

*This transcript was lightly edited for readability.*

## Introductory Remarks

**Moderator, PhD, RTI International**

Thank you for joining us today for the CMS Medicare Drug Price Negotiation Program town hall. I am **[Moderator]** from RTI International. I will be the moderator for the town hall today. If you would like to listen to this town hall in Spanish, please follow the directions for accessing the Spanish line on the screen. We will also have sign language interpretation throughout the town hall.

## Welcome and Overview

**Moderator, PhD, RTI International**

To start us off, I will share a brief introductory video from Dr. Oz, the administrator for CMS.

**00:04:56**

**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.

**00:06:48**

**Moderator, PhD, RTI International**

Thank you. The town hall meeting today and tomorrow has a morning and afternoon session. For the morning session, we will hear from speakers on four drugs in the order that you see listed here.

The goal of the town hall is to provide an opportunity for clinicians, researchers, and other interested parties to share input focused on the clinical considerations related to the drugs selected for the current cycle of negotiation and renegotiation. CMS will use the information shared during the town hall meeting to better understand clinicians' experiences prescribing or managing treatment with the selected drugs or therapeutic alternatives, and clinicians' considerations that drive treatment choice between the selected drugs and therapeutic alternatives.

In addition to the town hall meeting, CMS hosted private, patient-focused roundtable events, one for each drug selected for negotiation and renegotiation. Each roundtable event was open to patients, patient advocacy organizations, and caregivers. CMS will use the information shared during the roundtable events to better understand patients' experiences with the conditions and diseases treated by the selected drugs, and patients' experiences with the selected drugs themselves.

The information shared during both the town hall meeting and the roundtable events will also inform CMS' identification of key therapeutic alternatives, key outcomes, and holistic adjustment of the starting point to develop the initial offer in negotiating with manufacturers of selected drugs.

The speakers at today's town hall meeting may include clinicians, researchers, patient advocates, patients, and caregivers. The number of speakers for each selected drug varies based on how many speakers registered to speak for each of those drugs.

This meeting is being livestreamed. Participation is voluntary, and speakers acknowledged and agreed by participating in the meeting that any information provided, including individually identifiable health information and personally identifiable information, will be made public during the meeting through a livestream broadcast.

This event is also being recorded. Recordings will only be used for internal program documentation and to produce redacted materials for public release, consistent with Federal privacy guidelines. By participating, speakers consent to being recorded for these purposes.

Clinicians should be mindful of their obligations under HIPAA [Health Insurance Portability and Accountability Act] and other privacy laws. CMS intends to make a redacted version of the transcript for the meeting available after all the events have ended.

Speakers were also asked to disclose any potential conflicts of interest with the drug they are speaking about. As I introduce each speaker, I will note, and you will see on the slide, any disclosed potential conflict of interest.

To accommodate as many speakers as possible, each speaker will be limited to four minutes for their remarks. There will be a brief time for a follow-up question after each set of speakers. I appreciate speakers sticking to these time limits so that we are able to hear from everyone. I note that the town hall meeting may end before the scheduled time, depending on the number of speakers.

The first three speakers this morning will share remarks about Anoro Ellipta. Anoro Ellipta is commonly used to treat chronic obstructive pulmonary disease, or COPD.

The first speaker is **[Speaker 1]**. This speaker has indicated that there is no conflict of interest.

## Speaker Remarks for Anoro Ellipta

00:11:03

**Speaker 1 (registered as a health care professional, academic researcher or other subject matter expert, and representative of a patient advocacy organization)**

Declared Conflicts of Interest	
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Good morning and thank you. I speak today as a respiratory therapist on behalf of the millions of Americans living with chronic obstructive pulmonary disease, or COPD.

Inhaled medications have long been a mainstay of treatment for COPD for a variety of reasons. The inhalation route allows us to use lower doses, facilitates faster onset of action, and reduces the risk of adverse systemic effects. Unfortunately, administering medication this way has a unique set of challenges. Generally speaking, if a person can swallow a pill, they can also swallow a capsule, or a tablet, or a gel cap, and so on. However, just because somebody can use a metered-dose inhaler does not necessarily follow that they can use a dry powder inhaler, a slow mist inhaler, or a nebulizer. Each of these delivery devices has their own benefits and drawbacks, and it is essential that a person be prescribed the device that best fits their goals and abilities.

Despite long-standing evidence-based practice guidelines, delivery device selection is rarely considered during the prescribing process. This leads to many situations where patients can be prescribed multiple devices with multiple dosing frequencies and multiple administration techniques, which reduces the likelihood that someone will stick with their regimen over the long haul. In turn, that reduced adherence often leads to increased health care costs and eventually increased disability and mortality.

Current recommendations from the Global Initiative for Chronic Obstructive Pulmonary [Lung] Disease, or GOLD, call for most people with COPD to be prescribed dual bronchodilator therapy using the fewest possible devices. Anoro Ellipta provides both a long-acting beta-2 agonist



bronchodilator and a long-acting muscarinic antagonist bronchodilator in a single device dosed once daily. It truly does not get much simpler than that. While dry powder inhalers are admittedly not the ideal choice for all patients, for those cases where they are appropriate, this medication and its associated delivery device provide a solid, evidence-based solution to appropriately managing COPD symptoms based on current science and expert consensus.

Last year's round of Part D price negotiation successfully included Trelegy Ellipta, which is very similar to Anoro except that it includes an inhaled corticosteroid. Ongoing research tells us that inhaled corticosteroids are not appropriate for all people with COPD. Therefore, it makes good sense to make a non-steroid alternative accessible for this population. Ensuring that people have access to the most appropriate medication and delivery device for their condition and health status ultimately leads to improved adherence, more consistent treatment, reduced costs, and most importantly, improved quality of life.

The COPD community appreciates the opportunity to contribute to these discussions, as well as the desirable CMS and industry to improve access to therapies that allow people to truly live their best lives. Thank you again.

00:14:02

**Moderator, PhD, RTI International**

Thank you for your remarks. The second speaker is **[Speaker 2]**. This speaker has indicated that there is no conflict of interest.

00:14:12

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

<b>Declared Conflicts of Interest</b>	
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Good morning. My name is **[Speaker 2]**. I am **[Redacted]** at the Allergy & Asthma Network, a national patient advocacy organization, representing over 100 million individuals impacted by respiratory, allergic, and related immunological conditions.

