

This transcript was lightly edited for readability.

Introductory Remarks

Moderator, RTI International

Hi everyone, and thank you again for being here today. My name is **[Moderator]**. I'm with RTI International, and I'm also joined today by my colleague, **[Secondary Moderator]**, who you may also hear from during today's session. The Centers for Medicare & Medicaid Services, which we're going to refer to throughout today as CMS, the acronym, is convening this patient-focused roundtable event and others as part of the Medicare Drug Price Negotiation Program. The information shared during these roundtable events will help CMS understand patients' experiences with the conditions and diseases treated by their selected drugs. It will also help them understand patients' experiences with the selected drugs themselves, and patients' experiences with other drugs that are used to treat the same conditions. The information shared during these events will also help CMS identify other medications used to treat these 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 drugs.

The purpose of today's event is to hear from you, a group that may include patients, caregivers, and patient advocates, about your experiences with breast cancers and drugs treating breast cancers, including with Kiskali or ribociclib. I want to emphasize that our focus today will be on the patient experience, so if you wish to share input on other topics related to the Drug Negotiation Program that are not focused on patient experiences, we ask that you send that input to the mailbox IRAREbateAndNegotiation@cms.hhs.gov. Your experiences and perspectives are very important to us, and we genuinely appreciate your time today. Along those lines, let's watch a brief welcome video from CMS leadership, so you can hear from them about how much they value your time and input.

CMS Remarks

00:02:42

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.

00:04:34

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 about your experiences and opinions directly. Let me hand it over to **[CMS Staff]** at CMS for a moment so that they can say hello.

00:04:52

CMS Staff

Thank you, **[Moderator]**. Welcome, everyone. My name is **[CMS Staff]**. I'm from the CMS Drug Price Negotiation team. There are other CMS staff members on the call today, but we work on the policies, and we get input from the public on the Negotiation Program. On behalf of CMS, I'd like to thank you for being here today. We look forward to hearing the discussion. And we're going to go off camera so that the discussion's focused on the participants, but we will still be here in the background listening. Thank you.

Housekeeping

00:05:21

Moderator, RTI International

Thank you, **[CMS Staff]**. Before we dive in, I do want to review a few housekeeping items so that everybody knows what to expect today. Bear with me, there are quite a few things to go over.

Technical assistance. If you get disconnected today, please attempt to rejoin if you can. If you cannot rejoin or connect for some reason, please reach out to 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. Please do not share any unnecessary protected health information, such as doctors' names, the name of a medical facility, or any personally identifying

information, such as patients' names, or cities they live, or schools you attended, during the discussion. Following the event, CMS will prepare transcripts that have been redacted where they have removed participant names and identifying information, and these redacted transcripts will be available to the public.

On a related note, we are recording today's event. These recordings will not be shared publicly. Recordings will only be used for the 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 throughout the session. However, if there are questions you are not comfortable answering, that is okay. We ask that you minimize any background noises by silencing cell phones and other devices if you haven't already done so. If you would like, you can mute yourself when you are not speaking. And also, please do keep your video on throughout the discussion today.

We have reserved up to two hours for this session. However, it is possible we may not need the full two hours today. And if that happens, we'll let you all go a little bit early. I have a discussion guide here in front of me to help us stay on track, and I do have a lot of topics that I want to cover today, so I may need to pivot and move to new topics and questions to make sure that we cover everything.

If you do need to step away for a break during our discussion, that's fine. Just go ahead and turn off your camera, mute your microphone, and rejoin when you're able. You don't need to tell me that you need to step away. Just please do try to return to the discussion when you can. I was going to say to try to speak only one at a time, but there are only two of you, one of me, so I don't think that would be an issue, but I want to make sure that everybody's comments are heard. If you would like, you can use the raise hand feature to indicate that you would like to speak. Also, you may offer your comments as we're having this discussion. You can also add additional comments, if you would like, into the chat. This would be the case if you think of something later on that we didn't get to talk about, you can add that comment in there. Unless anyone has any questions, we can go ahead and get started. Anything from our participants today? Okay.

Discussion

00:08:58

Moderator, RTI International

Let's begin today's discussion by asking each of you to introduce yourself. Take a moment to share your first name, whether you're going to be sharing your experience as a patient, a caregiver, or as an advocate, or maybe you wear multiple hats. And then, a little bit about the types of breast cancer that you will be speaking about today. Who would like to kick us off?

00:09:46

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

Good morning. I'm **[Participant 1]**, I'm representing a patient advocate organization, and I will be speaking about all types of breast cancer today in all stages.

00:09:57

Moderator, RTI International

Very good. And **[Participant 2]**?

00:10:03

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

Good morning, my name's [Participant 2]. I'm representing the American Cancer Society Cancer Action Network. We are the advocacy affiliate of the American Cancer Society, and our mission is to work with cancer patients to advocate on behalf of cancer issues, whether that's anywhere along the cancer continuum from prevention to survivorship. I'll also be speaking to all sorts of breast cancer.

