Transcript: Erleada Roundtable Event, April 10, 2026, Medicare Drug Price Negotiation Program Public Engagement Events

This transcript was lightly edited for readability.

Introductory Remarks

Moderator, RTI International

Thank you all for coming today. I'm **[Moderator]**, and I'm from RTI International. I also want to introduce my colleague **[Secondary Moderator]**, who you may also hear from during today's discussion. The Centers for Medicare & Medicaid Services, which we'll be referring to throughout today's event using the acronym of CMS, is convening this patient-focused roundtable event, and others, as part of the Medicare Drug Price Negotiation Program. The information shared during these roundtable events will help CMS understand patients' experiences with the conditions and diseases treated by the selected drugs, patients' experiences with the condition, with the selected drugs themselves, and patients' experiences with other drugs that are used to treat the same conditions as the selected drug. The information shared during these events will also help CMS identify other medications used to treat the conditions treated by the selected drug, what matters most to patients in managing their conditions, and other important factors that CMS may consider in negotiating Medicare pricing with the manufacturers of selected drugs.

The purpose of today's event is to hear from you all, a group that may include patients, caregivers, and patient advocates, about your experiences with the conditions and diseases treated by Erleada, including non-metastatic and metastatic prostate cancer, with Erleada itself, and with other medications for the same conditions. I want to emphasize that our focus today will be on the patient experience. If you wish to share input on other topics related to the Drug Negotiation Program that are not directly focused on the patient experience, we'll ask that you send that input to the mailbox at IRARebateAndNegotiation@cms.hhs.gov instead of sharing it during today's discussion.

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

CMS Remarks

00:02:12

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.

00:04:02

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]**?

00:04:18

CMS Staff

Good afternoon, everyone. I am **[CMS Staff]** from the CMS Drug Price Negotiation Team. There are other staff members on the call today, and we work on policies to get input from you, the public, about the Negotiation Program. I would like to thank you for participating today, and we will be here in the background, but we'll stay off camera just to facilitate the discussion. Thank you.

Housekeeping

00:04:44

Moderator, RTI International

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

First off, technical assistance. If you get disconnected, please attempt to rejoin. If you cannot connect, 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 your doctor's name, the name of a medical facility where you receive care, or personally identifying information, such as your employer's name, the city you live in, and names of schools you attended during the discussion today. Following the event, CMS will prepare transcripts that have participant names and identifying information removed, and those will be available to the public.

Video recording. On a related note, we are recording today's event. These recordings will not be shared publicly. Recordings will only be used for internal program documentation and to produce the redacted transcripts for public release, consistent with Federal privacy guidelines. By participating, you consent to being recorded for these purposes.

Participation. First, we hope you will contribute your perspectives throughout the session. However, if questions arise that you do not want to answer, that's okay.

Background. Please minimize any background noise by silencing your cell phone and your other devices if you haven't already done so. Also, please mute yourself whenever you're not speaking.

Video. Thanks in advance for keeping your video on throughout the discussion today, to the extent that you can.

Timing. We have reserved up to two hours for this session. However, it's possible we may not need the full two hours to discuss all of the planned topics. If that happens, we can let everyone go a little bit early. I do have a discussion guide in front of me, that'll help me stay on track. I have a lot of topics that I want to cover, so I may need to redirect our conversation, or cut a conversation short at times. Just to make sure that we're able to cover everything, and that all participants have ample opportunities to share their perspectives.

Breaks. If you need to step away briefly during our discussion, that's totally okay. Just turn off your camera and your microphone and rejoin as soon as you're able to. You don't need to tell me that you'll be away from your computer, please just return to the discussion as soon as you can.

Speaking. We'd ask that you try to speak one at a time. I may occasionally interrupt if two or more people are talking, just in order to be sure that everyone can be heard, and that everyone's comments are accurately recorded. Please use the raise hand feature in Zoom to indicate that you would like to speak. This will help me know when someone is ready to add to the discussion. Take a moment to find this feature and see how it works.

Chat. While we're hoping that everyone will focus on our oral discussion, you can also add your comments into the chat if you don't get a chance to share them orally. This may be the case, for instance, if we don't get to hear from you before we need to move on to the next question, or if you think of something else to add later on. Please just be sure to note what question or topic that you're responding to in any chat comments.

Unless anyone has questions about the items I've just reviewed, let's go ahead and get started. I want to get us warmed up by beginning our discussion by asking each of you to introduce yourself briefly. Please take a moment to tell us your first name, whether you'll be sharing experiences as a patient, caregiver, or from the perspective of a patient advocate. And, if you're comfortable sharing, whether you have experience with non-metastatic or metastatic prostate cancer. Let's go ahead and get started. Let's start with you, **[Participant 1]**.

Discussion

00:08:50

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

I'm **[Participant 1]**. And 71 years old. And dealing with metastatic prostate cancer as a patient, and also as an advocate support person. I do volunteer two days a week at **[Redacted]**, at their request. I'm in my fourth year, so I just started my fourth year of doing that. Don't make any recommendations, but offer hope, let them know they're not alone, information to help them chart their own course and navigate their own course. Since I've been through the surgery, I've been through radiation, I've been through side effects, etc., and I'm willing to speak. So, a little bit about me.

00:09:40

Moderator, RTI International

Thank you very much, **[Participant 1]**. We appreciate having your perspective today. **[Participant 2]**.

00:09:48

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

Hi, thank you. My name is **[Participant 2]**. I am with the cancer support community, so I am coming from the perspective of a patient advocate. We appreciate the opportunity to participate in this panel. We are a nonprofit that's dedicated to providing support to people impacted by cancer, and that includes individuals that receive a diagnosis of prostate cancer, and we do that through our network partner locations as well as our helpline. A lot of the information that I'll be providing today will be based on the research experience from our cancer experience registry, as well as from the lived experiences that we hear and receive from our helpline, as well as through our 200 network partner locations that provide free services to those individuals impacted by cancer. Thank you for the opportunity to share those insights and perspectives related to lived experience and cancer-related distress.

00:10:48

Moderator, RTI International

Thanks, **[Participant 2]**, for joining today, we appreciate it. What about you, **[Participant 3]**?

00:10:55

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

Thank you, **[Moderator]**. I'm **[Participant 3]**. Like **[Participant 2]**, I'm with a national nonprofit called FORCE, which stands for Facing Our Risk of Cancer Empowered, so I will be sharing the perspectives of our constituents. Our focus is hereditary cancers, so individuals who often carry an inherited genetic mutation that causes increased risk of a number of different cancers, including prostate cancer. We have a helpline, we have peer navigation and support groups, so a lot of the perspectives I will be sharing will be from the participants in those programs and some of the information that they've shared with us. Happy to be here. Thank you.

00:11:40

Moderator, RTI International

Great. Thanks, **[Participant 3]**. We're happy to have you here. And **[Participant 4]**?

