to some of their experience. Because I think this is the kind of information that CMS is looking for. And I just have to say how pleasant it is to be on a phone call where we're all gonna talk about this. And I like **[Participant 4]**, really do want to hear what other people bring to the equation and are talking about in terms of it. Sounds like lots of great different experiences. So, thanks.

00:12:29

Moderator, RTI International

Great deal. Thank you, **[Participant 5]**. So, opportunity for group learning. And **[Participant 6]**? You were the last one on my screen, so I'll let you take it away.

00:12:39

Participant 6 (registered as other)

Thank you. My name is **[Participant 6]**. I'm **[REDACTED]** for Policy and Program of the National Minority Quality Forum. We are, I am not representing or speaking from a personal experience. And we are a disease agnostic or a therapeutic area agnostic organization, which doesn't mean that we don't work with cancer. It means that our doors are open to explore policy challenges associated with improving quality care for all therapeutic areas, and for those who may not be familiar with the National Minority Quality Forum, we are DC-based nonpartisan nonprofit research and advocacy organization.

00:13:23

Moderator, RTI International

Thank you, **[Participant 6]**. All right. So, my next question. I'd like folks to use the chat feature. But, **[Participant 6]**, I know you said, that's a little small for you, so you're welcome to say it verbally. So, my question is, have you, your loved one, patients you work with taken Ibrance, either currently or in the past? So, if others could enter those in the chat, and **[Participant 6]**, if you wouldn't mind saying verbally, yes or no, if you've had that experience.

00:13:51

Participant 6 (registered as other)

No.

00:13:52

Moderator, RTI International

Thank you, **[Participant 6]**. So, **[Participant 3]**. Yes, **[Participant 1]**, okay. Fantastic. Thank you. All right. So, we have a nice diversity of experiences.

All right. Well, I will get us underway with the meat of the discussion. And again, you're welcome to use the chat to enter any kind of supplementary information, and we will get underway. So, first question, thank you for taking your time to introduce yourselves and telling us what experience you'll be drawing from today.

I'd like to start by talking about your experiences or your loved ones' or other patients' experience with breast cancer treated by Ibrance. So, we know there's going to be a lot to talk about, so you can raise your hand or use the chat, whatever feels most comfortable to you. So, the first question is, in general, how does breast cancer affect your life or your loved ones' lives, or the patients that you work with? How does it affect their lives?

And you can just go off mute or raise your hand, whatever feels the most comfortable to you. **[Participant 3]**, it looks like you are our first one.

00:15:02

Participant 3 (registered as a patient)

So, earlier, when I introduced myself, I said I am the fourth generation on my dad's side of the family to have been diagnosed with breast cancer. I was **[REDACTED]** years old. I had been married about two and a half years, and at that age when my friends are getting married and having babies, the first ultrasound that I shared with my husband was of an angry breast tumor that was beginning to metastasize, and I had been familiar with Ibrance because of women in my family who had gone through breast cancer before me.

So, I knew what questions to ask, and I knew what to advocate for, and I'm so grateful that I had. It's unfortunate, but I'm also grateful at the same time, and we hear about the clinical benefits of Ibrance, and how it extended life, and how symptoms were managed, and but what we don't often hear that's not measured, are how many more holidays that I got with my family because of Ibrance, how many shopping trips we got together, how many hugs, how many selfies, how many times I got to taste my aunt's orange mandarin cake because of Ibrance. And yeah, I was told initially that I was too young for breast cancer. Whenever I went to the doctor and I had a lump in my breast. Screenings only look at our age, we have to fight to get our screenings if we're under the age of 14. Insurance only looks at age. So, what we also know is that for young women, our cancers are more aggressive, and that they're more difficult to detect, and they're more likely to be diagnosed late stage. So, I just think about if it was so hard for me to get the screening that I needed, I just ask that me, the young women and the people that I represent that we're heard when we need options for treatment and medication.

00:17:23

Moderator, RTI International

And **[Participant 3]**, before you go off mute, I just wanted to follow up, because you had mentioned counting your holidays, counting the times you get to have your aunt's cake. And so, I was wondering if you could kind of share a little bit more about how that breast cancer diagnosis affected your life, your relationships, your work, and that kind of thing. And I see **[Participant 1]** also is putting some things in the chat. So, we'll get to you, **[Participant 1]**, as well.

00:17:50

Participant 3 (registered as a patient)

Breast cancer, I hate to sound so morbid, but I would go to one funeral, and then it would be like, who, someone else would come back and get diagnosed. And when I was being diagnosed with breast cancer, I remember being in the ultrasound room with the radiologist, and I'm having to call my dad and tell him, because he's on his way to see my aunt, who's dying of breast cancer. So, he's on his way to go to a funeral, and his daughter is now telling him that it's her turn to fight the disease that has, it doesn't just run in our family. It has sprinted through our family.

So, this, it's always been a topic of conversation, and thankfully, because of the diagnosis that has just ran its way through my family, my sister thankfully was able to get prophylactic double mastectomy and a hysterectomy. Didn't have any issues with her insurance, showed the family tree of cancer history that lights up like a Christmas tree, brings it to the doctor, and says, I need every prophylactic surgery available to me to mitigate my risk for this, and it was done.

So, that's how breast cancer has affected our family in short.

00:19:09

Moderator, RTI International

Thank you for sharing that, as I could hear how emotional it is for you. I'll go ahead. And, **[Participant 4]**, I know you've been wanting to say something for a while, so come off mute and share.

00:19:21

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

Great. Yes, thank you, **[Participant 3]**. Thank you for that. It was really [inaudible] to hear that. And I want to be clear, I've been in my, I have chronic disease and I don't mean to imply anything. I don't have breast cancer, but I have multiple sclerosis. I am [inaudible] very public about that. And why that powers my advocacy in, for Solutions for Survivors. So, but what I don't talk much about which is how equally proud I am in this case is my wife's story. My wife's story, I asked her permission before this meeting, so I got clearance to share this, because it's equally powered by that, and her story is that when **[REDACTED]**, her mother was diagnosed with very aggressive breast cancer, and she passed away shortly thereafter. So, before my wife graduated from high school, she lost her mother. And so, I can't think. [I]t's sad, this life, I share my story only because I share with millions of others in the world, in the country that being touched by breast cancer, and I can't help but think how Ibrance would have, kind of preserved, given her maybe five more years, right? [inaudible] That would have allowed… [inaudible].

To graduate from high school and college. I'm sorry. So, I was just saying how… did I cut out?

00:21:04

Moderator, RTI International

You cut out for a second, **[Participant 4]**. But you were saying how, having access to medication for breast cancer, could have given your wife more time with her mother.

00:21:16

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

Yeah. It would have given her, my wife's mother, to watch her graduate from high school and from college, and I think the family tree will never know exactly. But I'm really grateful that there are, we are now in a world where we have these innovative treatments that are available. So, I want to say, **[REDACTED]** organization is disease agnostic. We just think that we need more solutions for everyone, right? Access. So, that's really what I want to say is, thanks for... can't wait for this conversation.

