Transcript: Session 4 Town Hall Meeting, April 23, 2026, Medicare Drug Price Negotiation Program Public Engagement Events

This transcript was lightly edited for readability.

Introductory Remarks

Moderator, PhD, RTI International

Thank you for joining us this afternoon for the CMS [the Centers for Medicare & Medicaid Services] 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 shown 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.

00:04:36

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.

00:06:23

Moderator, PhD, RTI International

The town hall meeting today and yesterday has a morning and an afternoon session. In this afternoon session, we will hear from speakers on four drugs in the order 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 to better understand clinicians' experiences prescribing and/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 disease 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 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 live streamed. 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 live stream 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 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 time for a brief follow-up 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 drug is Cimzia, with three speakers. Cimzia is commonly used to treat ankylosing spondylitis, Crohn's disease, non-radiographic axial spondyloarthritis, plaque psoriasis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, and rheumatoid arthritis.

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

Speaker Remarks for Cimzia

00:11:18

Speaker 1 (registered as a health care professional)

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Good afternoon. I'm a consulting rheumatologist in North Carolina. I will be speaking about Cimzia, as noted. The product is in fact used and is needed for Medicare beneficiaries with rheumatoid arthritis, psoriatic arthritis, and severe inflammatory arthritis associated with inflammatory bowel disease. Hand involvement is common and is severe, rendering the administration of a pre-filled syringe impossible. With severe hand involvement, activities of daily living are impaired. With the PEGylated [Polyethylene Glycol] formulation at administration by a physician office, this drug would have superb drug distribution in the affected joints and enhance the reduction of disease burden with improvement of quality of life, activities of daily living, and functionality, an option every Medicare recipient deserves.

The current formula for Part B drugs will negate any ability to effectively treat any Medicare beneficiaries with inflammatory arthritis. The risk and cost to a physician practice in community-based offices or rural practices are at highest risk with the proposed model. Rheumatology practices are expected to see the largest decline, with estimated add-on payment reductions of 31%. This will effectively close practices across the country. In conclusion, while I appreciate and support CMS' work to lower drug prices, the reality in providing these treatments to Medicare beneficiaries is severely impacted by the new reimbursement formula that is associated with this program. This will create a significant access challenge for patients, but there is a current technique fix for consideration in Congress right now. The bill is no cost to the government and fixes

this reimbursement issue at the expense of the drug administrator, and they support this. We highly recommend CMS' support for this bill, protecting patient access to cancer [therapies] and complex therapies. Thank you.

00:13:58

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.

00:14:11

Speaker 2 (registered as a health care professional)

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Thank you so much for having me. I'm **[Speaker 2]**, **[Redacted]** for the Coalition of State Rheumatology Organizations. I've spent more than 30 years in private practice, rheumatology practice, caring for patients with inflammatory autoimmune diseases, such as lupus, rheumatoid arthritis, vasculitis, and other difficult-to-diagnose conditions. Cimzia, or certolizumab pegol, is a tumor necrosis factor, or TNF, inhibitor with indications for Crohn's disease, rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, plaque psoriasis, and polyarticular juvenile idiopathic arthritis. Cimzia is also the only TNF medication indicated in the United States for non-radiographic axial spondyloarthritis. And while not indicated, Cimzia has also shown value in certain patients at risk for acute anterior uveitis flares.

Cimzia has two formulations, self-administered and provider-administered, and that flexibility can be especially important for patients with safety, dexterity, or cognitive concerns. In respect to reproductive-age female patients, a very vulnerable population with inflammatory diseases, the manufacturer has conducted studies showing minimal transfer into cord blood, placenta, and breast milk. No other therapeutic alternative has comparable data, which is why many providers and patients view Cimzia as the safest option for women of childbearing age. Also, Cimzia received a unique orphan drug designation, not indication, but designation, last month for antiphospholipid antibody syndrome. Evidence shows improved fetal survival in women with repeated miscarriages or late fetal demise who have not responded to any of the existing treatments. For those families, Cimzia represents hope where there are very few effective options.