00:11:55

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

My name's **[Participant 4]**. I **[Redacted]** the organization that you can see behind me, AnCan [Answer Cancer Foundation]. We hold 36 events a month for all kinds of chronic conditions, that includes 13 for prostate cancer and four for high-risk recurrent and advanced prostate cancer disease alone. I'm also a peer, a Stage III peer. Whilst I was never on an ARSI [androgen receptor signaling inhibitor], because they were barely approved 17 years ago, I have good experience with ADT [androgen deprivation therapy]. And I'm very familiar with all of the ARSIs, both in doublet use and in monotherapy use. We have approximately 200 men a week that either tune in to our recording or attend our meetings live four times a month.

00:13:16

Moderator, RTI International

Thank you, **[Participant 4]**. **[Participant 1]**, I see your hand up. Did you have something to add?

00:13:25

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

Yes, thank you. I wanted to add that I'm just about in my 12th year, and also, in seeing all these nonprofits, that I also do work with ICAN [International Cancer Advocacy Network]. I'm a **[Redacted]** and speak one-on-one with the prostate cancer patients through their organization.

00:13:48

Moderator, RTI International

Great, thanks for adding that, **[Participant 1]**. I appreciate it. All right, everyone, thanks for introducing yourselves and telling us what experience you'll be drawing from today. It sounds like we have folks here that can speak to both non-metastatic as well as metastatic prostate cancer, and I realize that some experiences or preferences may differ between the two, so if it's relevant context for your comment, and again, if you're comfortable, please consider specifying whether your comment is related to non-metastatic or metastatic cancer.

Let's jump in. First, I want to talk about patients' experiences with prostate cancer. Thinking about the different ways that prostate cancer affects patients' lives, what would you say are the most important aspects of the condition to have managed or treated? These could be things that affect patients in the short term or the longer term. So, most important aspects of the condition to have managed or treated. **[Participant 3]**?

00:15:03

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

I would say just based on the input that we receive from the community we serve, obviously delay in disease progression is their top priority, including delaying metastases and extending survival. That would be their absolute top concern. Obviously, quality of life is also very critical, the ability for them to work, to continue spending time with their families, and staying socially engaged. Of course, being able to manage side effects. And the symptom burden and anxiety that goes along with all that, and then finally, I would say the financial toxicity side of it. Those are pretty much the top items that we hear from our community.

00:16:02

Moderator, RTI International

Great, thank you, **[Participant 3]**. **[Participant 2]**?

00:16:05

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

Thank you. I wanted to echo what **[Participant 3]** said. Looking at our cancer experience registry from 2020, that has about 292 prostate cancer patients. When treatments can extend both survival and improve day-to-day well-being, and the quality of that additional time, that's what becomes especially important and meaningful as it relates to the impact of treatment. What might not be surprising is that physical well-being, like fatigue and pain, and being able to monitor that, the symptoms and side effects related to that can really impact the daily function. Physical well-being issues like pain and sleep disturbance and cancer-related distress. [Patients] can also talk about problems with eating, nutrition, difficulty with mobility. Again, it's really focusing on impact on their quality of life, being able to participate in their life to the extent that is appropriate for them. And of course, not surprisingly, because we are a cancer support community and we focus on the mental and emotional well-being, [which] also is very important, particularly for those with advanced prostate cancer. Which might not be surprising. There's significant psychological distress, including depression, heightened anxiety, managing fear, and persistent worry. We're sharing the whole-person aspect of what is important and meaningful to patients that are impacted by prostate cancer based off of our cancer experience registry.

00:17:48

Moderator, RTI International

Thank you, **[Participant 2]**. **[Participant 1]**, do you have anything to add about the most important aspects of prostate cancer to have managed or treated?

00:17:58

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

Thanks for asking, **[Moderator]**. I think the sexual aspect is a huge one. I don't remember hearing that, but that's something that I get asked a lot about when I speak with men. And I think that's an important one for them to manage and to know about. Also, **[Participant 2]** you touched on it a bit, was speaking to those people about the mental aspect of it, as I like to say, when I'm speaking with groups, I whisper and I say that men don't talk about these things, because they don't. And thank gosh for Susan G. [Komen], but we're 25 years behind the breast cancer awareness campaigns, etc., and finding whether it's an in-person support group or an online support group can be key to a lot of these men, and that's something that a lot of them are looking for someone to speak with, because they can't always come in and see me, although I do have people who come and see me, when it's not their day for a visit. They come in and talk, because they don't want to speak with their wives or children, so I think communication is a huge piece for them, because they've always been the provider, and now they're not able to, they're vulnerable.

00:19:26

Moderator, RTI International

Thank you for adding that angle, **[Participant 1]**. I appreciate it. I don't think I had heard it before, either. What about you, **[Participant 4]**? Do you have anything to add regarding the most important aspects of the condition to have managed or treated?

00:19:40

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

I have a lot to add. I would first say that the mental health aspect is prevalent throughout all levels of prostate cancer. We see more anxiety with our early, low-risk active surveillance than we should do with the men at end stage, because the men at end stage have come to terms with it and the people diagnosed with active surveillance feel like they just have a hammer hanging over their head, and as **[Participant 3]** knows, we've tried very hard to make the AUA [American Urological Association] and others aware that they need to do a heck of a lot more for mental health, and they continued to refuse that. But I don't think that the mental health is the most important. I think what's most important when people get diagnosed is their treatment choice. And that's what they come and review with us initially in our treatment groups. And then we have mental health groups as well that we can help them out with, but the treatment choice is really important. And if we narrow it down to those with high-risk recurrence and advanced, and we reject the non-metastatic/metastatic delineation, because if you have recurrent disease, you're metastatic, even if you can't see it. The non-metastatic refers to whether we can see it or we can't see it, not whether you're actually metastatic or not. And the new nomenclature addresses that, and it's none too soon. But to go back to treatment choice, whether they have the right doctor, and many times, whether they have the right level of intensification. And that's where I think the discussion starts, and from there, once the treatment is established, it moves into survivorship and the issues of survivorship, which we concentrate on, and we've done surveys on, and we do really well in helping them with survivorship. I just want to give one example. NCI [National Cancer Institute] has a trial right now. We call it the long game. It's essentially for men with recurrent disease and very low PSA [prostate-specific antigen] doubling time, and they can go into that trial and they can avoid active treatment, where many doctors would choose active treatment. And if you avoid active treatment, then you avoid the side effects of active treatment. So, the whole discussion has to start with what treatment choice you're electing and what treatment choice your doctors are recommending.

00:22:57

Moderator, RTI International

Thank you, **[Participant 4]**. There's a lot there, so I appreciate you elaborating on the mental health aspect associated with the active surveillance. I understand that's a big one. And I also appreciate you mentioning that about the importance of finding the right doctor and the right treatment option. And also, just wanted to acknowledge what you said about the nomenclature. That's really helpful to have an understanding of, so thank you for sharing that as well. I appreciate all of those thoughts.

Now let's turn to patients' experiences with medications for prostate cancer. What medications, if any, have you or the patients that you advocate for taken, whether currently or in the past for prostate cancer? I'm going to ask you all to put these in the chat, and I'll give you a minute, because I know that that there are probably a number of them to enter in there. These are medications that you or the patients you advocate for have taken for prostate cancer.

00:24:16

Moderator, RTI International

[Participant 4], did you want to verbalize those instead?

