

*This transcript was lightly edited for readability.*

## Introductory Remarks

### Moderator, RTI International

I'm **[MODERATOR]**, and I'm from RTI International. I also want to introduce my colleague **[SECONDARY MODERATOR]**, who you may hear from at a few points in today's discussion.

The Centers for Medicare & Medicaid Services, CMS, is convening this patient-focused roundtable event, and others, as part of the Medicare Drug Price Negotiation Program. The purpose of today's event is to hear from you all, a group that may include patients, caregivers, and patient advocates, about your experiences with the conditions and diseases treated by Xtandi, with Xtandi itself, and with other medications for the same condition.

If you wish to share input on other topics related to the Drug Negotiation Program, please do so through the mailbox at [IRARebateAndNegotiation@cms.hhs.gov](mailto:IRARebateAndNegotiation@cms.hhs.gov), and we'll provide that mailbox address a bit later in the meeting.

The information shared during the events will help CMS understand patients' experiences with the conditions and diseases treated by the selected drugs, patients' experiences with the selected drugs themselves, and patients' experiences with other drugs that are used to treat the same conditions as the selected drug. CMS may use this information in negotiating Medicare pricing with the manufacturers of selected drugs.

Your experience and perspectives are very important to us, and we genuinely appreciate your time today. Let's go ahead and watch a brief welcome video from CMS leadership, so that you can hear from them about how much they value your time and input.

## CMS Remarks

00:01:47

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.

00:03:44

**Moderator, RTI International**

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

00:03:59

**CMS Staff**

Thanks, **[MODERATOR]**. I just want to welcome everyone to this roundtable discussion based on CMS. I am a member of the Drug Price Negotiation Team, and we have other members here on the call. We're going to have our cameras off just to help with the focus of the discussion. But we will be here and taking notes in the background. Thank you.

## Housekeeping

00:04:21

**Moderator, RTI International**

Great. Thanks, **[CMS STAFF]**.

Okay, before we begin, I just want to review some housekeeping items and ground rules so that everyone knows what to expect today. First off, we hope that you will contribute your perspectives throughout the session. That said, if questions arise that you don't want to answer, that's totally okay.

In terms of background. Please just minimize any background noise by silencing your cell phone or any other devices you have in the area. Also, we'd appreciate it if you'd mute yourself when you're not speaking.

In terms of 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 don't share any unnecessary personally identifying information or personal health information during the 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 available to the public.

I also want to highlight a few things to keep in mind for our discussion. Video, we appreciate you keeping your video on throughout the discussion to the extent possible.

In terms of timing, the session will last about an hour and 30 minutes. I do have a discussion guide in front of me, and that's just to help me stay on track. We have a lot of different topics that we want to cover today. So, if you notice that I'm redirecting our conversation or cutting a conversation short at times, it's not that I wouldn't love to hear more about that. It's just I want to make sure that we can cover everything in the time allotted.

In terms of technical assistance, if you do get disconnected, please just attempt to rejoin. If you can't connect, please reach out to [IRADAPStechsupport@telligent.com](mailto:IRADAPStechsupport@telligent.com), and that address is in the chat for you if you need it.

In terms of breaks, if you need to step away briefly during our discussion, that's totally okay. Just turn your camera and microphone off and rejoin when you're able to. You don't need to tell me that you'll be stepping away from your computer. Please just return to the discussion when you're able to.

Please try to speak one at a time. I may occasionally interrupt you if two people or more are talking in order to make sure that everybody gets a chance to talk, and that everybody's comments can be accurately recorded. Please feel free to use the raise hand feature in Zoom. I think that you took a moment to find that feature during the tech checks, but feel free to use it as needed. And this will help me know when you would like to add to the discussion. You can always add your comments into the chat as well.

And, last of all, honest opinions, your opinions and experiences will differ. We want to know what each of you honestly thinks about the topics that we'll be discussing.

Does anyone have any questions about the housekeeping items or ground rules before we get started?

Okay. All right. Well, hearing none, I'd like to begin our discussion by asking you all to introduce yourselves. Please, if each of you could just take 30 seconds to tell us your first name, and whether you'll be sharing personal experiences or those of a loved one, or whether you're sharing patient experiences from the perspective of a patient advocate.

I'm going to go in order of who I see on my screen. Let's start with you, **[Participant 1]**.

## Discussion

00:07:52

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

Good morning. My name is **[Participant 1]**. I am here representing both patient advocate experience as well as the stories of individual consumers and patients.

00:08:06

### **Moderator, RTI International**

Thanks, **[Participant 1]**. **[Participant 2]**?

00:08:09

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

[Participant 2]. As [Participant 1], same. Patient advocacy perspective, as well as individual patients through a survey.

00:08:22

**Moderator, RTI International**

[Participant 3]?

00:08:25

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

Hi, I'm [Participant 3], with Cancer Support Community. We're a nonprofit, and I will be sharing patient experience insights from our network partner locations, as well as through our cancer experience registry. Thank you.

00:08:40

**Moderator, RTI International**

Thanks, [Participant 3]. And [Participant 4]?

00:08:44

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

That would be patient advocate, as most we've heard so far this morning, and also just some personal activities with family members and friends.