Cimzia also offers unique advantages in other high-risk populations. In patients with high rheumatoid factors, conventional monoclonal TNF inhibitors like adalimumab or infliximab may be less effective, because rheumatoid factor can bind to the Fc [fragment crystallizable] portion of those drugs. Because Cimzia lacks this region, it is not bound in the same way. That structural difference supports better clinical efficacy in these patients. That same difference also appears to reduce anti-drug antibody formation compared with drugs such as adalimumab in post hoc studies. These are not small distinctions. They reflect meaningful biologic differences among therapeutic alternatives that can affect response, durability, and patient outcomes.

Finally, CMS should be mindful of how these policies interact with formularies and access barriers. Coverage alone is not enough if patients are pushed into unfavorable tiers, forced through step therapy, or diverted to formulations that are not clinically appropriate or feasible for them. I want to emphasize the risk of including the maximum fair price in the ASP [average sales price] calculation for provider-administered Part B drugs. That could drive reimbursement below acquisition cost and make these therapies financially unsustainable for independent practices, pushing patients into higher-cost hospital settings or losing access altogether. This is not theoretical. We are already seeing similar access problems in Medicare Advantage patients across the country due to over-rebating by certain biosimilar manufacturers to gain fail-first formulary positioning. CMS has an opportunity to predict both affordability and access, but that requires recognizing that drugs like Cimzia are not interchangeable with every other therapy in class. Thank you very much.

00:18:46

Moderator, PhD, RTI International

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

00:19:02

Speaker 3 (registered as a patient)

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Thank you for the opportunity to speak today as a Crohn's disease patient of over 22 years. For context, Crohn's disease is one of two main forms of inflammatory bowel disease, or IBD, a chronic condition with no cure that causes ongoing inflammation in the digestive tract and can lead to

serious complications over time. Before I was even diagnosed with Crohn's disease, I spent five years living with symptoms that no one could explain. I developed perianal fistulas, which are a severe and painful complication of Crohn's disease. A fistula is an abnormal tunnel that forms between the inside of the intestine and the skin, and in my case, these tunnels form near the anal area, leading to chronic pain, infection, and needless to say, trauma, at a young age. At the time, I didn't even know what fistulas were, that they were a manifestation of Crohn's disease. I underwent multiple debilitating surgeries without a diagnosis. I was basically being treated for complications of a disease I didn't yet know I had. These experiences permanently damaged my body and the course of my disease.

By the time I was finally diagnosed five years later, my Crohn's had already progressed to a severe disease state. I began my treatment journey with several medications that simply did not work, and they were not effective for fistulizing disease. I had to undergo step therapy, where I tried and failed various medications until I could finally begin Cimzia, an anti-TNF biologic effective for fistulizing disease. And literally, within weeks, *weeks*, my fistulas that I had battled with for five years were suddenly healed. I'll forever remember my first subsequent colonoscopy where my gastroenterologist confirmed full healing of my fistulas.

Managing Crohn's disease is not straightforward. It often involves trying different therapies over time with no guarantee of response. So, when Cimzia did work, that stability became incredibly significant. It reduced my likelihood of complications that could lead to hospitalization or surgeries, and ultimately, reduced the mental and physical agony that I'd suffered in silence with for years. And it is what has now empowered me to speak openly about fistulizing disease, because I know all too well how traumatic this manifestation can be, and I'm here today to speak about the medication that changed my life, Cimzia. Since being on Cimzia, I've regained my quality of life, allowing me to live a fruitful, normal, healthy life on a professional and personal level, advancing my career, running multiple half marathons, dating, and ultimately knowing I can trust a medication that can keep my disease manageable and/or in remission. And from a patient perspective, that kind of stability is not something we take for granted, because with Crohn's disease, a change in therapy is not easy. Losing a response or being forced to switch treatments can lead to rapid disease progression, and once the damage is done, especially in complicated disease like mine, it's not reversible.