00:24:18

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

I do, because every single medication that there is, and to start putting them in the [chat], I can tell you what I've done, what I've taken personally is easy, but every other medication and many more that are in trial. To start listing them, I'd say go through the NCCN [National Comprehensive Cancer Network] guidelines, every medication that's mentioned, we've had experience working with.

00:24:49

Moderator, RTI International

I understand. This question, it's a little bit different for the patient advocates that are talking with patients that have been on quite a variety of different medications over time, so I hear you on that one. And thanks, **[Participant 2]** and **[Participant 1]**, for the list that you put in the chat. I appreciate that.

For the next few questions, I want to note that we want to hear about any experiences you or the patients you advocate for have had with Erleada or other medications used for prostate cancer. I'm going to ask that you please be sure to specify which medication you're talking about as you share experiences. To start with, what benefits have you or the patients you advocate for experienced with medications used for prostate cancer? And as a reminder, please make sure to let us know which medication you're discussing at any given time. What benefits have you or the patients you advocate for experienced with medications for prostate cancer?

00:25:58

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

I can share, based on our research and feedback, we hear the flexible administration comes up as top for Erleada. The single dosing, the being able to eat it with food, without food, it being able to be dispersed in water, there are no food restrictions, it makes it easier for the patient, even if there's a caregiver and caregiver responsibilities. We hear that that mode of administration is especially appreciated for Erleada versus other types of treatments out there. I'll just start by saying that. And it also helps with medication adherence. Also, having that once a day, it helps remembering, and there's not a specific time you have to take it. Just taking it once a day, that appears to be a pretty strong predictor of long-term medication adherence.

00:27:01

Moderator, RTI International

Thank you, **[Participant 2]**. Ease of use, dose infrequency, and the impacts that those things have on adherence. **[Participant 3]**?

00:27:12

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

Just very similar, the oral therapies are so much more desirable than some of the other options, and that flexibility that comes with Erleada. We've heard from our community really good things about the therapy in general, as far as their satisfaction with the drug itself and the ease of use and administration, compared to some of the other therapies that are available.

00:27:48

Moderator, RTI International

Thanks, **[Participant 3]**. So again, the ease of use or administration, it makes a difference to folks. What about you, **[Participant 1]**?

00:27:59

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

Similar echo, I speak for myself, as well as for men with whom I speak and their caregivers for Erleada, and the pill aspect of it, the simplicity of it, and the same thing for those who happen to be on an Orgovyx instead of a Lupron. Orgovyx is also a pill, and Lupron is a shot, whether it's monthly, every three months, every six months. The intensity of how those drugs are received by the body in the one-, three-, or six-month strength dosage is much more difficult to take than the daily pill, we'll put it that way. That's a huge positive for everyone I speak with.

00:28:50

Moderator, RTI International

I'm hearing a theme here of the dosage and administration being pretty convenient with these oral medications. What about other types of benefits, like how safe it is, or how effective it is, how easy it is to tolerate, how it affects quality of life? Any benefits on those? **[Participant 1]**, I'll turn to you again.

00:29:17

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

I've been on ADT, for it'll be five years in two months, so just about five years. And yes, the side effects, I've had a lot of the ones that are pretty common, the fatigue, the bone, the joint pain, the hot flashes. The only one that I can't find a solution for, or at least a way to mitigate the side effects, are the hot flashes. And the fact is that they typically don't last very long. They'll occasionally wake me up, and I'm in a sweat, and you know what? If that's the price to pay for still being here, I'm pretty happy to do it. But most of the other side effects, there are ways to manage and mitigate a lot of the side effects, and that's what I try to share with men when I speak, that through diet, through exercise, a lot of those can be mitigated, not always can they be eliminated, but they typically can be mitigated and reduced. That's an important aspect of the side effects.

00:30:29

Moderator, RTI International

Thanks, **[Participant 1]**. And would you mind elaborating on how side effects differ across the different medications that you and the patients you advocate for have experience with?

00:30:39

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

That's a good question. Actually, most of the side effects are similar for the three different drugs. I've been on three different drugs since the beginning, two of them have changed about halfway through. The Erleada remained constant, but the other two, the suppressant and the bone density have switched, but the side effects have remained the same. The combination of side effects, it's hard to tell which drug is actually causing it, if just one, maybe all three, or maybe two of them are, because they do result a lot of times in a similar group of side effects. From everything I've been able to hear, speaking with men, and also research.

00:31:32

Moderator, RTI International

Thank you, **[Participant 1]**. I hear you. It can certainly be difficult to disentangle when there's multiple different medications involved. Before we move on and focus more on drawbacks, any other benefits of medications for prostate cancer, **[Participant 4]**?

00:31:48

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

I would have to disagree with **[Participant 1]**. There are significant differences between the four ARSIs, so those would be abiraterone, and what we affectionately call the "-ide brothers" at AnCan: enzalutamide, apalutamide, and darolutamide. The enzalutamide and the apalutamide are very similar. Hard to really distinguish between them, but some men respond a little differently to each. The darolutamide, and if **[Participant 1]** looks into this, is significantly different because it doesn't cross the brain barrier, and what we've been advocating to Bayer for the longest time is to trial this with CMS on a monotherapy basis, because we see several very good genitourinary [GU] medical oncologists across the country prescribing it, darolutamide, as a monotherapy. When you prescribe it as a monotherapy, not as a doublet therapy in conjunction with an ADT drug, it's much easier to see where the side effects are derived. Now, the darolutamide leaves men much clearer in terms of their thinking, which is huge. And I would say for 90% of the men that take darolutamide, they feel a lot less fatigue, and they're switching over from either one of the other -ide brothers or abiraterone. I have to say, yes, there's a big difference, even within the -ide brothers, and then again, if abiraterone, which is a very valid choice as an alternative to the three -ide brothers is used. That, again, has different side effects, because it also includes a small dose of prednisone. Plus, there are heart issues, there are cardio issues that have to be considered, both with the ADT drug and especially with the ARSIs, or ARPIs [androgen receptor pathway inhibitors], whichever nomenclature you want to use. Abiraterone tends to have more significant cardiovascular connotations, and we see men say, with AFib [atrial fibrillation], who have a history of AFib, doing worse on abiraterone, exhibiting more. We don't see that with any of the -ide brothers, and I don't think that we see a difference between the three -ide drugs on cardiovascular. Those are some of the differences that we've seen. We've also seen, which are inexplicable, we've seen guys come onto darolutamide, and they can't tolerate it at all. We've seen other guys who are three years on monotherapy, darolutamide, and they're doing great. As **[Participant 1]** will recognize, no one reacts the same in prostate cancer. Everybody reacts differently to the drugs, so these generalizations may not hold for you. Not for you, but you know what I mean.

00:35:42

Moderator, RTI International

Not for everyone. I hear you, **[Participant 4]**. Thank you for sharing some of those differentiations in terms of side effects and what can be expected with the different drugs. I appreciate that. **[Participant 3]**?

