

This transcript was lightly edited for readability.

Introductory Remarks

Moderator, PhD, RTI International

Good morning and 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 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.

00:04:29

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. For this morning's 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 meeting 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 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 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 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 Xolair with three speakers. Xolair is commonly used to treat allergic asthma, chronic rhinosinusitis with nasal polyps, chronic spontaneous urticaria, and food allergies.

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

Speaker Remarks for Xolair

00:10:53

Speaker 1 (registered as a health care professional)

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Hello and good morning. I'm happy to be here today. Appreciate everyone's time. I'm **[Speaker 1]**, and I'm the **[Redacted]** of MedicoCX, as well as an **[Redacted]** for the National Infusion Center Association, or NICA. I represent over 600 providers specializing in allergy and immunology across the country. Four minutes is tough to explain a process or a problem that is taking us years to get to this point.

Our patients have absolutely no idea how complicated all this is. A patient managing severe asthma or chronic hives shouldn't need a graduate degree in Medicare reimbursement policy just to receive a medication their doctor prescribed. They should show up, get their injection, be monitored by someone who knows them and their condition and any potential side effects of the medication, and then go home with improvement or stability on the horizon. It is an incredibly important part of our care delivery system. Think of it like a restaurant. The diner just wants a good meal. They don't need to know about the supply chain or what happens when the delivery truck is late. Buy and bill, or in-office administration, is this kitchen. And right now, CMS is about to turn off the gas for us.

Our physicians acquire Xolair, carry the inventory risk, and are reimbursed at ASP [average sales price] plus a 6% add-on that barely covers acquisition, storage, staff, and clinical oversight today. When CMS folds the maximum fair price into that calculation, Avalere Health projects a 42%-61% reduction in that add-on. For an independent clinic or practice, or an infusion center, that's not trimming fat, that's cutting us to the bone. Providers can no longer afford to buy and bill Xolair to educate patients on the medication they're getting, and the process it takes to get these. They're

pushed to a pharmacy distribution model, white bagging, to throw a good buzzword in here, and that system is already strained. Cold chain management, shipping logistics, coordinating delivery, and like everywhere else, keeping well-trained employees to answer the calls and talk to these patients is difficult.

What doesn't change, though, is the administrative burden on both the clinical and administrative staff in our offices. Someone still has to verify these benefits, obtain any authorizations required, coordinate shipment, and follow up when something falls through. That work lives in our clinics regardless of who has this process.

The difference is that when we own the buy-and-bill relationship, we own the phone number. Our patients call a local number and talk to someone who knows their name, knows their chart, knows that Mrs. Johnson, for example, has never once answered a call before 10 a.m. When you hand that off to a specialty pharmacy, you get an 800 number, an automated system, and a patient who sees an unknown caller ID and lets it go to voicemail. Then they miss their appointment, then they have a flare. The administrative work doesn't get easier; it just got a lot less effective. We didn't save anything and we added friction to a system that was already overstressed. That's not a win, that's a rebrand.

Xolair carries a unique FDA [Food and Drug Administration]-approved indication for IgE [Immunoglobulin E]-mediated food allergy and the clinical evidence supports Xolair brands specifically. There is not a therapeutic alternative. It's Xolair. We think of food allergies as a pediatric issue, and yes, that's where much of this data does live, but food allergies do not card you at the door. Adults are increasingly diagnosed, and with the growing focus on health and wellness, more patients are seeking answers at every age. The opportunity to treat them safely in a community-based setting cannot be eliminated by a reimbursement policy that makes it financially impossible to keep this medication in office. Negotiating the price of a medication that inserts new players or steps truly means the patients can no longer access what is prescribed for them in a timely manner. How can you put that on a spreadsheet?

Three things. First, exclude the maximum fair price from the ASP calculation. Preserve the add-on payment so community-based administration remains viable. Second, protect against policies that accelerate the shift to pharmacy distribution, or Part D in this case, for provider-administered products, because that pipeline cannot handle the pressure. And third, recognize that for Xolair, where the brand-specific clinical evidence is the entire point, consistency in access in a clinician-supervised setting is not a preference, it is the treatment plan.

CMS has worked hard to negotiate lower drug prices so patients can better afford their medications. It's a worthy goal; there is no argument in that. But if the reimbursement structure that delivers those medications becomes financially unsustainable, meaning if the physician stops stocking this medication, the pharmacy can't reliably get it there, and the patient ends up in an emergency room instead of in our clinics, who exactly is going to be saving money?

My question to CMS is, what are you guys anticipating to provide for patients to better understand this potential shift from Part B to Part D?

00:15:53

Moderator, PhD, RTI International

Thank you for your remarks.

The second speaker is [Speaker 2]. And this speaker disclosed a potential conflict of interest, as shown on the screen.

00:16:08

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

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Hi, good morning. Thank you for the opportunity to speak today. I represent AllergyStrong, a national nonprofit serving the 33 million Americans living with food allergies with a focus on underserved and vulnerable populations.

For many, food allergies are not just an inconvenience, they are a constant medical threat. Every meal, every label, every social setting carries risk. Even trace exposure can trigger severe, potentially fatal reactions. This is a condition defined by uncertainty, where patients must remain hypervigilant, managing not only physical safety, but also significant psychological strain and financial burden. While food allergies impact everyone, they are more prevalent and reactions are more severe in minority populations, with Black patients experiencing the highest levels of multiple food allergies, and their impact is felt deeply among low-income patients. Avoiding allergens is mandatory, but avoidance alone is not enough. Cross-contact happens. Labeling is imperfect. Life is unpredictable. Treatment is therefore critical.

Patients consistently identify three goals for effective food allergy treatment: protection from accidental exposure, increased tolerance to allergens, and relief from daily physical and emotional strain. I would add two more essential goals: a treatment that achieves its endpoint quickly, and is widely accessible and affordable, able to benefit the greatest number of patients possible.

While immunotherapy is an important option, it comes with limitations. It requires ongoing exposure to allergens which carries risk of reactions. It can disrupt daily life for both patients and caregivers, is logistically burdensome for some clinicians, and is often not covered by insurance, placing it out of reach for many patients.