Effective treatment for Crohn's disease helps manage not just symptoms, but the broader burden of this disease. What I hope to convey is that for patients like myself, continuity of care of Cimzia is critical. When a therapy is working, maintaining access to that treatment is an essential part of managing a complex and lifelong disease. My experience reflects how individualized treatment can be and how significant the risks can be when stability is disrupted. As decisions are made about Cimzia, I hope my experience underscores how critical it is for patients to maintain access to treatments that are working, because stability and chronic disease is not interchangeable. We're trying to live our lives while managing conditions we didn't choose to have, and changes to effective treatment can have very real consequences. Thank you for listening to my patient perspective.

00:22:35

Moderator, PhD, RTI International

Thank you for your remarks and thank you all for sharing your experiences and perspectives about Cimzia.

I have one follow-up question. From your experience or understanding, what are the main benefits of taking Cimzia? We have just a minute for your brief response, and you can raise your hand to be called on. **[Speaker 2]**?

00:23:06

Speaker 2 (registered as a health care professional)

I think the main benefits to Cimzia, or any of the more modern medications for inflammatory arthritis and other autoimmune inflammatory conditions, is that it allows patients to lead a normal life. As a rheumatologist in practice for many years, I can say we don't have wheelchairs in our office anymore. These types of medications, like Cimzia, afford not only arthritis patients, but as you've heard, inflammatory bowel patients, to do those things you can't put the price on. Perhaps hold your granddaughter for the first time, or walk your daughter down the aisle, be able to do grocery shopping. All of those things that create the importance in our lives, in addition to less pain, less stiffness, less number of times we have to go to the bathroom. They can save lives, because we know these inflammatory conditions, because of the increased risk of continual inflammation, lead to things like heart attacks. It's not just the things that you can see with the reduced swelling and pain, but it's the reduction in other, comorbid conditions that require perhaps more steroids, which then leads to the patients having more infections with more high blood pressure, more diabetes, more hospitalizations. All of those things. Cimzia is a drug that confers success both in arthritis and inflammatory bowel patients, and now perhaps even in women who are trying to get pregnant and can't because of a certain condition called antiphospholipid antibody. I think there's no way to put a price on the things that it allows people to do that maybe they wouldn't have been able to do. Thank you.

Speaker Remarks for Entyvio

00:25:03

Moderator, PhD, RTI International

Thank you. We will now move on to Entyvio, with three speakers. Entyvio is commonly used to treat Crohn's disease and ulcerative colitis.

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

00:25:28

Speaker 1 (registered as a health care professional)

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Good afternoon. I'm a board-certified gastroenterologist and inflammatory bowel disease specialist at Capital Digestive Care, an independent community gastroenterology group in Washington, D.C. I treat patients with Crohn's disease and ulcerative colitis, chronic, often debilitating conditions that require long-term biologic therapy to achieve and maintain remission. Many of our patients receive those biologics as intravenous infusions administered directly in our office-based infusion suite. I am here today because Entyvio, one of the drugs selected in the third cycle of Medicare price negotiation, is central to IBD care, and the implementation choices CMS makes will have real consequences for where and how patients like mine receive treatment.

The biologic treatment landscape for IBD includes five classes of therapies, and while our toolbox is larger than in the past, it is not infinite. Further, efficacy sealing of our therapies is about 60%, making it important to have access to all FDA [Food and Drug Administration]-approved therapies. The goal of treatment across all of these agents is to induce and maintain clinical and endoscopic remission, meaning not just feeling better, but healing the intestinal lining while minimizing steroid use and preventing disease complications, such as strictures, fistula, bowel damage, and the need for surgery. What distinguishes Entyvio from the other classes is its gut selectivity. Rather than producing systemic immunosuppression, Entyvio works by blocking lymphocyte trafficking specifically to the gut, which results in a favorable safety profile and makes Entyvio a preferred choice for patients with systemic immunosuppression and represents a meaningful therapeutic advance over our older biologics. For patients with moderate to severe IBD, it is recommended as a first-line option by all GI [gastrointestinal] societies. It's one of the most important tools we have, and limiting access to it, whether through financial barriers or utilization management, directly narrows an already limited armamentarium for some of our most complex patients.

