Transcript: Biktarvy Roundtable Event, April 6, 2026, Medicare Drug Price Negotiation Program Public Engagement Events

This transcript was lightly edited for readability.

Introductory Remarks

Moderator, RTI International

Thanks again for joining, everyone, today. My name is **[Moderator]**, I'm from RTI International. My colleague **[Secondary Moderator]** is here with me today as well, and you may be hearing from her during today's discussion. The Centers for Medicare & Medicaid Services, which I'll call today by their acronym CMS, is convening this patient-focused roundtable event, and others as part of the Medicare Drug Price Negotiation Program. The information shared during these roundtable events will help CMS understand patients' experiences with the conditions and diseases treated by the selected drugs, patients' experiences with the selected drugs themselves, and patients' experiences with the drugs that are used to treat the same conditions as the select a 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 CMS may consider in negotiating Medicare pricing with the manufacturers of the 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 Biktarvy, including HIV (human immunodeficiency virus), with Biktarvy itself, and with other medications for the same condition. 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 related to or are not directly focused on the patient experience, we ask that you send that input to the mailbox at IRARebateandNegotiation@cms.hhs.gov, instead of sharing it in 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 video from CMS leadership so that you can hear from them about how much they value your time and input today.

CMS Remarks

00:02:07

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.

00:03:59

Moderator, RTI International

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

00:04:09

CMS Staff

Welcome everyone! I'm **[CMS Staff]** from the CMS Drug Price Negotiation team. There are other CMS staff on the call today as well. We work on the policies for getting public input and negotiating Medicare drug pricing. So on behalf of CMS, I want to thank you for participating today. We are looking forward to hearing about your experiences during this roundtable discussion. I'll just note that we are going to go off camera now so you all can focus on the discussion.

Housekeeping

00:04:42

Moderator, RTI International

Thank you, **[CMS Staff]**. Before we begin, I just want to go over a couple housekeeping items and ground rules, just so everyone knows what to expect.

First, if you get disconnected, please attempt to rejoin. If you have trouble reconnecting, please reach out to the email address shown here, IRADAPStechsupport@telligen.com.

Regarding privacy, this discussion is not open to the press or 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, including your employer's name, the city you live in, names of schools you intend and so forth, during the discussion. Following the event, CMS will prepare transcripts that have participant names and identifying information removed, and those will be made available to the public.

Regarding 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.

For participation. First, we hope that you will contribute your perspectives throughout this session. However, if questions arise that you do not want to answer, that is totally okay.

Please minimize background noise by silencing your cell phone and other devices if you've not already done so. Also, please be sure to mute yourself when you're not speaking. Thank you in advance for keeping your video on throughout the discussion.

Just a note about timing. We have two hours set aside for our discussion; however, it's possible that we may finish a little early and may not need the full two hours for our discussion. If that happens, we can let everyone go back a little bit early. I do have a discussion guide in front of me to help me keep track, and we do have a lot of topics to cover, so I may need to redirect our conversation or cut our conversation short at times to make sure that we are able to cover everything, and that all participants have had enough opportunities to share their perspectives.

Regarding breaks, if you need to step away briefly for our discussion, that's totally okay. Just turn off your camera and microphone and rejoin when you're able to. You don't need to tell me when you'll be leaving your computer, just try to come back as soon as you're able to.

I am going to ask that everyone just try to speak one at a time. I may occasionally interrupt you if one or two people are talking, in order just to make sure I can hear everyone. Please use the raise hand function in Zoom to indicate that you would like to speak, and that will help us know when someone would like to add to discussion. I know that during the introduction, they showed you how to use the raise hand function.

Finally on chat, while we are hoping everyone will focus on our oral discussion, you can also add any comments that you have into the chat, in case 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 you're responding to in any chat comments.

Any questions that folks have? Unless anyone has questions about what I reviewed, let's go ahead and get started. I want to first get a chance to get to know everyone, so if you all could introduce yourselves, and what I'm going to ask you to tell me is your first name, and then tell me whether you're sharing your experience as a patient, as a caregiver, as a patient advocate, or possibly multiple hats.

I'm going to start with **[Participant 1]**.

Discussion

00:08:34

Participant 1 (registered as a patient)

Hi, I'm **[Participant 1]**. I've been living with HIV since 2006. I've been a witness to the AIDS [acquired immunodeficiency syndrome] plague for years, and I'm serving as a patient, as well as a patient advocate.

00:08:48

Moderator, RTI International

Wonderful. Thank you, **[Participant 1]**. Next, I'll go with **[Participant 2]**.

00:08:54

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

Good morning or afternoon, everybody, and thanks very much for having us here. My name is **[Participant 2]**. I am a patient advocate for a Federally Qualified Health Center [FQHC] that serves about 19,000 unique patients, about 3,000 of those are people living with HIV.

00:09:16

Moderator, RTI International

Wonderful. Thanks, **[Participant 2]**. **[Participant 3]**.

00:09:21

Participant 3 (registered as a patient)

Hi, good afternoon, my name is **[Participant 3]**. I've been living with HIV since 2016, but I'm also serving in a patient advocacy capacity as well, as I work in the policy space for a national HIV organization.

00:09:39

Moderator, RTI International

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

00:09:43

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

Hi, my name's **[Participant 4]**. In the early days of the epidemic, I was a caregiver, and I've been an advocate in the HIV space. I run a national advocacy organization focused on HIV. For around 30 years, I've been in the fight.

00:10:03

Moderator, RTI International

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

00:10:08

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

Hi, my name is **[Participant 5]**. I am living with HIV for the past 18 years. I'm a patient advocate and policy analyst as well, and I've also been a caregiver to a person living on Medicare.

00:10:21

Moderator, RTI International

Thank you so much, **[Participant 5]**. And then finally, **[Participant 6]**.

00:10:25

Participant 6 (registered as a patient and representative of a patient advocacy organization)

Hi, thanks, **[Participant 6]**, here. Living with HIV for 34 years, as a patient and a patient advocate.

00:10:36

Moderator, RTI International

Wonderful. Thank you, **[Participant 6]**. Appreciate you coming. All right, so to start us out with, I want to talk a little bit about the patient's experience with HIV. Thinking about the different ways that HIV can affect patients' lives, what would you say are the most important aspects of HIV to have managed or treated? And this could be short-term things, or long-term outcomes, and so forth.

00:11:04

Participant 6 (registered as a patient and representative of a patient advocacy organization)

I think the quality of life is the most important thing.

00:11:11

Moderator, RTI International

Talk to me about quality of life, **[Participant 6]**.

00:11:15

Participant 6 (registered as a patient and representative of a patient advocacy organization)

And of course, nowadays, longevity also.

00:11:20

Moderator, RTI International

And **[Participant 6]**, tell me about quality of life.

00:11:23

Participant 6 (registered as a patient and representative of a patient advocacy organization)

Being able to get up every day without having to run to the bathroom and sitting there for three hours and taking 25 meds, I take 25 meds anyways, but being able to be a productive member of society, and to go about daily lives like everybody else. And feeling good.

00:12:29

Moderator, RTI International

Anyone else want to talk? Again, we're talking a little bit about the ways that HIV affects people's lives, and what are some of the most important aspects of the condition to have managed or treated. Yeah, **[Participant 5]**.

00:12:55

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

I would say, the important aspect of just managing the disease is being able to consistently access and keep medication that you find that works for you. Because so many times over the years, because of various reasons, because HIV is the kind of disease where it's not exactly predictable, and it's very person-specific and you have difficulties at times finding medications that work with you for long periods of time, and it's really good when you find something that you can actually stick with. Myself, the past 18 years, I've had to switch about seven different times for various reasons because different medications have done things to my body that, it started off okay, but then eventually you find out you're being harmed. And once you actually find something that works for you consistently, it's nice to be able to stick with it and not having issues with having to get off of it.

00:13:53

Moderator, RTI International

And you mentioned earlier at the very top about keeping access to drugs. Can you tell me a little bit more about what you meant by that?