00:08:57

**Moderator, RTI International**

Great thanks, [Participant 4]. Okay, thanks to all of you for being here. Now that you've introduced yourselves briefly, I'd like for us to use the chat feature to share one more piece of information that's helpful for me to know. Have you or any of your loved ones taken Xtandi, whether currently or in the past? Please enter your responses in the chat. Yes or no.

Okay. All right. And thanks for introducing yourselves and telling us what experiences you'll be drawing from today. Let's start by talking about patients' experiences with prostate cancer treated by Xtandi. We know that there will be a lot to talk about with this question, so please just feel free to raise your hand, to share briefly and/or add your comments to the chat, like I said, that's always an option.

In general, how does prostate cancer affect patients' day-to-day lives? Who wants to start on that one? Day-to-day impacts of prostate cancer.

00:10:18

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

I'm happy to jump in and share some related comments to this, which I think what's important to point out here about the impacts of prostate cancer on patients and consumers, as it relates to Xtandi, is just how expensive Xtandi is to those patients and consumers.

It's a cost that drives over three billion dollars to spend in the Medicare program, and for patients like [REDACTED] in Kansas, whose husband had to pay a copay of \$635 every month to afford their Xtandi, the price is unaffordable. It means for families like [REDACTED] and her husband, making impossible decisions between affording their medication, or frankly losing their lives.

00:11:02

**Moderator, RTI International**

Thanks, [Participant 1]. So, affordability and cost. Other impacts, family, work life, relationships, activities? [Participant 3]?

00:11:10

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

Yes, so I will be drawing on the insights from CSC's [Cancer Support Community's] 2020 Cancer Experience Registry Report that looked at prostate cancer from 292 patients and survivors at various stages of a prostate cancer diagnosis and recurrence.

I will be looking at quality of life, emotional/mental health, cancer-related distress. Just to provide some insights as it relates to patients' day-to-day experience. Quality of life was considered significantly worse than the U.S. general population as it related to fatigue at 28%, anxiety at 26%, depression at 21%, and physical function at 20%.

Sexual function and intimacy is actually very important for this patient population, where 73% reported experiencing erectile dysfunction since diagnosis and treatment, and 44% were concerned about intimacy, sexual function, and fertility. When we looked at emotional and mental health issues, 32% reported living quite a bit or very much in fear that their PSA [prostate-specific antigen] level will rise. And also, that same analysis, looking at 292 patients and survivors. When you looked at the cancer-related distress, 55% of those patients were concerned about the cancer progressing or coming back. Half were concerned about eating and nutrition, and 43% of patients reported worrying about the future. I'd also like to note that one-third of those patients of the 292 reported concerns about health insurance or money issues.

00:13:07

**Moderator, RTI International**

Thanks, [Participant 3]. [Participant 4]?

00:13:12

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

[Participant 3] mentioned something that I wanted to bring up, and I think that underlying this whole discussion, when you start talking about advanced cancers, and that's what Xtandi addresses, is there's still a confusion, and as a male, I can tell you my experience, there's a confusion in the medical world in terms of PSA. When they changed the guidelines, there was a lot of confusion, and I think it impacted patients overall and led to some advanced cancers that weren't necessary, and I don't think we've really resolved that.

00:13:54

**Moderator, RTI International**

Thanks, **[Participant 4]**. Can you tell me a little bit more about that confusion that you're referring to?

00:14:00

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

I found even talking to urologists, my own urologist, that there was confusion as to what to do if you have a high PSA, let's do a biopsy. Well, then, we had a lot of biopsies that were necessary. I had a family member recently that had the same issue, and I thought we got beyond that years ago. So, I think there is still some confusion. And because we're talking about a drug that addresses advanced cancers, I think it's important to at least bring it up.

00:14:32

**Moderator, RTI International**

Thanks, **[Participant 4]**, and thanks for clarifying. **[Participant 2]**?

00:14:35

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

Yeah, I want to echo a little bit of what **[Participant 4]**'s saying, because I do think that since Xtandi is specifically, at least being used now, though it is being used earlier in the course of treatment, because of the evidence, that this drug is for people with advanced cancers, so that I think, really creates a patient lens and a patient experience that is quite different than maybe a drug that's used earlier in a staging. And so, I want to, although there's no one on the call that's actually taken the drug, we did work with an organization called Magnolia Innovation and conducted a survey of cancer patients that are actually taking Xtandi. And so let me just highlight a few important things related to their patient experience.

So, those who participated in the survey said that there were three important factors in their decision to actually take Xtandi, and the most important was their impact on survival.

Also, the lack of side effects and their provider's recommendation based upon clinical guidelines. So, those three things, I think that as you're thinking about the value of the drug and sort of all of the things that will go into this discussion, I think those three things are important.

Ninety-two percent said that Xtandi had been very important to their cancer care and treatment, and one-third said it was the only effective therapy for managing their cancer. So, those are really powerful statistics. Only one in four said that there was any sort of alternative that they could have considered instead and then many said that they were subject first to some version of step therapy, and I bring up the step therapy, and I know everyone on this call will be familiar with that when you're dealing with advanced disease, that the amount of time that may be required to go through that step therapy process could be time that you actually do not have. So, I thought that that was a really important statistic to share with the group.