00:10:40

Moderator, RTI International

You both are going to have wonderful input to share today, given the backgrounds and organizations you represent, so we're really happy to have you here talking with us today. Let's go ahead and jump into the conversation.

We first want to talk about the patients you represent, their experiences with being treated for breast cancers, and specifically the types of breast cancers that would be treated by KISQALI, also known as ribociclib. I'm just going to call it KISQALI today, if you don't mind, rather than both. The first question I have for you is thinking about the different ways that breast cancer affects patients' lives, what would you say are the most important aspects of this condition to have managed or treated? What are the most important aspects to have managed or treated? And this can be short-term aspects or long-term.

00:11:50

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

This is [Participant 1], and I am representing Susan G. Komen Organization, and through our Patient Care Center, we address the needs of those that are currently in treatment of breast cancer, as well as those who are seeking information. And on average, in a calendar year, we provide about 30,000 services, and that's people with breast cancer in treatment, or living with metastatic breast cancer who are reaching out to us to have barriers addressed. And what we see is in the spectrum of who we see, especially if cared for through the Patient Care Center, about 62% of those calling us for services are experiencing an economic challenge or barrier with their condition. We also see about 21% who are actually experiencing access to care, about 3% are just wanting practical support, and about 8% are actually seeking emotional support. There's also a small percentage that is seeking education and information after their diagnosis. Certainly, the economics of breast cancer is a major challenge and barrier and concern, particularly of the patient's lives.

00:13:13

Moderator, RTI International

Thank you, [Participant 1]. I was wondering if you could elaborate, you said some of the patients who call in are seeking practical support. Could you elaborate a little bit on what type of support that might refer to?

00:13:27

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

Absolutely. It varies from, “Can you tell me more about what the provider just told me?” Meaning, I was just diagnosed as a stage whatever, and I don’t know what that means. I heard, “He or she told me a lot of things, and I don’t know, can you decipher that for me?” Also, that could represent, “I’m now in treatment, I’m receiving navigation services either with Komen or not, and I was told that I may be a good candidate for a clinical trial, what does that mean, and how can I get more information, and should I do it, should I not do it?” Those are the types of questions we get. Also, as it relates to many of them, economics may not be their first reason for calling, but that initial question can then circle back to the economics.

00:14:23

Moderator, RTI International

Thank you, that’s helpful. Turn to **[Participant 2]**.

00:14:28

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

In trying to answer the questions that CMS is asking. We did work to find and do a survey with patients who are currently taking Kisqali to understand their experiences. And I can tell you a little bit about the methodology. We reached out, we got 30 patients who were taking it, we did a survey asking them for what their experiences are and what they’re thinking about. I can speak a little more broadly because we do have cancer patients as part of our volunteer network. We have, frankly, thousands of volunteers. I think **[Participant 1]** referenced this, affordability, it remains a serious obstacle for many cancer patients, even with Medicare coverage. Beneficiaries who need to seek innovative cancer drugs may find their out-of-pocket costs running into the thousands of dollars each year, or maybe even each month. And we recognize that controlling costs is a really important thing, and at the same time, the reality is that that has to be balanced with the really important work of making sure that there are new and innovative cancer drugs, and I think the work CMS is doing is really important and will benefit cancer patients, and we also have to hold in our head what is the benefit going down the road for new and innovative therapies and we can’t impede that progress.

When we talk specifically about Kisqali, I think, one of the things that was important to think about in people’s treatment on Kisqali is that, of the 30 people who were on the drug, 21 of them told us that they had gotten to the drug through some other therapy. Of those, 7 of the 21, or a third of them, said that that was a forced, they had to go through a therapy in order to get to Kisqali. And I raise that because I think it’s true, and an increasing thing we are seeing for cancer patients is that there’s a step therapy protocol. They have to go through something in order to get to a drug that works for them. I can share more about the experiences people had, and I think we know how important it is for cancer patients and people who’ve had cancer. A lot of patients on Kisqali are people who have had cancer and are working against a recurrence of cancer. I think the cost is a big issue but also the quality of life and what it means to be on a drug that you can take orally as opposed to going [to an infusion center], and these are people who’ve often been through radiation or chemotherapy and surgery. And I think that’s one of the attributes of Kisqali that people report being, pleased is the wrong word, but has improved their experience.

00:17:44

Moderator, RTI International

I've made some notes here because you're raising a lot of great topics that we can turn to in a moment here. You've hit on quality of life, the goal of preventing a recurrence. I was wondering, a question for both of you. I suppose it depends on the type of breast cancer, but for your early-stage breast cancer patients, is the main topic to manage, would you say it's recurrence or other topics as well?

00:18:22

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

I'm not a doctor, I'm a patient advocate, someone who works with volunteers and patient advocates. My understanding is that KISQALI works as a way to inhibit more cancer, or recurrence of cancer. But I don't want to speak, I'm really not the scientist.

00:18:42

Moderator, RTI International

Maybe I should rephrase, when the patients speak to you about it, that is the symptom or the outcome that they're managing.

00:18:53

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

Exactly.

00:18:53

Moderator, RTI International

Okay.