For over 40 years, Allergy & Asthma Network has advanced its mission through outreach, education, advocacy, and research. We are guided by medical advisors to keep our work evidence-based, and we rely on patient insights to inform our content, policy positioning, and programming

to ensure that they are patient-centered. From a treatment perspective, the goals are clear for patients with chronic obstructive pulmonary disease, or COPD, to allow the patient to breathe more easily, to reduce exacerbations, and to allow people with COPD to maintain an active and fulfilling life.

The right treatment supports the patient to be fully functional and contributing citizens and reduces health care utilization. The right medication for a particular patient can achieve these goals. Anoro Ellipta is a combination inhaler for the treatment of COPD, including chronic bronchitis and emphysema, containing umeclidinium, a long-acting muscarinic antagonist, or LAMA, preventing the tightening of the airway, or vilanterol, a long-acting beta antagonist, or LABA, which relaxes the airways. Both actions keep the airway open and improve disease management for people with COPD.

Here are some factors that are important in the shared decision-making process for Anoro Ellipta as a treatment option for people and patients with COPD.

One is affordability. Clinicians work with patients to prescribe what they believe will be the best medication to manage their COPD when used as prescribed. Ultimately, treatment choices hinge on access and affordability, efficacy, and ease of use. Presently, some people can't afford Anoro Ellipta. Clinicians are then challenged to work with patients in these situations to find an alternative that may or may not work as well as Anoro Ellipta.

Therapeutic alternatives, although used interchangeably, sometimes are not equal or equivalent. The COPD guidelines offer different treatment options for patients based on their COPD severity. This does not mean that these drugs are the same, or that their dosages are comparable to one another. Switching between devices can impact efficacy and adherence, especially if different devices are involved.

The third point is that therapeutic alternatives may not work as well for the patient. Using a less optimal treatment option may lead to lower efficacy. This is an important factor when considering a switch from Anoro Ellipta to a medication that may be therapeutically equivalent but does not control COPD as well. We currently know that patients who do better on Anoro Ellipta but are not on other options because of the cost and have periodic COPD flares requiring a health care provider visit and oral steroids because the less expensive alternative doesn't work as well for them as Anoro does.

The fourth point I want to make is that combination inhalers increase adherence as compared to using two separate inhalers. We've heard from caregivers that patients with dementia might find two inhalers challenging, as would patients with multiple comorbid conditions who already have complicated medication schedules. Having to purchase two inhalers may also increase the cost.

And furthermore, this treatment is easier for patients to use, making them in a similar purpose, all with different delivery mechanisms. This is important because sometimes the delivery mechanism works well for one patient but does not for another.

Finally, I want to say in conclusion, from the clinician perspective, we know that COPD is a heterogeneous disease with different diverse phenotypes, severities, and that's why options are important, and that switching to alternatives might seem reasonable in concept but may not work in a uniform way. We would appreciate options available in the form of Anoro Ellipta. Thank you so much for your time.

00:19:11

Moderator, PhD, RTI International

Thank you for your remarks. The third speaker is **[Speaker 3]**. This speaker disclosed a potential conflict of interest shown on the screen.

00:19:21

**Speaker 3 (registered as an academic researcher or other subject matter expert, and representative of a patient advocacy organization)**

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Thank you for the opportunity to participate in this town hall. My name is **[Speaker 3], [Redacted]** with the Alliance for Aging Research.

Anoro, as has been discussed, is used long-term to treat chronic obstructive pulmonary disease, or COPD, including chronic bronchitis, emphysema, or both, for better breathing and to reduce the number of flare-ups. It's not for asthma, nor should it be used to relieve sudden symptoms of COPD or replace a rescue inhaler.

Currently, about 2.2 million Medicare beneficiaries rely on LABA combination therapies for COPD or asthma. Cost is indeed a barrier to access, though likely due to the existence of similar medications in this class. Patients increasingly have access to substantially discounted prescriptions for Anoro. Although, as mentioned, it is very important that patients have access to the best treatment for their condition as prescribed by their doctor. Common side effects include sore throat, sinus infection, lower respiratory infection, among others. Anoro can cause a number of serious side effects, and its use should be closely monitored. But it is important to note that failure to follow daily dosage requirements can exacerbate symptoms.

Medicines such as Anoro are an essential component of any strategy to address burden of respiratory illness on patients and the growing cost of health care. Not only do they prevent the development of other chronic diseases, the use of these medicines has long been credited with avoiding health complications and spending on other costly health care services, such as emergency room visits, hospital stays, surgeries, and long-term care. Combination therapies like Anoro have become the standard for these respiratory conditions. Patients need to maintain stable



access to a range of treatment choices within this therapeutic class, particularly for these patients with respiratory conditions where treatment non-adherence can result in worsened outcomes and hospitalizations.

Unfortunately, formulary restrictions in Part D for inhaled asthma and COPD medications have been linked to treatment delays and worsened outcomes. Although the Inflation Reduction Act requires Part D insurance plans that cover medicines that are selected for price setting, it does not prohibit plans from continuing to impose utilization management, higher cost sharing, or more restrictive formularies on beneficiaries. In fact, 95% of biologic add-on therapies for asthma and COPD that are covered on Medicare formularies are subject to utilization management, which creates barriers that can delay or restrict patients' timely access to clinically appropriate treatments. To manage costs through the Inflation Reduction Act, plans are increasingly shifting cost sharing for Part D medicines from copays to coinsurance. Patients who require a medicine within the drug class impacted by price setting that is not the selected drug would be both negatively impacted by this trend. That is because even if their medicine is in the same tier as the selected drug, they will face much higher out-of-pocket costs. CMS has, in the past, warned prescription drug plan sponsors to place drugs selected for non-formularies without clinical justification.

We urge CMS to use its authority to crack down on this process. We further urge CMS to improve plan transparency, so beneficiaries can easily see when drugs have utilization management restrictions. We further call upon CMS to enforce minimum payment rates to pharmacies to prevent sponsors from diverting patients away from community pharmacies, consider pre-funding program costs and requiring Part D plans and other payers to reimburse pharmacies no less than the maximum fair price.