00:14:01

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

The concern is whether you have insurance or don't have insurance. Specifically, you do have insurance. There are times where your insurance may change because of your job or insurance formularies may change, where your tiers of your drug have been moved to the point where you all of a sudden either have problems affording it, or not be able to get it at all, and you're always worried that something's going to happen to endanger your ability to consistently get your medication. And even when you have the same in policy for several years, changes happen where what you have to pay for it can change, and sometimes it can change drastically. I've experienced that before as well, where there are times where I needed assistance, then there were times where I didn't need assistance, and that was no change to anything I did. It was specifically just because of the changes in insurance policy and things of that nature.

00:15:00

Moderator, RTI International

All right, **[Participant 1]**.

00:15:06

Participant 1 (registered as a patient)

What I would start off by saying is that, as a person who was around in the '80s and '90s when HIV was a death sentence, what really worries me now is where we've actually evolved to the point

when, I've actually been a witness to the point where I've seen where we were with no medications, where we finally had some medications. Medications that didn't really do very much for us in terms of keeping us in a healthy condition. And then now we've gotten to the point where we can consider HIV to be a chronic condition, almost in the same way as we think of things like diabetes or heart disease. But we're actually just a medication away, just not having adherence to our medications will put us right back on that track of a death sentence. When I think about the medications that come under consideration here, for drug price negotiation, what really gives me a lot of fear is that we could actually be in a position where, because of being focused more on the cost of the medication, that we lose sight of the health of people who are taking the medication and put them at risk for being in that same death sentence spiral that we were 40 years ago. For me, it's a matter of why are we tampering with a medication that has to do with it, not just something that can ordinarily be a chronic condition, but actually it can lead to a death sentence if it's not taken properly.

00:17:02

Moderator, RTI International

Yeah, **[Participant 4]**.

00:17:04

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

Why don't we have **[Participant 3]** go first, I think? People living with HIV should go first.

00:17:10

Moderator, RTI International

Okay, **[Participant 3]**, go ahead.

00:17:11

Participant 3 (registered as a patient)

One of the things I want to lift up is just how HIV intersects with other comorbidities. One of the things that I'm concerned about, as well as cardiovascular health, and liver health, and kidney health, and how that intersects with HIV as well. And I've been grateful that the medication that I've been taking has been great, so far, and its impact on my other health systems of my body. And I think it's important that CMS supports the provision of medications that are effective and that have very low side effects when it comes to these comorbid conditions as well. And it's something I'm even more conscious of the older that I get, because people living with HIV also experience other medical conditions as well, not just HIV.

00:18:15

Moderator, RTI International

Thanks, **[Participant 3]**, and we'll definitely touch more on the treatments themselves, so don't worry, we'll get to that. **[Participant 4]**.

00:18:25

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

Thanks, and I do think some of the people living with HIV have already said a lot. They have the experience, and just as an observer, and maybe just to reiterate some of the points, but as someone commented, they took so many pills before, and they didn't work. And you had to take it at certain times, and with food, or without food, and you had so many side effects. And now we have single tablet regimen, and you could take it anytime, once a day. Adherence is still a problem, and so I think it's a lifetime commitment, HIV. And, so I think if we could get longer-acting drugs, that would be helpful for adherence purposes. I think someone already talked about the side effects, and they were bad in the old days, and people still have side effects, but there's better drugs these days. And of course, all the interactions with the comorbidities, as **[Participant 3]** talked about. And then, people are living, **[Participant 6]** started off with that. But one of the biggest concerns for HIV therapy is that people build up resistance to the medications, and when you build up resistance, you're resistant to that drug, and it doesn't work, and you can get sick, and you also build up resistance to all drugs in that class. And, we're going to get into specifics of the drug today, but in the ten years they have not found anyone who is resistant to this drug versus others. And that is a significant, and also, the other thing with resistance is if you pass the virus on to someone else, you pass that resistance on to that person, which it makes it harder to treat for others, as well. The other thing that's really important, I know we're talking about drugs today, but what's important to people living with HIV is also the whole support system. It's the health care system. And there's still so much stigma associated with HIV today, and so I think having people live healthy lives, and it helps with the stigma, and it helps people live a very, hopefully, a good quality of life, both mentally and physically.

00:21:19

Moderator, RTI International

Okay, thanks, **[Participant 4]**. And again, just for a moment, we'll focus more right now on the condition and how it affects people's lives, but we'll definitely talk about treatments. That's a big focus today. **[Participant 2]**.

00:21:30

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

Yeah, thanks. I want to say ditto to everything that everyone has said about this drug. Single tablet regimen, easy to take, very few drug interactions, actually very safe for people with renal insufficiency, which is incredibly important, and this drug is especially important for older folks living with HIV. Of our patient population, about 50% or more are over 50, so many of these people have been on many drugs over the years, suffered a lot of side effects from them. Biktarvy is incredibly efficacious. About 95% of our patients who are on Biktarvy reach viral suppression, which is great news for them. It means they're healthy. It's also great news because, as we all know, undetectable equals untransmissible. The other thing I wanted to add about Biktarvy, which I think is important to note, is anyone who takes pills knows you forget to take pills. And Biktarvy is very forgiving about missing pills, so if you miss pills occasionally, it has no effect on your viral load or your disease state, and you resume when you remember. Most people forget for a day or two, then they're back on it, but I just wanted to bring that up.

00:22:55

Moderator, RTI International

Thank you. And again, just for a moment, we'll just focus on HIV just for a second. We'll talk about the treatments here in a moment. I want to talk a little bit about how HIV does affect people's quality of life, and **[Participant 6]** had brought this up a little bit about how it can affect quality of life, in being in the bathroom, for instance. How does HIV affect people's quality of life? Yeah, **[Participant 2]**?

00:23:20

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

Let's go to the people who are living with HIV first, and then I'll come back to this.

00:23:29

Moderator, RTI International

Okay, **[Participant 1]**?

00:23:47

Participant 1 (registered as a patient)

Thanks. I was nearly 44 when I was diagnosed with HIV, but I was very familiar with HIV when I was younger, having had friends who had contracted it and passed away, and having a partner who was HIV-positive when I met him. And him being on early medications, HIV was a different way of coming out for me. I'm a Black man, and I think as a young person, I was dealing more with racism. I think it was acknowledged that I was HIV-positive, that I was a gay man. I had to deal with homophobia. With HIV, it was the stigma that's related with the disease. And so, that probably led to my own late treatment and diagnosis, because even though I was active in the HIV community and helping other people stay negative, I neglected my own health for a while, and it wasn't until I was diagnosed with pneumonia, I had a cough that just couldn't go away. I went to the doctor's office and they checked me into the hospital, and I found out I had about 40 T cells. And, that was a shock. I didn't realize I was that close to dying and this was when we had pretty decent medications. My story is one that gets replicated every day. There's still people like me who don't get diagnosed, aren't getting treatment, until it's almost too late. And, so, the medications are great, they've gotten better. For me personally, HIV, it still has a lot of stigma attached to it. I work a lot with aging populations. Oftentimes, people who are over the age of 50, their primary care physicians aren't asking them about whether or not they're susceptible to HIV. They're not asking them if they've been tested for HIV. They could actually end up just in the same boat that I was several years ago, 20 years ago, and end up with a pneumonia diagnosis that has 40 T cells attached to it, and just because a primary care physician isn't asking them if they've been tested. In this country now, 10% of the new diagnoses of HIV are among people who are age 50 and older. This is an important issue, obviously, for people who are on Medicare, because there are people who may not even be diagnosed and don't even know it, who are over the age of 50 who are Medicare patients, and it's because their primary care physicians are just not assuming that they're at risk.

00:27:10

Moderator, RTI International

Thanks, **[Participant 1]**. **[Participant 6]**.