00:18:58

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

If you could restate the original question, but I was thinking along the same lines as **[Participant 2]**, I'm not sure that I can speak to that specifically.

00:19:08

Moderator, RTI International

The question was more along the lines of, what's the most important aspect of having breast cancer that the patients are trying to manage? And **[Participant 2]** touched on recurrence. **[Participant 1]**, I was wondering if the patients with whom you speak with have any other thoughts on that.

00:19:27

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

Certainly, as the patients come to us or that we interact with have various concerns, and, I thought there was more of a stage-specific relationship in your question, but I will say that, across the

board, we see some of the same concerns, and I don't have specific information regarding, by stage, a specific concern. If I think of that data, I'll bring it up if it comes up for me.

00:20:03

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

Let me circle back around because I think the three things that patients talk about is, one, survival. These are patients who want to survive cancer and continue to survive cancer. Secondly is quality of life and their day-to-day, and I think a lot of the quotes that we have from cancer survivors, patients on Kisqali, is specifically to quality of life and how it improves life for them every day. And the third issue for them is cost. The cost of Kisqali is high. It's high not just for CMS, it's high for all the copays that people have to pay, and I think that's a piece of the puzzle that people have to be thinking about, too.

00:20:44

Moderator, RTI International

That's really helpful, and I'll be really interested here during the discussion to hear some of these quotes that you've collected from patients on quality of life. We're going to delve into that very soon, so thanks for raising that. That's a good kickoff to understand how Kisqali comes into the picture here.

I want to turn our attention a little more to patients' experiences with the medication, with Kisqali or other similar medications to treat breast cancer. And when I'm talking about medications to treat breast cancer, we don't want to focus on chemo, radiation, surgery, but we're talking more about these adjuvant therapies, such as Kisqali. If you could use your chat for a moment, and we want to see what medications do patients that you advocate for typically take to treat their breast cancer. This can include Kisqali, but maybe there are other alternatives in there that they have spoken to you about. But if you wouldn't mind using the chat and jotting down the names of some of the medications that come up.

00:23:06

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

I'm not going to tell you I'm an expert on what the drugs are. I mostly work with patients and staff.

00:23:14

Moderator, RTI International

Tamoxifen is one of the drugs that the patient mentioned to you as well.

00:23:20

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

Yeah, but my understanding is you can't take that with Kisqali, but I do think Kisqali is generally paired with an inhibitor. I'm not saying I understand them, or I understand exactly what gets prescribed with what, or why this versus that. I think it has to do with, obviously, a patient and their doctor.

00:23:46

Moderator, RTI International

Absolutely. No, we understand, we're here to talk about the patients' experiences, but it's helpful to see some of these other drug names that patients are familiar with. **[Participant 1]**, I don't know if you have any other—

00:23:58

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

I have tamoxifen, there's one I'm trying to think of the name of, and I'll type it here in a second, because it'll come to me as soon as I'm talking. I will say, of course, along the lines of what **[Participant 2]** said, when it comes to treatment, there's no one-size-fits-all, and it's in the conversation, of course, with their provider. I know we're going to probably get to that.

00:24:31

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

To this point, let me also say, one of the things we found in our research was that 63% of the people we interviewed who were on Kisqali said that there was no other alternative therapy they could have considered instead.

00:24:49

Moderator, RTI International

That is great to know. You said 63% of people said that there was no other [alternative therapy].

00:24:56

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

And to be clear, our policy department will follow up and make sure CMS has the survey, the methodology, as well as the information after. Not today, though.

00:25:10

Moderator, RTI International

That would be wonderful. Thank you for sharing that. This is a question about what patients perceive of the benefits. For many of the surveys or conversations that you've had with patients treated for these types of breast cancer, such as the type that Kisqali treats, what benefits have they mentioned from these medications?

00:25:52

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

I was really struck because we've done these kinds of surveys previously, but 29 of the 30 respondents say that Kisqali made their daily life much better. Quotes were, "It helps me to do my daily activities without any restrictions," "I was still able to work normally and enjoy life while taking the medication." Those are two different quotes. The difference for patients is their ability to live their life like they would regularly.

People also talked about improved well-being. Ninety-three percent say that KISQALI had a significant positive impact on their emotional and mental well-being. One quote is, “I’m living a better life now.” I’ve rarely seen people respond with that kind of clarity, and I think it’s important to note it is really making a difference for people. In terms of side effects, KISQALI works to extend survival while maintaining quality of life, including the ability to continue work, family responsibility, and daily routines. People talked about reduced side effects, better quality of life. It’s hard for me to say exactly what it was that had more side effects. “It helps me do my daily activities.” I think respondents emphasized overwhelmingly positive outcomes and the important role of KISQALI in their cancer treatment. It helped in slowing down the progression of my cancer. KISQALI is, quote, “effective in delaying progression and improving quality of life.” I think people also spoke to the ease of oral therapy, how convenient it was, that’s always important, quote, “easier to take and less disruptive to daily life.” And another quote, “It is very easy to take at home. KISQALI is effective and convenient.”