Xolair changes that equation. It plays a unique and essential role in addressing the burdens of food allergy and offers patients and clinicians several distinct advantages. Xolair is currently the only FDA-approved medication available that provides preventive protection for food allergies. It acts quickly, has a well-established safety profile supported by years of real-world use, and is effective



across multiple allergens. This last point is especially important because many patients are managing more than one allergy. In fact, among allergic patients, nearly half of adults and 75% of children live with multiple food allergies.

Xolair is also an effective option for those with conditions that might make them ineligible to pursue other treatments. People who live with food allergy often have other comorbidities, such as severe eczema, asthma, eosinophilic esophagitis, and oral allergy syndrome, which could complicate any treatment that exposes them to their allergens. However, patients with these conditions can still use Xolair effectively, offering them much-needed protection. Xolair provides a clinically meaningful margin of safety. For patients, that margin is transformative. It means fewer emergency situations, fewer hospital visits, and greater safety in eating, traveling, working, attending school, and other aspects of daily life. It also significantly reduces anxiety and stress, improving overall well-being. From a Medicare perspective, this matters. Without preventive treatment, costs don't disappear, they increase. Emergency care, hospitalizations, and complications from severe reactions are far more expensive than prevention. Covering Xolair is not just clinically appropriate, it is a cost-conscious strategy.

Access to therapeutics is also critical. Food allergies affect people across all demographics including adults, of which there are 26 million living with food allergy in America alone. Half of all food-allergic adults develop new allergies as adults. These individuals often have limited treatment options and may not be candidates for other therapies. Xolair fills that gap. If coverage is restricted, those most likely to lose access are patients with the fewest alternatives and the greatest need. The result is higher risk, higher costs, and widening health disparities. Patients who use Xolair report meaningful improvements in both safety and quality of life. For many, it is the first time they feel a sense of control over their condition.

In closing, maintaining strong coverage for Xolair is grounded in both clinical evidence and patient need. It supports improved health outcomes, reduced expensive emergency department usage, and addresses a significant gap in the current standard of care, all of which align with the goals of effective, preventive, and patient-centered health care. Thank you for your time and consideration.

00:20:27

Moderator, PhD, RTI International

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

00:20:39

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

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Hello, and thank you for the opportunity to speak today. I am **[Speaker 3]**, and I am the parent and caregiver of children with asthma and life-threatening food allergies. I am speaking today on that behalf, as well as a patient advocate **[Redacted]** Global Allergy & Airways Patient Platform, representing millions of patients living with asthma, chronic urticaria, and food allergies.

Today, we are at an inflection point. The Medicare drug price negotiations underway are being framed as a cost control exercise, but that framing is far too narrow and risks leaving value on the table. This is not just about lowering prices. This is about how we, as the U.S., use health care and our system as an economic asset because right now, we have a structural problem. The U.S. funds a disproportionate share of the global pharmaceutical innovation. At the same time, we carry the highest drug prices in the world, and we absorb the cost downstream for chronic disease at a scale that is fiscally unsustainable. So yes, price negotiation is necessary, but how we do this matters. If we treat this as a simple push for the lowest possible price, we will get short-term savings, but with a long-term cost. We risk compressing the very innovation engine that produces breakthrough therapies like Xolair. We risk weaning U.S. leadership in biotech, and we risk losing leverage to rebalance what is fundamentally a global pricing imbalance.

There is a better path. CMS now has something it has never had before, real pricing power. That power should be used strategically and thoughtfully.

First, prioritize value, not just price. Not all drugs are equal. In the case of Xolair, there is no therapeutic alternative, and it is a very concrete example in asthma care. For patients with moderate to severe allergic asthma, Xolair has been shown to reduce exacerbations by 25%-50% or more, significantly lower ED [emergency department] visits and hospitalizations and enable reduction in OCS [oral corticosteroid] use, which carries long-term cost and morbidity.

These outcomes translate into economic value directly. Fewer acute care events, lower total cost of care over time, and improved patient sustainability, stability, and productivity. This is not just a pharmacy cost. That is cost avoidance across the system, and this distinction is something that CMS must recognize and operationalize. First-in-class therapies and treatments that materially



reduce long-term disease burden, especially in areas like asthma, chronic urticaria, and food allergy, should be treated as investments, not just expenses. If a therapy keeps the patient out of the hospital, in the workforce, and off disability programs, that is not a cost. It is a return.

Second, we must align pricing with outcomes. We should increasingly link what Medicare pays to what the system actually gets. Fewer hospitalizations, better long-term health care, and lower total cost of care. That is how we begin to bend the cost curve in a durable way.

Third, this is the moment to think beyond just domestic pricing. The current system is unbalanced, and the U.S. pays more than other countries so that other countries can pay less. We understand this dynamic is not sustainable. While CMS operates domestically, it sends a signal globally. These negotiations should be part of a broader strategy to ensure that other advanced economies contribute more fairly to the cost of innovation.

Let me be clear, this process is treated purely as price suppression. We will get incremental savings but miss a larger opportunity. If it is treated as a strategic lever, we can reduce cost, improve outcomes, strengthen innovation, and enhance long-term economic stability. This is not just health care policy, it is economic policy, and the decisions here that are made here will shape not just Medicare spending, but the future of U.S. leadership and global health. Thank you.

00:25:40

Moderator, PhD, RTI International

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

I have one follow-up question for you all, and you can use the raise hand feature to answer. From your experience or understanding, what are the main benefits of taking Xolair? We have just a minute for your brief response. **[Speaker 2]**, go ahead.

00:26:07

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

Quite simply, from a food allergy perspective, it offers safety in a world that otherwise presents risk around every corner. For people with food allergy, trace amounts can cause serious, even fatal reactions, and that's the concern as they navigate life and so, imagine, not just at mealtime, snack time, but every time you use a health care product, every time you take a medicine, every time you put lip balm on your lips and kiss your child good night, we have to worry about every single ingredient that we touch. Xolair offers a real protection against a lot of those concerns and a lot of that risk. It mitigates some really serious reactions.