Finally, we urge CMS to improve its appeals and grievance processes to reduce the burden of challenging a plan's coverage decision. It is essential that price negotiation for Anoro truly does improve access for patients who rely on this medication. Thank you for the opportunity to participate in this important process.

**00:23:31**

**Moderator, PhD, RTI International**

Thank you all for sharing your experience and perspectives about Anoro Ellipta. I have one follow-up question for you all. You can use the raise hand feature to be called on. What would you consider to be a meaningful improvement or treatment response for the outcomes used to assess improvement or treatment response for this indication? We have just a minute for your brief response. **[Speaker 1]**, go ahead.

**00:24:09**

**Speaker 1 (registered as a health care professional, academic researcher or other subject matter expert, and representative of a patient advocacy organization)**

There are a couple of different ways you can look at that. There are several different patient-reported outcomes measures, such as the chronic airways assessment test, that look at symptom burden as interpreted by the patient. You can look at reductions in exacerbation frequency, short-acting bronchodilator use, so there are several different ways to look at it. It really depends on the individual and their clinical team and what factors they're most concerned about at the time. In

general, the biggest things to do in COPD are to reduce the risk of exacerbations and improve activity tolerance and symptom burden.

## Speaker Remarks for Biktarvy

00:24:51

Moderator, PhD, RTI International

Thank you very much for your response. We will move on now to Biktarvy with four speakers. Biktarvy is commonly used to treat human immunodeficiency virus, or HIV.

The first speaker is **[Speaker 1]**. This speaker disclosed a potential conflict of interest, as shown on the screen.

00:25:32

### Speaker 1 (registered as an academic researcher or other subject matter expert, and representative of a patient advocacy organization)

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Good morning and thank you for the opportunity to speak on this important topic. My name is **[Speaker 1]**, and I am **[Redacted]** at the Alliance for Aging Research. I'm speaking today on behalf of older Americans living with HIV, people who deserve the ability to remain on the drug regimen that they and their clinician have chosen together, and that is working for them.

Biktarvy is highly effective at achieving and maintaining viral suppression in both treatment-naive patients and those switching from other regimens. Its integrase inhibitor component has a high genetic barrier to resistance, meaning the virus is less likely to develop mutations that would render the drug ineffective. As a once-daily, single-tablet regimen, Biktarvy supports strong adherence and is generally well-tolerated, with most common side effects being mild.

For older adults managing comorbidities, Biktarvy offers additional advantages. Its active component is delivered to cells more efficiently than older formulations at a significantly lower dose, resulting in better renal and bone safety compared to TDF [tenofovir disoproxil fumarate]-based regimens. This distinction is particularly meaningful for older patients and for those with

kidney concerns. Biktarvy also carries a low drug interaction burden, an important consideration for patients managing multiple conditions and medications simultaneously.

Disrupting stable, effective therapy carries real clinical consequences. Evidence shows that treatment interruptions are associated with increased hospitalizations, greater risk of drug resistance, and new infections. Short-term restrictions on access ultimately generate higher downstream costs for the health care system and for patients.

The system of care surrounding HIV treatments also reflects meaningful financial support structures. According to 2023 CMS Part D claims data, approximately three-quarters of Medicare beneficiaries on Biktarvy receive some form of cost sharing assistance. Nearly 75% receive low-income subsidy assist benefits, and of those, nearly half receive supplemental assistance through AIDS [acquired immunodeficiency syndrome] drug assistance programs or supplemental benefit plans to cover remaining cost sharing obligations. The remaining 25% of Biktarvy patients are non-LIS [Low-Income Subsidy] beneficiaries. Under Part D redesign, these patients benefit from the out-of-pocket maximum, \$2,100 in 2026, and may further manage costs through enrollment in the Medicare Prescription Payment Plan.

We urge the agency to ensure that savings achieved through the Negotiation Program translate directly to lower out-of-pocket costs for beneficiaries, and that implementation does not create new barriers to access for older adults or any Medicare beneficiaries who depend on Biktarvy.

Ultimately, decisions about HIV treatment should remain where they belong, between a patient and their clinician, grounded in individual medical history, tolerability, and trust. Thank you.

**00:28:33**

**Moderator, PhD, RTI International**

Thank you for your remarks. The second speaker is **[Speaker 2]**. This speaker has indicated that there is no conflict of interest.

**00:28:45**

**Speaker 2 (registered as a health care professional, academic researcher or other subject matter expert, and representative of a patient advocacy organization)**

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Good morning. My name is **[Speaker 2]**. I'm an infectious disease physician who provides HIV care in one of the largest HIV clinics in the Midwest, and I appreciate the opportunity to offer comments today about Medicare price negotiations for Biktarvy.

As more than a quarter of people with HIV have Medicare coverage, I am participating in my capacity as a member of the HIV Medicine Association **[Redacted]**. HIVMA is a professional association that represents more than 6,000 HIV physicians, pharmacists, and advanced practice providers working in communities across the United States.

Biktarvy combines bictegravir, emtricitabine, and tenofovir alafenamide into a single-tablet regimen, or STR, that is highly effective at achieving and sustaining suppression of HIV, allowing people to benefit from extended, healthy lives. It has a high barrier to the development of drug resistance, has very few side effects, and as an STR, is easier for many people to take reliably on a daily basis.

The U.S. Department of Health and Human Services, DHHS, HIV treatment guidelines recommend Biktarvy as a first-line treatment option. The simplicity is particularly important for Medicare beneficiaries who are often taking upwards of six medications to treat co-occurring conditions.

Biktarvy is an integrase strand [transfer] inhibitor, or INSTI-based regimen. INSTIs are the U.S. DHHS-preferred class of drugs for first-line therapy because of their effectiveness at suppressing HIV barriers to drug resistance and tolerability.

As for alternative regimens, dolutegravir is an INSTI and also is a first-line therapy that is highly effective when taken with a second pill consisting of either tenofovir alafenamide or tenofovir disoproxil fumarate plus emtricitabine.

These regimens require more than one prescription, which creates treatment challenges if medications are filled or available at different times, leading to missed doses and the potential for developing drug resistance. They also require multiple copayments that may end up being cumulatively higher than one single tablet regimen copayment.