The current model also poses a lot of challenges to the way my practice operates, which I would like to make you all aware of. In a buy-and-bill model, my practice purchases Part B biologics like Entyvio up front and is reimbursed only once the drug is administered to the patient at the average sales price, or ASP, plus an add-on payment. That add-on helps my practice account for drug ordering, storage, clinical staffing, billing, and RCM [revenue cycle management].

This fall, the Medicare physician fee schedule confirmed that "units of selected drugs sold at the maximum fair price, or MFP, are included in the calculation of the manufacturer's ASP." If CMS blends the MFP into the ASP calculation, that add-on shrinks, even if our actual costs do not. We have already seen this dynamic with biosimilars. Rebate structures have driven ASP below acquisition costs in many practices, leaving physicians absorbing losses to keep patients in their care. That's not sustainable. And when community infusion sites become financially unviable, patients are redirected to hospital settings, which is ultimately more costly for everyone. Lowering drug prices should not come at the cost of dismantling the safe, low-cost access points [where] patients are already being served.

The administrative burden my practice carries is also substantial: benefit verification, prior authorizations, appeals, insurance communications, and purchasing risk. Research shows physicians spend the equivalent of two full business days per week on prior authorizations alone, time taken entirely away from patient care. And while statute requires plans to cover drugs selected for negotiation, it fails to mandate the drug's formulary placement. As we know, placement within the drug formulary is as much an indicator to access as the cost of the drug. If selected for negotiation, these drugs must also be accessible through preferred tiering. We're also concerned that health plans and PBMs [pharmacy benefit managers] could utilize prohibitive utilization management for selected drugs because they are financially less lucrative for them to offer. We encourage CMS to mandate preferred status on the drug formulary and also prohibit utilization management for selected drugs. The goal of drug price negotiation, reducing what Medicare beneficiaries pay out of pocket, is one I support. But negotiated prices only benefit patients if they can actually access those drugs, and so that requires adequate reimbursement for the practices that administer them, protection against financial models that impose unsustainable cash flow risk, and enforceable guardrails against utilization management barriers for negotiated Part B drugs. I urge CMS to keep the maximum fair price out of the ASP calculation, protect community practices from financial hardship, and take meaningful actions to limit prior authorization and step therapy barriers for Entyvio and other negotiated biologics. Thank you.

00:30:31

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.

00:30:43

Speaker 2 (registered as a health care professional and caregiver)

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Good afternoon. Thank you for the opportunity to speak. My name is **[Speaker 2]**. I serve as the **[Redacted]** for the National Infusion Center Association, but I'm speaking today as a certified infusion nurse with 18 years of experience administering infusion therapies, including Entyvio. I'm also speaking today as a caregiver. My father and partner both live with inflammatory bowel disease, Crohn's disease, so I've experienced this issue both professionally and personally.

I want to begin by saying that affordability absolutely matters. Patients living with chronic conditions already carry a heavy financial burden, and making these medications affordable is critical. But affordability policies have to work in the real-world care environment where the drugs are actually administered. Medications like Entyvio are not just picked up at a pharmacy, they're administered directly into the bloodstream by trained clinicians in settings where they can be monitored for safety, adverse reactions can be managed, and treatment can be coordinated. Patients receive these therapies in community-based infusion centers, which provide specialized nursing expertise, greater convenience, and in most cases, significantly lower costs than hospital outpatient departments.