00:21:48

Moderator, RTI International

Thank you, **[Participant 4]**. Yes, and thanks for bringing in the story about breast cancer. Because that's really where our heart is for today. **[Participant 2]**, I see your hand has gone up.

00:22:00

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

Yes, thank you. So, I wanted to share some insights from our 2020 cancer experience registry. It's a report of 984 patients diagnosed with metastatic breast cancer, patients and survivors at various stages of metastatic breast cancer, diagnosis, treatment, and progression. And so, what that analysis showed us, when we're looking at quality of life, those patients indicated, I'll just name the top three, 44% reported worse fatigue than the general U.S. population; 42% reported worse anxiety, and 42% reported worse physical function as well.

Fatigue is a moderate to serious concern of 60% of the patients in our registry report, and in a separate analysis of 273 metastatic breast cancer survivors, fatigue was associated with poor social functioning and increased feeling of loneliness and isolation. We also learned through our report, because we also receive insights from caregivers, caregivers of metastatic breast cancer patients also report high levels of cancer-related emotional stress; 85% of caregivers that participated in our workshops between 2014 and 2019 reported experiencing emotional distress due to their loved ones' cancer.

And I also wanted to just highlight some concerns that these patients also reported around mental health, physical health, and daily activities. Most had moderate to very serious concerns related to their emotional and mental health. Two-thirds worried about the cancer progressing or coming back; 65% worried about the future and what lies ahead, and more than half of the patients worried about their family and friends, and lastly, more than half of the patients had moderate to very serious concerns about their physical health, including eating and nutrition at 65%, 63% were concerned about their ability to exercise and be physically active, and 56% were concerned about their sleep problems.

00:24:19

Moderator, RTI International

So, **[Participant 2]**, it's very profound disruptions in multiple aspects of life from your survey. Did you by any chance collect any kind of open text or anecdotes from the folks you engaged in the survey?

00:24:33

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

So, I will say we usually do receive that, but I do not have that here. But what I could do is report back to the Research and Training Institute any anecdotes that might be helpful, and if you want any follow-up, if that might be helpful, you can reach out to me. I can reach out to you, and I can get that information to you.

00:24:52

Moderator, RTI International

If that's valuable, you're welcome to submit it via the mailbox. But thank you for sharing how multiple aspects of a patient's lives and their caregivers' lives are just very profoundly impacted. I want to go to **[Participant 6]**. And then, **[Participant 1]**, I want to circle back to what you've been raising in the chat, if that's all right. So, **[Participant 6]**, please take it away.

00:25:11

Participant 6 (registered as other)

Okay, thank you. [A]s I said, although I didn't have personal experience with breast cancer, I am a member of a population cohort that is at significant risk not only for cancer, but for being diagnosed later at a more advanced stage. And given that we've also experienced interesting challenges associated with being included in clinical research, far too often the therapies that are available have not been tested for any differences that may be associated with biochemistry. The National Minority Equality Forum has undertaken a cancer stage shifting initiative to attempt to address some of those issues, particularly in areas where environmental toxins are prevalent and due to in some areas the manufacturing railroad crashes that seem to be increasing, and unfortunately, the populations who took, whose homes tend to be adjacent to the polluted water, the toxins in the air, or the railroad tracks, tend to be populations that are disenfranchised through housing, and also disenfranchised in terms of access to healthy, robust health benefits, so that when one is diagnosed, then one can access the best possible care as quickly as possible. So, thank you.

00:27:16

Moderator, RTI International

I'm sorry. No. And **[Participant 6]**, in your networks, have you spoken with individuals who have had experience with breast cancer and shared their experience with you?

00:27:27

Participant 6 (registered as other)

I have not. Some of our other staff, as I said, I'm **[REDACTED]** for Policy, so we tend to work at the federal and state levels. But absolutely, we have staff who are on the ground in Texas and Michigan and Louisiana, in other areas, and working with those communities' local elected officials and others to do two things, find some way to mitigate the clear health challenges, and I can't see your name, **[Participant 3]**, is that it, the experience that you described is also true for populations who've been exposed to those environmental toxins and not just generations of the family, but entire communities experiencing outside of the belt, cancers, not but not just breast cancer. So, I didn't answer initially, because I wasn't sure if your question was limited to the HR [hormone receptor]-positive, HER [human epidermal growth factor receptor] 2-negative cancer for which Ibrance is indicated. If you move broader than that into triple-negative breast cancer and some other breast cancers, then there are other conversations, we can have, other remarks we can make about risk and the ability of the system to even document the cancer because the ICD-10-CM [International Classification of Diseases, 10th Revision, Clinical Modification] codes are not available to do so.

00:29:21

Moderator, RTI International

And I would encourage that to go to the mailbox to keep our conversation on the patient experience for today. But that's valuable information that we would really welcome having as part of the conversation. **[Participant 3]**, before we get to you, do you mind if we circle to **[Participant 1]**, has made a number of comments in the chat that I just wanted to be sure that we heard from **[Participant 1]**, and then we'll pop back over to you.

00:29:49

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

Yeah, no, thank you. I just wanted to really chime in and speak to the many patients that reach out to our helpline, who tend to be individuals. We were a national organization. So, we hear from individuals all over the U.S. We tend to hear from individuals that are under-resourced, whether that's in the resources they have available to them or those that they have access to. And really, my points in the chat just really speak to that. Ibrance is a lifesaver for many patients in MBC [metastatic breast cancer]. [T]his is something that's life or death for them. It's one of their only options, and keeping it affordable and accessible ensures that they don't have to choose between their family and their treatment, paying their rent. I would say that you know we often talk about individuals who are living with MBC. Especially those who are uninsured many times will delay treatment, or if there's high cost again to delay that treatment because they don't want to be burdensome to their family, or even take out credit cards right, that they just don't have the capacity to really pay for their care. So, thank you.

00:31:03

Moderator, RTI International

So, thanks. I think we've heard we heard financial disruption from **[Participant 6]**, as well as you, and I see others had mentioned that in the chat. So, **[Participant 3]** and **[Participant 6]**, did you want to speak again? Because we'll go to **[Participant 3]**, and we can come back to you. Okay, the hand. Okay, just wanted to confirm that I didn't miss anything. **[Participant 3]**, I know you had your hand up, so if you wanted to circle back on you had an additional comment?

00:31:27

Participant 3 (registered as a patient)

Yes, so to **[Participant 6]**'s point. I live in **[REDACTED]**, but I was born in **[REDACTED]**, where a lot of my family was from when they immigrated here over a century ago, they settled in **[REDACTED]**. And they call it **[REDACTED]**, and it's where you have coal mines. You have gas lines. And, as I've said breast cancer goes back four generations in my family. We have no known gene mutation that's been tested. Everyone in my family who has been tested. I'm not gene BRCA [Breast Cancer] positive, I'm not BRCA or any of the no, I'm not CHEK2 [Checkpoint Kinase] positive, anything. I'm actually going for another round of genetic testing. It's been five years since my last test, because they're trying to figure out what's going on in our family.