While today's session is focused on clinical issues to consider in comparing therapeutic alternatives to Biktarvy, the role of pricing in determining access to a preferred treatment for Medicare beneficiaries is important. Medicare Part D plans typically place Biktarvy on a specialty or other high cost-sharing tier. For beneficiaries who are not eligible for extra financial assistance, cost sharing for Biktarvy can range between \$800 and \$900 per month, until, thanks to the Inflation Reduction Act, the individual hits the \$2,100 out-of-pocket maximum.

The cost sharing that beneficiaries must pay when they have not yet met their deductible and coinsurance is directly tied to the underlying price of Biktarvy.

In addition, the maximum fair price negotiated for Biktarvy for Medicare beneficiaries may also set a new best price that could favorably impact Medicaid drug prices. Forty percent of people with HIV are insured by Medicaid, and state Medicaid programs are increasingly responding to rising drug costs by considering prior authorization or other utilization strategies that restrict access to preferred HIV treatment regimens.

Biktarvy has been an important therapeutic advance for people who have access to it. Bringing down Medicare drug prices through MFP [Maximum Fair Price] process is important to the program's solvency, and to ensuring that, in years to come, Medicare beneficiaries will have access to the latest therapeutic breakthroughs. The best way to ensure that scientific advances benefit

people with HIV, especially communities facing persistent access barriers, is to ensure that drug prices are fair.

In negotiating a fair price for Biktarvy, we urge CMS to balance the high therapeutic value of the drug with alternative regimens and the role of price in ensuring Medicare beneficiaries have affordable access to the most effective treatment option for them. Thank you.

**00:33:11**

**Moderator, PhD, RTI International**

Thank you for your comments. The third speaker is **[Speaker 3]**. This speaker disclosed a potential conflict of interest.

**00:33:32**

**Speaker 3 (registered as an academic researcher or other subject matter expert, and representative of a patient advocacy organization)**

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Good morning. I'm **[Speaker 3]**, **[Redacted]** with the HIV and Hepatitis Policy Institute. We advocate for quality, affordable health care for people affected by HIV, viral hepatitis, and other conditions.

HIV's transformation from a death sentence to a manageable chronic condition is one of modern medicine's greatest triumphs. Treatment has evolved from complex, toxic, multi-pill regimens with debilitating side effects to simpler, more tolerable regimens that are easier to adhere to and offer a much higher barrier to viral resistance.

Regimen selection and HIV treatment is highly personalized, especially for treatment-experienced patients who are switching regimens. Clinicians must account for resistance history, comorbidities, drug-drug interactions, side effects, and individual patient circumstances. There's no one-size-fits-all regimen. That said, Biktarvy is a key regimen for HIV treatment today, one of just three regimens recommended as preferred regimens for first-line treatment in government treatment guidelines. More than half of all people receiving HIV treatment in the U.S. take Biktarvy. It is the most prescribed regimen for both starts and switches.



Real-world evidence shows Biktarvy has higher persistence and lower switch rates than dolutegravir-based alternatives. Biktarvy's very high barrier to resistance is an important advantage. Resistance mutations are irreversible and transmissible, limiting future treatment options both at the individual and at the population level. Clinical trial data for Biktarvy showed zero cases of treatment-emergent resistance through five years, confirmed through an additional five years of follow-up. Real-world studies show that recommended alternatives for first-line therapy all have higher resistance rates. This matters, especially for patients with imperfect adherence. Pool data show Biktarvy delivers lower virologic failure rates than the dolutegravir-based regimens when adherence falls below 85%.

People facing housing instability, mental health challenges, or the daily burden of lifelong treatment, a forgiving regimen makes a real difference. HIV treatment access in Medicare is fairly good, and this framework should be preserved. Antiretrovirals are one of six protected classes in Medicare Part D, meaning plans must cover all drugs in the class. Antiretrovirals are the only protected class where prior authorization is prohibited. Combined with the new \$2,100 annual out-of-pocket cap, Medicare beneficiaries living with HIV have meaningful, timely access to their medications. This contrasts with commercial insurance, where patients may face restricted formularies and out-of-pocket maximums exceeding \$10,000. The AIDS Drug Assistance Programs also cover Biktarvy for people with lower incomes.

Despite remarkable progress, significant unmet needs remain, starting with a cure or long-term viral suppression that does not require lifelong treatment. These goals remain beyond current science.

But the drug development pipeline is full of promise. Long-acting formulations make adherence easier, new drug classes may produce options for those with high resistance burden, or those who still struggle with side effects. Continued drug development will yield new options for an aging population with HIV and multiple comorbidities who face high levels of stigma and discrimination and structural and social barriers to uninterrupted care.

As Medicare's HIV population is expected to double by 2035, we need continued innovation alongside continued access to current and new treatments. Thank you for the opportunity to share these perspectives.

**00:37:28**

**Moderator, PhD, RTI International**

Thank you for your remarks. The fourth speaker is **[Speaker 4]**. This speaker disclosed a potential conflict of interest.

00:37:41

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

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Thank you for the opportunity to speak today on behalf of the Global Coalition on Aging [GCOA], from the perspective of the aging community specifically, and healthy aging in general. Many patients worry about how the Medicare Drug Price Negotiation Program might impact access, treatment stability, and innovation for those with chronic and complex conditions, especially as our population ages. Older adults are the primary Medicare population, and they typically manage multiple conditions and medications alongside life changes that strain continuity of care. For them, affordability is only part of the picture. Policy incentives and negotiation timelines directly influence the real-world treatment options available to them, particularly for personalized, long-term therapies. Nowhere is this clearer than in HIV.

Four decades ago, a person diagnosed with HIV was handed a death sentence. Today, for the first time, people living with HIV can do so into old age. This is the miracle of medicines like Biktarvy. Ongoing innovation and access are paramount to ensure a living healthy, long life. Long lives with HIV remains the goal.

In the United States, more than half of people living with HIV are already over 50, and that proportion will continue to grow. Aging with HIV is complex medically, socially, and emotionally, increasing risks of isolation, stigma, and co-occurring conditions. Access and affordability are crucial for treatment continuity, adherence, and trust.

HIV treatment isn't simple. Regimen choice depends on clinical history, resistance, tolerability, and drug interactions, especially for older adults managing other health conditions. Polypharmacy makes medication interactions a real challenge, requiring careful regimen selection.