00:27:13

Participant 6 (registered as a patient and representative of a patient advocacy organization)

Being 34 years HIV-positive, I started off with AZT [azidothymidine]. So that was the kicker back then. And there was no quality of life back then. It was just, you take your pills, you deal with whatever side effect they gave you. And along the way, as the medicines got better, so the side effects got a little lighter, and a little lighter, and a little lighter, to until we got to Descovy and Truvada, and now we got Biktarvy, which I've been on since 2019 and it's working great. It's kept me undetectable. Side effects are nothing compared to the other ones. My quality of life has improved. It's gotten better, but of course, I have 34 years of catching up that I have to worry about also, with the comorbidities that have arisen, quality of life has been good, and Biktarvy, I get up every morning to make sure I get my Biktarvy in before anything else. The other 25 drugs that I do take, but quality of life is much better because of Biktarvy. And thanks.

00:28:39

Moderator, RTI International

[Participant 3].

00:28:41

Participant 3 (registered as a patient)

I'll just mention that as someone that was diagnosed in 2016, my experience was one where I started a medication and I was undetectable pretty quickly, and I didn't experience a lot of what some of some other people on this call might have experienced in decades past. But what I will say is that quality of life should also consider just the everyday experiences of people living with HIV. How HIV intersects with mental health. I know that as a Black gay man, navigating my HIV diagnosis was a very difficult situation, to say the least, because of stigma, and also I was a young person at the time, and really didn't have community, and that's the experience of many young people as they're diagnosed with HIV. There's a certain level of isolation that many young folks experience if they're not in the community. So mental health is a major aspect of quality of life that should be centered as well. And then I'll also say it's tough to separate out one's experience as a person living with HIV and the broader experiences of what it means to be Black and/or queer in the United States, especially today, when we're dealing with racism, homophobia, all of these isms, and so I say that to say that, all of these other systems, experiences also intersect with how people living with HIV experience the world. So it's not just solely medical access or interventions. It's all of these other aspects that intersect with our world and lives as well.

00:31:02

Moderator, RTI International

[Participant 5], go ahead and then we'll start talking about the medications.

00:31:11

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

One thing to answer your question as well, is living with HIV, where whether you've had it for a long time or were recently diagnosed, but living with HIV in general, it's not the kind of condition where every day this happened to me because of HIV. HIV can affect your body in so many different ways and cause so many different issues, and when you're living with HIV, the concern about wanting to

make sure your HIV is well controlled is because at least if your HIV is well controlled, when something's going on, you don't have as much of a question of, oh, is this HIV-related, or is this something else? And then when your HIV is not well controlled, it just causes all kinds of issues, and you're wondering what's going on in your body, interacting with the HIV and things of that nature. So that's why it's so important for people to be well controlled.

00:32:07

Moderator, RTI International

[Participant 1]?

00:32:11

Participant 1 (registered as a patient)

Before we move to treatment, I just want to say one other quality of life issue that I think is important. One of the things, before we had this thing called U=U [Undetectable = Untransmittable], which is undetectable equals untransmittable. One of the things that was stigma-related was the idea, and it migrated. In the early days of HIV/AIDS, there was this whole public health campaign that we needed to do to tell people, from, Princess Diana holding babies that had HIV/AIDS, whether or not we could touch people, or use the same toilets, or whether or not it was so communicable that if I breathed on you, that you would get HIV. And so then, people started getting more comfortable with people who are HIV-positive and didn't think about that. But then, until we got to the point where we could actually get our viral loads down to undetectable, that, I think, was a real marker for us, and it may not have been for people who are in the general public. But for our own quality of life, for my own identity as a person who is HIV-positive, for me to be able to think that somebody is not going to get HIV from me because my viral load is undetectable. That lifted a big weight off of my shoulders. So when we do get to the treatment discussion, if my treatment changes, and then it gets to the point where I cannot have that peace of mind about being undetectable, I think that would change things for me, and certainly my quality of life.

00:34:07

Moderator, RTI International

Thank you for that, **[Participant 1]**. And sorry, **[Participant 2]**, just for the sake of time, I do need to move on to the talking about the treatment. So we'll use the chat window for this part, and if everyone could write down in the chat window what medications, if any, have you yourself or people that you advocate for taken currently or in the past for HIV. And again, you can just type these into the chat window. And I realize there might be a lot, so if you just want to do maybe just a few, a handful, that's okay, too. Especially some of the newer ones, I would say, focus on that. So again, medications that you, your loved ones, or patients you advocate for have taken in the past, or currently take for HIV, and you can just put these in the chat window, and just hit send. So I see Biktarvy, Descovy, Truvada, AZT, and some others. And, Genvoya, Dovato, Atripla, Dovato, Tivicay, Dovato, Biktarvy, Descovy, Cabenuva. Great. Thank you so much. Thanks for sharing those medication names.

For the next questions, I want to note that we want to hear about your experiences that you and your loved ones, or people you advocate for, have had with Biktarvy, and also other medications used to treat HIV, so just not Biktarvy, but the other drugs as well. When you're discussing some points, one thing that would help me is that if you're talking about a certain drug, mention that drug,

so that I know what drug you're referring to. It helps me later understand some of the benefits. My first question for you all is, what benefits have you, your loved ones, or people you advocate for experienced with these medications for HIV? So again, some of the benefits you've experienced with some of these medications. **[Participant 6]**, and again, **[Participant 6]**, be sure to tell me which medication you're talking about.

00:36:22

Participant 6 (registered as a patient and representative of a patient advocacy organization)

I'm on Biktarvy now, and I think the benefit, it's given us life. It's quality, a better treatment. The other ones, I was on the Descovy and the Truvada, and I had trouble with kidney issues, and other liver issues, so they had to put me on Biktarvy. Before that, we go back to AZT and stuff like that, where life was unbearable for most of the time with that. But nowadays, with Biktarvy, there is no side effect, you can actually live somewhat of a normal life now. But you have to still understand the fact that you still have HIV, and it's still there. The stigma's still there, as **[Participant 3]** said. The stigma's out there. Thanks.

00:37:25

Moderator, RTI International

Thanks, **[Participant 6]**. Other benefits that you've experienced, **[Participant 3]**?

00:37:33

Participant 3 (registered as a patient)

I'll say that one of the major benefits is that I can take my medication, Biktarvy, and not even think about it, after that point. I just take one pill a day, and that's it. I don't have any side effects whatsoever. I was previously on a different medication, called Genvoya, and I believe with that medication, I had to take that with a meal, or it was recommended to take it with a meal, and at the time I was a college student that had a very hectic schedule, you know how that is, sometimes you don't actually eat meals, so it really didn't fit with my life. And it was just easier for me to be on a medication where I didn't have to think about all these other factors. I could just take it and move on with my day, and that's what my life is like right now.

00:38:33

Moderator, RTI International

What about some others, benefits have you experienced with Biktarvy or other drugs? **[Participant 4]**.

00:38:38

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

I can't add to all the experiences on the video, but one of the main objectives of ending HIV and treating HIV is to test people. And to bring them into treatment as soon as possible. And sometimes with other drugs, you have to do resistance testing, like I talked about earlier. You have to see if you are resistant to a drug or not. You have to see if you have hepatitis B or not. And other tests as well. With Biktarvy, you don't have to do that because there is no resistance. Yeah, you can use it for people with hepatitis B, like I have, and other drugs you can't. And, you can start immediately. You don't have to lose people when they get tested, take results, and come back and start treatment.

This way, you can start treatment immediately, and I think it's the only drug that you can do that. Also, if you fall out of treatment, it's the only drug that you can restart as well.

00:40:04

Moderator, RTI International

Thanks, **[Participant 4]**. **[Participant 2]**, go ahead.

00:40:30

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

I've been doing this work for over 40 years. I was a case manager during the bad years. I was a benefits specialist when antiretroviral treatment came in 1996. And so what I saw in front of me was people struggling with drugs that really were devastating their lives, let alone the HIV. AZT, for instance, there were people who just couldn't tolerate the side effects. And this went on and on and on and on. When antiretroviral treatment came on in 1996, what I found was that people who had been calling me, trying to figure out if they qualified for disability benefits, or were on disability benefits suddenly were calling me to see if they could return to work. And I think this speaks to the efficacy of the drugs, also the quality of life on these drugs. Biktarvy, as **[Participant 4]** said, as **[Participant 3]** said, you can take it any time. I can remember a time when people wore watches with timers on them so that they could time their drugs during the day. Biktarvy is a whole other story. Again, on resistance, a whole other story. Again, on renal conditions, a whole other story. I cannot say enough about how this drug has changed the quality of life for people who are on this treatment.