The only drawbacks that we heard from respondents were the high financial burden, some side effects, and that there were some clinical risks that come up. If you were to go to the website and look and read all the warnings about KISQALI, there are some big side effects, potentially. I don’t know how often that would happen, but I’m sure it plays into people’s idea of safety. I definitely think the thing that came up more, though, was the cost and the step therapy aspect of it, like having to go through other drugs to get to KISQALI, which was then very effective.

00:28:53

Moderator, RTI International

That’s really good information. Thank you for sharing that. And I’ve jotted down a bunch of notes, so it sounds like delaying progression is one benefit, and you talked about all these different dimensions of quality of life, of how the drug has improved across many dimensions, whether it be just participating in daily activities or their emotional well-being. That is all great to hear. And it sounds like another benefit is the reduction of side effects that they may have experienced on some of these other therapies that they had tried previously.

As a follow-up question to that, **[Participant 2]**, did the patients in the survey happen to be asked or provide any insight on the other medications that they would have taken prior to taking KISQALI?

00:29:44

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

I don’t know the answer to that question. My apologies.

00:29:48

Moderator, RTI International

No, that’s all right.

00:29:49

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

It’s just not something someone has shared with me.

00:29:52

Moderator, RTI International

That is just fine. **[Participant 1]**, I would love to hear from you on what you understand from patients to be some of the benefits of taking Kisqali or even similar drugs to it.

00:30:04

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

Sure. Of course, I don't have the specific survey of our Kisqali patients. However, the feedback that we get, of course, is for those that have access to care and oral therapy certainly is beneficial. Those that are in rural areas or other transportation, where transportation can be a burden. And so, certainly convenience and the ability to not impact other areas of their life, like workforce, etc. And certainly, when insurance design also accompanies a medication, that certainly helps, but as always, we still go back to the financial impacts, and certainly, any person that's experiencing an insurance design that doesn't accommodate the medication is not a satisfier. Some positives and negatives.

00:31:07

Moderator, RTI International

Thank you for that. You both touched on some really important benefits, so I feel like I have a really good list here. We started to touch on drawbacks or challenges, and I've already heard a little bit about the financial challenges that patients can experience. Do you have any information about some of the physical or medical drawbacks from taking Kisqali or drugs similar to it?

00:31:43

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

I would say that the top answers we got when we asked this question were really about the implications of the cost for treatment is the way I'd put it. Two patients said they skipped doses of Kisqali, or split pills due to cost. Two patients said they did not pick up their prescription due to cost. Nearly one quarter of the patients that were on Kisqali say they experienced treatment delays or interruptions in accessing Kisqali. Specific reasons for treatment delays include insurance coverage, prior authorization or approval, and out-of-pocket costs. Affordability. I think you can't take those issues, they're important to patients. That's the real world of how it is to be a cancer patient.

00:32:36

Moderator, RTI International

That's important to share. Thank you. And then, did they mention any other side effects or drawbacks to taking the treatment itself once they do access it?

00:32:48

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

No, really, people talk about how great it makes their life. It really improves their quality of life. Twenty-nine out of 30 say it's amazing. "It improves my quality of life." I think that is overwhelmingly where people end up, and they're not having big side effects from it, or tolerability for the drug itself.

00:33:09

Moderator, RTI International

It sounds like the benefits are greatly outweighing the drawbacks here, and they hardly mention any drawbacks to taking the drug itself. That's really important. Thank you. That's good insight. And **[Participant 1]**, I was curious if the patients that you speak with through Komen, do they have any thoughts on taking the medication? Any drawbacks itself to taking these medications? Or similar medications?

00:33:33

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

Certainly. I'll comment on, what we hear from patients is because of advancements in treatment, they certainly have a different outlook on quality of life and survivorship, etc. And I think the biggest comment is when patients want to know that they are being made aware of treatment options from their providers. In addition to what they reach out to us for, I think we hear that more, overwhelmingly more, patients are often unaware that providers might be making treatment decisions based on nonmedical factors, such as all of the things we said, administrative burden, pricing, etc. However, they're interested in knowing the treatment advances, and that's where we certainly can provide that support.

00:34:26

Moderator, RTI International

I want to move on to a slightly different question. Overall, when considering potential medication to treat these breast cancers, what factors matter to patients the most?

00:34:46

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

We asked this question, and one was this whole issue about cost, faster pre-authorization, or prior authorization. The question of cost and insurance approval takes time. They would like to see it move faster from, like **[Participant 1]** referenced, they have a conversation with the physician, the physician says, "I would like you to try this drug," and then from that moment to them being able to fill a prescription can take a long time. That's not me taking my ibuprofen. I'm trying to think of something that's a common drug that you would take to a pharmacy and get filled. It doesn't work that way for most patients, and I think that's something we need to take into account because it's a challenge for patients when they hear something's available to them, and then they can't access it.