Speaker Remarks for Cosentyx

00:26:48

Moderator, PhD, RTI International

Thank you all for your remarks and for your time today.

We will now move on to Cosentyx with three speakers. Cosentyx is used to treat ankylosing spondylitis, enthesitis-related arthritis, hidradenitis suppurativa, non-radiographic axial spondyloarthritis, plaque psoriasis, and psoriatic arthritis.

Also, as a reminder to the upcoming speakers, today’s event is being translated into American Sign Language and Spanish. Therefore, please try to speak at a moderate pace.

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

00:28:03

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

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Good morning. Thank you for the opportunity to speak today. My name is **[Speaker 1]**. I am a dermatologist at the University of California, San Francisco, and I’ve dedicated my career to caring for patients with hidradenitis suppurativa, or HS. I’m also **[Redacted]** of the HS Foundation, and I **[Redacted]** the American Academy of Dermatology and the HS Foundation’s first HS clinical practice guidelines. The Medicare Drug Price Negotiation Program is important work, and I’m grateful for the care that CMS is taking to hear from clinicians in this process.

HS is a common, painful, and disabling disease that typically begins in adolescence. It causes recurrent abscesses, dermal tunnels, permanent scarring in the most sensitive areas of the body, and it keeps people out of school, out of work, it impacts relationships, it impacts income potential and life trajectory. For more than a century, there were no approved therapies for HS, but today, we have three. Cosentyx is one of them.

In speaking today, I’m thinking about one patient in particular. He’s a retiree in his 60s, a former construction worker, he’s active in his church and in his community, until HS took all of that away from him. By the time he came to me, his disease was so severe he could not sit long enough to drive to his daughter’s house. He had a new granddaughter he had never met. He was afraid that if he held her, his pain would cause him to drop her. We tried a TNF [tumor necrosis factor] inhibitor for his disease first, and it didn’t work. When we started Cosentyx, his disease responded in a way that frankly surprised me. Within months, he was back at church, he was back volunteering, and holding his granddaughter for the first time. This is what access to the right treatment makes possible.

I want to offer three points for CMS to consider as they think about price negotiation for Cosentyx. First, the three FDA-approved therapies for HS are not clinically interchangeable. Three separate



meta-analyses have reached three different conclusions about relative efficacy, reflecting genuine uncertainty in the evidence base. Some patients respond to adalimumab, others to Cosentyx, and others to bimekizumab, and we can't yet predict who will respond to which. Until we have predictive biomarkers, which my research program is actively working to develop, preserving access to all three approved treatment options is the standard of care.

Second, Cosentyx's approval by the FDA in 2023 was more than just another option for HS. It was the first safe FDA-approved treatment for HS patients who had no safe option before. TNF inhibitors carry documented risks for demyelinating diseases, for skin cancers, and congestive heart failure, which are the defining comorbidities of the Medicare population. For a Medicare-aged HS patient with a history of cancer, with a history of MS [multiple sclerosis], or heart failure, the IL-17 [interleukin-17] inhibitor class that Cosentyx opened is often the only safe option.

Third, I want to share a concern about implementation. In HS, disease progression is often irreversible. Time on an ineffective drug produces new abscesses, new tunnels, new permanent scarring, and new functional limitations that no subsequent therapy can undo. Step therapy and non-medical switching are particularly damaging in HS in ways they may not be in other inflammatory conditions.

I would ask that CMS take this into consideration and how therapeutic alternatives are characterized, because that characterization will shape the formulary policies that plans build around the negotiated price. That characterization will be the most authoritative public document describing how these drugs relate. Commercial payers will look at that. Getting it right serves the Medicare mandate and protects patients well beyond Medicare. Thank you for your work on this and for the opportunity to contribute.

00:32:52

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.

00:33:15

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

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Thank you for the introduction. My name is **[Speaker 2]**. I'm a senior dermatology resident at the University of Pittsburgh Medical Center, the quaternary referral center for a catchment of roughly four million patients across western Pennsylvania, West Virginia, and eastern Ohio. My clinical focus is in inflammatory skin disease that includes moderate to severe psoriasis, psoriatic arthritis, hidradenitis suppurativa, all of which I manage in a combined rheumatology-dermatology clinic. The patients referred to me have typically failed two or more biologics before I see them.

I've published on inflammatory dermatology in the *Journal of American Academy of Dermatology*, the *Journal of Investigative Dermatology*, and the *British Journal of Dermatology*, as well as contributed to *Wolvertson's Comprehensive Dermatologic Drug Therapy*. I hold sub-investigator experience on industry-sponsored trials in these therapeutic areas. I want to describe what this disease actually looks like at a referral center because it is different from the clinical trial population. The patients I see have almost always failed the standard pathway. Topicals, phototherapy, methotrexate, and typically at least one TNF or IL-23 [interleukin-23] inhibitor. By the time they reach us, the disease is no longer just a skin problem. For example, erythrodermic psoriasis patients are admitted for fluid loss and infection. Hidradenitis suppurativa patients present with draining sinus tracts, recurrent abscesses, and opioid-dependent pain. Psoriatic arthritis patients carry erosive joint damage that will not reverse. These are systemic inflammatory diseases, and morbidity is cumulative.

I want to give a concrete, de-identified example from my practice. A patient in his late teens was referred to us in our pediatric clinic with Hurley Stage III HS, the most severe classification. He had failed topicals, doxycycline, antiseptic washes, Humira, and high-dose infliximab. His disease had progressed to the point that he required months-long inpatient admission, with multiple operative interventions, surgical exploration, and washout of commonly involved areas of HS, including the chest, bilateral axilla and the groin, as well as requiring skin grafting. He was an adolescent on intravenous antibiotics and all because of a skin primary process. He was transitioned to Cosentyx, and at his most recent visit with me this month, his skin exam was normal. No fistulas, no draining



tracks, no active disease. He has had no further hospitalization, no further surgery. Only occasional nodules that resolve in a day or two. That is the difference between a young adult whose life is organized around wound care, and one who has it back.