Policies or processes that unintentionally encourage forced switching or destabilized coverage pose a real clinical risk, a concern HealthHIV has consistently raised, noting that even small disruptions in HIV care can lead to viral rebound, resistance, and loss of stability.

Single tablet regimens have meaningfully improved adherence, which is foundational to viral suppression and long-term health for people living with HIV. For older adults in particular, simpler



regimens can reduce treatment burden and help maintain independence, a factor that is itself a determinant of healthy aging.

Looking more broadly, there is a long-term concern in the aging community that different negotiation timelines for small- and large-molecule medicines could shift investment away from key chronic disease therapies like HIV. Small molecule treatments are vital for conditions affecting older adults, and a strong pipeline is crucial for future options, competitions, and patient care.

As CMS evaluates Biktarvy and considers therapeutic alternatives, GCOA's request is that these decisions be anchored in the real-world needs of people with HIV: continuity, adherence, viral suppression, and clinician flexibility. And we ask that CMS weigh carefully how today's negotiation design will shape the treatment options patients depend on tomorrow. Thank you for the opportunity to share this perspective.

**00:41:15**

**Moderator, PhD, RTI International**

Thank you for your remarks and thank you all for sharing your experiences and perspectives about Biktarvy. I have one follow-up question for you all. What other information or evidence do you think CMS should consider in the evaluation of Biktarvy? Please raise your hand. **[Speaker 3]**, go ahead.

**00:41:38**

**Speaker 3 (registered as an academic researcher or other subject matter expert, and representative of a patient advocacy organization)**

One other indication that Biktarvy has is that CDC [Centers for Disease Control and Prevention] added Biktarvy in 2025 to its Post-Exposure Prophylaxis, or PEP, guidelines. It's the first and only single tablet regimen recommended for use as PEP. Medicare's Part D protections mean that beneficiaries can access PEP within the critical 72-hour window after a potential exposure to HIV, and they can do that without prior authorization, and that's an advantage that many commercially insured patients lack.

## **Speaker Remarks for Botox; Botox Cosmetic**

**00:41:20**

**Moderator, PhD, RTI International**

Thank you. We appreciate your input. We will now move on to Botox; Botox Cosmetic with three speakers. Botox; Botox Cosmetic is currently commonly used to treat blepharospasm, or eyelid spasm, cervical dystonia, chronic migraine, detrusor overactivity due to a neurologic cause, overactive bladder, severe axillary hyperhidrosis, or severe underarm sweating, spasticity, and strabismus, or eye muscle misalignment. The selected drug name reflects the manufacturer's naming convention, and the use of the manufacturer's assigned name when describing the selected drug is not indicative of any change in Medicare coverage or payment for this selected drug when used for cosmetic purposes.

The first speaker is **[Speaker 1]**. This speaker has indicated that there is no conflict of interest.

00:43:47

**Speaker 1 (registered as a health care professional, academic researcher or other subject matter expert, and caregiver)**

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Good morning, and thank you for the opportunity to speak in regards to the use of Botox in chronic migraine and its coverage. My name is **[Speaker 1]**, and I'm a practicing neurologist in North Carolina of nearly 40 years with plans to retire this summer. I have board certification in neurology, pain medicine, and credentials in headache medicine. In full disclosure, I was a **[Redacted]** for Allergan, the product manufacturer, now AbbVie, since the 1990s, no longer affiliated, but attending a yearly advisory.

Again, I first injected Botox for headache in 2003, and that disabled and Medicare-supported patient has been injected every three months ever since.

I was an **[Redacted]** for the trial leading to approval of Botox while at University of North Carolina in Chapel Hill, and upon approval of Botox for chronic migraine in 2010, I actively injected now thousands of patients, including hundreds of injured soldiers, as a contractor for the Department of Defense, treating active-duty Army service members at **[Redacted]**. While there, I trained many clinicians to inject Botox for headaches resulting from injuries sustained during the Global War on Terror, and from where we published a case series of soldiers, many of whom did not have migraine prior to injuries, mostly with blast injuries from improvised explosive devices.

I come before you today to testify to my real belief and experience that this product and its administration is a crucial part of treating patients with chronic debilitating headaches, and without naming or identifying individuals, can attest to the fact that there are those in my clinic who credit Botox with saving them and allowing them to lead healthy, productive, and valuable lives.

I treat many patients who come on Medicare as a result of injuries or illness, and because of Botox treatment, many of them were able to return to the workforce. The larger group of Medicare recipients who age into the program have even more pressing needs when chronic migraine and its correlates impact their lives catastrophically. That population has medical needs requiring complex treatments where drug interactions with medicines given for post-traumatic stress disorder,



psychiatric diagnoses, and life-threatening illnesses of the immune and cancer type must be avoided, and where many other drugs typically used for chronic migraine are not safe.

Newer medications, biological and small molecule modulators of calcitonin gene-related peptide have fewer concerns, but with higher costs than Botox and limitations imposed by payers. The current proposal will add cost, and this drug negotiation of Botox might have a chilling effect. Essentially, if CMS negotiates the price of Botox, the resulting changes to reimbursement and medical billing could create significant administrative and financial uncertainty, making providers perhaps less likely to offer this treatment for migraine patients.

The current proposals to require additional clinical encounters, repeated documentation, and confirmation of effect in patients treated for years on schedule will impose more than usual tasks. It was not my intent to take this brief opportunity to put into the record granular details of the science or clinical experience, and these proposals again, I request that when considering this vital treatment for people of great need, that you hear the voices of soldiers, veterans, civilians, and those disabled by headaches, whose testimony would likely make you think of those loved ones in your life. And in our great American society, who will lose life traction if, for reasons not related to their well-being, they no longer receive the effective treatments they have come to rely upon. Thank you for this opportunity to speak on their behalf.

00:48:07

**Moderator, PhD, RTI International**

Thank you for your remarks. The second speaker is **[Speaker 2]**. This speaker disclosed a potential conflict of interest shown on the screen.