I think the other thing that people talk about is that when we're thinking about this, the cost is important, and the efficacy and safety. That's something you guys need to be thinking about as well, and clearly, it's been through clinical trials, we have a drug that's effective and it seems reasonably safe. I'm not the doctor, I'm not the scientist who can speak to that, although clearly there were some issues in clinical trials. And that should be the priority. Is it effective and is it safe? Or do patients feel like those should be the priorities. And then facilitating access and its impact on quality of life should be considered when it undergoes price negotiation that often, when we're thinking about drugs, we're thinking, is it curing the patient? But if you're a patient, what you're thinking about, and particularly cancer patients, is, people talk all the time about how having had cancer changes your life, and I think one of the things about that is people are incredibly grateful for both the extension of their life and the quality of that. And I think Kisqali speaks to that, and we

need to be thoughtful about how we're, in this country, we've done an amazing job of science that has led to treatment that has meant that cancer patients survive. We have so many survivors in this country. And it can't be that you survive, go to the doctor all the time, or can be treated in ways that impact your life all the time. I think we have to be thinking about what is the quality of that life and what does it mean to continue to be a cancer survivor? Because it's not all thriving. People have been through a lot when they've survived cancers, and that's something that CMS has to weigh as they're thinking about all these issues.

00:38:01

Moderator, RTI International

A really insightful point.

00:38:04

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

I want to expand on that again, especially with insurance design. Usually it focuses on the cost and the coverage, but to **[Participant 2]**'s point, in addition to the coverage, should there also be no prior authorization, meaning you get the prescription, you don't have to have it prior authorized, and that's all part of insurance design. In addition, part of insurance design is, patients have to also think about, with multiple visits comes multiple copays. And so, the overall insurance design, and certainly we know copays are part of the process and won't debate that on this call. However, the design regarding prior authorization could be something that's negotiated with certain classes of medication as we continue to have advances because that will often come up, so certainly the higher out-of-pocket costs, more so than perhaps IV [intravenous] medications. So, the insurance design does become important. Again, similar to what **[Participant 2]** also stated, patients are concerned. When we say quality of life and surviving and thriving, side effects, long-term effects, how that will impact them. That comes later. Initially, when they're thinking about the economics, they're not just necessarily thinking of dollars and cents, but they're quickly saying, "What will I have to cut back on?" So, it's not a matter of just can I afford it, but I can afford it if, and we know that 71% make significant changes in the way they manage their finances based on their diagnosis and what treatments are prescribed to them, whether that's cutting back on food, cutting back on other expenses, going into their savings. So, I think it's a broader picture than just economics, or just insurance.

00:40:12

Moderator, RTI International

Yep, absolutely. And I think you both touched on the word safety, and I'd love to unpack that a little further. And again, I know you're limited by what the patients have shared with you personally about taking this drug, but in your experiences advocating for these patients or speaking with them, do they have any particular concerns about KISQALI's safety? Has that been voiced or shared with you at all?

00:40:43

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

It's interesting, I think people recognize that there may be issues with safety, but people we surveyed did not have any of those issues with safety. I think as a clinical matter, there may have

been issues with safety, but as a practical matter, that is not something we're hearing from patients. **[Participant 1]**, do you have anything to add to that?

00:41:08

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

I know that patients necessarily use the word safety, or we understand what we mean by safety. I feel that it's wrapped up in many of their other concerns, so I would say that, based on some of the comments and feedback that we get and questions that are asked, not so sure that they necessarily see safety in the same way that we do from a broader perspective in looking at medications. However, not to diminish how important that is, and that CMS should certainly look at patient safety, as we know that's a key cornerstone to overall health outcomes.

00:41:49

Moderator, RTI International

And related to safety, **[Participant 2]**, I don't know if your survey touched on this, but did patients share any specific side effects that they were dealing with, with these types of drugs?

00:42:03

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

They really didn't, and I've been part of other surveys we've done on different drugs, and I will say that a lot of other things have come up in other surveys we've done, so people aren't speaking to that. Now, I also recognize that when you are a cancer patient, when you have been through treatment, you recognize that you're balancing all the time. It's not as if there is a risk to not doing as well, I guess is the way I would put it. To **[Participant 1]**'s point about safety, I think people see it maybe a little bit differently.

00:42:39

Moderator, RTI International

That makes a lot of sense. And I think you both mentioned that the patients were using KISQALI on the recommendation of their oncologist, their provider. How important would you say those recommendations are for them? I think you both touched on the evidence, the idea of having some clinical evidence behind these drugs. Do you have any further insights on those two topics?

00:43:11

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

I'll say that patients certainly are looking to trust their provider in this situation, whether they understand at that time or not, and then call us, it's still wanting to know that their provider is providing them with the best information for them. Treating, knowing, appreciating that there's no one-size-fits-all for their cancer, and that treatment is being recommended for where they are, whether it's long-term or short-term.

Also, I think it's important to patients, patients express [to PAO reps], [that] they may not use the words "evidence-based, clinical practice guidelines" like we do, but they want to understand the science behind it and what the treatability or their survivability is with that medication. I think also wanting to understand when it's mentioned about certain guidelines, they may not totally understand it, but I think appreciating the more information that's given, although, having to, again,

as **[Participant 2]** mentioned, weighing, there's this entire game of weighing, because then it's the weight of too much information versus the weight of not knowing. But to go back to your original question, I think the conversation and the recommendation from the provider is hugely important if patients are looking for that.