On mechanism, Cosentyx is an IL-17A inhibitor that is distinct from TNF and IL-23 blockade, and this distinction is clinically meaningful. I have patients, like this patient, who have failed adalimumab and IL-23s in sequence, and breached psoriasis area severity scores of PASI [Psoriasis Area and Severity Index] scores of over 90, meaning 90% improvement on Cosentyx within three to four months. In HS specifically, Cosentyx is the first and most established IL-17A inhibitor with an FDA approval for this disease. And for a defined subset of patients, it is the first therapy that has meaningfully altered their natural history. On access, step therapy and prior authorization delays are not abstract in our region. A refractory patient typically waits weeks to months between the decision to escalate and the first dose. Restricting early access to IL-17 inhibition in appropriately selected patients is a false economy.

I have two points for CMS to weigh. First, Cosentyx is not clinically interchangeable with all the other listed alternatives. TNF and IL-23 inhibitors are reasonable first-line biologics for many patients, but a defined subset, as we continue to understand these diseases, respond specifically to IL-17A blockade, and HS patients have limited mechanistic alternatives.

Second, timing matters. In these diseases, delayed treatment does not just prolong symptoms, it changes the trajectory. Joint erosion, sinus tract formation, cumulative cardiometabolic risk, these are not reversible once established. Thank you very much.

00:38:58

Moderator, PhD, RTI International

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

00:39:11

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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Thank you for allowing me to speak today about Cosentyx. I'm a rheumatologist by trade. I am the **[Redacted]** of the Gout Support Group of America, as well as **[Redacted]** for Arthritis Foundation, as well as the Alliance for Patient Access.

Cosentyx was first approved by the FDA, Federal Food and Drug Administration, on January 21st, 2015. In the rheumatology, biologic, large-molecule space, Cosentyx holds a particularly unique position. It was the first IL-17 inhibitor to come to market. Although it was initially approved solely for psoriasis and psoriatic arthritis, further hallmark studies showed that it was effective in several other critical arthritic conditions, including ankylosing spondylitis, a non-radiographic axial spondyloarthritis, and most recently, as was noted earlier, hidradenitis suppurativa. This is an important distinction with the seemingly exponential growth of tumor necrosis factor biosimilars, many of which have similar indications, but most do not have hallmark clinical studies in the other arthritic diseases other than rheumatoid arthritis. I believe most rheumatologists find a greater comfort level in prescribing medications that actually have clinical trials in all the diseases they are indicated for.

Cosentyx is also unique in that it is available in both subcutaneous and IV [intravenous] injection infusion forms. There are only two other large-molecule biologic, biologics approved in the seronegative inflammatory arthritis space that offer both formulations, Simponi and Orencia. However, only Cosentyx is indicated for non-radiographic axial spondyloarthritis. This allows physicians to have more flexibility to prescribe Cosentyx. While commercial patients usually find copay assistance to allow them to afford the subcutaneous injections, Medicare patients are able to utilize their Part B benefits to obtain the medications through IV infusions.

Lastly, Cosentyx is the only non-TNF inhibitor, to my knowledge, that has been tagged by health plans and pharmacy benefit managers as a step therapy. We have seen over the last year that plans have decided to use Cosentyx to construct another barrier to access to newer anti-IL-17 biologics beyond just biosimilars. Our hope is that by lowering the cost of Cosentyx, it will be placed on the same step as biosimilars, giving more options to patients. It goes without question that large-molecule biologics have had a revolutionary effect in rheumatologists' success in treating inflammatory arthritic conditions. Without their existence, remission was only a dream for most patients. Now, it is a reality for the majority of patients. However, as rebates paid to PBMs [pharmacy benefit managers] restricted the spectrum of large-molecule DMARDs [disease-modifying antirheumatic drugs] available to most patients with inflammatory arthritis and the proliferation of biosimilars added further barriers to access, patient-centered treatment has taken a backseat. It is our hope that CMS price negotiations will result in better access to all large-molecule disease modifying anti-rheumatic drugs, like Cosentyx. Because in treating inflammatory arthritis, one size does not fit all. Thank you.

00:43:06

Moderator, PhD, RTI International

Thank you all for sharing your experiences and perspectives about Cosentyx.

I have one follow-up question for you all. What outcomes, such as clinical, functional, or patient-reported outcomes, do you use to assess improvement or treatment response for conditions treated by Cosentyx? You can raise your hand to respond.

[Speaker 3], go ahead.

00:43:33

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

One of the things that we use in practice on arthritis, as a rheumatologist, is the CDAI [Clinical Disease Activity Index], which is a measure of inflammation in the joints. It's been standardized, it's been reproduced and validated tool to assess disease activity. We use it in rheumatoid arthritis, but it also has been shown to be effective use of monitoring psoriatic arthritis as well.

00:44:03

Moderator, PhD, RTI International

Okay, and **[Speaker 2]**, if you have a very brief response, you can take a moment.

00:44:07

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

We use a few different metrics. Body surface area, BSA, is probably the most common and easiest to track in the clinical setting. In other settings, we use DLQI, Dermatology Life Quality Index, that measures the impact on quality of life. These are probably the two main metrics that we use. There are a lot of other validated metrics. These included H[S]-IGA [Hidradenitis Suppurativa Investigator Global Assessment], PASI scores, high score, more recently, IHS4 [International Hidradenitis Suppurativa Severity Score System] in the world of hidradenitis.

Speaker Remarks for Orencia

00:44:36

Moderator, PhD, RTI International

Thank you both. We will now move on to Orencia with three speakers. Orencia is commonly used to treat acute graft-versus-host disease, or GVHD, prophylaxis, 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.

00:45:11

Speaker 1 (registered as an academic researcher or other subject matter expert)

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Thank you for giving me the opportunity to speak with you today. My name is **[Speaker 1]** and I'm the **[Redacted]** for NORM, the National Organization of Rheumatology Management. NORM managers have first-hand experience navigating regulatory obstacles facing successful health care practices while supporting financial sustainability. We assist patients to navigate the multitude of regulations such as prior authorization to ensure that patients receive the medication the physicians prescribed based on sound medical decision making. In addition to the clinical services rheumatology practices provide and are reimbursed for, practices also generate revenue through the administration of prescription drugs that patients cannot self-administer, including injections and infusions. Rheumatology infusions and IV treatments that manage and treat autoimmune and inflammatory conditions, such as rheumatoid arthritis, and are administered by a licensed health care provider. This is a valuable option when oral medications or other treatments are not effectively or clinically appropriate.