As Medicare works to bring down drug costs through this program, it's critical to recognize that some mechanisms to lower drug prices can also unintentionally reduce provider reimbursement to the point where it falls below the cost of acquiring and safely administering these medications. If a center loses money each time it administers a drug, it will eventually have to stop offering that drug. No business can operate at a loss. When that happens, patients face two possible outcomes. One option is they try to move their care to a hospital outpatient department, but hospital-based infusion is typically far more expensive, generally two to three times more expensive than the cost of the same care in community infusion centers. That increases costs for both Medicare and the patient and ultimately works against the goal of lowering health care spending. The second possibility is even more concerning, and that is that patients may delay or forego treatment entirely because access becomes difficult. I grew up in **[Redacted]** Maine. My father, with Crohn's disease, would have had to drive over an hour each way to get to a hospital outpatient department to receive infusion therapy. I can tell you he would not have done that; he would have gone without. For

patients like him with Crohn's or other inflammatory or autoimmune conditions, interruptions in therapy can lead to disease flares or progression, which is often not reversible. When that occurs, patients often require significantly more health care services, including emergency department visits, hospitalizations, and sometimes surgery. These outcomes, not surprisingly, cost significantly more than maintaining access to the therapy that was keeping the disease under control, which, again, works against the goal of lowering health care spend. But more importantly, it's much worse for the patient.

As CMS continues implementing the Medicare Drug Price Negotiation Program, I encourage the agency to consider not only the price of the drug itself, but also the price of the care, losing the care delivery system, that makes these therapies possible. Drug affordability absolutely matters, but affordability policies only work if patients can still access the therapy that keeps them well. Thank you for the opportunity to share my perspective.

00:34:27

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.

00:34:38

Speaker 3 (registered as a health care professional)

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Good afternoon and thank you for the opportunity to speak. I'm a clinical gastroenterologist with Gastro Health in Birmingham, Alabama. When we consider moderate to severe inflammatory bowel disease, our treatment goals have evolved well beyond symptom control. Today, we are focused on achieving and sustaining deep remission, including mucosal healing, steroid-free remission, and prevention of disease progression. These goals are not just clinical ideals. They directly translate into fewer hospitalizations, fewer surgeries, and lower long-term health care costs. This aligns closely with Medicare's emphasis on value-based, outcomes-driven care. The real value comes from maintaining remission over time. Patients who lose response and cycle through flares often require escalation of care, driving both cost and complexity. Stability is where we see the greatest return on investment.

This brings us to the role of Entyvio in long-term biologic therapy. Entyvio offers targeted anti-inflammatory activity with limited systemic immunosuppression. This is particularly important in Medicare populations, where patients are older and often have multiple comorbidities. In both clinical trials and real-world practice, Entyvio has demonstrated durable remission and a favorable safety profile, making it well-suited for long-term disease control. For a chronic condition like inflammatory bowel disease, that durability is critical, not only for patient outcomes but also for predictable health care utilization. I'd like to focus on real-world buy-and-bill considerations, which play a critical role in patient access, especially in community-based care like mine. In many gastroenterology practices, biologics like Entyvio are delivered through a buy-and-bill model, where the practice purchases the medication up front and is reimbursed after administration. When functioning well, this model supports timely access in lower-cost community settings, which benefits both patients and the Medicare system. However, this model is increasingly under pressure. Policies involving maximum fair price provisions and pricing caps, while well-intentioned, can create challenges when reimbursement approaches or falls below the acquisition cost of the drug. Community practices, unlike large systems, cannot absorb sustained financial losses. In addition, average sales price-based reimbursement compression combined with delays in pricing updates and administrative hurdles introduces uncertainty into the system. This makes it more difficult for practices to confidently offer in-office infusion services. The downstream impact is significant. We may see reduced availability of biologics in community settings, delays in treatment, or a shift toward hospital-based infusion centers, which are typically more expensive for Medicare. In effect, policies designed to control drug costs may unintentionally increase total cost of care while limiting access.