And I would add in that to the extent people did talk about side effects, they talked about a lesser side effect with KISQALI than other drugs that they had been on. They talked about manageable side effects. So, I do think people are not seeing it, they see it as a better alternative.

00:44:56

Moderator, RTI International

Alternative. That is really interesting to know. **[Participant 2]**, I'm curious if they mentioned what alternatives they were using or comparing it to, or in general?

00:45:05

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

No. Clearly, though, 21 of the 30 had to go through other things before they got to KISQALI, so I don't know what it was they went through, but they had to. That's the way they described it, so they found it more manageable for their side effects in their life.

00:45:21

Moderator, RTI International

Right. And I guess it wouldn't have mentioned how many of those would have said that their previous treatment failed before they moved to KISQALI. It wasn't effective, or the side effects were too much to bear, and then they switched.

00:45:42

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

Twenty-one of 30 said they had to go through some other therapy before they got there. Seven of those 21 said that that was required by insurance. I would tell you that it clearly is not the first thing off the shelf that it seems to me that most patients are having access to. It is something that insurance companies are managing access to is maybe a way to put it.

00:46:09

Moderator, RTI International

That's really helpful. And actually, **[Participant 1]**, I wanted to go to your comment in the chat, because I would love to explore this a little bit about your patient navigators. It appears that the patient navigators will provide patients seeking information with some details, but could you talk more generally about that service and the types of information provided to patients on these types of drugs?

00:46:40

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

Our helpline has patient navigators that can answer initial questions, whether someone is seeking information about general breast health, or newly diagnosed, or living with metastatic. That patient

can then agree to have assistance from a long-term navigator. And that's a person, one of our clinically trained, culturally sensitive navigators who walks alongside that patient for the duration of her treatment as long as she needs them, or someone living with metastatic can also have access to our navigation services. And the goal of the navigators are not to take away from the clinical team, but to work alongside the clinical team. We know many oncology centers have navigators who help patients navigate transportation or appointments or internal system questions. Our navigators help patients navigate the external. Again, deciphering or helping to understand the information that was given, helping the patients explain their situation to their family, or their friends, or their caregivers, having an unbiased opinion, if you will, when such decisions need to be made, or having those conversations, perhaps it's family members who disagree on the next steps, the patient having someone to help talk them through it, seeking financial support, and then we have a second arm of where they can apply for financial support. And being an emotional support is something that the navigators provide as well. So, that's the navigation services that are offered.

They also help the patients understand when they are faced with the decision of a treatment change, or treatment fail, if you will, or even the insurance, a benefit plan, again, cannot stress enough how important that is with the design. As we've talked about, when insurance companies require, I don't like to use the word "failure," on one medication, but when another medication is recommended, you have to have gone through, as **[Participant 2]** just eloquently explained, several until you get there, and that goes back to where conversations can happen initially, as a part of the insurance design. Our navigators are also well-versed in helping patients understand their insurance. There may be patients who previously had health insurance through their jobs, lost their jobs through the course of their treatment, and now have to see other forms of insurance that they're eligible for, or other forms of financial assistance. Those are the various areas in which our navigators are able to assist.

00:49:25

Moderator, RTI International

That's a really nice service to be able to provide. I'm sure there are a lot of questions that come up when somebody's diagnosed in the subsequent months and even years that follow, so I'm glad to hear that that is strong. I feel like we've talked a lot about the benefits of these types of drugs. I think what I'm hearing is that the benefits potentially far outweigh the drawbacks and negatives, and as **[Participant 2]** said, in your survey, the side effects and drawbacks weren't really even raised, but the benefits were voiced very loudly, so that's good to hear, aside from the financial challenges, the insurance challenges that people encounter with this type of drug.

I want to pivot slightly to talk about how these types of treatments, such as KISQALI, meet or do not meet patients' needs. We've been talking about how these types of drugs meet the needs of slowing down disease progression. And that they're important, that they also meet the need of not having side effect or safety issues. Which of these medical needs would you say are being sufficiently or even partially addressed by existing treatments? Again, what type of medical needs do you feel like are being sufficiently addressed through these existing treatments?

00:50:56

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

By existing treatments, are you referencing KISQALI?

00:51:01

Moderator, RTI International

We're going to reference Kisqali or similar adjuvant therapies to Kisqali. Do you feel like these types of drugs are meeting patients' needs?

00:51:16

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

I think patients are looking to live their lives and these drugs, and I'm not familiar with what any similar treatment might be, but I think the point is that they're meeting the need of patients living their lives fully, the day-to-day, they're able to do what they need to be able to do, whether that's probably in a non-Medicare setting, but maybe in a Medicare setting, working, taking care of their families, traveling, I don't know, going to the bank, all the things one does in a week, getting their car fixed. I'm trying to think of all the day-to-day activities we all engage in and thought about a few I've been involved in in the last couple weeks. But that's what this is doing, and it's slowing the progression. My understanding of the drug is it slows the progression of cancer so that it is not spreading in their bodies, and some of this stuff is almost miraculous, how cancer treatment has really changed, and I think one of the challenges we have in health care, or oncology care specifically, is how to get those treatments to real people. And it's a challenge. And I think people are pretty unhappy with the health care system. People have a real challenge with their doctor telling them they should be able to do this, but they can't quite get to that recommendation.