Orencia is a biologic used in rheumatology practice frequently and comprises approximately 25%-30% of biologics used in our offices. Orencia is a very effective drug for a variety of disease states and is one of the safest biologics we use. Allergic reactions are relatively rare, and this medication does not require premedication and does not have a black box warning. Our patients like Orencia. It is a short infusion, is safe, and has great coverage. Because of this, patients stay on therapy. The weight-based dosing ensures that patients are receiving the most appropriate dose.

As you can see, Orencia plays an integral role in treating our patients. This is why having Orencia included on the maximum fair price within the ASP calculation would make it nearly impossible for rheumatology practices to continue to administer medications like Orencia without a significant change to the way the provider add-on payment is calculated. According to CMS estimates, the MFP [maximum fair price] could lower the net spending on prescription drugs by 22%. If applied to Part B drugs, a 22% drop in the ASP would significantly drop our percentage-based add-on payment, leading to a detrimental cut to this essential provider reimbursement. Underwater reimbursement forces practices to choose between administering therapies at a loss, or referring patients to a high-cost facility, like the hospital outpatient departments. We are seeing this today



with biosimilars and this can adversely affect Medicare patients. Without adequate reimbursement that keeps pace with the actual cost of running a physician practice, our rheumatology offices face growing financial instability. This also leads to practices being acquired by hospitals and large health care systems. While we understand that the inclusion of the MFP with the ASP calculation was addressed in the physician fee schedule this fall, this is a very serious concern for rheumatology practices across the U.S., and we urge CMS to work with Congress to address it.

In conclusion, I would like to ask CMS to confirm. For selected drugs with both physician-administered Part B and self-administered Part D formulations on the IPAY [initial price applicability year] list, does the MFP apply to both formulations, or does it apply to one formulation and not the other? From the list of national drug codes, it appears to be both, which is confusing, particularly when selected drugs also appear on the Medicare self-administered drug exclusion list and are excluded from coverage. I want to thank you for your time, and NORM offers to continue to be a resource to CMS.

00:49:30

Moderator, RTI International

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

00:49:42

Speaker 2 (registered as a health care professional and representative of a patient advocacy organization)

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Thank you for having all of us here, and for the transparency of this process. My name is **[Speaker 2]**, and I'm a rheumatologist in clinical private practice, and I routinely prescribe and manage advanced therapies for rheumatoid arthritis and psoriatic arthritis.

Orencia, or abatacept, is a selective T-cell co-stimulatory module, a modulator that inhibits cell signaling and prevents full T-cell activation, and it's a distinct mechanism of action as opposed to TNF inhibitors, IL-6 [interleukin-6] inhibitors, JAK [Janus kinase] inhibitors and B-cell depletion therapies. It's been FDA approved since 2005 and has two decades of clinical trial and real-world



data supporting both efficacy and safety. And very importantly, it is the only drug in this class and there's no alternative therapy. If Orencia were to be removed from our armamentarium, there's no alternative therapy in this drug class. Other drug classes, such as TNF inhibitors, have multiple biologics. In the co-stimulatory class of medications, Orencia is the only medication we have. And as many of the speakers have said today, if we include the MFP and the ASP calculation for these provider-administered Part B medications, like Orencia, we're going to see an unintended consequence of cost shift of these patients from private practices, which is the most cost-efficient place to take care of these patients, to hospital outpatient departments. The buy-and-bill margins, as has been stated, are already very thin, and if these are reduced another 40% to 60%, we're going to see that shift happen, and that's undesirable for the patients, for the practices involved, and certainly for Medicare.

Another very important point with Orencia is that there's a critical distinction between the IV and the sub-Q [subcutaneous] formulation that the previous speaker touched on. The IV formulation allows for weight-based dosing, which is highly relevant given the wide variability in patient body mass. This avoids us underdosing larger patients, which could lead to inadequate disease control, and it avoids us underdosing smaller patients, which could lead to toxicity. The subcutaneous formulation is fixed dose and does not provide the dosing precision that you have with weight-based IV dosing.

In the Medicare population, real-world adherence is a major determinant of outcomes. Many of our patients have cognitive impairment, and with the aging of our population, this is increasing. These patients have physical impairments, and they've got very complex outpatient medication regimens. In-office administration assures near-complete adherence, whereas self-administered therapies for serious diseases, like the ones that Orencia treats, are associated with missed doses and treatment gaps. These gaps end up costing Medicare much more money over the intermediate and long term due to worse disease control and complications. And for these reasons, the IV formulation is not interchangeable with the subcutaneous formulation, and is often the preferred route of administration, particularly for our older, higher-risk patients.

In summary, Orencia is a very well-established therapy, two decades. It has a unique mechanism of action. There's nothing else that can replace it in the same drug class if this drug becomes unavailable for the treatment of our patients' autoimmune diseases, such as psoriatic arthritis and rheumatoid arthritis. It's important to recognize that the IV option is not interchangeable with the sub-Q option and has significant benefits. And finally, reiterating the comment that several speakers have made, that if the MFP is included in the ASP that we're going to see the unintended consequence of a dramatic shift to hospital outpatient departments which is going to lead to the unintended consequence of a dramatic increase, rather than decrease, in total cost of care that CMS is looking to achieve. Thank you very much for your time and the ability to talk to you today.

00:54:13

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.

00:54:26

Speaker 3 (registered as a health care professional, and academic researcher or other subject matter expert)

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Thank you for the opportunity to speak to you today on Orenca. My name is **[Speaker 3]**, I'm a practicing rheumatologist in Clearwater, Florida, and I've been in practice for 37 years. I'm currently **[Redacted]** of a coalition called the Alliance for Transparent and Affordable Prescriptions, that's a coalition of patient and provider groups that are looking to decrease out-of-pocket cost and cost for our patients, as well as lower the prices of drugs, as well as increasing access. I'm **[Redacted]** of the Florida Society of Rheumatology and recently was named **[Redacted]** of the Coalition of State Rheumatology Organizations [CSRO].