[D]uring the Industrial Revolution going back to the first generation that they do have documented as having breast cancer. [M]y family, they grew crops and drank well water off of their own land in a holler, as they call it in Kentucky, down the holler from coal mines. They didn't know what carcinogens were, and they believe that may have disrupted our family genetically in some way. But that's something that happens to a lot of families up in the Appalachia area, the coal mines, and where you have a lot of people working around chemicals. So, I know if you look at how many women in my family have had breast cancer, reoccurrences, metastatic breast cancer, and having access to Ibrance has been pivotal and vital for them to extend their lives.

00:33:07

Moderator, RTI International

So, I have one more question in this section that I'll briefly cover. I'd love to hear the patient perspectives on what aspects of breast cancer are most important to you as a patient or your loved ones or patients you work with, what are the most important aspects of breast cancer that are most important to have managed or treated?

00:33:36

Participant 3 (registered as a patient)

I guess I can speak to this. Some of the most important aspects to have managed or treated is one, getting insurance to approve the treatments that we need, not have it being to jump over the hurdles and jump through hoops of prior authorizations. And, I could go into stuff about PBMs [pharmacy benefit managers], but I won't. And all the issues related to that. Symptom management is very important, because often that's a race we kind of fight within ourselves. It's like, how long can I endure X symptoms to, if this treatment is effective and it's working for me. And then the cost, I think we've had multiple people say that the cost is also a barrier that needs to be managed as well, and a medication isn't necessarily accessible, if it isn't affordable either. So, it's the affordability and getting approved for it. And then symptom management is really important.

00:34:33

Moderator, RTI International

Thank you. And then, **[Participant 6]**, and followed by **[Participant 5]**. What are the most important aspects of breast cancer to have managed or treated? Oh, four more hands going up.

00:34:44

Participant 6 (registered as other)

I'm going to try not to be redundant, but I think, being diagnosed early, we have, I can't remember the survey, but anecdotally, you hear that certain populations don't keep their appointments or don't follow the mammogram schedule that apparently turns out not to be true. It's more anecdote than other, but getting diagnosed early, and then being referred into treatment in a way that is not blocked by formulary management tools. And you do have different populations who can buy their way out of the utilization management tools because they have more financial resources available to them. That, actually, I would submit should not be the case in the United States, but it is because the formulary management tools are not associated with quality of care. They're associated with financial risk management. And so, they're I think, what populations, families who experience this want to be able to do, I would say, is trust that the system is going to assign value to their lives regardless of their phenotype, regardless of their location, whether it's urban or rural. Bring that support to all families.

00:36:33

Moderator, RTI International

Thank you, **[Participant 6]**. And **[Participant 5]** and **[Participant 2]**. I need to move to another topic area. Could you give us the short version of what are the most important symptoms to have managed or treated?

00:36:50

Participant 5 (registered as a representative of a patient advocacy organization)

I can hold.

00:36:52

Moderator, RTI International

Okay. And **[Participant 2]**, did you have? Wanna do the short version of what aspects of breast cancer are most important to you or to the...

00:37:03

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

I said I'll put them in the chat.

00:37:05

Moderator, RTI International

Great. Thank you. Okay, so I want to move, the next topic is about experiences with the selected drugs and therapeutic alternatives. So, I want to talk about experiences with Ibrance itself. In addition, I would love to hear about the experiences you or the patients that you work with have had with other medications like Kisqali for breast cancer. So, folks in the patient advocate world know that these drugs are often referred to as therapeutic alternatives. So, if I use the word therapeutic alternatives, it's those other drugs for breast cancer. So, the question for this section to start us off are, when considering potential medications for breast cancer, what matters to you, your loved ones, or the patients that you serve the most?

00:37:55

Participant 5 (registered as a representative of a patient advocacy organization)

Can you say that again?

00:37:56

Moderator, RTI International

Yes. So, when considering the potential medications for breast cancers, what matters to you as a patient, patients you serve the most?

00:38:07

Participant 3 (registered as a patient)

I think a question in my family that's come up, is this going to work, and how much time is it going to give me, and that's, I feel like that's what at the heart of it, what it comes down to. I think being able to take Ibrance in a pill form rather than going to a clinic once a week, once a month, every other week, and being hooked up to IVs and having to take pre-meds, and having taking time out of your day and having a functional life outside of that, is also really important. Being able to have Ibrance, you take a pill and you have a regimen that you follow. You track your symptoms. You talk to your doctor. It's a lot easier to manage it, and it gives you a better quality of life.

00:38:51

Moderator, RTI International

And **[Participant 3]** you had mentioned what matters most is, how well does the medication work? Would you mind saying a little bit more about what that means to you? How well does it work?

00:39:04

Participant 3 (registered as a patient)

I mean, how long do I have to live? Simply put, how long do I have to live? That is, basic way to put it. Yeah.

00:39:20

Moderator, RTI International

Thank you. So, **[Participant 4]**, I'll go ahead and go to you, considering the medications for breast cancer. What matters most to, I guess your wife's experience?

00:39:36

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

Well, obviously having the option, right? In her case, there was no option. Now there is. So, that is, that's that. Seems like it's number one, two, and three of the list. Like, if you have no drug to choose to help fight your disease, then it doesn't matter what the cost is, it doesn't exist. Then that might as well be the cheapest or most expensive drug. Like in my case, personally, I'm chronic disease. I have, my MS **[REDACTED]**, and there were zero drugs to fight disease management, that year. Later that year, the first one came out. I went on it soon thereafter. It did not work for me, but it was really bad news. It worked for a lot of people. It was great, not for me. But it was because of, other drugs came online, I could I fight [inaudible] with high adoption. I had plan B, plan C, plan D, and no, having multiple choices made all the difference in the world, in several seizure-like diseases. So, having a plan B, like in the first time, first one didn't work. Second one did. Then, 20 years later, I had friend, they needed another something else, because it was trying to break down. Third option was a, my body said it. It didn't work at all. So, I need a plan T, so my point is just having options. Yeah.

00:41:10

Moderator, RTI International

I think that, as you said, it applies to breast cancer as well as MS that you're experiencing, having multiple options to address the symptoms that you have. Thank you for raising that up and showing its broad value. **[Participant 2]**, did you want to add to that?

00:41:27

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

Yeah, I wanna echo what **[Participant 4]** said about having multiple options, multiple options, therapeutic alternatives available. I put that in the chat earlier. But that can't be highlighted in terms of just how truly important it is.

To answer the question that you were asking with respect to what's important in the treatment or what do patients look for in the treatment? So, again, I'm coming from the experience or sharing the experience of the breast cancer, metastatic breast cancer patients and caregivers and survivors that responded to our survey. So, we did a 2024 analysis last year, looking at 41 MBC patients, and they indicated that the factors that they need that they're looking for when determining whether or not, a treatment is tolerable—41 out of 41 indicated the ability to slow disease progression was somewhat to very much important; 95% of patients felt symptom relief was important; 95% also felt that side effects of treatment were important; 93% felt that the treatment's impact on daily life was important; 93% felt the treatment's impact on emotional well-being was important. And I think this point can't be underscored too much, either, 93% of patients found the cost or affordability of treatments as important and notably based on our survey respondents, MBC patients found these factors more important than ability to cure, which was at 75%.