And to **[Participant 1]**'s point about patient navigation, oncology is a really complicated space. We both work in it, and we're not going to tell you anything about how someone should get treated, not get treated, because we don't know. We are not expert in that, and that's why patient navigation is so important, and actually is a cost-saver in a lot of this, is because it enables someone going through a cancer journey to have someone who knows something, or can access something, or is objective, or can bring information, or simply ask, help someone, ask the questions that need to be asked as part of the journey. I think it's great you guys have that, **[Participant 1]**, glad to hear.

00:53:40

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

It's a great service. And you asked what medical need is being met, and I'll reiterate, when a person gets the diagnosis, whether it's a first diagnosis or that there's recurrence, it's such a change, it's such a showstopper, or they know that something's going to change. As we mentioned before, their lives will never be the same, so the need that's being met is when we continue to look at patient specificity and start to have the science with the new treatment, I think it's what's most important is for patients, their medical need being met is the convenience, as **[Participant 2]** mentioned, that the rest of their life is disrupted the least, and that they have the knowledge and the conversation with their providers, that there are multiple tools that they're able to choose from to optimize their outcome. Again, educating providers with the options, educating those responsible for the coverage design, and all of those working together. As we advance treatment, we can meet those additional medical needs because then it won't impact the patients as much with those other aspects of their life. Improve survivorship. That's the short answer, is improving survivorship and the quality of life during survivorship.

00:55:14

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

For cancer patients, a lot of them talk about, “I am not my disease. I am a person who has this disease. And the care I get, or I need, is not just about the disease, it’s about who I am as a person. Can I continue to be the person I am?” And the question and the way you’re framing it seems to me a little off, because it’s not only about the medical impact. It’s about how the patient can, or the person with the disease, can continue to live in the world as themselves. It’s very important to cancer patients. They are not breast cancer, or they are not whatever kind of cancer they have. They’re a human being who happens to have that problem.

00:56:00

Moderator, RTI International

That is a very excellent point. They’re more than just whether or not the cancer is progressing and what the tumor is doing. There’s a person and a life behind that. That’s a really well said point, so thank you for raising that one. Appreciate that.

[Participant 2], I was curious, again, I know that your survey only asks so many questions, I’m so intrigued by the survey, so thank you for offering to share it, too, at the end of the session, but did patients share any success stories or quotes from using these types of medications?

00:56:36

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

I think someone’s saying that “It improves my day-to-day, I’m able to go about my life.” To me, that’s a success story, so it is. I will say, my understanding of KISQALI is that it’s not a forever drug, it’s something that people go on for a while. But I think most people aren’t on it in perpetuity. It’s not like, I take a blood pressure medication, I’ll probably be taking that in perpetuity, despite my many efforts to be lowering that all the time. And I think that’s interesting, too, because I think that it’s a question of what type of pharmaceutical intervention is it. I would just add that.

00:57:28

Moderator, RTI International

Thank you, that’s a really good point. This is a short-term medication, it’s not meant to be for the duration of their lives.

00:57:38

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

That’s my understanding, again, not a doctor.

00:57:41

Moderator, RTI International

And neither am I, so we can all take in what the patient experience is about.

00:57:49

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

Yeah.

00:57:49

Moderator, RTI International

I wanted to shift slightly to the other side of that coin. We just talked about how these medications and treatments are meeting patients' needs, and these needs are to live their best lives and be themselves again. Are there any important aspects of having these types of breast cancers where existing treatments are not meeting their needs? In other words, are there major gaps that remain with the available treatments?

00:58:28

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

It is my understanding, again, KISQALI, common treatment, HR+/HER2- [hormone receptor positive/human epidermal growth factor receptor 2 negative] when found early, when cancer requires treatment beyond surgery and radiation therapy. I think what you're asking is, have patients indicated that there was a gap until they learned about this? Is that the question?

00:58:58

Moderator, RTI International

Are there any gaps in their current treatment regimen that are still not being met? They might still have a medical need that these treatments are not sufficiently addressing.

00:59:15

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

I think, until you hear the words "You have breast cancer and everyone survives," there are gaps.

I'm having a hard time parsing the question. Right now, not everyone gets breast cancer, survives breast cancer, and then lives to a healthy old age. Until we have that, to me, there are still gaps. I'm not sure I can speak to the specificity that that might need, I think if you had a medical doctor or somebody with that experience, an oncologist, someone who treats patients with this all the time, they might be able to speak to that in a way that I can't.

00:59:55

Moderator, RTI International

It sounds like until there's a cure, there's the gap, is the absence of the cure, I think.