To address this, it is essential to ensure that reimbursement frameworks reflect real-world acquisition costs, that pricing updates are timely, and that safeguards exist within maximum fair price policies to preserve provider viability. In closing, managing moderate to severe inflammatory bowel disease is a long-term commitment. By focusing on durable remission and sustainable reimbursement models, we can improve outcomes while controlling costs. Thank you for your time.

00:38:14

Moderator, PhD, RTI International

And thank you for your remarks and thank you all for sharing your experiences and perspectives about Entyvio.

I have one follow-up question for you all. Thinking about the topics discussed today, how would you summarize the importance of Entyvio for patients? We have just a minute for your brief response. **[Speaker 1]**?

00:38:41

Speaker 1 (registered as a health care professional)

Thank you. Entyvio is one of the first-line recommended options for moderate to severely active Crohn's disease and ulcerative colitis. Losing one of our first-line options would be a huge detriment not only to physicians but to patients and their quality of life. It is a very safe, gut-specific therapy, as we mentioned, in that it has a minimal side effect profile without any malignancy risk or other autoimmune risk, and is gut-specific, and so maybe a safer option for others with multiple comorbidities, history of malignancy, or who are on other immunosuppression for other reasons. It's one of our safest therapies, it's an appropriate first-line therapy, it has already changed lives

since it was FDA-approved over 10 years ago, and we would love to keep it in our armamentarium. Thank you.

00:39:33

Moderator, PhD, RTI International

All right. Thank you. **[Speaker 3]**, we have a few seconds if you want to just add to that.

00:39:38

Speaker 3 (registered as a health care professional)

I would just echo that. While it's first-line for all patients, in my experience, it's first-line especially in Medicare patients, the older patients with multiple comorbidities. It is an outstanding, safe, effective drug.

Speaker Remarks for Trulicity

00:39:54

Moderator, PhD, RTI International

Okay, thank you. And unfortunately, due to timing, we need to move on, but if you have other comments, you could submit them through the online portal noted earlier.

All right. We will move on now to Trulicity, with three speakers. Trulicity is commonly used to treat type 2 diabetes mellitus and cardiovascular disease.

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

00:40:33

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

Declared Conflicts of Interest	
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Good afternoon. My name's **[Speaker 1]**. I'm a primary care physician in Boston at Brigham and Women's Hospital, an instructor of medicine at Harvard Medical School, and a prescription drug

policy researcher at PORTAL, formerly the Program on Regulation, Therapeutics, and Law**.** Thank you all for the opportunity to speak today. I just want to be clear that the views I express today are my own and not that of any organization.

In my clinical practice as a PCP [primary care provider], I care for patients with type 2 diabetes and prescribe Trulicity. The goals of treatment are to improve their glycemic control and blood sugar and to prevent complications like heart disease and kidney failure. However, the clinical practice has really evolved. When I first started prescribing Trulicity, it was my first choice. But I now prescribe newer, more-effective medications, like semaglutide or tirzepatide, first. Trulicity is no longer the most clinically effective option within its mechanistic class, and I reserve Trulicity for four specific clinical situations. First, patients who prefer to stay on Trulicity and not switch medications. Second, patients who cannot tolerate newer GLP-1 [glucagon-like peptide-1 receptor agonists] medications due to side effects, often gastrointestinal. Number three is when Trulicity is the preferred medication on the patient's drug formulary or health insurance. And finally, number 4, when patients cannot afford other GLP-1 medications. Trulicity has several therapeutic alternatives. That includes other GLP-1 receptor agonists like semaglutide, liraglutide, dual agonists like tirzepatide, SGLT2 [sodium-glucose cotransporter 2] inhibitors, empagliflozin, dapagliflozin, among others, and even DPP4 [dipeptidyl peptidase-4] inhibitors, sitagliptin.

Despite this, though, affordability remains a significant challenge for my patients. In my primary care clinic, I co-founded our Rx Navigator program, which helps patients access their medicines affordably following the standardized algorithm because of how bad affordability challenges were. Trulicity is often flagged as unaffordable for my patients with Medicare. Many patients face high out-of-pocket costs, and our program helps eligible patients apply for patient assistance based on their income and assets. It's a lot of extra work, but it's worth it for those who really need the help and can't afford the medicine.