00:35:57

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

I just wanted to build on a little bit about what **[Participant 4]** said. There are a lot of positives with the oral administration, and only once a day, that type of thing. But we have heard from our community concerns around the cardiovascular and metabolic risks for those issues. Unfortunately, that seems to be consistent with a lot of the androgen receptor agents, but some folks shared with us that they felt Erleada, while it maybe raised their blood pressure, it was more tolerable than some of the other options. But people with a history of those types of issues definitely wanted to be monitored closely, and they had concerns. At the same time, their top priority of course was the treatment of the cancer. It’s a balance of those different potential implications from the medication.

00:37:15

Moderator, RTI International

Thanks, **[Participant 3]**. Thanks for that comment regarding the cardiovascular and metabolic risks. That’s helpful. I’ve started hearing about some drawbacks or challenges with medications for prostate cancer, which is fair, because there’s definitely a mixed bag, and we’ll talk more about those in a minute, but before we turn to focus more on the drawbacks or challenges, any other comments regarding benefits of medications for prostate cancer? **[Participant 2]**, did you have something else regarding clinical?

00:37:47

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

My comment was to piggyback off of some of the side effects and some of the considerations. Thank you.

00:37:59

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

I have a comment on the benefits. And it always makes me smile. We’ve had guys who have gone on abiraterone with a small dose of prednisone and told us they’ve never felt better and their golf game is much easier because of the prednisone. I think they’d rather not be on abiraterone, but it is a little bit of a silver lining for them.

00:38:29

Moderator, RTI International

That’s interesting. Golf game improvement, that’s quite a benefit.

00:38:35

Moderator, RTI International

Let’s turn our attention to focus more on the drawbacks and challenges. I know that we’ve already started to get into that to some degree, and **[Participant 2]**, I’ll call on you first here. This question is, what are the drawbacks or challenges that you or the patients you advocate for have experienced with medications for prostate cancer? And as a reminder, please make sure to let us know which medication you’re discussing at any given time.

00:39:01

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

This goes a lot to the comments that you probably hear from us and others that multiple treatment options are so important and considering the unique needs and preferences of each individual as they make their treatment decision. We hear that quite a bit from individuals that are being treated for prostate cancer, particularly. There’s no one-size-fits-all, and you have to really factor in the patient’s needs. For example, if someone has a history of falls, they may be less likely to take Erleada or another treatment and prefer another treatment option that has less central nervous system side effects like seizures. And all of that plays into physical health, well-being, and psychosocial factors. I wanted to just build on what **[Participant 3]** was saying, the real careful need and consideration for, goals, life preferences, what other conditions they might be receiving treatment for and the need for that really close physician-patient shared decision-making when determining what the appropriate treatment is for that person. Because we understand that not all are completely interchangeable, and so we’re mindful of those distinct side effect profiles and how someone may respond differently to treatment over time.

00:40:31

Moderator, RTI International

Thanks, **[Participant 2]**. I heard more in there about the risks and the side effects and the different needs and preferences of different patients. That’s definitely helpful to hear. And towards the end there, you mentioned over time how effective things are. Would you mind elaborating on that piece?

00:40:52

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

We understand that over time, a treatment may work as effectively, [or] may not work as effectively, and the need for being responsive and on top of things, and monitoring, and if there needs to be changes or adjustments, that being factored into, and why having multiple treatment options are just so critically important, particularly for individuals impacted by prostate cancer.

00:41:20

Moderator, RTI International

Great, thank you, **[Participant 2]**.

00:41:21

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

The need for surveillance. Yep, absolutely.

00:41:24

Moderator, RTI International

And I also heard you mention comorbidities. Does anybody have any comments regarding drawbacks or challenges of the different medications for prostate cancer in terms of other comorbidities that are at play?

00:41:59

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

As I mentioned, cardio [cardiovascular] is real important, and a lot of times it's so important that we've actually just started an email distribution group. Not a support group yet, but it could turn into that, for men diagnosed with prostate cancer who have cardio issues. If a man comes into our high-risk recurrent or advanced groups, de novo metastatic or recurrent, and has heart issues. More and more, we are ensuring that they've informed their provider and we're encouraging them to add a cardio-oncologist to their team because, as **[Participant 3]** mentioned, the ramifications of the hormone therapy job drugs, both ADT and the ARSI, are significant. Personally, it affected my blood pressure, and I started blood pressure medicine when I went on ADT. And when you layer over that, a doublet therapy, it can be very significant, and it can influence the choice between abiraterone and the -ide brothers. That's one issue. And then there are other considerations. There are people, for example, who cannot tolerate prednisone for whatever reason. And that takes them away from the abiraterone, and the trials have suggested that abiraterone should be the first choice drug, the reason being that the -ide drugs following abiraterone don't do as well as abiraterone following the -ide drugs, and that's why ideally you want to go on to abiraterone first, but there are men for comorbidity reasons that cannot do that.

00:44:15

Moderator, RTI International

Thanks, **[Participant 4]**. I've heard a lot of drawbacks related to safety and tolerability, and keeping in mind the comorbidity is there. Any other big drawbacks or challenges associated with medications for prostate cancer? **[Participant 1]**?

00:44:34

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

It seems pretty basic, but having the right care team. A care team that actually does it on purpose, as I like to say. They're focused on just prostate cancer and they focus on it, I think that and the focus is attending seminars and etc. multiple times a year to be cutting edge to look at the different impacts, the comorbidities, and look at the options, because there are usually options. And that's a good thing. Options are good. A lot of times, certainly early in prostate cancer treatment, outcomes are similar. Based on the different options. Not all the time, but they're typically similar options, statistically. But to have somebody navigate that for the patient, and the patient's loved ones, I think that's as important as anything that we've discussed so far.

00:45:50

Moderator, RTI International

Thanks, **[Participant 1]**. So, the importance of the care team, and coordination of care, and then being focused explicitly on prostate cancer.

00:45:58

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

And the coordination of that team with the cardiologists, with the oncologists, knowing that they have someone to go to and to refer a patient to. That that doctor already knows, and already has a relationship with, and so they're not recreating the wheel.

00:46:19

Moderator, RTI International

Thanks for that. **[Participant 4]**?

00:46:25

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

I'd endorse what **[Participant 1]** says. I think the strongest message we give to most men and carers who come into our groups is to make sure they have a genitourinary medical oncologist on their team, and if their treatment is currently run by a urologist or even a radiation oncologist as the quarterback, they need to change that. And also, specifically, if it's a general medical oncologist, to switch to somebody who's a genitourinary medical oncologist, because the science in prostate cancer is moving so quickly that unless you specialize in it, you can't keep on top. But I want to come back to your question, which was, what other adverse effects of the drugs do you see? And, from 30,000 feet, I would have to say the biggest issue is the fatigue and what we affectionately call "Lupron brain," but it's not just Lupron anymore. It's the inability to concentrate, the inability to work. We have an under-60s group, and most of those men are working and pretty advanced in their careers, and high-level executives. Recently received a patient who was the **[Redacted]** of a major **[Redacted]** brand that probably everybody has **[Redacted]**. So, we're dealing with pretty high-level guys, and all of a sudden they find they can't think straight anymore. And that's a huge issue and here's where it becomes really important. These men get put on drug regimens, sometimes a monotherapy ADT, sometimes a doublet, and they're told they're going to have to deal with this initially for a fairly long period of time. Maybe 18 months to 30 months, somewhere in that region. And they're working, and they're corner office level, and they can't concentrate. So, what do they do? They come off after six months, which is the minimum they need to stay. And what happens when they come [off] after six months? The disease comes back in two years or three years. And then what they're faced with is having to retire because they've got to go through chemotherapy and all the subsequent. That's why I'm focusing in on this fatigue and mental health issue, because it can adversely change the treatment path, because these guys have other responsibilities in their life at that period of time.