00:48:24

**Speaker 2 (registered as a health care professional, and academic researcher or other subject matter expert)**

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Good morning, and thank you, **[Moderator]**. I'm **[Speaker 2]**. I serve as **[Redacted]** of neurology at Vanderbilt University in Nashville, and like **[Speaker 1]**, have been injecting Botox for medical conditions for over 25 years.



Botox in Medicare is a critical medication used to treat medical conditions. In my practice, I treat cervical dystonia, which is a condition that's often very painful and causes abnormal head positions. I treat blepharospasm, which is involuntary eye closure, and I treat both children and adults with spasticity, which can result from things like stroke or cerebral palsy or developmental disabilities in children. And without treatment, many of these patients experience major loss in function and the ability to be independent.

Professional society guidance, like from the Academy of Neurology, for instance, puts Botox injection as first-line therapy for many of the medical conditions that I just mentioned. Oral alternatives, such as muscle relaxants or anticholinergics, come with a raft of side effects, and some of the medicines are even addictive, and so that's why professional societies place Botox first in the line of treatment before those other less effective and potentially dangerous therapies.

Beyond oral therapies, if someone's failing or can't get access to Botox, we could offer deep brain stimulation, which is brain surgery to implant a device which carries obvious risk and is very expensive.

There are other botulinum toxins, but I want to make sure that everyone understands that in the labeling of botulinum toxins, the FDA [Food and Drug Administration] has placed a boxed warning about the risk of distant spread, but the FDA has also put language in every toxin that's available that they are not interchangeable. The idea that you can make one less available and the others are there, if one government agency were to decide that, with the other government agency, the FDA, is saying they are not interchangeable. It is absolutely in the label of every one of the toxins.

So then, what to think about, as CMS considers negotiation. How the maximum fair price is operationalized will actually directly affect whether people can still get this medication in community settings. Because Botox is buy and bill, if practices can't get access to the drug, then it'll lose its availability in community settings. Then Medicare recipients have less options, or have to travel further with delays to get access to care.

As mentioned by **[Moderator]** at the very beginning, Botox has a number of medical indications. Set aside cosmetic, and **[Speaker 1]** just talked about headache. I don't do that. But all of these other medical conditions are critical and must be considered, the full breadth of all of the different conditions that this treats when CMS considers negotiating the price.

Finally, I would say Medicare patients receiving Botox for movement disorders, like cervical dystonia, are seeking it for serious medical reasons. I'll give an example of a patient with cervical dystonia who, left untreated, her head is twisted, so Medicare recipient, her head is twisted and turned and tilted in a manner like this [tilts head to the left and places left hand on left side of neck], with pain that's persistent day in and day out. And without the treatment, the activities are severely limited in this patient. However, with treatment, the pain relief is dramatic, and then the relief in head position, too, is so helpful to people. I give that example to try to help everyone understand how important the therapy is. Thank you for the opportunity to weigh in, and thank you for CMS' continued engagement of clinicians and patients. Thank you.

00:53:03

**Moderator, PhD, RTI International**

Thank you for your remarks. The final speaker is **[Speaker 3]**. This speaker disclosed a potential conflict of interest, shown on the screen.

00:53:15

**Speaker 3 (registered as a health care professional, academic researcher or other subject matter expert, and representative of a patient advocacy organization)**

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Good morning and thank you for the opportunity to comment. I'm a neurologist and headache specialist at a large tertiary academic headache center in Philadelphia, Pennsylvania, and my practice is comprised almost exclusively of headache medicine. The majority of patients I see have migraine, and many have chronic migraine, the most disabling subtype. There's only one U.S. Food and Drug Administration-approved treatment for it, and that is Botox. There are many other treatments that we still use to treat chronic migraine, and in fact, in most cases, they must be used off-label in order for Botox to be approved through the step therapy process. But it remains a critical element of the treatment plan for a substantial number of my patients, including a large number of Medicare beneficiaries, for whom nothing else works to reduce the burden of their disease. And we measured this not only by reduction in days with headache and other symptoms, but also reductions in the use of acute medications for breakthrough symptoms, office visits, emergency department visits, and very importantly, disability caused by the totality of migraine.

Botox has proven to meet all these goals. It's been approved for chronic migraines since 2010. I've actually been injecting Botox since 2005. And over that time, I've seen firsthand how Botox can restore the livelihoods of thousands of patients in our headache center, and far more across the country, freeing them to be productive members of society and to enjoy life to the fullest.

And Botox does this uniquely, with few adverse events and no drug-drug interactions through complex mechanisms we are still striving to understand fully. And while other neurotoxins exist on the market, all of which have similar mechanisms of action, none have yet proven to be effective for migraine. This leaves Botox as a treatment beyond compare in headache medicine.

I'd also like to take an opportunity to address practical issues that I feel CMS should consider in evaluating selected drugs and therapeutic alternatives.

As mentioned before, for physician-administered drugs furnished under Medicare Part B, clinical decision-making must include recognizing the delivery system behind these treatments, and this includes our ability to acquire the product, store it, and administer it safely. For selected physician-



administered drugs, I would ask CMS to consider three administrative questions as part of its assessment.

First, when comparing a selected drug with therapeutic alternatives, how will CMS account for the fact that a treatment is clinically appropriate, must also remain practically available in the settings where Medicare patients actually receive care currently? And second, how will CMS consider the operational realities of physician administration, including acquisition costs, inventory carrying costs, storage, wasted risk where applicable, staff time, and the administrative burden associated with furnishing these drugs? Third, how will CMS monitor whether implementation changes unintentionally shift patients away from community-based care and toward hospital outpatient settings, where Medicare's total cost of care may be higher, and the burden of patients may also increase?

As CMS evaluates the clinical benefit, the unmet need, and therapeutic alternatives, please also consider whether Medicare patients will continue to have reliable access to these therapies at physician offices and community practices.

I would encourage CMS to consider that preserving access in these settings is part of preserving access to care. Thank you for the opportunity to share these comments.

**00:56:49**

**Moderator, PhD, RTI International**

Thank you for your remarks. And thank you all for sharing your experiences and perspectives about Botox; Botox Cosmetic. I have one follow-up question for you. What considerations drive treatment selection among Botox; Botox Cosmetic and its potential therapeutic alternatives for the indications? Please raise your hand to respond. **[Speaker 2]**, go ahead.