00:43:01

Moderator, RTI International

Yeah, a whole constellation of things that are very important, all kind of at that 90% level.

00:43:10

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

If you think about it, you're hearing similar points coming back. So, I think this is just really underscoring the impact and the value of these types of medications on their ability, their quality of life, their well-being, their ability to be able to continue to contribute and actively participate in their lives and in their communities and with their families, and the way that they feel is necessary. And so if you hear us saying the same things multiple times it's probably a point that bears repeating, because it's that important.

00:43:53

Moderator, RTI International

Thank you.

00:43:54

Moderator, RTI International

Yeah. And I was, when you were saying, everything was over 90%, just to show like how valuable that is to individuals who are suffering.

Did anyone else want to share what is the most important with the folks that they serve, for breast cancer? **[Participant 1]**, it looks like you're waving your hand. Go ahead.

00:44:19

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

So, just to follow up some notes that I put in the chat. [W]hen we're speaking with patients, I think it's, what we hear is that it's really important for them to be making the best decision in partnership with their provider. And their provider is going to be the best one to determine what medication is working for them, how best it's working. In **[Participant 3]**'s case, how long it will work and how long that individual should stay on it and not come off to an alternative if that is the best option. So, again, having that, just the personalized nature, and really, the decisions about treatment really should be made between individuals and the doctors themselves. Thank you.

00:45:00

Moderator, RTI International

And **[Participant 6]**, go ahead and round us off with this question.

00:45:04

Participant 6 (registered as other)

Well, I think I'm just going to reinforce the statements that have been made about how essential it is that there be options available for treatment because there are different responses to drugs in the same class. So, the A, B, I understand that in terms of price negotiation, one looks at cost and price and financing. But unfortunately, I'm concerned that it's only through the lens of the payer. The cost of the experience is not being looked at also through the experience of the patient and the family, and that needs to be factored in as well. And I, as I was preparing, and I'll be honest with you, I didn't know if we were gonna present or not. So, I actually wrote some things up, but I can't type it all into the notes. A concern that the National Minority Equality Forum has also based upon our engagement on this issue is that assigning priority to price reduction often then leads to intentional planned rationing of access through formulary management tools, which in and of itself not only puts the patient at increased risk for a progression of the disease before access to the most efficacious treatment is available. But I would submit it's unconscionable. It's unconscionable. And it's not that we don't recognize that cost and price are a critical issue here, but there has to be a better way of doing this than sort of the structured delays in access to treatment that we see in the formulary management tools.

00:47:27

Moderator, RTI International

Thank you, **[Participant 6]**, and I think **[SECONDARY MODERATOR]** had flagged a question, a follow-up question. So, **[SECONDARY MODERATOR]**, would you mind coming off mute for a moment?

00:47:34

Secondary Moderator, RTI International

Yeah. Hi, everyone. I feel like I've been lurking here in the background.

00:47:37

Moderator, RTI International

Yeah.

00:47:38

Secondary Moderator, RTI International

[Participant 3], I think you mentioned the phrase, fighting the medication, and you were talking about side effects. What are some of the specific side effects or aspects of the medications that you would be most concerned about with Ibrance?

00:47:57

Participant 3 (registered as a patient)

Anything that affects quality of life, like nausea is a big one, headaches, anything. Also, we kind of play this game in the cancer community. Is it a side effect, or is it metastasis? Do I need a scan, or is this something that can be managed? So, it's different for how it's affected people throughout my family, it's been different. I recall headaches, nausea being two things, and am I going to be able to manage those symptoms, those side effects, and still spend time with my family, still participate in the activity. So, I think those were important, and to be managed.

00:48:45

Moderator, RTI International

Thank you. And I'm going to go ahead and move on to our next question. But folks are welcome to put some additional thoughts related to the most important aspects of breast cancer they'd like to have managed or treated into the chat. I wanted folks who have experience or know patient experience with Ibrance itself, what are the main benefits of Ibrance, as well as, what are the drawbacks of Ibrance? And **[Participant 5]**, looks like you have your hand up.

00:49:23

Participant 5 (registered as a representative of a patient advocacy organization)

Yes, so, we did this study. We pulled people who were cancer patients who had taken Ibrance, had taken it in the last 18 months for treatment and were on Medicare. Of those patients, and we had about 33 patients who met those criteria, 85% said that one of the most important things about taking Ibrance to them was, and then this sort of gets to the earlier point, it did not have a lot of difficult side effects. That was an important piece of it that I think everyone noted that it was fighting the disease. And so that was a big, important piece of it for them. But I'd say it was important to treatment, right? Seventy-nine percent said, Ibrance has been really important to their cancer treatment. And most say, critically important, very important. Many noted, there were no other alternatives. About half of them said that there were no other alternatives for their treatment.

And I'd also just like to say, because this is something we've been talking about in terms of utilization management or step therapy, about a quarter of the people, seven of the 33 well, actually, 12 patients said that they had tried other therapies. Of those 12, seven said that they tried other therapies because of utilization management. So, I just throw that into the conversation, because I think it's important to be thinking about when you're thinking about the drug, like, what is the real-life experience? Already we have almost a quarter of the people we talked to said that they had the experience of having to go through other treatments before they could get to Ibrance. Ibrance was effective, and it managed their disease without difficult side effects. And so that was just an important piece of the puzzle, I think, to be thinking about.

00:51:24

Moderator, RTI International

So, **[Participant 5]**, before you go back on mute. You had mentioned the side effects, or not having side effects. Are there other benefits or drawbacks that came through in your survey for patients who've used Ibrance, whether it's convenience or ease of use, that kind of thing?

00:51:40

Participant 5 (registered as a representative of a patient advocacy organization)p

Well, I mean, I think someone mentioned this earlier, I mean number one for people was that it was recommended by their provider. So, it was the recommended course of treatment. It was the only course of treatment or therapy for what they had. Secondly, they did mention that it was an improvement in daily life; 85% of the people who had taken it said it improved their daily lives, and it improved in addition, about the same amount, said it improved their well-being, their ability, I mean, I'm not quite sure how that is so different, but it is their ability to take part in daily life, how they felt on a day-to-day basis. I think all of those are important pieces of the puzzle.

00:52:23

Moderator, RTI International

Thank you, **[Participant 3]**. **[Participant 5]**, and I see **[Participant 3]**, I know you have direct experience with Ibrance. **[Participant 4]**, do you mind if we, because we're talking about the drug itself, do you mind if I go to **[Participant 3]**?

00:52:36

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

Not at all.

00:52:37

Moderator, RTI International

Okay, thank you. And then I'll circle back for you to have the closing thoughts n this question before we move on. So, **[Participant 3]**, could you share what you found were the main benefits as well as the main drawbacks of Ibrance for you or your family members?