And I just want to add to that. We also feel that more work needs to be done on developing monotherapy because we think, and what we see anecdotally, from working with a lot of men who have been on apalutamide monotherapy, enzalutamide monotherapy, darolutamide monotherapy, and abiraterone monotherapy, is that for these different gents, and I can think of maybe 20 or 30 over the years, apalutamide going back six, seven, eight years, that it does seem to hold the disease. And these men then have a degree of testosterone in their bodies that helps them function whilst they still maintain control over their disease and it's a possible solution, so we will always encourage, go back, talk to your GU medical, you cannot talk to a general medical oncologist about this, because they don't understand it, but you can talk to a GU medical oncologist, and a lot of the ones who are more farsighted at certain centers of excellence will move a man onto monotherapy, and that man feels so much better. They come in and it's, "Oh my gosh, I can't believe how much better I feel just from dropping the ADT drug."

00:50:57

Moderator, RTI International

Thank you for sharing those additional details, **[Participant 4]**. I appreciate it. It's helpful to have a good understanding of the degree to which fatigue and these cognitive issues play into things, and adherence, and future treatment paths, etc. **[Participant 2]**.

00:51:13

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

I just wanted to piggyback just really quickly, because I think **[Participant 4]** explained it better than I ever could have, but I was listening to what **[Participant 1]** said, and **[Participant 4]** described it so well, but, again, coming from our perspective, working with patients in the community through our network partners and through our experience registry, that what we do hear particularly for advanced prostate cancer patients, that it really is overwhelming, not just for the patients, but for their families as well. And they mentioned feeling shocked, uncertain, and unsure where to turn for support, so I really wanted to reiterate, I didn't want us to forget or underappreciate the cancer-related distress, particularly as it relates to the mental health and the well-being aspects, where you're trying to understand your diagnosis, get the care, guidance, and the treatment you need, and I think **[Participant 4]** illustrated very well. An individual, I think **[Participant 1]** said it, working in a corner office, all of these things going well for them, very high level, executive level. But then there's also just trying to understand the diagnosis, where to turn to for support, getting that guidance and treatment, and what that can do, and how that can impact an individual's mental health and well-being, because we hear through our network partners that some of the individuals, particularly, I wish they knew about AnCan and other ICAN and CSC [Cancer Support Community], and even FORCE, the support groups that we provide, because a lot of them say they don't know where to turn to help for a men-only type of support group, where they don't feel ashamed, for lack of a better term, so I want to [im]press upon CMS and others the very real, whole-person aspect that relates to this, and not forgetting how this really does truly impact the person as well.

00:53:17

Moderator, RTI International

Thanks, **[Participant 2]**.

00:53:18

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

Can I add something to that? I love what **[Participant 2]** just said. **[Participant 2]**, we actually run a mental health group, which is open to anybody with chronic disease, but it's 95% prostate, unfortunately. I wish there were others that were there. But we run that every two weeks. And we call it **[Redacted]**, it's a men-only group. And they don't have to, but they can't talk about treatment, so they've got to focus on the "e" word, but we never use that word in the group, emotions. We never say that. We get 25 to 30 guys every two weeks in that group talking about issues that are bothering them, they may be some of the sexual issues, because it's men only, but there's a lot of emotion, and we're really lucky to have in that group two psychiatrists who are also peers, because we're totally peer-led. But we've got two peers who are trained psychiatrists who are in there, and it is a wonderful group. Most of the guys say it's their favorite AnCan group. It is so important to draw these guys out, so they've got a place where they can express themselves because they can't do it to their wives, and the mental health state is so impacted by the treatment that they're on.

00:54:56

Moderator, RTI International

Thanks, **[Participant 4]**, and **[Participant 2]**, for those comments regarding mental health and how critical that is.

00:55:01

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

I would say that's consistent across treatments, though. I don't think it's unique to any particular therapy, it's just the cancer experience.

00:55:12

Moderator, RTI International

Thanks for clarifying that, **[Participant 3]**. I hear you. So, that's not a medication-specific type thing, that's a prostate cancer, thing. I hear you.

00:55:22

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

I think that prostate cancer exacerbates it because of the nature of the medication, because it's hormone-directed. Yes, I would say it's true for ovarian, or it's true for breast. Is it true for lung? Is it true for colon? Yes, there's the concern that cancer brings, but it doesn't affect the hormones that affect your whole body to the same degree. It affects, but it's not to the same degree, **[Participant 3]**.

00:55:58

Moderator, RTI International

Thanks, **[Participant 4]**. I hear you, that the medications are definitely playing a role in the mental health issues. I think her point was just that there's not necessarily a big difference between the different medications available for prostate cancer in terms of that. **[Participant 1]**, I wanted to hear what you were thinking.

00:56:16

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

I want to thank you, **[Moderator]**, **[Participant 2]**, responding pretty much to what you had said a minute ago, because I think that's critically important. One of the things I try to share with people is the need to get a care team together, to get a support team together, and it has to have three legs to that stool, and I think family is a piece of that, and the actual care team is a piece of that, and fellow patients is a piece of that, and that's where I think trying to force them to get into a different support group, or two, or three, or try different ones, try one if it doesn't work, try another one next week, or next month, or whatever it is, because that's how they're going to talk to men and caregivers about, "Oh, did you hear about this? Did you hear about that? Have you tried this? Have you talked to your team about that?" You're going to get people in all of those support groups who have the gamut of experience, and if you can put somebody in touch with their fellow patients, I found that to be very helpful for the patient and their caregivers.

00:57:30

Moderator, RTI International

Thanks, **[Participant 1]**. The importance of connecting with peers that are having some of the same and some different experiences, I'm sure can't be understated. I want to move on to the next question, because I am cognizant of time, and we've already gotten at this to some degree, but overall, when considering a potential medication for prostate cancer, what factors matter to patients the most? The most important factors when considering a potential medication for prostate cancer. **[Participant 1]**?

00:58:06

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

In my mind, at least, the most important aspect is can we cure the **[Redacted]** thing? Can we solve the problem at hand, which is cancer? The efficacy, the track record, the opinions of my care team, those kinds of things, to me, it doesn't trump anything else in there, but it somewhat trumps some of the other aspects that we've discussed in terms of the ease of dosing, etc. What's the most logically successful tried and true path that's out there? I think that's probably to me the most important aspect of things.

00:59:01

Moderator, RTI International

Thanks, **[Participant 1]**. So, efficacy and what your care team recommends, I heard. **[Participant 3]**?