00:41:59

Moderator, RTI International

[Participant 6]?

00:42:01

Participant 6 (registered as a patient and representative of a patient advocacy organization)

I think, one of the things we leave out is relationships, too. It affects your relationships, it affects your sex life, your love life, it affects everything. But, being on Biktarvy and being undetectable, it eases that effect, it helps ease things in. We know that we're not going to spread it, nobody's going to come chasing after us the next day, so to speak, so but it does, it affects every aspect of your life, and not just whether I feel good, it affects what's going to happen between the relationship with my husband who I've been with for 33 years. Thanks.

00:42:58

Moderator, RTI International

Thanks, **[Participant 6]**. **[Participant 1]**.

00:43:01

Participant 1 (registered as a patient)

When I was diagnosed, I started on a three-drug regimen, including Truvada. And Norvir, and something else. And I wasn't really happy with that, but that was the state of things, and also I think it was because of my early diagnosis that that was recommended.

But then after Truvada I went to Descovy, and I also did a clinical trial with Dovato at one point, before returning to Biktarvy. And, throughout that, I was always concerned about whether or not I was going to develop resistance at some point. But that didn't develop, but, I do say that Dovato got me a little "blippy." So I was happy when the trial was over so that I could go over to Biktarvy again. And, since I've been back on Biktarvy, my viral load has stayed undetectable.

00:44:43

Moderator, RTI International

Any other parts on the benefits that people have experienced? Yeah, **[Participant 5]**.

00:44:51

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

I'm personally not taking Biktarvy right now. I'm glad, actually, **[Participant 1]** mentioned Dovato. I'm currently taking Dovato. But I know two friends personally who are taking Biktarvy, and other people that I've talked to about it, and one of my friends who just turned 61, he got moved to Biktarvy because he was having other drug interactions with other pills he was taking for other medical problems. And ever since he's been on that, he hasn't had any kind of interactions, and it's kept his viral load down, because the problems he was having, drug interactions with stuff he was taking and his viral load wasn't staying consistently unsuppressed. So it's been working for him for that aspect. Another person I know, they also, with the same reason, they got switched to Biktarvy because they were having problems with other medications they were on, and interactions and things of that nature, so that's it's been working for them.

00:45:46

Moderator, RTI International

And **[Participant 5]**, in the chat, I think you mentioned also that you had tried Tivicay, is that right?

00:45:52

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

Yes.

00:45:53

Moderator, RTI International

How does Tivicay compare to Dovato, or what you know about Biktarvy?

00:45:59

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

I personally had a very bad experience with Tivicay, because at the time Tivicay wasn't, you can't take it alone. So I was taking, just several years ago, I was put on Truvada with Tivicay, and both together, I was taken off of them quickly, in about a month and a half, I think it was, because both of them were causing me to have liver and kidney problems; my blood work was awful. My doctor immediately took me off of them.

00:46:32

Moderator, RTI International

For those who have experienced more than one medication for HIV, how do the benefits of different medications differ, if at all? One thing I heard is frequency, how often you have to take it, for instance, or how many pills you have to take. **[Participant 5]**?

00:47:00

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

I'll say that it's the experience of the medications varied greatly, like you said, some of them you have to take with food, some of them you don't take with food, some you should take at night, some you should take in the morning. There's a lot of variance. It's more helpful when you have something that doesn't have a lot of stipulations of when you can or cannot. Because I can't remember if it was oh, Complera was another medication I took that I didn't put in the chat. But there's some medications, I think, like **[Participant 3]** mentioned, you have to take with a meal that has a certain amount of calories, and that just complicates when you're going to take your medication. So even if you're someone who, say you have food insecurity or, your work or just your lifestyle is not conducive to that. It's better when it's just easy to take your medication, as far as, basically what I'm trying to say. And you have a bunch of stipulations and things you can and cannot do, or have to worry about, what you can or cannot eat, or when to take it, and things of that nature, or worried about if you miss a dose, how drastic it is going to affect you, because some medications, if you don't take them on time, and the concentrations build up too much in your blood, for example, then you have side effects. And then or some of the cases are more sensitive to the concentrations if it gets too low. So it's just better when you have a medication that's easy to take, easy for your body to deal with, that interacts with anything else you might be taking for other conditions, and things just work well, that it's better when you have something that's easy to deal with, and that works with you, and your body and what your needs are.

00:48:46

Moderator, RTI International

Great. Thanks **[Participant 5]**. **[Participant 4]**.

00:48:49

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

Speaking as a patient advocate. I think we should focus on other populations, too. We're a very male-oriented group here, but Biktarvy is the only HIV drug, I believe, that's recommended for pregnant adults, and then also it's recommended for children, as well. I already talked about hepatitis B as well, some of these other drugs. And by the way, it's really difficult as a patient advocate to just talk about one drug. We're not in that business. I think we're drug agnostic, but we know that's your mission and the goals and, of the legislation to look at one drug, but I just have to say, speaking for a patient advocate, we don't really focus on specific drugs, so I feel a little uncomfortable, but, we do have to respond to your questions. And I think, **[Participant 2]** and others talked about the older populations as well, and people living with HIV and this is a drug that can be well tolerated for people with kidney issues, diabetes, some of the other issues that people get when they're getting older.

00:50:20

Moderator, RTI International

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

00:50:24

Participant 1 (registered as a patient)

I just want to actually say again, too, about the importance of the one pill a day regimen, because as a person who's aging and somebody who has comorbidities, I'm now taking medications for cholesterol, for high blood pressure, for a whole bunch of things. Even if I went back to my prime, the first regimen I had 20 years ago, which probably still is in existence. Which probably still would probably create more issues for me in terms of bone density issues or kidney issues. Those medications are still out there, but there's also they're three, I was taking three at a time. So now, when I'm already taking all these other medications to go back to a regimen where it's not one pill a day, it would be just as crazy for me.

00:51:31

Moderator, RTI International

[Participant 6], then I'm going to turn to challenges. Go ahead, **[Participant 6]**.

00:51:34

Participant 6 (registered as a patient and representative of a patient advocacy organization)

Yeah, I was just going to say, one of the things that we didn't really talk about is state of mind with Biktarvy as a quality of life. Being on Biktarvy you know that you have that extra protection that's there, so it does help with your state of mind, also.

00:51:53

Moderator, RTI International

Tell me a little bit more about that, **[Participant 6]**, about state of mind and extra protection.

00:51:58

Participant 6 (registered as a patient and representative of a patient advocacy organization)

I know that, I can go around people and not have to worry about people saying things because I'm HIV-positive, I can converse with people and talk about my HIV-positive status without being discriminated against for the most part. I think it helps with quality of mind, quality of life, because you're not constantly worrying about people finding out whether or not you're HIV, because it's not a deadly disease like it used to be and the stigma's still there, but not as bad.

00:52:40

Moderator, RTI International

Great, thank you, **[Participant 6]**. We've been talking about the benefits that Biktarvy and all the other drugs for people living with HIV. I want to also talk about some of the drawbacks and challenges that you or people you advocate for have had with medications used to treat HIV. Again, what are some of the drawbacks or challenges people have had? And again, let us know what medication you're talking about when you give your answer.

00:53:10

Participant 6 (registered as a patient and representative of a patient advocacy organization)

I'm on Biktarvy, and I'm here because I'm on Biktarvy because the other medicines didn't work. Or they worked, but the side effects were just too bad for me to continue taking them. So I think being on Biktarvy without having to worry about the long-term side effects and the kidney and the liver disorders is easy on the mind.