00:16:57

**Moderator, RTI International**

Thanks, **[Participant 2]**, and we'll definitely be delving deeply into the benefits of Xtandi as well as therapeutic alternatives and drawbacks. And so, you've set the stage for us very nicely with some of those facts. Okay, so let's turn our attention to the aspects, and you got it this a little bit, the aspects of prostate cancer that are most important to patients to have managed or treated? The most important aspects of prostate cancer to have managed or treated? **[Participant 2]**?

00:17:33

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

I would just re-echo the side effect issue. I think that again, when you have advanced cancer, there's so much surrounding your treatment and the demands on you with that type of diagnosis, that taking into account side effects of any drug is a really important part of patients' value of the therapy that they are on.

00:18:03

**Moderator, RTI International**

Got it. Thank you, **[Participant 2]**. **[Participant 1]**?

00:18:06

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

I mean, I'm going to bring up the point about affordability again, that in order for advanced cancer patients or any cancer patients to be able to access their treatment, they have to be able to afford their drug. Xtandi is an example of a drug that is unreachable and unaffordable for many seniors who rely on that in the late stages of their fight against prostate cancer.

And I think it's important to not only point out the sticker shock, which is for **[REDACTED]** from Arizona, for her family, it cost \$1,500 every two weeks to afford Xtandi, to attain Xtandi, and so that for many families that is unreachable, it's unaffordable.

And it's important to remember that that is just one of many drugs that cancer patients and prostate cancer patients have to be able to afford to make it through their treatment regimens, as well as many other interactions with the health care system, which also each come with their own cost.

And so, when you start telling up the cost of the high price drugs, not just Xtandi, but in the context of other price drugs as well as other interactions with the health care system, you're looking at a complete inability of cancer patients to afford their treatment, or if they are able to, they find themselves in medical bankruptcy, or they leave their families an insane amount of debt that has to be paid back, so the affordability issue cannot be understated.

00:19:31

**Moderator, RTI International**

Thank you, **[Participant 1]**. Okay, **[Participant 3]**? The most important aspects of prostate cancer for patients to have managed or treated?



00:19:39

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

I want to echo a lot of what **[Participant 2]** said, and even what **[Participant 1]** said. They both make some really important points. When we talk about what's really important for prostate cancer patients, particularly those that may have metastatic or advanced, what we find is that managing the side effects are really important.

And there are some side effects that can really impact their quality of life or their day-to-day function, such as, there's hot flashes, there's fatigue, there's joint pain, there's muscle weakness, and those are really important to be managed for a patient with a prostate cancer diagnosis, particularly when you think about what their treatment goals are or what they want to do, what's important to them with respect to their quality of life and how they want to continue to participate. What is also really important for men with advanced prostate cancer, when we talk about side effects, and just how this impacts them. What we find is that there is actually evidence that shows that men with advanced prostate cancer are at an increased risk of death by suicide. There appears to be an association between erectile dysfunction, depression, and suicidal ideation that is compounded by patients with prostate cancer.

So, there's a lot that is being managed, and that is affecting a man with advanced prostate cancer. There's the side effects. There's the treatment. There's bringing the PSA levels down. There's making sure that the cancer, whether it's metastatic, is it controlled? There's that. But then there's also that very real quality of life. How is this impacting how I function, how I show up in the world, and in some cases, there might be a tradeoff between overall survivability and having less of those side effects that may make them feel like they're not presenting, as they have been historically.

00:21:43

**Moderator, RTI International**

Thanks, **[Participant 3]**. Okay. Any other comments on the aspects of prostate cancer that are most important to patients to have managed or treated before we start to dive into Xtandi specifically?

All right.

Okay, well, I appreciate you all sharing those experiences and facts. Very helpful. Now let's talk about experiences with Xtandi. Specifically, in addition to Xtandi, I do want to note that we also want to hear about experiences with other medications like Xtandi for prostate cancer. We sometimes refer to these other medications used to treat the same condition or symptoms as therapeutic alternatives. So, you may hear me use that term.

When considering potential medications for prostate cancer, what matters to patients the most? **[Participant 4]**?

00:22:54

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

I'll only refer to a couple of patients that I know personally and have experienced by, really by trial-and-error in terms of medication that was going to work for them. And I think in the one case, this individual wanted to have the ability to continue to travel, continue to be involved in activities that he'd been involved in for a long time. And side effects. Side effects were the key. And that's why he focused in on this particular drug that we're talking about, because for him it provided fewer side effects.



00:23:39

**Moderator, RTI International**

Okay, so side effect profile. **[Participant 2]**?

00:23:43

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

Yeah, some qualitative response from, and again, I want to echo **[Participant 1]**. Obviously, the survey that we conducted were people who had access to Xtandi. There's surely people who should have access to Xtandi that don't have it so, therefore, wouldn't have been able to respond to a survey. But for those who do have access, I think **[Participant 4]** noted. But we asked this specific question. A physician's recommendation, critically important. Proven to slow down the spread of cancer. So, the fact that there's evidence is important to patients. If they're being prescribed a therapy, it's the medication that doctors prescribe most. And then someone actually commented that this drug is very effective in treating my condition to the point where my care team is recommending a medication holiday. So, I think that there is incredible effectiveness for some patients. And I think that's really a critical component of this particular drug for prostate cancer.