**00:57:19**

**Speaker 2 (registered as a health care professional, and academic researcher or other subject matter expert)**

In my practice, I treat only medical conditions. I'm a neurologist focused on movement disorders, so the conditions I mentioned during my remarks. Botox Cosmetic is not an option for treating patients in my clinic. We only use Botox for that.

**00:57:45**

**Moderator, PhD, RTI International**

All right. We have time for one more response, if you'd like. **[Speaker 1]**, go ahead.

**00:57:55**

**Speaker 1 (registered as a health care professional, academic researcher or other subject matter expert, and caregiver)**

As **[Speaker 3]** has said, the administration of Botox for chronic migraine is, in my estimation, probably the foundational treatment upon which we build other treatments, and the fact that it is so safe, and also that we have metrics that we can use, including instruments collected at many community and academic practices, that show the progress and improvement, that I don't think that there are really any black holes in our treatments of chronic migraine with Botox, which, according to the World Health Organization and CDC, still remains one of the two to seven most

disabling conditions, and though not lethal, much like **[Speaker 2]** our patients can lead much more gratifying and successful lives, including return to work and coming off of things like Social Security Disability and Medicare.

## Speaker Remarks for Rexulti

00:59:00

**Moderator, PhD, RTI International**

Thank you and thank you all for your remarks this morning. We will move on now to Rexulti with three speakers. Rexulti is commonly used to treat agitation associated with Alzheimer’s disease, major depressive disorder, and schizophrenia.

The first speaker is **[Speaker 1]**. This speaker disclosed a potential conflict of interest, shown on the screen.

00:59:46

**Speaker 1 (registered as a health care professional, academic researcher or other subject matter expert, and caregiver)**

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Good morning and thank you for the opportunity to speak. My name is **[Speaker 1]**. I’m a psychiatrist with a focus on geriatric psychiatry population. I’ve been in practice across outpatient, hospital, and long-term care settings for over three decades. Long-term care means nursing home.

Today, I would like to share practical, real-world considerations regarding Rexulti, particularly in the long-term care and assisted living population, where both the clinical complexity and the regulatory environment significantly shape the treatment decisions.

In long-term care settings, the patients we treat for agitation associated with dementia are among the most medically and behaviorally complex individuals in health care. These are older adults with multiple chronic medical conditions, moderate to severe cognitive impairment, and high levels of functional disability. Most require assistance with nearly all activities of daily living. They are also typically on many medications, often ten or more, which significantly increases the risk of drug-drug interaction and adverse events. Their physiological reserve is limited, making them far more

vulnerable to even small medication changes. At the same time, prescribing decisions in this setting do not occur in isolation. They are shaped by quality measures from CMS, including the long-stay antipsychotic use matrix, as well as a survey process that closely examines the medication use.

Within this context, even modest improvement in agitation or behavioral symptoms can have a disproportionately large impact. A reduction in agitation may mean fewer staff injuries, fewer resident-to-resident incidents, less use of emergency medication and fewer transfers to the hospital emergency room, et cetera. It can also significantly reduce caregiver stress and improve overall care environment within the facility.

The goal of treatment in this population extends beyond symptom reduction. Our primary focus is functional stability and safety. We aim to reduce the frequency, severity, and duration of agitation episodes, improve the sleep-wake cycle, particularly by reducing late-day or nighttime agitation, and decreased reliance on as-needed medication, especially sedating agents.

We also look at system-level outcomes, such as fewer behavioral escalations, fewer incident reports, and lower rates of emergency room transfers and psychiatric hospitalization. These are meaningful outcomes, not only for patients, but for staff, families, and the broader health care system.

When used earlier in the disease course, particularly in the home setting, effective treatment can help stabilize patients, reduce caregiver burden for the families, and delayed placement in extended care facilities, and allow individuals to age in place. Importantly, these improvements also translate into meaningful reduction in overall health care costs by decreasing hospital utilization and reducing polypharmacy-related complications, and improving efficacy of care within the facilities.

So, first, from a policy perspective, I would highlight three key considerations. First, the value of treatment in long-term care can extend beyond the individual patient. It impacts patient safety and caregiver burden, and overall stability of the care environment. Second, the regulatory environment plays a critical role. The CMS initiative appropriately aimed to reduce inappropriate antipsychotic use. But clinicians still require a safe and effective tool to manage serious behavioral symptoms. Access to an FDA-approved, better-tolerated therapy supports alignment between regulatory goals and clinical care. Third, there are important downstream cost implications. Effective management of agitation can reduce emergency visits, hospital admissions, and overall burden, making appropriate treatment not only clinically necessary, but also economically responsible. So, in summary, Rexulti addresses a significant and long-standing unmet need in a highly vulnerable population, ensuring appropriate pricing and access will be critical to translate the clinical benefit into meaningful improvement in patient outcomes and health care system, efficacy, and it's the only FDA-approved medication for this indication. Thank you all for your time and consideration.

**01:05:24**

**Moderator, PhD, RTI International**

Thank you for your remarks. The second speaker is **[Speaker 2]**. This speaker disclosed a potential conflict of interest, shown on the screen.

01:05:36

**Speaker 2 (registered as an academic researcher or other subject matter expert, and representative of a patient advocacy organization)**

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Good morning. My name is **[Speaker 2]**, and I serve as **[Redacted]** of the Alliance for Aging Research. I'm also a family caregiver for my mom, who lives with Alzheimer's and recently moved to nursing home care. Thank you for the opportunity to participate in the town hall.

It was only three years ago, in May 2023, that the FDA announced the supplemental approval of Rexulti as the first-ever treatment option for agitation associated with dementia due to Alzheimer's disease. Having a safe and effective on-label treatment option for people living with agitation and Alzheimer's was incredibly promising news for the patient community and millions of families.

Signs of agitation in Alzheimer's disease include restlessness, pacing, screaming, shouting, hitting, and physically resisting assistance, and the experience at the individual level often includes more than one of these, and they can worsen over time.

Not surprisingly, agitation in Alzheimer's is often incredibly challenging for the people experiencing it and for those providing care. Research studies report that it can increase the risk of Alzheimer's disease progression, nursing home placement, and death. Social isolation due to lack of awareness and support, as well as stigma, is also common.