00:53:37

Moderator, RTI International

What were some side effects you experienced, **[Participant 6]**? And what were the drugs that you were taking?

00:53:42

Participant 6 (registered as a patient and representative of a patient advocacy organization)

When I was on Truvada and Descovy, I had some real bad problems with kidney and liver. Blood problems. They made me stop taking them right away.

00:53:54

Moderator, RTI International

[Participant 3].

00:53:57

Participant 3 (registered as a patient)

I'll just name that a few folks that I'm in community with have taken different medications that caused them significant weight gain as well, and how that intersected or impacted their overall health, their cardiac health, their cholesterol numbers, things of that nature. And so, with taking Biktarvy, I haven't had one side effect. Not one. But I can say that for other folks, that's been one issue that I've heard about the weight gain piece, and also just impact on cardiovascular health, like cholesterol numbers being impacted by different medications, in a negative way, and for many, a lot of people already have family predispositions to different things, so adding on a medication that exacerbates that as well is obviously not helpful.

00:55:03

Moderator, RTI International

What are some of those dispositions, **[Participant 3]**?

00:55:07

Participant 3 (registered as a patient)

There are some communities that experience higher rates of diabetes, or higher rates of high blood pressure. And we obviously know that people living with HIV also experience some of these things disproportionately as well, so it's just compounded, really, when you have medications that have this impact. So it's beneficial when you have medications like Biktarvy that have minimal side effects when it comes to cardiac health, or liver health, or kidney functioning.

00:55:49

Moderator, RTI International

Thanks, **[Participant 3]**. And I actually did want to touch a little bit more about that, about a potential drawback being interactions with other medications for treating some comorbidities. Have you seen that as a drawback? Biktarvy or other drugs for treating HIV? Interactions with other drugs? Okay, **[Participant 5]**?

00:56:25

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

As I was mentioning earlier, especially one of my very good friends, I personally have not had different interaction issues with HIV medications and other things I was taking. But I have had friends who have problems with it interacting, I don't remember which specific one, but I know he had issues with it interacting with one of his high blood pressure medications and there was a cholesterol drug that he was taking. I think one of his drugs had an interaction with that. Unfortunately, I can't remember what specific medication it was.

00:56:59

Moderator, RTI International

No worries. Thanks, **[Participant 5]**. **[Participant 4]**.

00:57:01

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

I'm not an expert on every single drug, but one of the alternative drugs that you're looking at, I know you cannot take when you have hepatitis B. So that's one of the benefits of, Biktarvy, that you can. But one of the alternatives I believe you're looking at, you cannot take it. And I think around 5%-10% of people living with HIV have hepatitis B.

00:57:28

Moderator, RTI International

And do you know which drug that is, **[Participant 4]**?

00:57:30

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

No, does someone else know? As I said, I usually don't focus on specific drug names and drugs.

00:57:39

Moderator, RTI International

[Participant 1].

00:57:50

Participant 1 (registered as a patient)

One of the things I wanted to go back to was being undetectable, untransmittable concept, because I remember one time in community when I was praising that whole U=U concept, I ran into

some of my long-term survivor friends who said that that wasn't something that they'd been able to attain with any of the medications that they had been on previously, and because of their resistance that they had experienced to medications, that U=U is still a goal for them. I haven't talked to some of these same people, but I suspect, because I think Biktarvy came around after these conversations, is that perhaps maybe they had been switched over to Biktarvy, which I understand, actually works better in some cases where people have been having this drug resistance, then that would have been a good thing for them. For as far as comorbidities are concerned, for me, Biktarvy hasn't been an issue for all, like I was saying for all the other medications that I've been taking. Although, there has been some times when I've wanted to take a supplement to improve my health in other ways, I think there's some things like magnesium that will prevent Biktarvy from being absorbed in my system if I was going to take it. So it's always important for anybody who's taking any of these medications to check for drug-drug interactions.

00:59:47

Moderator, RTI International

Also, I want to talk about whether there's any potential drawbacks of multi-tablet regimens. This is a three-combination therapy drug. Is that a drawback, or maybe that's a benefit? I just want to hear from you all. **[Participant 5]**.

01:00:03

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

It's a benefit for the fact that it's a one-pill regimen. And one-pill regimens vary between I think two drugs, maybe up to four drugs, maybe, but the fact that it's a one-pill regimen is more important than the fact that it has three medications in it. Because the one-pill regimen, it's better for adherence, it's better for just keeping up with all your other medications that you have that you're taking for other things you may be dealing with, chronic issues or whatever. The three different medications, that just depends on the person and their health situations. But the number of medications in the drug is not as important as the fact that it's a one-pill regimen.

01:00:52

Moderator, RTI International

And **[Participant 5]**, I think I know the answer to this, but I'm going to ask it, which is, how does a one-pill regimen help improve adherence?

01:00:57

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

Because it's the one thing you're going to keep up with. If you have a multi-pill regimen, you have to keep up with taking two or three different pills, and most time, multi-pill regimens, you also have to take them more than one time a day. So if you're also having other chronic medical issues, you're taking three or four other medications on top of trying to keep up with those other multi-pills. Your likelihood of staying adherent to your medication is drastically decreased.

And also, even if you're trying to and if you're someone who has to worry about your privacy, or storing your medication, or taking your medication with you, you travel, things of that nature, and you have multi-pills, it's just a lot more to keep up with.

01:01:36

Moderator, RTI International

That makes sense. Let me actually go to **[Participant 6]** first, and then I'll go to **[Participant 4]**. **[Participant 6]**.

01:01:40

Participant 6 (registered as a patient and representative of a patient advocacy organization)

I think you hit it right on the head there with the multi-pills. I take 13 pills at night, and I take 11 pills in the morning. And I used two machines to help me do it, because otherwise I'd get all screwed up. And so taking one tablet to manage my HIV is a blessing in disguise.

01:02:07

Moderator, RTI International

Thanks, **[Participant 6]**.

01:02:08

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

Just to add to that, recently the Centers for Disease Control and Prevention [CDC] came out with this medical monitoring report, and what they do is, it's a sampling of people who are in HIV care in the United States, and it had some revelations that I was really shocked at. It said only 83% of the people were on HIV treatment, but only 62% were taking every dose as prescribed. And that's dismal. And so I think having a single tablet regimen really helps, as the gentlemen have described. But I think it's also important why people aren't taking their drugs. And there were a number of reasons, I forgot. I didn't have the money, I went to sleep, was dealing with other things, but I think looking and this is from the same report, that the population who is impacted by HIV in the United States, and this is from the report of the sample, 34% of them were living in poverty, 20% experienced homelessness or unstable housing, 15% were unemployed, and 20% experienced hunger or food insecurity. And then so many also experience mental health issues as well. And so, I think, to make the regimen as easy as possible for people to take, because our whole goal is to get people on stable treatment for the rest of their lives so they can remain virally suppressed.

01:03:54

Moderator, RTI International

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

01:04:00

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

I just want to add to something that **[Participant 4]** said, which is that the adherence, the frequency of forgetting to take medications, is not very different in this population than it is in the general population, and especially among older American adults who are taking multiple pills for multiple conditions. You would think no one would forget to take a pill, but everybody does it.

01:04:29

Moderator, RTI International

All right, thanks, **[Participant 4]**. Thanks, **[Participant 2]**. **[Participant 5]**.

01:04:33

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

I would also like to add, too, for people who aren't as self-sufficient, if they had to rely on people who are taking care of them, that's also an issue for someone to try to have to manage multiple pill regimens to take care of someone as well.

01:04:47

Moderator, RTI International

And when you say it's self-sufficient, what do you mean, **[Participant 5]**?

01:04:49

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

Meaning, if you need to help just for your daily living, you need someone to help you feed yourself, or take your medications, or even bathe yourself, or just your everyday day-to-day needs. If you're not someone who can take care of yourself, you have someone, a caregiver who's responsible for doing that for you. A single pill regimen is much easier for that person to manage for your health care needs.