00:52:52

Participant 3 (registered as a patient)

I remember, something **[Participant 5]** had said, I had an aunt, well several aunts, that were on Ibrance, and I had an aunt. I remember when it first came out, and my aunt had been on a clinical trial. It wasn't going very well, she felt terrible, and when Ibrance was introduced to her, and it was new to the market, it was like she was a complete, she was herself again, and it's almost like you forgot that she had breast [cancer]. I mean she looked, because she had lost hair, and through other therapies and things that she had gone through, but she was more of herself. And I just remember thinking, oh, like it's the Aunt **[REDACTED]** that I've always grown up with. And, like **[Participant 5]**, just said some things that reminded me of that like she's back to herself again, and I was able to cherish more. I'm thinking about like vacation with her, being on a boat with her, being out in the pool with her, being on the beach with her, because and she was doing really well on Ibrance compared to some of her previous therapies.

00:54:01

Moderator, RTI International

And when you said she felt like herself again, what did you observe, or what did she share with you?

00:54:06

Participant 3 (registered as a patient)

It was just like her humor, her personality, who she was as a person and not as a breast cancer patient. The nurse that I always knew her to be, the fun-loving person, the person who has taken me shopping so many times. I was raised by my dad. She was like a mom to me, and having that and having her back again. It just kind of gave us that extra time with her as a person with autonomy, as her relationship with us, and not the disease that did eventually take her from us. But she wasn't that to us anymore.

00:54:43

Moderator, RTI International

Thank you. And did they have any drawbacks for you or your aunt?

00:54:48

Participant 3 (registered as a patient)

My aunt was always just like this strong person. If she struggled or suffered from something, she didn't show it, because she always wanted to show it. She's, very pretty hardheaded in my family, so I mean there are times she'd have to lay down or take care of herself, which that was pretty normal. But she would rest, take time for herself and come back. You know she'd join us for dinner, or again, it was just if she needed to step away, she would, and then she'd come back as herself. and it seems like things are just so much more manageable for her, and that.

00:55:22

Moderator, RTI International

Thank you, **[Participant 3]**. All right, **[Participant 4]**. If you want to kind of wrap up this question, we'll keep moving along. Any experience with Ibrance that, and the benefits or drawbacks that you can comment on? And you're on mute.

00:55:35

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

If I can figure out the buttons. No, thank you very much. Thank you. And **[Participant 1]** on chat, I think quality of life is really important here. I do want to pull back a little bit and talk about side effects of CMS. This very exercise we're going through. What I mean by that is look, Ibrance is small, a pill, a small molecule drug, and in history, when those pills often hit the market, they are very expensive, right? Price is crazy. And that's where companies help out. And there are all kinds of things that need to take place to make sure that comes along. But the drugs, Ibrance in particular, has a patent on a drug until 2027, which is the year after the CMS new price control will go in effect.

Now, historically, when drugs like this pill come off their patents, and you can see new competition come in, price almost every time comes down 80% or 90 in some cases, but mostly 80%. So, that that's their Humira. Lots of drugs have gone through this cycle. So, that's what would have been right until this, so, range entry into the government getting too involved in pricing. It's like, I think I worry, that the uncertainty that is brought into this is currently no, it's showing no rate. There's less discovery on new drugs. And therefore, I feel like there's fewer options down the road, and I feel like my fear is that providers [inaudible] fact, they won't have expensive drugs to pay for, because they won't exist. So, I really think we need to lean into, in fact, we have multiple choices in option to provide…

00:57:37

Moderator, RTI International

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

00:57:38

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

Our life. And then have the price come down. But I don't know that's happening.

00:57:45

Moderator, RTI International

Thank you, **[Participant 4]**. And I think that's one of those general points that, thank you for sharing. So, I'm going to go back to other medications for breast cancer. So, for folks who have experience with Ibrance or know patients who have experience with Ibrance, what other medications, whether you or your patients, have they tried to treat breast cancer? So, what other medications other than Ibrance?

00:58:14

Participant 3 (registered as a patient)

There's IV therapy. [T]hey call it the, I mean at the very beginning, what you get to go through before [inaudible]… Well, I'm not a doctor. They call it the red devil, and you take pre-meds. You have to take your anti-nausea medications. You have to take a Benadryl for it. I mean, it's an all-day event. Some, well, pretty much, yeah. If you get there early you might get out early, but you take your pre-meds, you take your chemotherapy, and then when you leave, you've got side effects and symptoms that kick in about two, three days later, when you're on, it's called the red devil. I am drawing a blank because I'm just a little bit nervous. But Adriamycin Cytoxan, and so it's so toxic and heavy on your body. It's what made me lose my hair. It's awful, like it's bad. It was probably one of the worst things I've ever experienced, but you go through that, and then you go through Taxol treatments, which aren't as bad. But it causes neuropathy in your hands. And then, when you're done with treatment, I've been on aromatase inhibitors as well. And then I'm actually getting ready to start another clinical trial that I'm a little nervous about. But it's like there's a ladder that you go through. And it's like we're gonna try this based on this. We're gonna try this based on that. We'll see how long that it works. But sometimes you just kind of feel like a human experiment to some extent, trying this, doing this. Let's take you off this. Let's take a break off of this. Let's go with something else. But kind of rambling a little bit, but anything that's an alternative to an IV therapy where you're not spending the day there. You're not hooked up to things, and you're not just in this subjectively uncomfortable chair. You've got to bring a family member with you. You can't drive home on your own. It just takes so much out of you. And so anytime there's a pill that you can take, that's an alternative to an IV therapy. It just does wonders for you.

01:00:35

Moderator, RTI International

And **[Participant 3]**, before we move on, have you had other therapeutic alternatives as part of your treatment that you've tried?

01:00:43

Participant 3 (registered as a patient)

Not as of yet. I'm getting ready to start a clinical trial, but not as of yet.

01:00:48

Moderator, RTI International

Okay. Well, thank you, **[Participant 3]**. And **[Participant 2]**, and then we'll move on.

01:00:54

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

Yes, thank you. So, what we found in our research, and through our research and training institute and through our network partners in the communities that actually provide the supportive services for people impacted by cancer, for MBC patients, we found that, compared with therapeutic alternatives, patients taking Ibrance may experience less severe side effects.

So, for example, patients taking Kisqali are usually recommended to have two EKGs during the first cycle of treatment because of the higher potential of cardiovascular events. And for Verzenio, they're much more likely to cause diarrhea and other GI [gastrointestinal] issues that can affect quality of life.

So, for certain patients, they may prefer taking Ibrance if they experience less side effects, like I said, especially related to the cardiovascular and the GI events that I mentioned with the other therapeutic alternatives.

And I also thank you, **[Participant 3]**, for making the point about the importance of taking the pill and the convenience of a pill, because we actually surveyed 129 MBC patients in 2020, asking them about their preferences for oral versus IV cancer treatments and assuming equal effectiveness, most MBC patients reported a preference for oral treatment, citing less traveling for treatment, easier medication management, more freedom for travel and work, avoiding a needle, less disruption to work, home and family life. So, this just shows how critically important it is to have multiple oral therapies available for advanced and MBC patients.