00:24:55

**Moderator, RTI International**

Thanks, **[Participant 2]**. So, we've heard side effect profile, efficacy, physician recommendations, and how often they prescribe. **[Participant 1]**, do you have anything to add to that list?

00:25:07

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

Yeah, of course, I'm going to add affordability and costs. We know the monthly price of Xtandi is just shy of \$16,000, priced at least \$1,000 more than some of its other therapeutic alternatives. Even when you see similar side effect profiles, similar extension of life profiles, and in some case, the alternatives having a longer extension of life, but priced lower. So, I think, I'd be curious in that survey if you asked about affordability and pricing directly. But I think absolutely what we hear from consumers and patients, is that the number one issue that they have with the health care system, with their treatment regimens, is being able to afford the care, to be able to afford the drugs that they need to actually address the health issues that they have.

00:25:59

**Moderator, RTI International**

Okay, thanks, **[Participant 1]**. Any other important considerations when considering potential medications for prostate cancer? How well the medication works, we've already talked about. How quickly it helps, how frequently it's taken, ease of use, any of those? **[Participant 3]**?

00:26:21

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

One thing that I will mention is that it is an oral pill, and I know for a lot of cancer patients being able to receive their medication via an oral route is really important to them, as it relates to reducing some of those barriers, some ease, and being able to take it at home and not having to go to an infusion center. My understanding is that in earlier stages of prostate cancer, they may have to go to

an infusion center or receive an IV [intravenous]. And with this oral drug, that matters with respect to a metastatic prostate cancer patients' quality of life and what they look for and what's really important to them. That's one other point that I would like to highlight.

And then again, I know we're probably all saying the same thing, but the side effect profile is really important, and having access to various treatment modalities is also very important, because we know for people that are experiencing metastatic or advanced types of cancer, like prostate cancer, there may come a point where that treatment is no longer working. And it's really important that they have access to another treatment or another type of alternative. And so, I just want to underscore that when we talk about side effects of what's important to a patient, for example, if there's an individual with metastatic prostate cancer who's still working, they may decide the brain fog from Xtandi might be a bit much, and Zytiga, for example, might be a better therapeutic alternative if they don't have a history of seizures or something like that.

I just want to underscore, it's just really important that the shared decision-making between the patient and the physician is always factored into this and that we're talking about people who have unique needs, unique goals, unique treatment decisions, and unique outcomes on what matters to them. And so, I just want to just continue to reiterate that throughout this conversation.

00:28:22

**Moderator, RTI International**

Thanks, [Participant 3]. [Participant 1], do you have something else to add on this one?

00:28:26

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

Just one additional point related to [Participant 3]'s point, which is, I think one of the important things to point out about Xtandi when thinking about what is a fair price, this ease of side effects, ease of taking the medication, absolutely, and part of what plays into that is drug interactions. Xtandi has a significantly high number of drug interactions, which just means from the clinical perspective, there's more to navigate in terms of what is the drug profile that a prostate cancer patient can take to meet all the needs in terms of their treatment regimen. It has nearly 700 drug interactions, 669; 240 of them are major, 400 of them moderate drug interactions. When you look at some of the therapeutic alternatives, cuts that in half. So, I think it's another important factor to be thinking about when you're when you're pricing Xtandi.

00:29:13

**Moderator, RTI International**

Thanks, [Participant 1]. [Participant 2]?

00:29:15

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

Yeah, I just want to echo, I think we're all going to start repeating our themes. But, the more we discover about cancer, which is really being propelled, it is really an incredible period of time right now for cancer discovery, because the biology of cancer is so much better understood, really just within the last few years, that there is incredible uniqueness to the needs of literally individual patients and the subcategories. We talk prostate cancer just like we might talk breast cancer, but there are so many subtypes.

And so, for people who fall into subtypes with lots of their own individual issues, it really is about access to the right therapy for the individual patient. Part of the challenge with any cancer drug, again, if it's not affordable, it comes off the table completely. So, the affordability is so critical. But the unique need of individual patients, because of the complexity of not just the cancer diagnosis but the subtype of the cancer and the specificity of the cancer and the advancement of the cancer, really needs to be taken into effect as we think about what people need to have access to, when it becomes affordable. So, I do think that we're all thinking about that as patient advocates in our head. And more and more stories are about those individuals, and as **[Participant 3]** mentioned, people who want to be able to work. So, all of those types of things become really important from an access standpoint, as well as an affordability standpoint.

00:31:17

**Moderator, RTI International**

Thanks, **[Participant 2]**.

Okay, so the next two questions are going to focus specifically on Xtandi. But then we'll have an opportunity to talk more about the therapeutic alternatives, and how they compare to Xtandi.

What are the main benefits that patients experience with taking Xtandi? What do patients like about Xtandi? And this can be clinical benefits or non-clinical benefits, like convenience and ease of use. **[Participant 4]**?

00:31:53

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

Well, as **[Participant 2]** said, we moved to a very personalized approach to cancer treatment and based on the experience. And it's certainly not evidence-based, because I'm talking about a few people that I actually know and have observed, it's quality of life. We've talked about that before.