01:05:16

Moderator, RTI International

We compared a little bit about, in a previous question, the benefits of different drugs against each other. For those who have experience with more than one medication for HIV, how do the drawbacks of the medications differ at all? So we talked about benefits, and how do the drawbacks differ from each other? Hey, **[Participant 6]**?

01:05:45

Participant 6 (registered as a patient and representative of a patient advocacy organization)

I think there's no drawback with Biktarvy right now. Like I said, I've been on it for seven years, and I haven't had a complaint. And the people that I know I that are on it also have no complaints whatsoever. And I think the drawbacks from the other drugs were interactions with kidneys and liver issues. And, there was a bone density incident, I think, with one of them also.

01:06:15

Moderator, RTI International

Yeah, **[Participant 3]**?

01:06:18

Participant 3 (registered as a patient)

For Biktarvy, there are no drawbacks, for me, at least. I know that when I was previously on Genvoya, when I had to take that medication with a meal. There were obviously instances where I wasn't able to take it with the meal, but I wanted to make sure that I took my medication and would just have stomach aches, things of that nature. Now, obviously not the end of the world, but also not something that people want to experience either. So the drawbacks currently are just night and day. I just take my medication and don't have to think about it, don't have any side effects whatsoever.

01:07:01

Moderator, RTI International

Overall, when considering a potential medication for HIV, what do you all think matters most, or what factors do you think most matters to patients? Again, when considering a potential medication for HIV, what factors matter to patients the most? **[Participant 6]**.

01:07:26

Participant 6 (registered as a patient and representative of a patient advocacy organization)

Living. Again, I keep on going back to that because every day is a blessing. And with Biktarvy you get that every day. I've been on so many medicines, and it's always, when's this drug going to. It's not if, it's when is this drug going to fail, and when are my numbers going to go back up. Now, with Biktarvy, it's been seven years, and I've been having no problems whatsoever. The others, I usually go six months, and I have to stop for some reason or another.

01:08:03

Moderator, RTI International

And **[Participant 6]**, when you said living, do you mean a longer life, or a better quality of life, or both?

01:08:09

Participant 6 (registered as a patient and representative of a patient advocacy organization)

Both, living a longer, better quality of life.

01:08:13

Moderator, RTI International

Again, what factors matter most to patients for potential medications? Yeah, **[Participant 4]**?

01:08:27

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

One, if you can access it. I know we're talking about Medicare today, but with Medicare it's on formulary, it's part of the six protected classes, and so it shouldn't be a problem, and we have a CMS policy of no prior authorizations or utilization management tools, and then we do have copay limits now in Medicare. Most of the people on Medicare who have HIV are LIS [Low-Income Subsidy], so their cost sharing should be lower as well. For Medicaid, I think every state Medicaid

program covers it. Where we're seeing some issues is in private insurance, but they could put prior authorization on it. They put it on a high tier, which makes the patient pay higher cost sharing. Some plans have taken it off formulary, but I think since it is the most recommended drug for HIV, it has an A1 rating on our treatment guidelines and by the HHS [Department of Health and Human Services]. And we do have laws that say you have to follow treatment guidelines. I think almost every plan covers it, which is good. Additionally, we have the AIDS Drug Assistance Program [ADAP] in the United States that fills in the gaps and helps with Medicare. And, every state ADAP program does have Biktarvy on its formulary. So I think that's a big issue for patients, if they can access and if they can afford it.

01:10:19

Moderator, RTI International

From others, again, when considering the different medications for HIV, what factors matter the most to patients when choosing a drug? Yeah, **[Participant 5]**.

01:10:58

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

Mentioned it a little bit earlier, but just the ease of being able to take it. Something very simple, there's not having a bunch of stipulations of what you can take with it, when you have to take it, how you have to take it, and things of that nature. And as **[Participant 4]** also said, just being able to get it. Just making sure that it's a drug that is widely available as far as being covered, pharmacies, different people's insurance plans, and things of that nature. You're not having to worry about jumping through hoops to get your medication, just something that's easily accessible, that people aren't having problems paying to acquire, and things of that nature.

01:11:32

Moderator, RTI International

[Participant 6].

01:11:42

Participant 6 (registered as a patient and representative of a patient advocacy organization)

And I'd just like to kudo what he said. Cost is one thing that is a factor. I live in a state that I won't name, but just actually had its ADAP program hijacked. So we're in a crisis mode right now where people are trying to figure out if they're going to be able to afford their drugs next month. But I think cost is a is a big factor, because I think it's almost a $4,000 a month cost. And if you don't have Medicare or Medicaid and private insurance, you're screwed. Pretty much.

01:12:25

Moderator, RTI International

Thanks, **[Participant 6]**. All right, you've all provided a lot of helpful input so far. Thank you. Let's talk now about how well Biktarvy and other medical treatments, or other treatments for HIV meet patient needs. So at the beginning of our discussion, we asked you all to reflect on the most important aspects of HIV to have managed or treated. Aside from the aspects that you have already shared, what other medical needs related to HIV are important to you, your loved ones, or patients

you advocate for? Again, what other medical needs related to HIV are important to you, your loved ones, or patients you advocate for? Yeah, **[Participant 6]**.

01:13:10

Participant 6 (registered as a patient and representative of a patient advocacy organization)

Mental health.

01:13:11

Moderator, RTI International

Mental health. Tell me about mental health, **[Participant 6]**.

01:13:13

Participant 6 (registered as a patient and representative of a patient advocacy organization)

Your state of mind, your cognitive being. Being on Biktarvy, you feel somewhat secure because you know that HIV isn't going to creep up behind you and get you right away. You're buying some time here with it. For sure.

01:13:35

Moderator, RTI International

[Participant 3].

01:13:36

Participant 3 (registered as a patient)

That was going to be my exact answer as well, mental health. I know that as someone that was recently diagnosed ten years ago, it did provide just quality of mind to know that I was on a medication that was easy to take, and that I could access particularly as a young person at the time, a younger person at the time. And I would also add just the other comorbidities that we experience as well. Cardiovascular health is something that I'm keeping a closer eye on the older I get as well. Kidney health. And increasingly, actually, dermatology, health as well, which is not something that was really top of mind for me when I was diagnosed but has come to be an issue as of late. I just say that to say that people living with HIV, we are whole people with more than just HIV, and like the rest of the population experience other medical conditions as well that have to be managed and treated as well.

01:15:04

Moderator, RTI International

Thanks, **[Participant 3]**. **[Participant 5]**.

01:15:07

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

I think we may have touched on it a little bit earlier, but, as far as Biktarvy is concerned, it's just the issue that there are a lot of older adults who are undiagnosed and they'll become diagnosed, it's much later in life by that point, HIV is at a much later stage, and Biktarvy's a drug that they can get right on. They don't have to worry about interaction with any of the medications they're taking, and

they can just get right on to it. And mentally, that's definitely a good thing for them, but, as far as it's their care. It's good that they have something like that, they don't have to worry about having to jump through a bunch of hoops and seeing what they're going to take to try to take care of their issues, just to get right on it.

01:16:02

Moderator, RTI International

What other medical needs related to HIV are important to you, your loved ones, or patients you advocate for? **[Participant 6]**.

01:16:14

Participant 6 (registered as a patient and representative of a patient advocacy organization)
As we're living longer, so we're now thinking about geriatric needs. And there's a common saying that I've heard for many years that people with HIV age 10 years faster than those of our counterparts, so technically, I'll be 73 next year, so geriatrics is more is coming up, and I'm dealing with a lot more issues that are related to that, that are not HIV-specific.

01:16:53

Moderator, RTI International

Any other thoughts there? Now, reflecting on your experience with treatments for HIV, to what extent are important aspects of the condition or other important medical needs being addressed, or not being addressed by existing treatment options? These treatments include Biktarvy, other medications for HIV, or also non-pharmacological treatments as well. So again, to what extent are medical needs being addressed or not being addressed by treatment options for HIV today?