I treat patients with chronic inflammatory autoimmune disorders, such as rheumatoid arthritis, psoriatic arthritis, systemic lupus. I also specialize in bone diseases. Rheumatologists and other health care practices directly administer Part B biologic drugs to patients in their in-office infusion suites, and I have just the same. Practices engage in the buy-and-bill model. That's where the medical practice pre-purchases medications and submits a claim to the health plan for reimbursement once the medication is administered to the patient. And this model has been described by previous speakers and is most convenient in terms of obtaining the drug, acquiring the drug. And smooths the process as much as possible. This allows us to give the patient the medication in our office, reduces exposure to hospital-based infections, and that's a particularly important consideration in our immunocompromised patients who receive provider-administered drugs. For my patients who come to the infusion suite or receive in-office treatments, this is really a very comfortable place and also the most cost-effective and probably the safest place, which has been published in the literature, of all the locations that a patient can receive infusion or in-office administered drugs.

As the two previous speakers and others have said, we really recommend, advise CMS against including the maximum fair price within the ASP calculation for provider-administered Part B medications. As **[Speaker 2]** just mentioned, what the essential result of this will be that these drugs, the acquisition cost will be higher than the amount we are compensated to give the drugs, putting us as infusion providers underwater. That's not sustainable. You can't make that up on



volume. It's very important that there is some margin that is maintained so that we can pay our expenses and run our infusion suites for the benefit of our patients and our practices. The margins currently are very thin. ASP plus 6%, it's been minus, plus/minus sequestration. These reimbursements are, there's very slim margins, and it turns out that the biosimilars are not able to be given by our practices because the ASP is under the acquisition cost of the drugs. This is a real problem that needs to be taken into consideration when the MFP comes into effect.

I want to say that, about therapeutic alternatives, that CSRO urges CMS to proceed with caution, and recognize that not all therapeutic alternatives are equivalent and they have drastically different clinical outcomes for patients. When health care providers evaluate medication substitutions, we consider these therapeutic equivalents, not alternatives. And deeming medication alternatives is a one-size-fits-all approach that disrupts our ability to talk to our patients, look at their comorbidities, look at them as individuals, and decide what's the best therapy.

In terms of Orenzia, I want to mention that Orenzia has been shown to have safety margins, discontinuation for adverse event compared to adalimumab in the ADEPT [Adalimumab Effectiveness in Psoriatic Arthritis] trial was decreased with Orenzia, and also, that Orenzia has been shown to have lower hospitalization rates, lower infection-related costs, lower diabetes and cardiovascular-related costs in patients with comorbid diseases, and fewer emergency room visits and inpatient stays. What I'm trying to say is we have an excellent alternative, for us and our patients with rheumatoid arthritis, with great persistence, and for all of the considerations that I have stated, we need to be able to give our patients this medication and do it in a way that keeps our practices viable. Thank you for your time, and I'm happy to answer any questions.

01:00:25

Moderator, PhD, RTI International

Thank you, and thank you all for sharing your experiences and perspectives about Orenzia.

I have one follow-up question, and you can raise your hand to respond. Thinking about the topics discussed today, how would you summarize the importance of Orenzia for patients? Go ahead, **[Speaker 3]**.

01:00:48

Speaker 3 (registered as a health care professional, and academic researcher or other subject matter expert)

As I mentioned in my remarks, Orenzia is very important for our patients. Medicare patients tend to have more concomitant diseases and more comorbidities, and this drug really has been shown, based on its safety, lack of black box warning, and safety margin, is really terrific compared to everything else that we have to offer our patients. For Medicare patients, for a whole host of reasons, but most importantly, safety, this drug is critically important for us to have in our armamentarium.

01:01:27

Moderator, PhD, RTI International

Okay, and **[Speaker 2]**, you have about 30 seconds to respond.

01:01:31

Speaker 2 (registered as a health care professional and representative of a patient advocacy organization)

In addition to its safety long-term, it also has fantastic safety in the infusion suite. It's infused very quickly in under an hour, does not require any premedication, and it's exceptionally rare to have any type of infusion reaction, again, leading to better continuation rates for the patients, better disease control, and really much lower costs for Medicare and the health care system. In general, it's a win-win-win all around with this medication. Losing it would be a big problem.

Speaker Remarks for Xeljanz; Xeljanz XR

01:02:02

Moderator, PhD, RTI International

Thank you all for your remarks today. We will now move on to Xeljanz and Xeljanz XR with three speakers. Xeljanz and Xeljanz XR are commonly used to treat ankylosing spondylitis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, rheumatoid arthritis, and ulcerative colitis.

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

01:02:39

Speaker 1 (registered as a health care professional)

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Thank you so much for the opportunity to support Xeljanz and Xeljanz XR, generic name, tofacitinib. My name is **[Speaker 1]**. I'm a rheumatologist at Endeavor Health in Chicago, the third largest health care system in Illinois, and currently I serve as **[Redacted]** for the American College of Rheumatology's Government Affairs Committee. Xeljanz is a key treatment for my patients with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and juvenile idiopathic arthritis. Xeljanz's effectiveness is on par with other biologic medications but has advantages of being oral rather than an injection or an infusion, and a chemical structure that resists the formation of anti-drug antibodies. The disadvantage of an oral therapy is, of course, the high cost when patients pay



for it through their pharmacy benefit, which is why my patients and I thank you for negotiating its price.

I prescribe Xeljanz for patients who have difficulty with injections due to fear of needle injections, needle phobia, expansive skin disease limiting choice for injection sites, injection site reactions, and lack of dexterity due to hand pain and deformity. And I prescribe it also because oral therapy improves patient access. Travel to infusion centers is a hurdle for patients with arthritis, and particularly those of our patients who live in underserved and rural communities. Time in an infusion center also causes absenteeism from work and from school. Other therapies for our diseases, biologic therapies, unfortunately have a high failure rate, up to 40%, and part of the reason for this is anti-drug antibodies. Xeljanz is not a biologic and resists the formation of these inactivating antibodies through its structure as a small molecule with low immunogenicity. Xeljanz targets cell membrane receptors called Janus kinase proteins, abbreviated as JAK, blocking the activation of intracellular inflammatory cascades.