I think when you weigh aspects of any medication or any treatment, does it work for me? And I have seen that it works for the people that I know to the point where their life has been changed, and how long do they have that life? Well, who knows? But in terms of day-to-day, they're able to function and deal with realities of life a whole lot better. And I think that's important. And it does get back to the personalization. We've moved to that point, one drug does not work for everyone, and that's why we'll be talking about some alternatives. There may be some alternatives that work much better, and as we talk about negotiating prices and so forth, that needs to be taken into consideration, alternative medications, alternative treatments.

00:33:14

**Moderator, RTI International**

Thanks, **[Participant 4]**. Other comments on the main benefits that patients experience with taking Xtandi?

Okay. What about the main drawbacks or challenges that patients face when taking Xtandi? What do patients wish was different about Xtandi?

**[Participant 3]**?

00:33:45

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

Yeah, I think I'll mention, a lot of it is the side effect profile. Some of these side effects can be pretty severe, like I mentioned there could be some cardiovascular events. There could be an increased risk of diabetes, osteoporosis. Those are really serious and need to be managed. So, I'm sure that is something that these patients wish were not the case. However, what we see is that a lot of these side effects are also present or prevalent with some therapeutic alternatives, as well.

And so, while it's not ideal, they may have learned to navigate and understand that these may be some of those really unfortunate side effect profiles. So, if I were to speak off of what we see in our cancer experience registry, and then what we hear from these patients, ideally, the side effect profile. And again, I mentioned at the outset that a lot of these medications can really change their life, and their intimacy, and that is really important. And they can have physical changes, like hot flashes and gynecomastia that impacts them, as well. And so, I don't want us to forget that there is a real emotional and mental health, and maybe even sense of self that is also factored into this. Because we're talking about the whole person. And so, I know your question is very specific to what might they not like about Xtandi. And I kind of talked about that. But I don't want us to lose sight of the whole person and their experience as we think this through.

00:35:39

**Moderator, RTI International**

Thanks, [Participant 3]. [Participant 1], the main drawbacks of Xtandi?

00:35:45

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

I think I'll continue on my theme here, since others are covering the other dimensions very beautifully. But I think price, I mean we have price and cost affordability. We have stories from [REDACTED] in California, [REDACTED] in Florida. We've got [REDACTED] in Washington, [REDACTED] in Missouri, [REDACTED] in Virginia, [REDACTED] in Oregon, [REDACTED] from Arizona, [REDACTED] from Kansas, and it goes on and on, [REDACTED] from New Mexico, [REDACTED] from Arizona, people across the country, seniors across the country, prostate cancer, people with prostate cancer who are fighting for their lives and taking Xtandi and the number one drawback is how expensive it is: \$15,000 a month, for a 30-day supply almost \$4,000 copay for some of these folks. Every two weeks spending \$1,500 for our nation's seniors. Its price is too high, even with cost sharing. Its price safeguards, even with out-of-pocket costs capped. It's priced too high. And I think one of the things that's important to be considering when in the program and negotiating for a fair price is looking at the international points of comparison, the rest of the world gets Xtandi for a fraction of the cost that we pay for it. And so, I think the question is, why does the rest of the world get a better deal than our nation's families in the United States?

00:37:05

**Moderator, RTI International**

Okay, thanks, [Participant 1]. So, cost and affordability. Any other drawbacks of Xtandi before we shift our focus to talking about how it compares to those alternatives? Okay.

All right. Oh, sorry, [Participant 3].

00:37:24

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

Sorry. I just wanted to share some insights we have related to financial burden, just underscoring what **[Participant 1]** said and what **[Participant 2]** put in the chat that our cancer experience registry, looking at 107 prostate cancer patients, elucidated financial burdens. More than half spend at least \$100 a month on all out-of-pocket costs, 30% spent \$250 or more, and 16% spent \$500 or more monthly. So, there is that financial toxicity, that cost burden, that absolutely is Xtandi, and I think, prostate cancer treatment more broadly.

00:38:13

**Moderator, RTI International**

Thanks, **[Participant 3]**. Okay. Aside from Xtandi, what medications have patients that you all are aware of and representing the experiences of, taken, whether currently or in the past to treat prostate cancer? So, this is just kind of a list of some of the therapeutic alternatives that you all are familiar with experiences with.

**[Participant 3]?**

00:38:37

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

Yes, so I mentioned at the outset. We know that they take Zytiga with a steroid. But when there's a steroid, patients really need to be monitored for the long-term side effects of steroids. There's also Erleada that we know that they can take, which might be more effective than Xtandi and Zytiga for metastatic castrate-sensitive prostate cancer, and it may also be a little bit more cost-effective. That's what we know. And then there's also Nubeqa, which has been approved for non-metastatic castrate-resistant prostate cancer and metastatic castrate-sensitive prostate cancer plus the chemo. There haven't been any head-to-head comparisons looking at Nubeqa and Xtandi, but that is another treatment alternative also, that is out there that we've looked at. Looking at the National Comprehensive Cancer Network guidelines, looking at the American Urological Association, some of their guidelines, that's what we see are some treatment alternatives that could also be used by the population.

00:39:47

**Moderator, RTI International**

Thanks, **[Participant 3]**. **[Participant 1]?**

00:39:49

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

And I think those are the two I was just going to just add the point to that to those two drugs in particular, that **[Participant 3]** mentioned is that Xtandi is priced much higher, yet the efficacy is about on par with the alternative. So, I think the question of why is it priced so much higher and really questioning it's priced as though it's a cure, but I think really, we know that it's not. And so, I think that's an important consideration in thinking about what's a fair price for Xtandi.