00:59:08

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

I agree with **[Participant 1]**, that is the top priority. I think next in line would be quality of life and that would mean minimizing the treatment burden and the side effects. Because obviously, let's beat this, that's the number one goal. But you also have to be able to function, and it has to be tolerable. If for some reason one therapy is just causing all kinds of side effects and quality of life issues, the ability to shift and try another therapy is definitely something that patients desire is to have some options if one therapy is not tolerable for them. We've heard that some people end up cutting their dosage down to try to minimize some of the side effects, which may or may not be that desirable if you really want to beat the cancer back. We want to make sure that while we're able to fight the disease and, hopefully, overcome it, those quality-of-life side effect profiles are really critical, as sort of second in line.

01:00:43

Moderator, RTI International

Thanks, **[Participant 3]**. I hear you. Quality of life and the way the different side effects and risks can affect that. **[Participant 4]**?

01:00:57

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

It's not quite as clear-cut from where we see it at AnCan. So much so that we just had a whole session in **[Redacted]** dedicated to quality versus quantity of life. I tend to agree with **[Participant 3]** and **[Participant 1]** that quantity, meaning efficacy of treatment, is more dominant, but I would say it's probably around 60% to 40%. We've got a lot of guys who don't want to do certain treatments, even though we know they're best, because they don't want to deal with the quality of life. Back in 2008, **[Redacted]**, who was the **[Redacted]** of **[Redacted]** for many years, introduced me to a term at UCSF [University of California San Francisco], where I was being treated and he worked, which was "ABC men." And ABC man stands for "anything but chemo." And even today, we see guys who won't do a triplet therapy up front, even though it's been shown in trials to be the most efficacious. We've seen it work the best. They don't want to do chemo. They don't want to consider chemo. Now they can go through the doublet therapy, they can go on to Pluvicto and not having done chemo, so they can push that chemo off, and that's a really good example of where quality of life issues trump the efficacy issues. And we see it enough, so I would have to say probably quantity 60%, quality 40%.

01:02:58

Moderator, RTI International

Thanks for that comment on balancing quality of life and efficacy. That's helpful to hear. **[Participant 1]**?

01:03:05

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

Let me phrase it a little bit differently, because I think we're saying some similar things, **[Participant 4]**. Every person's different, as we've already talked about. The disease impacts people differently, the drug regimens impact differently. For a person who is an ABC, then certain aspects are not even they're not even being questioned. They're not on the table. You're left with what's on the table after your "hard noes." And then you're looking at the efficacy, etc., so, I think we're saying some similar things there, but if I had a "hard no" about surgery, then I wouldn't have the surgery. What's the best option? What's the best efficacy outcome of anything that's still left on the table? Does that make any sense?

01:04:03

Moderator, RTI International

It does, yeah. The question was, what are the considerations? And you're saying, they have to be things that you're willing to consider, for those other considerations to come into play. That makes sense to me. Being cognizant of the time, I'm going to move on to the next topic. You all have provided a lot of really helpful input so far, and I really appreciate it. Now let's talk about how well Erleada and other treatments for prostate cancer meet patients' needs. At the beginning of the discussion, I asked you all to reflect on the most important aspects of prostate cancer to have managed or treated. Aside from the aspects that you already shared and that we've already talked about, are there other medical needs related to this condition that are important to you or patients that you advocate for? Any medical needs we haven't discussed at this point? I know we've covered a lot. **[Participant 2]**?

01:05:00

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

Just very quickly, and it's kind of related to your question, but I just want to make sure that we address this, that we were talking about the cardiovascular and what's needed for patients and treatment. I did want to just highlight really quickly that there are some disparities in access to Erleada, and that we do know that, particularly among Black men, there tends to be a higher prevalence of cardiometabolic conditions, like hypertension, obesity, and diabetes. And so I wanted to underscore that cardiovascular safety is a critical factor in therapy selection, and I wanted to raise, not setting anyone apart from another, but that there is a real disparity in Black men, and the importance of making that connection and link between the cardiovascular and the prostate cancer treatment.

01:06:00

Moderator, RTI International

Thanks, **[Participant 2]**. So, cardiovascular safety, and the disparities.

01:06:05

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

And Erleada may have less serious cardiovascular side effects when you think about Xtandi or Zytiga, for example. Just wanted to bring that point to the table when we're thinking about all Medicare beneficiaries in this case.

01:06:23

Moderator, RTI International

Thanks, **[Participant 2]**. **[Participant 4]**?

01:06:26

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

Just a correction, I don't think there's any difference between apalutamide and enzalutamide. There's a significant difference between apalutamide and abiraterone when it comes to cardio. **[Participant 2]**, you might want to check into that. And I also want to make a correction, because this is a bugbear for us at AnCan. We acknowledge the significant higher incidence of prostate cancer in Black men, but we also want to point out that it's also very high in Hispanics, it gets forgotten, and in Pacific Islanders and in Native Americans. And the point here is that Pacific Islanders, Native Americans, and Hispanics test at a 50% lower rate than African Americans. And we focus, correctly, on African Americans, but we do it at the expense of other minorities, and that's the reason we have never supported the HIM Act [Prostate-Specific Antigen Screening for High-risk Insured Men Act], by the way. We think it needs to be wider.

01:07:56

Moderator, RTI International

Thanks for those clarifying comments, **[Participant 4]**. The question is, any other important medical needs.

01:08:02

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

Yes, we've talked about cardiovascular, and **[Participant 3]** very correctly at one point mentioned metabolic. We want we want to stress the metabolic because the ADT drugs, in particular, can certainly affect diabetics, the level of glucose in your body, which affects your diabetic status and other metabolic issues. Whilst we know cardio is very important, there are other metabolic diseases that are affected. One of the common things we often forget about is just weight gain. We frequently see significant weight gain in men going on ADT, because it slows the metabolism, the lack of testosterone slows the metabolism. Most men put on weight, and some of them a very significant amount of weight, and then they can't get rid of it afterwards. So, I want to broaden that beyond the cardiovascular.

01:09:24

Moderator, RTI International

Thanks, **[Participant 4]**, for that point about metabolic concerns. **[Participant 3]**?

01:09:30

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

A quick note about the community we serve. I know we're talking about the Medicare community, which people think of 65 and older, but obviously there are some younger individuals who are Medicare beneficiaries, and especially in the hereditary cancer community and some of these higher risk populations that we're talking about, a lot of times we do see earlier-onset disease. The importance of convenience and functioning is, I think, even higher in that younger population. These are people who definitely are working full-time, often have young families, and I wanted to point that out. The other unique thing about hereditary cancers and those who carry inherited mutations is that they have higher risk of multiple types of cancer, and it's not uncommon for these individuals to have second or even third primaries. We know a man who carries a BRCA [BReast CAncer gene] mutation, for instance, is also higher risk of potentially male breast cancer and pancreatic cancer. Those with Lynch syndrome have exceptionally high risk of colorectal cancer, in addition to the increased risk of their prostate cancers, and so these therapies can have cumulative effects as well. And I'm just pointing out that aspect of the puzzle when we're talking about the benefit and risk profiles, and the cumulative effects, but also I think the different needs depending on the age of diagnosis.