And so just really wanting to reiterate supporting access to those oral pills, and mitigating any of those unintended consequences where it may relate to there might be certain incentives for biologics versus small molecule drugs. And I know that there's been I think President Trump, yesterday or two days ago, released an Executive Order talking about Congress working with Secretary Kennedy to address that disincentive that could actually really stifle and hurt innovation, particularly as it relates to the small molecule or the pill space, particularly when we hear from patients that they really do have a preference for oral treatments, especially if effectiveness is equal.

01:03:21

Moderator, RTI International

Thank you, **[Participant 2]**. And does anyone else want to comment on other therapeutic alternatives and the benefits or drawbacks of those therapeutic alternatives before we move on? All right. Okay, thank you. Before we switch gears, **[SECONDARY MODERATOR]**, anything else that folks wanted to follow up on, that I may have failed to ask?

01:03:47

Secondary Moderator, RTI International

No further questions.

01:03:49

Moderator, RTI International

Okay, great. Thank you. Okay. So, thanks everyone for the helpful input that y'all have shared so far. So, I'd like to talk now about how well Ibrance and other medications for breast cancer meet patients' needs. So, what would it be like for someone who has breast cancer if Ibrance or other medications for this condition were not available. So, another way of stating that, what needs of people with breast cancer does Ibrance or other medications for this condition meet?

01:04:26

Participant 3 (registered as a patient)

[O]ne thing that came up just a moment ago was the fact that, and I put it in the chat, I don't have to travel back and forth to the hospital for IV therapy, which is fantastic. I live an hour away. The traffic's horrible in the **[REDACTED]** area, so it's great, and that's part of accessibility in everything. So, I think that's a huge benefit right there in and of itself.

01:04:58

Moderator, RTI International

And I guess, kind of the general, what would your life be like, or how would you manage or cope if you didn't have access to Ibrance or other cancer treatment medications, **[Participant 3]**?

01:05:10

Participant 3 (registered as a patient)

[W]hen I said earlier, it was so fortunate that I knew about it because of other family members that had been through it, and I would probably be going down rabbit holes wondering what my options and choices would be, probably having more anxiety about what's available. Again, we kind of like, there's this timer that's been flipped. The hourglass has been flipped over, and maybe it would feel like that sand is moving faster. It's just the familiarity of it, and knowing the benefits of that, it's had in other people in my family, I feel like I wouldn't have that or know about it. And so, you worry also, like what other medications would have side effects, or how it would impact my daily life, or if I'd have to go on an IV therapy, just so many, I think it's the fear of the unknown versus what's familiar and what we know to work really well already.

01:06:13

Moderator, RTI International

Thank you, **[Participant 3]**, and it looks like **[Participant 4]**. I don't know if you have a breast cancer–specific example to share about what life would be like without these medications for persons with breast cancer, maybe from your wife's experience or her mother?

01:06:27

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

Yeah, I'll say right there. She would give anything to have an option she didn't have right now. Time goes on things. But having, that's the cruel thing is like, if we slow down innovation, people who are facing disease, don't know what they don't know. Like you want to have people have options to fight their disease. But if you don't have the drug ever developed, how you gonna know, if these things don't keep on coming out, like you don't know, we don't know. So, my fear is that, well, like **[Participant 3]**, and everyone here won't have, myself, I put myself in a camp, because, like I said to you earlier, I had no option for disease management when I first got MS. Then I did have one. That one did work. I was in a nursing home until I found second one. I was able to get myself, give my body a break to recover enough to actually start a family, get married, have a life, and if I didn't have the option, second, third, fourth option, it would have spent everything. So, I really fear anything that shut down the development of new options. And I feel that's the path we're on.

01:07:46

Moderator, RTI International

Thank you, **[Participant 4]**, for reading the importance of options, as one thing doesn't work for someone that they can go to something else to manage their condition. I'll go ahead and go to **[Participant 6]** for this question, what would it be like, or how would people manage or cope with their breast cancer if Ibrance or other medications didn't exist?

01:08:07

Participant 6 (registered as other)

Well, I think there's an obvious answer there, which is that there would not only be no quality of life, but we would have a jump in what amenable mortality. But I'm also hearing two things. One is, we need small molecule options. But we also need large molecule options, and the National Minority Equality Forum has taken a position for decades that formulary should be limited to a list of drugs that have been approved by FDA, and when you move past that, then the formulary is not prioritizing access to more effective therapies. It's a business to it. And I'm not saying that there's not business that needs to be done, and that the cost and price are not a concern. But they're, and I will say, when he made this statement almost 20 years ago, the response it received in the room was one that obviously was based upon an assumption that it was not possible to have access to pharmaceuticals without a formula. Because we thought of formularies as improving access to quality care.

It's a business, too. And that's okay. This business. But I think the American public needs to understand that. And I'm going to speak to, I think her name is **[Participant 3]**, again. Yes. More, if the small molecules are available and work, they need to be available. The large molecule treatment is much more cumbersome, but there may be a reason, I don't have that answer, that the large molecule option is the better option for treatment than the small molecule option. Those need to be available, as well. And so that tends to be the position we're taking here, which is that rationing for cost purposes, as I would say, violates what we believe should be the integrity of the health services, research, delivery, and financing system. And that's where we are.

01:10:49

Moderator, RTI International

Thank you, **[Participant 6]**. And **[Participant 5]**, did you want to share a little bit about how the patients that you engage would manage or cope with breast cancer if Ibrance or other medications weren't available?

[Participant 5], did I mute you? Oh, there you are. Okay. Thank you.

01:11:06

Participant 5 (registered as a representative of a patient advocacy organization)

I think the critical thing here is one, we know it extends life, right? I mean, maybe that's such an obvious answer that it's almost hard to put our fingers on it. It extends life. There are people living today because of Ibrance that would not be alive. That's number one. Number two, it helps them manage their lives in a way that improves their personal well-being. I think **[Participant 3]** talked about, I mean, it really touched me, about her aunt and how she was herself again. And I think this drug provides that for people. And I think whenever we're talking about a chronic disease, we have to remember, there are people here. It's not the disease. It is the people who have the disease that we're treating. And to me, that's a critical piece of this puzzle. It's not just about making sure people are alive, it's making sure their life is what it should be. And so to me, those are the two key things that I think we've heard in various ways that also came through, and I'm happy to share the information we have like through the mailbox, but that's what we should be thinking about. That's the point. That is the point of our healthcare system or should be.

01:12:25

Moderator, RTI International

Help people live the best and quality of life as they can. So, thank you. And before we wrap up with this question, I don't know, **[Participant 1]**, if you want to comment from patients you've heard through your helpline, about how they would manage or cope with breast cancer if they didn't have Ibrance or another medication? And, **[Participant 3]**, I see that you want to also weigh in. Did you want to say anything, **[Participant 1]**? Or okay, thank you.

01:12:56

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

Yeah, I would default to **[Participant 3]**. I think **[Participant 5]** said it really well. It's an option that works; they would be looking at a very different life trajectory if it was not available to them.

01:13:09

Moderator, RTI International

All right, **[Participant 3]**. Please say more about your experience or your family's experience. Thank you.