00:40:18

**Moderator, RTI International**

And [Participant 1], specifically, which alternatives were you just speaking of?

00:40:22

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

Two in particular, Nubeqa and Zytiga.

00:40:26

**Moderator, RTI International**

Thanks for clarifying. Okay, any other therapeutic alternatives that you all can share experiences related to. Okay. I know that you already got at this a little bit, **[Participant 3]** and **[Participant 1]**. But let's talk about the benefits of these therapeutic alternatives that we just heard about, and how they differ from Xtandi, if at all. Can you tell me a little bit about how the benefits of these other medications differ from Xtandi?

00:41:01

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

Yeah, I'm happy to share. Just again, it all depends on the side effect profile and what that individual's treatment goals are. So, for Zytiga, what we have observed in talking with some of our medical experts as well is that Zytiga is known to have more serious cardiovascular side effects, but maybe less brain fog or fatigue than Xtandi. So that's something that might need to be considered as well.

Zytiga may have slightly worse overall survival than Xtandi, especially for patients with cardiovascular disease, diabetes, older age, and a high comorbidity burden. As **[Participant 1]** mentioned, Zytiga has significantly lower cost, and they're generic. So again, those are decisions that the patient with their physician would have to think about.

For Erleada, that might be more effective than Xtandi and Zytiga in metastatic castration-sensitive prostate cancer. Xtandi has fewer severe skin reactions and lung disease than Erleada, and it may be a little bit more cost-effective. But they both have increased risks of seizure, heart diseases, falls, and fractures, unlike Nubeqa.

I mentioned that Nubeqa, there aren't any direct or head-to-head clinical trials. But what we have seen is that Nubeqa appears to have lower risk of serious side effects, lower risk of fatigue falls, fractures, heart disease, brain fog, and rash, and Nubeqa appears to have a faster and deeper PSA response in metastatic castration-sensitive prostate cancer, and appears to offer a longer overall survival benefit and non-metastatic castration-resistant prostate cancer. So, there's a lot to consider. Nubeqa, compared to others, must be taken with food. So, when you think about what might be more beneficial, having to take food when you take a medication might mean you have to make sure that I eat. Those are just those types of things that an individual would have to consider when making trade-offs on what's important for me and most effective. So, those are some of the side effects, some of the therapeutic alternatives and kind of what someone might need to consider when making a decision about what's right for them.



00:43:29

**Moderator, RTI International**

Thanks, **[Participant 3]**, and I know you got at both some of the benefits and drawbacks of these other medications, and how they compare to Xtandi. So, let's open it up to both benefits and drawbacks, and how those other medications compare. **[Participant 1]**?

00:43:46

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

I don't have much to add, but just to co-sign what **[Participant 1]** articulated really beautifully. And just to say, I think we want to make sure that, I think one of the points in considering is we want to add meaningful time to patients' lives so they can spend that time with their families with dignity, how they have the ability and the power to make those decisions for themselves, but not having to be on the phone to figure out how they're actually going to pay for the drug, or even worse, in cases where they might be facing medical bankruptcy for their families, that families have to deal with instead of being able to deal with grief. And I think that's an important thing that we hear from patients and consumer groups, as well.

00:44:25

**Moderator, RTI International**

Thanks, **[Participant 1]**. **[Participant 2]**?

00:44:27

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

Yeah, I just want to echo. I mean again, our goal as a cancer patient advocacy organization is to allow for choice, and that means people have to be able to afford it to even have a choice. But if you're forced into a choice that does not match your cancer diagnosis, that's not a choice. That's not an alternative. So, the complexity, particularly of prostate cancer, and the ongoing discovery as it relates to treatment of prostate cancer. And this kind of goes back to what **[Participant 4]** noted, there's a lot of continued challenge within the prostate cancer diagnosis pathway, where people should go. But there is a significant amount of research that is now directing treatment for these multiple types of subtypes that **[Participant 3]** was so clearly articulate about. And I just I think that part of the challenge that CMS has with all of this, and I don't know other diseases as well, obviously, as I know cancer. But an alternative for one patient is not necessarily an alternative for another group, another patient, and that has to be taken into consideration, and there has to be monitoring of step therapy, utilization management, prior authorization. Because this gets caught up particularly for cancer patients with metastatic disease in a way that is not beneficial to them and their quality of life and their longevity.

00:46:16

**Moderator, RTI International**

Thanks, **[Participant 2]**. Okay, before we switch gears a little bit, any other comments on how the benefits and drawbacks of therapeutic alternatives compare to Xtandi?

All right, I think we covered that pretty comprehensively. In cases that you all are aware of, where a patient has tried multiple medications for prostate cancer, what were the reasons for changing



medications? If any of you all can represent that experience of situations where patients have changed medications for prostate cancer. **[Participant 4]**?

00:47:00

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

Again, I'll just go to experience that I've had through friends or family members. And this may sound a little bit strange, but I know in one instance it was the recommendation of the doctor. The doctor observed what had been happening and took the position that medication should change.

00:47:23

**Moderator, RTI International**

Okay, when you say observed what had been happening, do you know specifically what types of things they were observing?