01:17:42

Participant 1 (registered as a patient)

Can we unpack that a little bit? Because it sounds as if what you're saying is, if I'm going into a physician's office and I'm dealing with HIV, are they dealing with everything else at the same time? Is that what the question is?

01:18:01

Moderator, RTI International

It's a hard question. Let me ask it like this. What are medical needs that are not being addressed currently, for HIV? Let me start it simple that way, so it's not double-barreled. So what are medical needs today that are not being addressed when it comes to HIV? **[Participant 4]**.

01:18:25

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

I think longer-acting treatments. Biktarvy is a once-a-day pill. There is a once-every-two-month injection. And there are needs. We talked about adherence, we talked about the populations impacted and there are needs for longer-acting treatments. So I think that's important. Once a week. Actually, the company that that manufactures the drug that we're talking about did have a failure last week on looking at a combination with Biktarvy and another drug as a once-a-week option. But they're working on some others, I think they're looking at once-a-month pills, looking at

long-acting six-month or one-year injections in the future. That would be a game changer for people living with HIV. And we're still looking for a cure. So we talked about this is a lifetime commitment, but wouldn't it be great to have a cure for HIV, as well? So those are some of the unmet needs.

01:19:43

Moderator, RTI International

What I heard from **[Participant 4]**: One, there's no cure. Two, once-a-day therapy, there's not longer-lasting therapies. What are some other unmet medical needs today for HIV?

01:20:00

Participant 1 (registered as a patient)

If I could, I would go back to the idea that, if we are not testing people regularly for HIV, we're dealing with a population that may not even know that they could be transmitting the disease, or could actually get treatment for it. There is a huge unmet need in terms of just trying to find people who are not diagnosed.

01:20:35

Moderator, RTI International

So testing as prevention, **[Participant 1]**. **[Participant 6]**.

01:20:39

Participant 6 (registered as a patient and representative of a patient advocacy organization)

I think a little bit is just, we think about homelessness, we think about people who are on the streets, people who are using drugs. We still need help for those people there. And they're not being assessed, they're not being checked to see if they got HIV, so they're not, we're not doing our due diligence when it comes to our homeless and IDU [injection drug user] communities.

01:21:13

Moderator, RTI International

And then, are there any major gaps today in treatment, or concerns that remain despite the currently available treatment options. What are some of the biggest gaps that we have today?

01:21:28

Participant 6 (registered as a patient and representative of a patient advocacy organization)

Funding.

01:21:30

Moderator, RTI International

Okay.

01:21:34

Participant 1 (registered as a patient)

Gaps that we haven't talked about already? That we haven't said already?

01:21:39

Moderator, RTI International

Yes, any additional ones? **[Participant 4]**.

01:21:44

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

I think someone just mentioned about, I think it was **[Participant 1]** who talked about all the people who were undiagnosed. And then, all the people who are diagnosed and not virally suppressed. And, so I think that's the biggest gap, that we have to find the people who need treatment, make sure they're linked to treatment, and make sure they adhere to treatment. We have a Ryan White Program in the United States that provides a lot of the wraparound services, in addition to the AIDS Drug Assistance Program. That helps. We also have the CDC, that's supposed to be, that is doing all the testing and outreach and linkage to care, but, it is a fragile environment, and I'm very unstable right now in this administration. There's been proposed cutbacks, elimination of HIV prevention, which means HIV testing and surveillance, and linkage to care, linkage to treatment, linkage to PrEP [pre-exposure prophylaxis], which is another story. So I think those are the big gaps, and still stigma with HIV in the United States. That's a barrier to care and treatment these days.

01:23:13

Moderator, RTI International

And **[Participant 2]**.

01:23:14

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

I'm going to ditto **[Participant 4]** again, but I want to talk about stigma here for a minute. Where we see the greatest evidence of stigma is among populations that are at risk, but are not on PrEP. And at least where I live, in the county where I live anyway, that is primarily young African American gay men and Latino gay men. But when it comes to gaps in treatment, what we see, especially in the Latino population, is that they are the latest testers. So they come in to test late, and then they're the most likely to be diagnosed with AIDS upon testing, which really just shouldn't happen, but much of this relates to stigma and access to health care. Again, stigma is just an enormous issue for people at risk and people living with HIV, and access to care where I live is plentiful compared to many other parts of the country where access to care is really a dicey matter. The other thing that I want to note about gaps in HIV care. Another area that I want to mention specifically is access to specialty care, in general. In some places, like where I live, access to specialty care is generally pretty good. It's not always great, but it's pretty good. But in some cases, if you're dealing with a comorbidity or another issue, depending on your health insurance, who's paying you what, we're not talking about Medicare here, but depending on what you got in your paperwork, access to specialty care for those comorbidities can be extremely limited, If accessible at all.

01:25:16

Moderator, RTI International

So, early testing, early treatment, and then comorbidities. **[Participant 1]**.

01:25:22

Participant 1 (registered as a patient)

I don't know if this has been raised yet, but out of any of the conditions that I think CMS is considering in this whole process, I think HIV is the only one, probably, that is still subject to criminal laws in this country. There are many states that still criminalize people who are HIV-positive, and subject them to criminal penalties for non-disclosure of their HIV status. And here we are in an environment where if they were in care, and they were untransmittable. Then, whether or not they were going to be able to pass on this HIV to anybody else would be a moot issue. And it's criminal laws against people who are HIV-positive that are impacting the already great level of stigma that people with HIV have.

01:26:29

Moderator, RTI International

[Participant 3].

01:26:31

Participant 3 (registered as a patient)

I'll state that another gap is also vision and dental care, which is increasingly outrageously priced, even for people not with HIV. But for people living with HIV, just access to those two things can be incredibly difficult to get, as well.

01:26:52

Moderator, RTI International

Yes, **[Participant 2]**.

01:26:53

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

I'm glad **[Participant 3]** brought that up. The organization I work for has been providing oral health care for people with HIV since the late 1980s, and there used to be a significant involvement with oral care and HIV in that people would develop candidiasis or yeast infections orally. I had no idea why, and then were diagnosed in a dental office at a time when most dentists wouldn't see people with HIV. Oral health care for people with HIV is incredibly important, especially as they age of course, and Medicare doesn't have a dental program unless you're in some select advantage plans. And, again, getting back to the funding side of this, the administration is talking about cutting oral health care in the Ryan White Program, and what that would mean for the population that we see in our dental offices living with HIV is that they could get routine dental care, maybe, but if it came to specialty care, extractions, root canals, abscesses, that sort of thing, they're simply out of luck. Also, while I'm talking about this, I want to mention something else about the Ryan White Care Act, which it's something close to, and has always been close to a miracle for people with HIV, but Ryan White, care on the care end, not on the drug end, but on the care end is somewhat limited. It does not cover hospitalization unless it's related to HIV, and it does not necessarily cover treatment for any condition that is not related to HIV. So while the Ryan White Care Act has for decades now saved hundreds of thousands of lives, it is not complete coverage, and that shouldn't be overlooked in the discussion of what's lacking in HIV care.

01:29:11

Moderator, RTI International

Thank you, **[Participant 2]**. We're almost at the end, but before we end, I did want to give everyone an opportunity to summarize your thoughts on the importance of Biktarvy for patients, or to raise any topics that you feel weren't covered adequately in our discussion today. So do you all have any final thoughts about Biktarvy, HIV, and other medications that treat HIV that you feel are important to share with CMS? Yeah, **[Participant 6]**?

01:29:40

Participant 6 (registered as a patient and representative of a patient advocacy organization)

Just that Biktarvy is a lifesaver. And they need to definitely keep on funding it.

01:29:48

Moderator, RTI International

Thanks, **[Participant 6]**. **[Participant 5]**?

01:29:52

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

I also piggyback what he just said as well, but also, we didn't mention, or we didn't talk about really, but the fact that as far as just being able to access Biktarvy. There's so many differences in access, depending on with Medicare, because there's so many different Medicare plans, and things of that nature, and things that people have exposure to and access to. And specifically, I don't really know how to put it, but just to say that payment policy can't be separated from the patient experience, especially because I know Black and Latino patients in general usually have access to lower quality Medicare plans, especially when it comes to Medicare Advantage and things of that nature. It's really important to look at the fact that even people on Medicare don't even always have the same access, because they don't have the same exposure or availability for different plans, they have better coverage than some people do.