Importantly, Trulicity is classified as a biologic. It's unlike most other GLP-1 drugs, and research shows that its manufacturer submitted almost 50 new patent applications after FDA approval, creating a patent wall, thereby blocking biosimilar competition. There is no competition currently within class, within the specific drug type for this medication.

CMS should be aware of all the strong international pricing data as well. In 2021, the GAO [Government Accountability Office] reported that Trulicity was priced at $76 per month in France and Australia, and it's noted that that's just a fraction of the current net price here in the United States. CMS has already established a pricing framework across diabetes for diabetes drugs. Lower-value therapies, like DPP4 inhibitors, have been negotiated to around $80 per month, while higher-value therapies, such as SGLT2 inhibitors and GLP-1 receptor agonists, have been priced higher based on their clinical benefit. And Trulicity falls within the spectrum, closer to the lower end based on its clinical effectiveness, and its price should reflect the relative value that it provides to patients.

In negotiating a maximum fair price, I encourage CMS to pay attention to the comparative effectiveness and the international pricing benchmarks. Ultimately, the goal is not just lower spending, but access to medicines at prices for patients that reflect their clinical value. Patients suffer the consequences and experience worse health when prices are high, and my patients and millions of other Medicare beneficiaries are counting on this process to work. Thank you so much.

00:44:54

Moderator, PhD, RTI International

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

00:45:06

Speaker 2 (registered as other)

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Good afternoon. I'm **[Speaker 2]**, **[Redacted]** with the National Forum for Heart Disease & Stroke Prevention, a coalition of patients, providers, public health, payers, purchasers, and innovators. Thank you for the opportunity to comment on Trulicity, or dulaglutide, and its importance for Medicare beneficiaries living with type 2 diabetes and related chronic conditions.

I urge CMS to weigh not only cost, but also the real-world consequences of coverage decisions for adherence, continuity of care, and patient outcomes. Dulaglutide has important advantages for many patients because it is a once-weekly therapy with evidence of strong real-world persistence and adherence. Studies show that dulaglutide initiators were more adherent and more persistent than semaglutide initiators in some settings, and one study found better compliance with administration instructions for weekly injectable dulaglutide than daily oral semaglutide. That simplicity can make a meaningful difference in staying on therapy for many older adults managing multiple medications. Dulaglutide also has relevance for patients with cardiovascular risk. It remains an evidence-based option for people with type 2 diabetes who need glucose lowering and a regimen that can be used consistently over time, and recent literature continues to examine its role in routine care and comparative outcomes among GLP-1 therapies.

For Medicare beneficiaries, the practical value of a therapy that patients can remain on should be part of the access discussion. Dulaglutide may also be especially useful for patients with chronic kidney disease. Recent analyses and reviews continue to support dulaglutide as a useful option in type 2 diabetes with kidney disease, including patients who need a regimen that does not add complexity to already difficult medication schedules. For beneficiaries with multiple chronic conditions, reducing treatment burden can improve the likelihood of staying on therapy. Tolerability is another reason many patients remain on dulaglutide. Like other GLP-1 therapies, it can cause

gastrointestinal side effects, but comparative evidence continues to show that tolerability and discontinuation are important drivers of adherence. In practice, patients often do better when they can remain on the medication they know, tolerate, and can reliably administer. We urge CMS to guard against unintended consequences. For example, institute safeguards to ensure a payer does not use formulary or procedural changes that shift Medicare beneficiaries from a medication they are currently using to one that's more financially advantageous for the payer. This would reduce beneficiaries' access to medications that work well for them, with the harm falling disproportionately on disadvantaged populations, who already face greater health challenges.