01:13:15

Participant 3 (registered as a patient)

Additionally, not having access. It means more scans, which cost more. It means more MRI [magnetic resonance imaging], CT [computer tomography] scans, PET [positron emission tomography] scans. Also, if let's say only IV therapies maintaining your port, which doesn't cause, but it can contribute to blood clots and the maintenance around that. So, I feel like it's more of if that wasn't available or other treatments, you don't want to use this victim mentality, because that's no one in my family, but it's almost like you live your life around hospital visits, and no one wants to live like that. So, I thought that **[Participant 5]** had said some things like, wait a second. That's what you would have to do, all of these things. That's what's required. And I think it's just been so part of my life and my family's lives. I just sort of forgot about it because I'm used to it. But if the treatments weren't available, it'd be exacerbated.

01:14:19

Moderator, RTI International

Yeah, it's very much, it's the disease becomes an all-encompassing part of your identity as well as how you structure your life is what I'm hearing. Thank you. So, one more question in this section, and then we'll move into some closing. So, what aspects of breast cancer, if any, are Ibrance or other medications for this condition, unable to address?

01:14:52

Participant 6 (registered as other)

Sorry. Could you repeat that?

01:14:54

Moderator, RTI International

Absolutely. What aspects of breast cancer are Ibrance or other medications unable to address? What can't the drugs do?

01:15:10

Participant 3 (registered as a patient)

I'm so hesitant to say this, because I mean in the back of all of our minds, and it's the awkward answers like, can you give me a date? Like what's my expiration date? Like, it can't do that. But we do know that the life that we have on it, is going to be improved, and it's going to be better. And we're gonna make the most out of it.

01:15:36

Moderator, RTI International

Thank you, **[Participant 3]**. How about others? What can't these drugs do for breast cancer patients? Thank, thank you. **[Participant 1]**?

01:15:46

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

I was gonna say that Ibrance, like **[Participant 3]** said, cannot cure this disease, right? But it's a really amazing option, and sometimes the only option for individuals living within MBC to have more quality life with their family, to see their children grow up, make it to that high school graduation and be able to live a full life, not swallowed up, or having to always be managing their side effects.

01:16:17

Moderator, RTI International

A life without managing side effects. It kind of distills the issue nicely. **[Participant 6]**?

01:16:26

Participant 6 (registered as other)

So, yeah, I mean, I agree, you're asking some difficult questions. But in my lifetime, when I was much younger, a cancer diagnosis was a death diagnosis.

01:16:39

Moderator, RTI International

Yes.

01:16:40

Participant 6 (registered as other)

It was a matter of time, and so I would say, these medicines can't prevent cancer yet.

Okay, but what we need to do is enable the system to continue to innovate, so that eventually the question is not, how do you manage the disease, but how do you eradicate the disease? Okay? And so, you don't, you can't do that if you don't have these therapeutic options available that can continue to be monitored to determine where they're working, how they're working, in whom they're working. Okay? But I would also say that, even if your diagnosis, and fortunate that's not a disease that in my immediate family of the experience, but what the pills don't cure you yet, but they give you time, I'm going to say, to plan your leave taking. It's not just to also live as long as you can, but to bring some dignity and order to your home and your family, as you deal with a disease that in, now I won't say all likelihood, I don't have statistics in front of me, at some point may be the cause. Yeah, okay? And it can eventually get to the point perhaps, as it has with some other diseases, that you live long enough, that the cancer doesn't kill you. A heart attack kills you, or something else. Something's going to kill you. But what we want is a life that is, as long as it can be, with some dignity. And that's what these medicines offer, as well.

01:18:43

Moderator, RTI International

Thank you. And **[Participant 2]** and **[Participant 4]**, if I could invite you to put your response into the chat, so I can move to the last little bit, because we're coming on to the end of our conversation today.

01:18:55

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

I was just gonna say, I put my response in the chat. That was literally it. I raised my hand...

01:18:59

Moderator, RTI International

Oh, okay, thank you.

01:19:00

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

Put my response to your great question in the chat.

01:19:03

Moderator, RTI International

Great. Thank you, **[Participant 2]**. All right. So, again, thanks everyone for working together, collaboratively. And to give us input, as we close to the end of the discussion. Today, I just wanted to kind of reflect, overall and wrap up by thinking of this kind of broad question. So, thinking about the topics we discussed today, and patient experiences with Ibrance and other medications, how would you summarize the importance of Ibrance for people with breast cancer? So, big picture thinking, how would you summarize the importance of Ibrance for people with breast cancer? **[Participant 4]**, do you want to then kick us off?

01:19:48

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

Yeah, I'll be quick, I promise.

01:19:50

Moderator, RTI International

Okay, that's okay. You're all right.

01:19:53

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

Because **[Participant 5]** and **[Participant 6]**, you guys did a really good job summarizing points **[Participant 3]** was making. I think the critical thing that Ibrance provides is hope, right? Having an option gives you hope for another month, another year, another two years, another ten years. Like this is what life is about. You have planned wedding, planned graduation, big plans for your end of life, whatever it is, you have hope, because the drug allows you to pull the trigger to spend a short amount of time we have on this earth. So, I just want to say what that does, in my mind, so all these innovations do is give us hope, for a little bit better chance to make this world a better place.

01:20:47

Moderator, RTI International

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

01:20:50

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

He said it perfectly. I was gonna say, it gives hope, so I don't have to add anything to what he said. Thank you.

01:20:56

Moderator, RTI International

Yeah. Well, I love closing a question on hope. Anyone else have other things about how would you summarize the importance of Ibrance for people with breast cancer? Hope, quality of life, I think I heard earlier, but anything else that was very salient or important?

01:21:17

Participant 3 (registered as a patient)

Just echoing on the quality of life. You feel like you're just not defined by the disease, and that if you can feel that other people will see you that way, and that there's something we have in the breast cancer community called cancer ghosting. And it's when people can't face the reality of your mortality. But when you feel like you, and you can present that to people confidently that you're valued as a person with autonomy and not just breast cancer as the defining factor in your life.

01:21:48

Moderator, RTI International

That's beautiful. Thanks for sharing that term. I hadn't heard it before.

01:21:53

Moderator, RTI International

And **[Participant 5]**, looks like you are off mute as well. Did you want to say something else that's very salient?

01:22:00

Participant 5 (registered as a representative of a patient advocacy organization)

I just wanted to say, thank you, actually. Like, I've loved having this conversation. And it grounded in the patient experience and informed by people who work with cancer patients all the time and in policy. Just think it's been a really useful conversation for me, personally, and I hope it's been the same for you all and for CMS.

01:22:26

Moderator, RTI International

And I don't know if anyone else wants to make a comment on what has kind of been something salient related to the importance of Ibrance for folks with breast cancer?

01:22:37

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

I want to just piggyback off of something **[Participant 1]** said at the outset, which is the importance of affordability, and being able to afford and have access, and not having to make difficult decisions between, do I pay my bills, like my rent, my mortgage or do I have access to treatment? So, a financial burden is a significant concern for this population. And I just wanted to underscore the point she made. I'm not going to belabor it.