All forms of Xeljanz are important. XR, extended release, improves compliance. Five milligrams allows for liver and kidney dosing, and the liquid formulations are important for weight dose basing for our pediatric population.

In the diseases that we treat with Xeljanz, rheumatoid arthritis is the most common, 1% of the population, and the effectiveness of this medication is measured by the reduction in the number of painful and swollen joints, improvement in markers of inflammation in the blood in both the patient and physician's assessment of disease activity. Reduction is measured by percentage improvement in these measures. ACR20, American College of Rheumatology 20, for instance, means a 20% reduction. Damage to joints is measured on x-rays via a Sharp score. Xeljanz works better than methotrexate but can be used solo when methotrexate is contraindicated. For instance, many of our patients have liver disease or rheumatoid arthritis-affected lung disease. Alone, Xeljanz achieved ACR20 at three months of 43%. Some patients also have more severe at three months. Some patients also have more severe disease that doesn't respond to therapies, like methotrexate or the TNF inhibitors.

Last week, I saw one of my patients who had suffered from chronic pain due to failure of numerous medications, and every time I see her, she proclaims with a bright smile that Xeljanz has been a life-changing medication. Medical studies support its effectiveness in patients whose disease also didn't respond to TNF inhibitors. After six months, Xeljanz plus methotrexate, we saw an ACR20 of 51%. A key reason to report the ACR20 at three months, for instance, is that this medication works quickly. Xeljanz prevents joint damage as measured by lower Sharp scores at six months. Xeljanz prevented damage in 73% of patients versus only 55% on methotrexate alone. And when we used these therapies together, it was an 84% reduction.

Psoriatic arthritis is a disease in adults and children where the immune system attacks the skin and joints. Psoriatic arthritis affects 2.4 million Americans. After three months on Xeljanz, patients achieved ACR20 in 50% of the cases, and by one year, 68%. And those patients who didn't respond to TNF blockade on Xeljanz at three months, the ACR20 was received in 50%. It's a very effective medication.

Ankylosing spondylitis is a disease where the immune system attacks primarily the joints of the spine and the pelvis, as well as joints in the arms and legs, affecting three million Americans. Inflammation and, ultimately, joint fusion make the spine so stiff they cannot take a deep breath. One of my patients is having trouble driving because he cannot look over his shoulder because of the fusion of his spine. Disease response to medication is measured by a decrease in spinal pain

and stiffness, decrease in markers of inflammation in the blood. And we have a similar measure, ASAS [Assessment in SpondyloArthritis International Society]-S20, and reduction by 20% would be an ASAS20. Ankylosing spondylitis patients who failed to respond to two or more nonsteroidals did very well on Xeljanz. At three months, ASAS20 was achieved in 56%, and ASAS40 in 41%.

Juvenile idiopathic arthritis causes stunted growth and joint damage in 100,000 American children, and it's really effective very quickly. At 18 weeks, juvenile idiopathic arthritis, ACR30, 50, and 70 were 77%, 70%, and 49%. In summary, Xeljanz fills a unique need for an orally administered medication, improves patient access, and is vitally important for people in whom other medications, methotrexate and TNF inhibitors, may have failed due to side effects, or these neutralizing anti-drug antibodies. Thank you for your time.

01:08:30

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.

01:08:39

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

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Thank you, and good morning. I'm [Speaker 2] with Public Citizen's Health Research Group. We're a not-for-profit that has over 50 years of experience tracking FDA-regulated drugs on behalf of the American public. The remarks that I'm going to make today are a summary of comments submitted to the docket for this particular pricing endeavor.

Tofacitinib, or the brand name Xeljanz, is one of three RA [rheumatoid arthritis] drugs and related autoimmune disorder drugs currently up for price negotiations. The other two, one we heard about, abatacept (Orencia), and then also certolizumab pegol, or Cimzia. These drugs are all second- or even third-line, I think, in the case of Xeljanz's treatments, and thus plausible substitutes for one another to treat, in particular RA, but other related disorders like psoriatic arthritis, as we've heard. First-line treatment commonly includes methotrexate, of course. The average wholesale price for a



30-day supply of methotrexate generic, just to remind everybody, is about \$25. Way cheaper than what it would take to get infusions or supplies of tofacitinib and, and the other drugs that I mentioned. There are several other first-line therapies for RA as well. Several more second- and third-line therapies, as we've heard also, such treatments span at least five distinctive drug classes, tofacitinib being a Janus kinase inhibitor, JAK inhibitor, as we've also heard from others.

Public Citizen advocates for the avoidance of certolizumab pegol because it carries unique risks of hair loss, kidney failure, and cardiovascular disease, among other risks. For other reasons, we actually recommend avoidance of tofacitinib, as well. More on this in a moment. Regarding effectiveness, I'm going to briefly describe one pivotal trial that's on the label of tofacitinib that summarizes the effectiveness of the drug to treat RA. And the effect sizes reflected are relatively similar to those of other second-line or third-line therapy drugs I described here and described in our written comments. That trial involved an asymmetric randomization of 481 participants who, for 24 weeks, received either methotrexate and tofacitinib, or methotrexate and placebo. The American College of Rheumatology criteria improvement of at least 50%. The ACR50 was achieved in 32% of those on tofacitinib. And 9% of those on placebo, certainly a significant difference, but far from a perfect remedy.