01:11:28

Moderator, RTI International

Thanks, **[Participant 3]**. I heard a lot there. The cumulative aspect, the age aspect, as well as comorbidities, and including potentially inflated risk of cancer, other types of cancer, being added to the situation. Any other medical needs that we haven't already talked about before I move on? **[Participant 1]**?

01:11:52

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

Real quickly, it goes to what **[Participant 3]** was saying is the need for gene testing. You won't find the downstream linkages early enough unless you actually do that testing and actually put that out there for the offspring.

01:12:12

Moderator, RTI International

Thanks, **[Participant 1]**. I think that's an important point. I've heard about a lot of important aspects and needs of this condition. We've talked about mental health needs and sexual needs, and quality of life type needs, and the importance of symptom management, ease of use. Thinking about all of these different, various needs, I want you to reflect on your experiences with different treatments for prostate cancer. And for these next few questions, treatments could include Erleada, other medications for prostate cancer, or other types of available treatments for prostate cancer. Which important aspects or medical needs of prostate cancer are being addressed, at least partially, by existing treatment options? Which of those medical needs that we've talked about are being, whether fully or partially, addressed by existing treatment options? **[Participant 4]**.

01:13:19

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

I think one of the biggest issues beyond just the treatment management of the disease is this mental clarity issue and fatigue. I think most prostate cancer patients would agree on that. It's what we've learned through our surveys. And the one drug that does address that is darolutamide. And I just want to add, by the way, that we favor darolutamide solely based on patient response to it, and patient experience from it. And we received no sponsorship money from Bayer, and they've told us we cannot promote their drugs, and we've said, we do promote darolutamide because it has the best experience, and we will continue to do that because if it's available, and it's a lot more widely available today than it was two or three years ago. The men are so grateful to move to darolutamide. I would say that the one drug that really hones in and addresses mental clarity and fatigue, more than the other three ARSIs, is darolutamide.

01:14:50

Moderator, RTI International

Those mental acuity or cognition issues and fatigue, it sounds like, from your perspective, is being addressed by darolutamide, but not necessarily as much by some of the other alternatives. **[Participant 3]**, do you have something to add to that in terms of medical needs that are being met?

01:15:12

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

We heard similar feedback to what **[Participant 4]** expressed, so I was nodding my agreement.

01:15:20

Moderator, RTI International

Thanks, **[Participant 3]**. Any other comments on that? Important aspects or needs that are being addressed, at least partially, by existing treatment options?

01:15:30

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

I will say that oral therapy, I think, is super appealing and important to the patients, and it helps with adherence, which is which is huge, because we see so many individuals don't adhere to the regimen if it's burdensome, multiple pills a day, and very specific parameters around the ingestion of that therapy. I think Erleada makes it pretty easy.

01:16:12

Moderator, RTI International

Thanks, **[Participant 3]**. It sounds like in terms of the ease of use, that that is a need that is being met by existing treatments. **[Participant 4]**?

01:16:26

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

Another really burgeoning area, which we're very excited about, are the radioligand therapies, and especially the radioligand therapies being introduced much earlier in the treatment process, and I specifically want to reference two trials, LUNAR [^{177}Lu-Prostate-Specific Membrane Antigen Neoadjuvant to Stereotactic Ablative Radiotherapy for Oligorecurrent Prostate Cancer] and ANDROMEDA [Alpha-Emitting Radionuclide or Beta-Emitting Radionuclide With Metastasis-Directed Stereotactic Body Radiotherapy for the Treatment of Recurrent, Oligometastatic Prostate Adenocarcinoma]. There's a certain organization and a certain doctor that's doing some tremendous work, and we are actively literally today, last week, this week, next week, working with patients who are trying to get into these trials. These are men with recurrent disease. And I also did reference the NCI, which is also trying to figure out how to minimize treatment on recurrence. These two trials are looking at giving men with a recurrent disease a shot of radioligand therapy. Depending on the trial, it may be a beta particle, it could be an alpha particle, in place of putting them on hormone therapy. Which is huge. It's huge, because if they don't, the side effects from the radioligand therapy are relatively minimal. Dry mouth and stuff like that, but they pass relatively quickly versus going on hormone therapy for an extended period of time. And if these trials work as well as we think they might, it's going to be an incredible change in how we treat prostate cancer. Again, the importance of all this radioligand, radionuclide ligand therapy is huge. It's huge.

01:18:38

Moderator, RTI International

Thanks for sharing, **[Participant 4]**. And just as a preview, next I'll be asking about medical needs that are not being met by existing treatments, and it sounds like the reduction of certain symptoms is one that might be met at some point in the relatively near future if those things pan out. **[Participant 1]**?

01:18:56

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

I'm going to hold my comment for the next step that you just prefaced.

01:19:01

Moderator, RTI International

All right. Like I said in my preview a minute ago, which important aspects or needs of the condition are not being addressed by existing treatment options?

01:19:16

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

Let me jump in on that, because I think the elephant in the room is we don't screen enough, early enough. If you get it upstream faster, it basically wipes a lot of these needs that we've been discussing for an hour and a half, or whatever it is, right out the back door. And I can't say it will go away, but that's the elephant in the room. That's what we're not addressing, and that this could be a Medicare issue.

01:19:51

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

At least Medicare covers prostate screening, right? Which is better than some other bodies. I do think, and I'm sorry to jump in, but we don't as a country do a good job of risk stratification. I'm not going to say, when it comes to men, or individuals with prostates, that you can always know who's going to develop disease. But we do know that certain communities are higher risk, certain individuals are higher risk, and we're not doing a good job of identifying those people and making sure that they are getting appropriate screening. I think you're probably preaching to the choir here, I understand the movement away from over-screening as well, but you're right, the earlier we identify people, the faster we can get in there and treat it, and hopefully eliminate the need for some of these more intensive therapies.

01:21:07

Moderator, RTI International

Thanks, **[Participant 3]**. I've heard that early screening and risk stratification are two needs that are not really being met by existing treatments or processes. **[Participant 4]**?

01:21:21

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

Just to develop [build] on **[Participant 3]**, because I couldn't agree with her more. The misunderstanding when it comes to prostate cancer is that the PSA test is about information, not treatment. And we don't screen enough people because we think the PSA test leads to overtreatment. It's not the PSA test that leads to overtreatment, it's what the doctors do with the information that leads to the overtreatment. We always say it at AnCan, and have for many years, that PSA is about information, not treatment.

01:22:10

Moderator, RTI International

Thanks, **[Participant 4]**. Any other medical needs, or important aspects of managing or treating prostate cancer that are not being addressed currently? Before we start wrapping up today's discussion, I just want to turn to **[Secondary Moderator]** for a moment, see if there are any other questions for the group?

01:22:46

Secondary Moderator, RTI International

No further questions. Thank you, **[Moderator]**.

01:22:48

Moderator, RTI International

Great, thanks. Like I said, you all have provided a lot of really helpful feedback, and **[Secondary Moderator]** and I really appreciate it. This event is nearly over. Before we part ways, I just want to give you an opportunity to summarize your thoughts on the importance of Erleada for patients, or to raise any topics that you feel were not adequately covered by our discussion today. Do you all have any final thoughts about prostate cancer, Erleada, or other medications that treat prostate cancer that you feel are important to share with CMS? **[Participant 2]**?