CMS should also recognize that switching a patient from dulaglutide to another therapy is not a neutral administrative change. Real-world research has found significantly higher medication adherence and persistence with dulaglutide compared with semaglutide in some studies, and forcing a switch could lead to lower adherence, worse diabetes control, negative impacts on other chronic conditions, and avoidable downstream costs for patients and Medicare. So, recommendations for CMS. [First,] preserve access to dulaglutide for beneficiaries who are stable and doing well on therapy. Second, protect against nonmedical switching that disrupts adherence or continuity of care. Third, give appropriate weight to real-world persistence and treatment burden when evaluating access decisions.

In closing, CMS should support policies that keep patients on medications that are effective, practical, and sustainable in everyday use. For many Medicare beneficiaries, dulaglutide is exactly that kind of therapy, and coverage decisions should reflect its value in the real world, as well as in clinical studies.

00:49:26

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.

00:49:36

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

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Thank you very much. My name is **[Speaker 3]**. I am the **[Redacted]** of the National Association of Nutrition and Aging Service Programs. We serve older adults every day with meals and related services. I strongly support efforts to negotiate a lower price for Trulicity. The medication has been shown to significantly improve outcomes for people living with type 2 diabetes. Lowering prescription drug costs is not just a policy priority, it is a matter of health and economic security, particularly for older adults.

Older adults, as it's well known, are disproportionately impacted by chronic conditions. Nearly 30% of adults over 65 are living with diabetes, and many rely on medications like Trulicity to manage their blood sugar, reduce complications, and reduce the risk of major cardiovascular events, all of which are important to maintaining their quality of life. For these individuals, access to medication is not optional. It's essential to staying healthy, avoiding hospitalizations, and remaining independent. However, far too many older adults face significant financial barriers when it comes to accessing these treatments. Even with insurance coverage, high out-of-pocket costs, deductibles, and coinsurance requirements can make medications unaffordable. As a result, many ration doses, delay refills, or forego treatment altogether, decisions that can lead to serious and costly health complications later.

We also know that older adults often live on fixed incomes, which makes them especially vulnerable to rising drug prices. When the cost of a single prescription competes with everyday necessities, as Dr. Oz pointed out, like rent and groceries or utilities, people are put in an impossible position. Negotiating lower drug prices is a common-sense solution that can help address these challenges. It has the potential to reduce out-of-pocket costs, improve medication adherence, and lead to better health outcomes, which is a goal. For medications like Trulicity, which are widely used and clinically effective, price negotiation can mean a meaningful difference in the lives of millions of older adults. At the end of the day, no one should have to choose between their health and their financial stability. Ensuring that older adults can access affordable, life-sustaining medications must remain a top priority, and negotiating drug prices is a critical step toward achieving that goal. Thank you very much.

00:52:14

Moderator, PhD, RTI International

Thank you for your remarks. And thank you all for sharing your experiences and perspectives about Trulicity.

I have one follow-up question for you all. What other information or evidence do you think CMS should consider in the evaluation of Trulicity? We have just a moment for your brief response. Please raise your hand to be called on. Go ahead, **[Speaker 1]**.

00:52:59

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

Thanks, **[Moderator]**. I mentioned this in my remarks, but I would just reemphasize that the international pricing here for Trulicity is something to pay attention to. That's publicly available, how much other countries pay for this drug, and the value that's been assigned. And we have our process to follow, but it would be helpful if CMS paid attention to what other countries are paying for this drug and followed the official process for negotiation with that in mind.

Speaker Remarks for Tradjenta

00:53:33

Moderator, PhD, RTI International

We have a little bit of time if either of the other speakers would like to add anything. Okay, seeing no takers, then we will move on to the final drug. The final drug is Tradjenta. There are no speakers here to speak about Tradjenta. We note that Tradjenta was first negotiated last year, and the negotiated price will become effective January 1, 2027. It was selected for renegotiation this year, with any renegotiated price becoming effective in 2028.

Closing

That brings us to the end of this Town Hall session. I would like to thank all 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 listed on this slide. Thank you all, and have a good rest of your day.

===== 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