00:47:29

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

I won't go into that. But just from a personal standpoint, I think it was obvious. But my friend who was explaining all this to me was quite surprised that it was the doctor that made the decision.

00:47:46

**Moderator, RTI International**

Got it. So, doctor recommendation? Okay, other factors involved in changing medications for prostate cancer? **[Participant 1]**?

00:47:56

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

Affordability. I think we have stories of folks who, getting into the treatment, but after a couple of months, they can no longer afford the sticker shock and have to change course, which can be a devastating experience for cancer patients.

00:48:13

**Moderator, RTI International**

Got it. Okay, cost considerations, physician recommendations. Any other factors that prompt patients to change medications for treating prostate cancer?

Okay. All right. Well, let's move on, thanks to everybody for all of the helpful input so far. I really appreciate it. Now let's talk about how well Xtandi and other medications for prostate cancer meet patients' needs.

What would it be like for someone who has prostate cancer if Xtandi or other medications for prostate cancer were not available? In other words, what needs of people with prostate cancer does Xtandi and other medications for this condition meet? How would folks manage or cope with prostate cancer if Xtandi and its therapeutic alternatives were not available? **[Participant 3]**?

00:49:20

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

Quite frankly, it's hope. It's medication that is giving them a chance to continue, it's working, and it's allowing them, if it's working and if they're showing that the PSA levels are not doubling, and they're decreasing, and they're able to manage. That's really important that they're still able to be here and be able to function and contribute and be a part of society. I think that's really important, that they're still able to function and be a part of society. I don't think that can be understated. I think that's what's so important, being able to be with their family, being able to work, being able to meet what their treatment goals are, which is why we have all said at the outset, individual choice, personalized treatment decision-making is so important. Because if there is a treatment alternative that's out there and it stops working, what might that alternative look like? And that's not, of course, what we want to see. So, I think, just quite frankly, it's hope. It's survivability. It's being able to continue to contribute and function in their life in society with family, friends. That would be my initial reaction.

00:50:40

**Moderator, RTI International**

Thanks, [Participant 3]. [Participant 1]?

00:50:44

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

Thank you. So, I'll say on this, related to your question from our perspective as consumer patient advocates is one of the things that's so important to the Medicare Drug Negotiation Program is that the fair prices that are being established under the program are as competitive as possible, and that's not only to reduce the cost of prescription drugs for seniors and families, but also to generate savings for the overall Medicare program, which, by the way, allows Medicare to then do things like cap out-of-pocket costs without increasing premiums. But it's also super important because it creates the competitive playing field, the financial incentives within the drug system which currently the drug pricing system, which prior to the Drug Negotiation Program did not exist. That forces drug companies to actually compete, based on meaningful innovation, to find the real cures, to find the higher value therapeutic alternatives and not just based on their current monopoly power and their ability to game the drug supply chain and its regulatory oversight.

So, I would say in thinking about the pricing program, and what would happen if Xtandi wasn't there and access, this is really about, we want the innovation. We want drug companies to be incentivized and to compete based on real innovation that's going to actually improve the lives of patients at a price that people can afford. And that's really the main function of the drug pricing program.

00:52:10

**Moderator, RTI International**

Thanks, [Participant 1], and I want to put another plug in for that mailbox that I mentioned at the outset for comments related to the Negotiation Program and policy. I think that's definitely a good avenue to submit those sort of comments for sure.

Anything else on what it would be like for someone with prostate cancer if Xtandi and other medications were not available? On the flip side of that, what aspects of prostate cancer, if any, are

Xtandi or other medications for this condition unable to address? What's not being addressed by the medications that are out there right now for prostate cancer?

Let me repeat that one more time, just in case. What aspects of prostate cancer, if any, are Xtandi or other medications for prostate cancer unable to address?

All right. Okay, let's move on then.

Thanks again for all your input so far. I appreciate it. And we're getting a little close to the end of today's session. And so, I want to wrap things up by talking about your perceptions of the overall importance of Xtandi to patients. Thinking about the various topics that we've discussed today, how would you summarize the importance of Xtandi for people with prostate cancer?

**[Participant 2]?**

00:53:58

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

Just want to reiterate a theme here that, because Xtandi is for advanced disease, people who can access it are accessing it, because they have tried other things that have not worked or they are not responding to. So again, when you're getting into alternatives, I think the use of that drug, at least the broad use of that drug for now, and it is starting to be used earlier in the course of people's diagnosis, but the alternative for whom?

The 'for whom' part has to be asked. And I think that's really important. From a consumer standpoint, it's a challenge. So, innovation comes onto the market. Pricing is a complicated construct in our country, but creating something that, therefore, is no longer available, is not the right outcome either. So, trying to figure this out and balance this out in a way, don't envy the people that need to do it. But, the broad brush here, particularly for this drug, I think, is going to be not the right outcome.

00:55:25

**Moderator, RTI International**

Thanks, **[Participant 2]**.

Okay, **[Participant 4]?**

00:55:29

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

Looking at statistics, we see that advanced cancer in the prostate area is actually increasing. If you take a look at stats in particular states, it's getting close to breast cancer. And so there has to be, as far as the patient's concerned, there has to be hope. There has to be something out there, and we see that this particular drug and some alternatives we talked about are at least available and may provide the help that the patient needs. One of the things we haven't talked about, and it's not germane to discussing when you're talking about prescription drugs is non-prescription drug treatment options. And there are those.