01:30:45

Moderator, RTI International

[Participant 2], **[Participant 4]**, I'm going to jump to **[Participant 3]** first, but I'll come back to you. **[Participant 3]**?

01:30:50

Participant 3 (registered as a patient)

I have been taking Biktarvy since 2019. Before that point, I was taking another medication named Genvoya. Since 2019, I have been undetectable with Biktarvy, honestly barely even think about having to take my medication. I take it in the morning, and I go on with my day. That's what health care should be like for people living with HIV. We shouldn't have to worry about all of these stipulations about what medications, whether I have to take it with a meal, or whether it'll interact with other medications. We have to realize that people living with HIV, like everyone else, lead busy lives, have other things going on, and we need to provide medications that are very low barrier and low side effect, where people can live and thrive. And in addition to that, it's important that these

medications be accessible for folks, and Biktarvy is the number one, I believe, prescribed HIV regimen in the country. And this medication is known to be effective, with very low side effects for folks across the lifespan, and I'm hopeful that these negotiations will yield reduction in price for this medication.

01:32:29

Moderator, RTI International

Great, thanks, **[Participant 3]**. **[Participant 1]**?

01:32:32

Participant 1 (registered as a patient)

I don't think I had the opportunity to say this earlier, but when you asked about what factors matter most, when I don't know if this was raised, but I think any patient in health care, what matters most is their doctor's, primary care physician's recommendation. And if Biktarvy was probably one of the top medications being out there, it probably is because a lot of physicians are recommending it. I wanted to bring that up, and also as you weigh consideration of this issue, maybe one of the other reasons why Biktarvy came up in this drug price negotiation process was the fact that, and it has been mentioned earlier, that over 50% of the people who are living with HIV today are over the age of 50. When you're talking about HIV these days, you are talking about a Medicare issue because most of the people who are HIV-positive today could be eligible Medicare patients. I think if CMS is going to look at HIV medications even going forward, they should consider that they are dealing with a significant population of HIV-positive people, and whether or not and what that impact is on HIV in this country. Especially as it concerns the issues that we've raised like adherence, and whether or not we're getting to the point where, we're not, even if we don't have a vaccine, if we're actually getting to the point where nobody can pass along the virus because of the fact that we're all undetectable, then we've gone a long way to eradicating HIV in this country. But to actually, to take a system that seems to have issues, but then to create more issues for it could put this whole, whatever it is that we're trying to do and trying to solve this HIV crisis, it could put it all at risk. And I think CMS really could think about their impact on HIV in America by simply picking on this one particular medication. The impact, I think, will be larger than maybe they're anticipating just by looking at this as a drug price negotiation, especially since this is the only medication, I think, that is regarding that they're looking at that is part of the treatment for a communicable disease.

01:35:36

Moderator, RTI International

Great. Thank you, **[Participant 1]**. **[Participant 2]**?

01:35:39

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

Yeah, thanks. I want to say something about HIV as a chronic medical condition. HIV is, for some people, a chronic medical condition in no small part thanks to a highly successful, and easy-to-take drug like Biktarvy. But for many people, especially people who've been living with HIV for a long time, HIV is not just a chronic medical condition. It's a disabling medical condition. We're talking about people who have been on medications for 20, 30, 40 years, starting with AZT, which some people still consider to have been poisonous to a degree, and their bodies and their lives have been devastated by HIV. But the key to their staying alive, the key to their survival, the key to whatever

quality of life they can maintain often has to do with that one drug they have to take for HIV. And so Biktarvy makes that that much easier when they are often taking, as I think **[Participant 6]** said, 14, 15, 16, 17 other medications a day for other conditions. I think it's just important to remember that HIV is much more than just a chronic medical condition.

01:37:05

Moderator, RTI International

Great, thanks, **[Participant 2]**. And **[Participant 4]**.

01:37:08

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

I wanted to touch on some issues that didn't get raised yet, and one is Biktarvy is one of the three drugs and one of the only single-tablet regimen that is approved for post-exposure prophylaxis [PEP]. And so that's when someone is exposed to HIV, or thinks they're exposed to HIV, you can take medicine to actually prevent the virus from staying in your system. Again, Biktarvy is easy to use, and it acts as a PEP drug as well. I know you said we have to just stick to the patient experience, and we talked about the different payers, we also talked about the Ryan White Program, which is so critical, for access to prescription, antiretrovirals, and including the AIDS Drug Assistance Program. But there's so many other programs as well that ensure that people with HIV get their medication that the companies provide, like patient assistance programs to wraparound copays. They can't do it in Medicare, but the other programs as well. They have free drug programs for people. They also provide rebates to the AIDS Drug Assistance Program. Last year it was over $1.5 billion, and it was only funded at $900 million from the Federal government. So that makes more access to people. There are also 340B rebates as well that the companies provide that help people access their medications in health care. They also provide testing programs, education programs, clinical programs that help people. And I don't think when you talk about the patient experience, we should also talk about all the people around the world with HIV as well, just not here in the United States. And again, this is where the companies that manufacture, I think uniquely in the HIV space, we have PEPFAR [President's Emergency Plan for AIDS Relief], where they provide the drugs across the world, primarily in Africa, at very, very low cost. They offer generic licensing almost immediately after initiating the drugs here. And they also have voluntary licensing agreements as well. No profit at all. So I think when you consider looking at an individual drug, you have to look at those factors that go into it as well. And of course, I talked about the need for further research on new drugs and a cure, and the company that manufactures this drug, I know is working on other cures, too, like hepatitis B and other drugs as well.

01:40:12

Moderator, RTI International

Great, thank you so much, **[Participant 4]**. Anything else before we adjourn? I just want to say a couple quick things. **[Participant 2]**, yeah.

01:40:22

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

I want to thank my advocacy partners, and all the guys living with HIV for all of the great input here. Really proud of you guys. Thanks very much.

Closing Remarks

01:40:37

Moderator, RTI International

I second that, thank you, **[Participant 2]**. And I just want to thank all of you, again, for participating in today's event. I really appreciate your time to talk with us today. Your experiences and input were really important to us and valuable, and will help inform CMS' negotiations for Medicare prices for Biktarvy. As I mentioned, CMS staff have been listening in to the roundtable just so they could hear from you directly, to bring your feedback back to their teams. And, **[CMS Staff]**, I just want to see if you had any final thoughts, before we adjourn?

01:41:08

CMS Staff

Yeah, thank you, **[Moderator]**. I just want to take a minute to thank everyone so much for sharing your experiences and knowledge with us. You've given us a lot to think about and consider, and we're just really grateful for your participation today, so thank you.

01:41:24

Moderator, RTI International

Great, thank you so much, **[CMS Staff]**. Also, if you have any questions following today's session, you can submit them to this email address, which should be in some of the materials you received earlier, so you don't need to remember this, but it's IRARebateAndNegotiation@cms.hhs.gov with the subject line Public Engagement Events. And again, thank you all for your time today, and take care and have a good day. Thanks, everyone.

===== 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, the conditions treated by the selected drug, or other treatment(s) or drug(s) similar to the selected drug for those conditions; 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
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No	Any other personal or professional relationship or interaction with a company or related association with direct or indirect interest in the Negotiation Program that may be considered a financial conflict of interest

Participant 3: Registered as a patient who has experience with the selected drug, the conditions treated by the selected drug, or other treatment(s) or drug(s) similar to the selected drug for those conditions

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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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 5: Registered as a patient who has experience with the conditions treated by the selected drug, or other treatment(s) or drug(s) similar to the selected drug for those conditions; 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 6: Registered as a patient who has experience with the selected drug, the conditions treated by the selected drug, or other treatment(s) or drug(s) similar to the selected drug for those conditions; 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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