A survey that we released in November 2025 called *The Agitation Blind Spot in Alzheimer's Care* of 1,000 U.S. Alzheimer's caregivers found that 93% of caregivers of people living with agitation in Alzheimer's reported feeling overwhelmed or emotionally drained. For those interested in learning more about agitation and other neuropsychiatric symptoms of Alzheimer's, visit us at [agingresearch.org/NPS](https://agingresearch.org/NPS).

Our concerns about Rexulti are related to access, which should not be compromised in the effort to drive down costs for the Medicare program. Nearly a quarter of second-generation antipsychotics, like Rexulti, that are covered on Medicare formularies are subject to utilization management, or UM, which creates barriers that can delay or restrict patients' timely access to clinically appropriate treatments.



We appreciate this administration and CMS’ commitment to improving prior authorization and encourage them to do even more to crack down on UM abuse.

We also asked CMS to enforce minimum payment rates to pharmacies to prevent sponsors from diverting patients away from community pharmacies, and to also consider pre-funding program costs and requiring Part D plans and other payers to reimburse pharmacies no less than the maximum fair price.

I also want to thank CMS for engaging with us and our partners in the Project PAUSE [Psychoactive Appropriate Use for Safety and Effectiveness] coalition regarding our concerns about the unintended consequences of the current nursing home quality measure on antipsychotics, and how it discourages access to guideline-concordant care for beneficiaries with agitation and Alzheimer’s and other neuropsychiatric symptoms. Its use in the Five-Star [Quality] Rating System does not provide meaningful information to patients and their families, and it distorts treatment in ways that undermine rather than advance patient safety.

But we share CMS’ goal of preventing and reducing misuse of antipsychotics among long-term care residents, and we maintain a strong commitment to working with you in the months ahead to find a solution that will help ensure more residents and skilled nursing facilities are able to receive the individualized care that they need and they deserve, and I know that we can do this. Thank you.

**01:09:21**

**Moderator, PhD, RTI International**

Thank you for your remarks. The third speaker is **[Speaker 3]**. This speaker has indicated that there is no conflict of interest.

**01:09:34**

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

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Thank you for the opportunity to speak today. My name is **[Speaker 3]**, and I’m speaking on behalf of the Depression and Bipolar Support Alliance, DBSA. I’m also speaking as a person with lived expertise. I was diagnosed with major depressive disorder as a young adult, and I have lived with that condition my entire life.



DBSA is the leading national organization focused on mood disorders, including depression and bipolar disorder, which together affect more than 23 million Americans, account for over half of the nation's suicides each year, and cost an estimated \$23 billion in workplace losses. Every day, we hear from people who are trying to find not just any treatment, but a treatment they can actually live with. For people with mental health conditions, treatment decisions are not theoretical, they are deeply personal. They are often the result of years of trial, careful adjustment, and persistence. While many medications may exist, individual response, including efficacy, side effect burden, and overall tolerability, vary significantly from person to person.

For those who have worked for years to find an effective and tolerable treatment, uninterrupted access to the medication that works is not a matter of convenience, it is a clinical necessity. For those who have finally achieved stability, non-medical switching from one antipsychotic to another can have serious consequences, including symptom recurrence, acute crisis, and sometimes death. That's right, this is a life-or-death situation.

DBSA has been closely monitoring how price negotiation and related policies could affect access for the communities we serve. Early evidence suggests that some provisions may be associated with rising out-of-pocket costs and shrinking formulary access for negotiated drugs, often through prior authorization, step therapy, and higher cost sharing. These barriers can be especially harmful for people with mood disorders, many of whom live on fixed incomes and may skip doses or stop treatment when cost or trouble accessing medication increases.

Our message is that affordability is important, but it cannot be the only value that guides policy. People living with mood disorders deserve affordable, effective, and individualized mental health treatment, and those with lived experience must be meaningfully involved in decisions that shape access to care.

DBSA's Transforming the Definition of Wellness initiative has shown that peers prioritize the ability to act independently, have purpose in life, and experience contentment, not only symptom reduction. Those patient-defined outcomes should inform how CMS thinks about value and quality of life.

When evaluating treatments like Rexulti, DBSA urges CMS not to look at this medication only through narrow trial endpoints or a simple comparison of alternatives. Instead, we ask that you consider patient variability, the risks of non-medical switching, the importance of maintaining stability, and the need to preserve access to a full range of antipsychotic options for Medicare beneficiaries with mental health conditions. Policies that protect individualized, patient-centered care are not only clinically sound, they are fiscally responsible and ethically imperative. Patients and providers should be able to make collaborative decisions based on what is best for the individual, not solely on what appears most affordable on a spreadsheet.

Thank you for the opportunity to share DBSA's perspective and to bring lived experience, my lived experience, into this important conversation.

**01:13:40**

**Moderator, PhD, RTI International**

Thank you all for sharing your experiences and perspectives about Rexulti. I have one follow-up question for you. What outcomes, such as clinical, functional, or patient-reported outcomes do you use to assess improvement or treatment response for this indication? We have just a minute for your response. Please raise your hand. **[Speaker 1]**, go ahead.

01:14:05

**Speaker 1 (registered as a health care professional, academic researcher or other subject matter expert, and caregiver)**

In patients in long-term care, if they have a diagnosis of agitation associated with dementia due to Alzheimer's disease, we use a scale called CMAI, Cohen-Mansfield Agitation Inventory, that has 29 different agitation behaviors, and we use the scale to look at what current agitation behaviors they have, and look at the frequency of this behavior, and before we initiate the medication, and then we follow up to see how these behaviors are improving over time. If you are using it for depression, then we use a scale called PHQ-9 [Patient Health Questionnaire-9], or simple scale like that, to evaluate their baseline depression and then follow up over time to see how their depression is improving. These are some simple scales that I use to monitor the symptoms of either agitation or depression.

## Closing

01:15:03

**Moderator, PhD, RTI International**

Thank you very much for your response. That brings us to the end of this town hall session. I would like to thank all of our speakers for joining us today and providing important input for the Medicare Drug Price Negotiation Program. You can find additional information and news about the Negotiation Program on the CMS website listed on this slide. If you have questions, please contact CMS using the email address that is also listed on this slide. Thank you and enjoy the rest of your day.

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

For a list of the drugs selected for the third 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>