00:56:19

**Moderator, RTI International**

Thanks, **[Participant 4]**. Do you want to say any more about that? The non-prescription options?

00:56:24

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

Oh, again, some of the experiences that I have been associated with, and some of the advocacy work that I've done, use of protons. I think there's development taking place that will make a difference in terms of alternatives to prescription drugs.

00:56:49

**Moderator, RTI International**

Thanks, **[Participant 4]**. Okay, any other comments on the overall importance of Xtandi for people with prostate cancer? **[Participant 3]**?

00:57:03

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

Yes, there's one point I wanted to make, piggybacking off of something **[Participant 2]** said. She made a really important distinction. She said, when people are able to access this treatment. What it means, I did want to share, like when we're thinking about access and disease impact, just something for consideration. There was a UCLA [University of California, Los Angeles] study from 2023 that actually found that black men with advanced prostate cancer were actually less likely to receive any of these survival prolonging drugs. And this study actually looked at Medicare patients. Now, the reasons are multifactorial and need to be studied.

But just to her point, there are populations within the larger population that are less likely to receive any of these survival-prolonging drugs. And so when we talk about access, just broad access and subpopulation impact. I just wanted to share that as an example of what we're seeing, that maybe not everyone who would be eligible or could likely benefit are even receiving access to this. And when we think about prostate cancer, cardiovascular disease, hypertension, and diabetes, they disproportionately affect blacks more than other populations. So again, looking at the risk profile and really deciding, what's the right treatment alternative, those are very important considerations that also need to be factored for this population when deciding who may be likely to have a clinically measurable benefit to these treatment alternatives.

00:58:47

**Moderator, RTI International**

Thanks, **[Participant 3]**, for sharing that about disparities and other factors to keep in mind. Okay, unless anybody else has anything else that they'd like to say regarding the importance of Xtandi for people with prostate cancer. I want to open it up and ask if there's anything else like what **[Participant 3]** just mentioned, that wasn't covered in our discussion today that you feel is important to share with CMS before we close out?

Anything else you'd like to share with CMS? **[Participant 1]**?

00:59:25

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

First of all, just a huge thank you to you guys for hosting the call and inviting Families USA in to participate in the conversation. So, thank you so much.

And then, I think, just to reiterate our support for the Medicare Drug Price Negotiation Program, and how important it is for CMS to establish competitive prices for drugs that are subject to the negotiation to both lower the direct cost of drugs for seniors and their families to generate savings for the Medicare program that can be reinvested back into helping to lower broader health care costs and drug costs, such as caps of out-of-pocket costs, without increasing in premiums, which is extremely important to our nation's seniors, and to generate a competitive price for drug companies to actually compete for innovation, real innovation, to find the cures, to find the high-value therapeutic alternatives, and not just to leverage their monopoly power. So, thank you very much for the conversation and appreciate all the work you guys will do and continue to do to make sure that Xtandi is priced competitively and at a fair level.

01:00:30

**Moderator, RTI International**

Thanks, **[Participant 1]**. Anybody else? Any final comments that you want to make sure are shared with CMS?

01:00:38

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

Yeah, I just would like to echo, thank you. Cancer Support Community wants to extend our gratitude to CMS for facilitating this discussion to really allow for meaningful patient engagement, particularly for members of the community that are most impacted by cancer. And we look forward to identifying other ways to continually engage with CMS on the Medicare Drug Price Negotiation Program.

01:01:04

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

Yeah, and I'll echo from ACS CAN, American Cancer Society Cancer Action Network, the evolution of this discussion from the first round to the second is very much appreciated, and I'm not sure if you've done it yet, but I know you're doing a clinician roundtable, and I think that that will also provide a lot of really important perspectives that, particularly for a disease like prostate cancer, and for this particular drug, Xtandi, that will also be an important contribution to the discussion.

01:01:40

**Moderator, RTI International**

Thanks. **[Participant 2]**. Okay.

01:01:44

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

Thank you.

01:01:45

**Moderator, RTI International**

Thanks. Well, thanks to all of you, thank you so much for participating in today's group and for all of the helpful input that you shared. We really appreciate you taking the time to talk with us today. Your experiences and input were extremely valuable and will help inform CMS' negotiations for

these drugs. CMS staff, as we mentioned at the beginning, have been listening to the roundtable, and will be able to bring your perspective back to their teams. **[CMS STAFF]?**

01:02:14

**CMS Staff**

Yeah, just to echo **[MODERATOR]**, thank you all for this discussion. We appreciate everything that we've learned from this session, and we'll take it and use it for our Negotiation Program. So, we're really grateful for you guys all coming out.

01:02:28

**Moderator, RTI International**

Thanks. **[CMS STAFF]**.

Okay, well, if you have any questions following today's session, you can submit them to the mailbox listed here at [IRARebateAndNegotiation@cms.hhs.gov](mailto:IRARebateAndNegotiation@cms.hhs.gov) with the subject line, public engagement events. Thanks again for your time, and I hope you all take care.

01:02:48

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

Thank you, you too.

01:02:50

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

Thank you.

**=== 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	
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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Participant 3: 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 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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