And the point that **[Participant 6]** and I believe some others made as well about utilization management practices. The prior authorization techniques that are in some ways delaying or denying care. In addition to the stresses of affordability, these are external pressures that are being put on patients that want to be healthy, get back as close to themselves as they can, and it's not really helping with the quality of life or the well-being. And so, I just do an appeal to the humanity of those that are making these decisions, right? Considering what some of the impact of this could be to a person's eventual OS [overall survival] or any other factors that they term, determine to be important to them.

01:23:59

Moderator, RTI International

Thank you. And **[Participant 3]**, I'll give you the closing remark before I ask the last question.

01:24:05

Participant 3 (registered as a patient)

Oh, go ahead, then. I thought this was the closing so…

01:24:09

Moderator, RTI International

Oh, no, no, the closing question is there anything else we didn't talk about. So, this is the meaty question. Please share.

01:24:19

Participant 3 (registered as a patient)

Well, I'll just say, I advocate for the young breast cancer community. Those of us under the age of 40 that have been diagnosed with breast cancer. We know, according to the Breast Cancer Research Foundation, breast cancer in younger women is more aggressive, and it's more likely to be diagnosed at later stages. There have been reports that have come out over the past, maybe six to eight months that have said that breast cancer rates in women are rising under the age of 50, faster than they are of women over the age of 50. And yet our screening guidelines say that, hey, at 40 we'll cover this. You can get a mammogram at 40, and it's only looking at age. So, if we're, I said this before, if we're going to have our screenings denied, or we have to fight for them, having Ibrance available in our later stages of diagnosis is exactly the hope that we need to know that, hey, something's got our back if we're going to get diagnosed.

01:25:27

Moderator, RTI International

Thank you, **[Participant 3]**. Any other closing thoughts? Or is there anything else that we didn't have a chance to talk about today that you really wanted CMS to know about in consideration for patient experiences with Ibrance or therapeutic alternatives?

01:25:48

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

I just would like quickly echo what was said. We just thank CMS for doing this interactive exchange. We have feeling this is a good start to how, taking on patient impact and hearing from real-life experiences on the ground. And again, what I think is centering around the need for hope, the theme for this pipeline, do a better job of how we act, people help people pay for these many times expensive drugs, but managing that, keeping that flow of access going, and make sure that people have choices and have hope.

01:26:32

Moderator, RTI International

Thank you, **[Participant 4]**. And, **[Participant 6]**. Yes, thank you.

01:26:37

Participant 6 (registered as other)

Just that, and this isn't specific to Ibrance so much, but it is to breast cancer. There is a history of bias in breast cancer risk assessment tools in this country that steered, would steer people away from, or physicians away from, a physician who would then explore breast cancer as a possible option. Very specifically, one was the Gail Model that was used for years, and they supposedly addressed some of it, but they have not. I know that that's my personal experience. Because I was recruited, someone called me to recruit me for a clinical trial for breast cancer, and they, whoever she was conducted the survey and asked the questions, and when they asked me my race, she made a noise, and I asked why? And she said, because the assessment tool required her to deduct points from my score.

So, I'm saying that because we've got all this, it's extraordinarily important that we do everything we can to strengthen the pipeline of knowledge and innovation that makes efficacious therapies available. [Inaudible] Ibrance and alternatives to Ibrance. Other breast cancer therapies, other prostate cancer therapies. And what we need to have is a delivery system that is figuring out how to say yes, not how to say no, and is making decisions based upon that. So that's one of those maybe sort of idealistic issues. But until we're there, we're going to continue to try to pick and choose a particular, try to norm, find a med that works in the most people, which means that by default you're sacrificing others, and there's no need to do that. There just needs to be a different values construct as we move forward. That's my belief.

Closing Remarks

01:29:02

Moderator, RTI International

Thank you, **[Participant 6]**, and I think it kind of closes the loop nicely on where you started about particular populations being diagnosed later because of the assessment tools not being designed or not being accommodating enough across different populations. So, with that, we will wrap up today. So, just thank you everyone for participating in today's group. We really appreciate the time that you took to talk with us. Your experiences and your input from a wide array of organizations and individual experience will help inform CMS' negotiations for these drugs. And so, CMS has been listening to the roundtable, and will be able to bring back all the ideas that you shared with their teams. So, I'm going to hand off to CMS for some closing remarks.

01:29:54

CMS Staff

Thank you, **[MODERATOR]**, and I can confirm, **[Participant 5]**, that this session and your comments were valuable to CMS, and we really do appreciate you sharing your experiences and the experiences of the patient communities you represent. We appreciate you taking the time to speak with us. You have given us a lot to consider, and we are deeply grateful for the information that you shared. Thank you.

01:30:23

Moderator, RTI International

Thank you. And so, as I mentioned, I know folks had some other ideas outside of the patient experience, and I wanted to offer this opportunity for you to share those via the mailbox you see here on the screen. Or if you have questions following today's session, you can submit them to the same mailbox and then use the subject line 'public engagement events,' so that the mailbox can be appropriately directed. So, with that, I close up today. Thank you again for joining us and giving us more than an hour and a half of your time if we include the tech checks. Hope everyone has a good afternoon.

01:31:02

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

Same to you. Thank you so much.

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

For a list of the drugs selected for the second cycle of the Medicare Drug Price Negotiation Program, click on the following link: https://www.cms.gov/files/document/factsheet-medicare-negotiation-selected-drug-list-ipay-2027.pdf

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

Appendix

Participant 1: Registered as a representative of a patient advocacy organization

Declared Conflicts of Interest	
No	Receipt of financial payments (e.g., gifts, funding, research support, honoraria, travel, or other expenses) from a company with direct/indirect interest in the Negotiation Program, in excess of $10,000 by you, your spouse, or an immediate family member
No	Direct assistance preparing your remarks from someone who is NOT a family member, caregiver, friend, or your healthcare provider
No	You, your spouse, or an immediate family member is employed by or holds equity interest (stock or ownership interest) in excess of $10,000 in a company or related association with direct or indirect interest in the Negotiation Program
No	Any other personal or professional relationship or interaction with a company or related association with direct or indirect interest in the Negotiation Program that may be considered a financial conflict of interest

Participant 2: Registered as a representative of a patient advocacy organization

Declared Conflicts of Interest	
No	Receipt of financial payments (e.g., gifts, funding, research support, honoraria, travel, or other expenses) from a company with direct/indirect interest in the Negotiation Program, in excess of $10,000 by you, your spouse, or an immediate family member
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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 condition(s) treated by the selected drug; a patient with experience with other treatment(s) similar to the selected drug for those condition(s)

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

Participant 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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Participant 5: Registered as a representative of a patient advocacy organization

Declared Conflicts of Interest	
Yes	Receipt of financial payments (e.g., gifts, funding, research support, honoraria, travel, or other expenses) from a company with direct/indirect interest in the Negotiation Program, in excess of $10,000 by you, your spouse, or an immediate family member
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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 6: Registered as other

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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