Regarding safety of tofacitinib, noting that it carries a boxed warning for infection, cancer, blood clotting, and other cardiovascular risks. Higher doses, 20 milligrams per day versus 10 milligrams per day, the higher doses show higher risks. 20 milligrams per day are significantly higher than placebo. For example, the incidence of major cardiovascular adverse effects over 100 patient years of exposure was 1.1 on the 20 milligram dose, 0.9 on the 10 milligram dose, 0.8 on the placebo dose. Serious infection risk for tofacitinib at 20 milligrams or 10 milligram daily doses was 3.7, and 3.0 per 100 exposure years, markedly higher than the TNF class rheumatic drugs, which also, of course, carry substantial infection risks. Pivotal trials of tofacitinib for ulcerative colitis also found that 20 milligrams, or 10 milligram daily doses of the drug, correlated with markedly higher risks of elevated cholesterol, sort of a unique risk component there. Two recent observational studies confirmed how JAK inhibitors, including tofacitinib, have markedly higher serious infection risks.

Overall, and in conclusion, tofacitinib, we believe, offers relief for RA and related maladies. However, it has many substitutes, as a third-line treatment, and it has concerning safety signals. These facts should help CMS negotiate lower prices of this medicine. And by the way, by that we mean acquisition prices for physicians as well, on the infusion side. Moreover, as is the case with all pharmacotherapies for RA, regular clinical guidance is essential. Accordingly, drug therapy costs should be carefully calibrated to avoid overshadowing critical patient doctor, the critical patient doctor alliance. Thank you.

01:13:52

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.

01:14:05

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

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Yes	Any other personal or professional relationships or interactions with companies or related associations with direct or indirect interest in the Negotiation Program (e.g., drug companies, health plans) that may be considered a financial COI.

Thank you for the opportunity to share the clinical perspectives and patient perspectives on treatment decision-making for patients with immune-mediated inflammatory diseases, including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, which also includes the broader axial spondyloarthritis, for which I am a patient and I have also personally used Xeljanz, ulcerative colitis and juvenile idiopathic arthritis. My name is **[Speaker 3]**. I am speaking on behalf of patients with these conditions as the **[Redacted]** of International Foundation for Autoimmune & Autoinflammatory Arthritis, AiArthritis for short, the only organization in the world that narrows down the auto plus inflammatory arthritis diseases into one cohort, as multiple diagnoses and re-diagnoses in these conditions is common.

Across these conditions, clinicians today have many therapeutic options including biologics and targeted oral therapies, but these are not therapeutic alternatives or are substitutable. The choice is rarely about a single, best drug. It is about matching the right treatment to the right patient at the right time, based on disease severity, prior treatment response, comorbidities, and patient preferences that can impact adherence, like an injection versus a pill.

A key reality in clinical practice is that many patients do not achieve sustained remission and often cycle through multiple therapies over time. Each treatment failure can mean ongoing inflammation, worsening function, increased steroid exposure, and significant disruption to daily life. For many patients, Xeljanz is not another option. It is the option.

Patients are not managing just one symptom, they manage a whole-body disease. It impacts every aspect of their life. Multiple therapeutic options with different mechanisms and delivery methods is essential as the diseases progress. Xeljanz is a targeted JAK inhibitor. It fills a unique and important role in the landscape for certain patients.

One of the clearest clinical scenarios is where Xeljanz adds value in patients who have had inadequate response to intolerance to TNF inhibitors. These patients often have limited remaining options and ongoing disease burden. Clinical trials and real-world evidence show that Xeljanz provides meaningful disease control in these populations, including even achieving remission,



which is a word we don't often hear in our community. In this, in ulcerative colitis in particular, it has demonstrated rapid symptom improvement within days and weeks. Often biologics take months to reach full efficacy, and it has shown sustained remission, including steroid-free remission, which can be translated into other disease states.

Another key differentiator is that Xeljanz is an oral therapy, as you've heard from others. This is very important to understand, because some patients, particularly those with limited access to infusion centers, needle aversions, or groups like the elderly or in rheumatoid arthritis, cannot actually use the injections, and if they don't have somebody to inject them, they go without.

It is also important to recognize these diseases are complex, multiple parts of the body, overlapping, dual diagnosis, many diagnosed, such as rheumatoid arthritis and ulcerative colitis at the same time, so this makes Xeljanz a better option for those who have the dual diagnosis indicated by both. Some older patients may also benefit from Xeljanz, particularly when therapies are not suitable, when an oral option is necessary, when rapid steroid sparing control is clinically important, especially in the older age.

For all of these reasons mentioned, access decisions should be driven by what is clinically appropriate for patients and not solely chosen by cost considerations. Policies that encourage non-medical switching or removing a therapy like Xeljanz from a formulary for cost reasons, or conversely, forcing a patient not on Xeljanz or on a therapeutic alternative to switch to Xeljanz just because of saving money for the system is a risk that undermines patient health. Patients often respond very differently to therapies, even within the same class. CMS should support policies, not restrict the ability of clinicians to make individual treatments based on patient treatment history and needs. Thank you very much.

01:18:26

Moderator, PhD, RTI International

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

I have one follow-up question for you all. What other information about Xeljanz, or its therapeutic alternatives, do you think CMS should consider in its evaluation of Xeljanz? We have just a minute for your brief response. Please raise your hand to answer. **[Speaker 3]**, go ahead.

01:18:58

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

It's in response, actually, to another comment that was made. I want to clarify that when we're thinking of therapeutic alternatives, methotrexate and other lower-cost disease-modifying agents are not appropriate past, typically, either low-disease activity, so some patients can stay on methotrexate for a while, but biologics are for moderate to severe. The majority of patients are moderate to severe, so suggesting any type of therapeutic alternative that is less than an inhibitor, like a JAK inhibitor or a biologic, is potentially dangerous for recommendations. Thank you.

01:19:39

Moderator, PhD, RTI International

We have about 30 seconds, if anybody else would like to weigh in. **[Speaker 1]**, go ahead.

01:19:52

Speaker 1 (registered as a health care professional)

We really need to individualize care for our patients, and certainly, frequently, we'll use combinations of different medications, because a single one will not be effective alone, and we have great data that methotrexate and Xeljanz work very well together.

Closing

01:20:09

Moderator, PhD, RTI International

Thank you. That brings us to the end of this town hall session. I would like to thank all our speakers for joining us this morning 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, which is listed on this slide. If you have questions, please contact CMS using the email address that is also listed on this slide. Thank you all and enjoy the 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>