01:23:32

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

I wanted to underscore something that Administrator Oz said at the top of the hour that I don't think we really spent a lot of time on, and I think we're probably all—well, I can't speak for others. I think there's a lot of alignment there about the financial stressors of having to make trade-offs and make decisions about being able to afford treatment, and so I wanted to share that what we do know, what we do hear, is that cost remains a primary barrier with about 18% of Medicare beneficiaries reporting problems paying for it, and across all of our helpline calls received in 2024, financial stressors like insurance challenges, medical bills, and household expenses, like Administrator Oz mentioned, they're common. And that's an initial reason, quite honestly, for people reaching out to our helpline. And I'm mentioning that as it relates to prostate cancer patients, because our 2021 CER [Cancer Experience Registry] data shows that of the 107 prostate cancer patients, more than half, 52%, reported at least spending $100 monthly in out-of-pocket cost, and 16% said they spent about $500. We underscore and agree with Administrator Oz that there are financial pressures that can be overwhelming and also have an impact and effect on someone that is undergoing treatment for prostate cancer, as well.

01:25:10

Moderator, RTI International

Thanks, **[Participant 2]**, for those comments on access and affordability. **[Participant 3]**?

01:25:15

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

I mentioned financial toxicity earlier, same thing, affordability is huge. I think one of our concerns is that despite a lot of efforts to lower patient out-of-pocket costs, we're not actually seeing that trickling down to the patients at this point, despite efforts from at the top, and there are various reasons for that. I think, importantly, we want to make sure that, whatever happens in the way of price negotiations and other things that the drugs remain accessible to patients, so that they have choices, and that we have to think about value beyond clinical endpoints, as we've talked about, maintaining independence and that ability to reduce time in infusion centers and other things. And finally, I think we see the and options to switch medications, even in a longer-term picture, because if they don't have options and they may not adhere, then ultimately it increases the need for additional therapy in the future, potentially hospitalization and later-line therapies, and so we have to look at this holistically. That's my closing thoughts.

01:27:01

Moderator, RTI International

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

01:27:05

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

Financial toxicity, clearly a major issue, but I also want to add, it's nowhere near as great an issue today as it was a couple of years ago with the $2,100 limit that can be stretched over 12 months and we're so grateful for that. And I want to thank CMS and for that, for the introduction of that limit. Yes, $2,100 a year is still a significant amount of money that many cannot afford. But we are not hearing the unaffordability, for an ARSI, and so I'm going to focus on ARSIs, because that's what Erleada is. Abiraterone is now generic and has a higher cost but is available at a pretty cheap rate. The other issue with abiraterone is that it can be taken with food, and you need a quarter of the dose, which Johnson & Johnson never sought approval for, understandably. Men can deal with a quarter dose, take it with food, and have exactly the same impact. As far as apalutamide and pricing is concerned, we honestly look at apalutamide and enzalutamide as being biosimilars. There's just not a lot of difference, and then enzalutamide, I think, is going to come off patent very soon. But there's really very little difference, so I think for CMS, they've got to be looking at where they put their dollars. Do they need to subsidize both of them? Are they really different? Because we're not sure that they are significantly different. We don't see men switching from enzalutamide to apalutamide and experiencing much of a difference, except the odd person, because no drug affects each man exactly the same way. The darolutamide is definitely a much better drug. I think hands down, and I think any research evidence will support that statement. The bottom line for us is that whilst apalutamide pricing is important, there's always the fallback on enzalutamide. Acknowledging that people, like **[Participant 1]**, have trepidation over that because they're used to a particular drug and they don't want to be forced to change, but there just isn't a lot of difference between those two drugs.

01:29:56

Moderator, RTI International

Thanks, **[Participant 4]**. **[Participant 1]**?

01:29:59

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

I would say, if Medicare could recognize some of the issues that we're discussing here that are interpersonal, that are unique, that can be assisted and mitigated by some of the things we've discussed. Wouldn't it be cool if Medicare put that out there on their site somehow? To say, hey, "find a support group." [Or] "we've found that 85% of men with prostate cancer really wish they had [XYZ]." We have 22% of people with breast cancer, or whatever it happens to be, talk to your caregiver, talk to people, and because there are people out there who want to help you, as opposed to, I suspect that most of the people are going through this alone, whether it's prostate cancer or whether it's any kind of cancer. And that's maybe a silly thing to throw into this conversation, but because of some of the people who are on the call, I think that could be something that could be relatively easily done on the website. It's a fairly robust website as it is.

01:31:17

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

I don't think it's silly, From the perspective that we're coming from, we support people impacted by cancer, and we hear "The one area that I wish was factored into the care decision was my mental health." That comes up a lot. We're here to focus on prostate cancer, I will respect that, but it comes up in the mental health needs, and what was needed there, and the support, and not feeling alone. Because again, we're all talking about the whole person. And the whole person extends beyond just the treatment, but quality of life, treatment goals, what matters to them. Hope. I do think that while that might not directly relate to the purpose of this conversation, it does give some context to CMS that we're talking about people. And what people need to feel supported. And if having some resources to that could help someone feel less alone, that's why we are here, to help those individuals.

Closing Remarks

01:32:19

Moderator, RTI International

Thanks, **[Participant 2]**, for piggybacking on that. I've heard final thoughts related to access and affordability, the importance of access to multiple options, the importance of that interpersonal aspect of things, and the mental health needs. And I appreciate all of those thoughts. Any other final thoughts before we part ways? Thank you so much for participating in today's event. 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 Medicare pricing for Erleada. CMS staff have been listening to the roundtable and will be able to bring your perspective back to their teams. **[CMS Staff]**?

01:33:14

CMS Staff

On behalf of CMS, I would just like to echo what **[Moderator]** said. This was a really thoughtful and informative discussion for us, and we're going to take everything that we've learned here back and to help us with the negotiations, so thank you.

01:33:27

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

Let me throw out there that if you guys want to reach out to me, feel free.

01:33:32

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

I was just going to say the same thing. If you want to reach out for clarification, that's fine.

01:33:39

Moderator, RTI International

Thanks, **[Participant 4]**. If you all have any questions following today's session, you can submit them to the mailbox at IRARebateAndNegotiation@cms.hhs.gov with the subject line Public Engagement Events. Thanks again for your time today. I hope all of you take care. We really appreciate your time.

===== 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 patient who has experience with the selected drug or the conditions treated by the selected drug; representative of a patient advocacy organization

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

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
No	Direct assistance preparing your remarks from someone who is NOT a family member, caregiver, friend, or your health care provider
No	You, your spouse, or an immediate family member is employed by or holds equity interest (stock or ownership interest) in excess of $10,000 in a company or related association with direct or indirect interest in the Negotiation Program
Yes	Any other personal or professional relationship or interaction with a company or related association with direct or indirect interest in the Negotiation Program that may be considered a financial conflict of interest

Participant 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
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