00:59:59

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

The reality is, we have treatments that are keeping people alive for much longer than we used to have, but it could be better. There will never be a cure. There will be treatments or curing things that help people, but it's a lot of different diseases, not just one, and people's bodies are different, and how we're treating it is so personalized now.

01:00:35

Moderator, RTI International

[Participant 1], do you have any other thoughts on what gaps might remain in treatments for breast cancer?

01:00:43

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

I can't speak to anything more than what we've said. An oncologist, perhaps, would know that. And again, I wholeheartedly agree, until there's total eradication, there's a gap.

01:00:57

Moderator, RTI International

We are getting to the end of our time, and before we wrap up, I'm going to do a few things. I'm going to first ask you to share some final thoughts or even ask some other questions that may not have been addressed today, and then I'm going to go back and see if CMS has any further questions for both of you. But let's start with your final thoughts. Are there any further insights that you would like to provide us today?

01:01:34

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

I want to say, as CMS continues to evaluate and assess patients' access to therapies and therapeutic alternatives, certainly consider often those that are, especially with patients that are living with metastatic breast cancer, considering if a patient is not advised to switch treatment regimens unless the cancer stops responding to the current therapy or side effects from the prescribed therapy, or severely impacting life. I think the majority of your questions today did talk about impacting patients' quality of life, and I think we should continue to have that as the center focus. Because I think if that's the center of our focus, all of the other challenges and barriers that we talked about today will subsequently fall under that. We'll think about insurance design. We'll think about side effects. We'll think about gaps in between treatments. We'll think about lessening impacts so that patients can do other things in their lives, and what those long-term impacts of that medication are.

Certainly, my final thoughts are continue to keep the patient and the patient's quality of life at the center, and I think all the other barriers and challenges will fall in line. With that being said, I think it's also important to not forget about the physician, the oncologist, confirming that there are educational pipelines so that all oncologists have the same information and are having information in a timely manner so that they, too, can pass that information on to their patients and prescribe the best treatment for them, and again, with the quality of life of the patients at the center, I think everything else will fall.

01:03:31

Moderator, RTI International

That's a great point. Sounds like quality of life has been a very key takeaway today, and I also really appreciated your point about physician education as well. Thank you. [Participant 2], do you have any other insights or takeaways that you wanted to share today?

01:03:48

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

I would say, I think what CMS is undertaking is important. Cost is not just a factor for Medicare, cost is a factor for patients.

How we, as a broad society, but also government, deal with cost will matter to the whole system. And, I think it has to be really balanced and not go too much to one side or another side. We want new drugs that save people's lives and improve people's lives. And at the same time, we need to somehow be able, for real people, regular people, to be able to afford those. And, to **[Participant 1]**'s point around insurance design, it's problematic when some people can access and other people can't based on how much money they make. I think we should, as a society, be very concerned about that. And I particularly think government, which should not be about only helping those with the most needs, to be really thoughtful about how Medicare is managed, and what the design looks like, and how people with cancer can access care.

I put all that, not that I have answers, I have real concerns, and part of my job is talking to patients and people with cancer and engaging them in advocacy, and I will say, there is real unrest around health care, and real concerns about cost, and when people talk about affordability, there are some hard questions people are having to ask themselves about. I said as part of this, people who say, they all said it's a great drug, it's helping me. And yet, we had a number of different instances of people who delayed, who were either splitting the drug itself, or were picking it up late, or were having a challenge accessing. I don't know what to say about it other than to say, you're being given a sacred trust to do what's best for people as you're trying to negotiate a price because you have to balance a lot of really important aspects, not just of care now, but care into the future as well.

Closing Remarks

01:06:31

Moderator, RTI International

I appreciate you sharing those examples. They were very troubling to hear about splitting a pill or delaying a few days. I'm going to turn to CMS and see if they have any follow-up questions for the two of you. No, they have no further questions, so this has been very helpful, and we really appreciate your particular perspectives as advocates in these large organizations that have such a wonderful presence in the cancer and breast cancer community.

Thank you for all both of you do at the ACS and Komen for breast cancer patients. Thank you again, and CMS staff have been listening today, and will be able to bring this information back to their teams as they have further discussions on drug negotiations, so they want to thank you for that as well. Before we close, I'm going to turn to the CMS team again to round things out.

01:07:39

CMS Staff

I'd like to echo what **[Moderator]** said. Thank you guys for the discussion and your work in this field. We learned a lot from today, and we're going to take it and, of course, use this information for our Negotiation Program, so thank you.



01:07:54

Moderator, RTI International

If either of you have any other further thoughts after today's call, or a write-up, or **[Participant 2]**, you mentioned this wonderful survey you have with some quotes and information, so if you are comfortable sharing some of those findings with us, you could follow up with this mailbox, it's IRARebateandNegotiation@cms.hhs.gov. We've placed it in the chat, and on the slide, so if you want to grab that and put any information that you have in an email with the subject line "Public Engagement Events." I'm sure CMS would appreciate any other findings you have very much.

===== 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
No	Any other personal or professional relationship or interaction with a company or related association with direct or indirect interest in the Negotiation Program that may be considered a financial conflict of interest

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

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