

CMS Medicare Drug Pricing Negotiation
Patient Experiences Driving Change

Wednesday, February 19
6pm ET/5pm CT/3pm PT





Ensuring Access through Collaborative Health (EACH) & the Patient Inclusion Council (PIC)

The PIC is part of a bigger coalition.
PIC participants include patients
and caregivers.

Welcome!





Patient organizations & allied groups (doctors, pharmacists, etc.) who advocate for drug affordability policies that benefit patients.



Patients & caregivers who participate in activities that ensure patient-reported needs are incorporated into drug affordability solutions.

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COMPANY/EACH-PIC-COALITION



This is a transparent, judgement-free space.

Who are we? People living with chronic conditions that require treatment with high cost prescription drugs. We are also leaders within the Patient Inclusion Council (PIC).

Who are you? We invited patients/caregivers as our primary audience, as we would like to inform you about CMS negotiation and make sure you know how vital it is to get involved. Feel free to introduce yourself, where you are from, why you are here, etc., in the chat.

Participation. Share experiences and concerns in the chat. Be respectful. You may submit questions using the Q&A, which can be anonymous.



It's just about putting patients in the pilot seat. If you support or do not support drug negotiations, if you love or hate insurance companies or pharmaceutical companies, it's not relevant to this conversation. This is about patients using our voices for change.



We will discuss opportunities and concerns regarding CMS. The goal is to encourage patients/caregivers to get involved.

Q & A



Please submit your questions at any time. We will pause throughout the presentation/discussion to answer these. Any questions not answered, we will follow up afterwards!



Disclaimer/Transparency: As a non-profit, we accept funding from corporate donors, including pharmaceutical companies. However, our work to manage the Patient Inclusion Council is driven by addressing patient-reported issues and patient-infused solutions (data-driven, factual). Our corporate donors have no influence over the mission or objectives of our organization or any of the work we do. **We do not discriminate regarding who can support the PIC.** Any entity who agrees to support our efforts must agree our work is and always will be led by what patients say is the truth.

EACH/PIC is a program led by AiArthritis (International Foundation for Autoimmune & Autoinflammatory Arthritis), but is disease agnostic.

Is your drug up for review? Are you on Medicare?

Drugs Selected for 2025 Review

Would go into effect in year this will go into effect in 2027

Drug	Condition	Drug	Condition	
Ozempic, Rybelsus, Wegovy	Type 2 Diabetes, Obesity	Austedo	Chorea in Huntington's disease, Tardive dyskenesia	
Trelegy Ellipta	Asthma, Chronic obstructive pulmonary disease	Breo Ellipta	Asthma, Chronic obstructive pulmonary disease	
Xtandi	Prostate cancer	Tradjenta	Type 2 diabetes	
Pomalyst	Multiple myeloma, Kaposi sarcoma	Xifaxan	IBS, Hepatic encephalopathy	
Ibrance	Breast cancer	Vraylar	Schizophrenia, Bipolar Disorder, Major depressive disorder	
Ofev	Idiopathic pulmonary fibrosis	Janumet	Type 2 diabetes	
Linzess	IBS, Chronic idiopathic constipation	Otezla	Plaque psoriasis, Psoriatic arthritis, Oral ulcers	
Calquence	Leukemia/Lymphoma			

What is a Medicare Drug Review/Negotiation?



The portion of Medicare that covers prescription medications is known as Medicare Part D or Medicare Advantage.



In 2022, the passing of the Inflation Reduction Act (IRA) gave CMS the authority to negotiate with drug manufacturers to **establish the price of a handful of drugs for Medicare Part D** each year. The negotiated price is called the Maximum Fair Price (MFP).

- Negotiations started last year. 10 drugs were selected for negotiation and those prices for Medicare will take effect in 2026.
- This year, CMS has selected 15 more drugs for negotiation, and those prices for Medicare will take effect in 2027.



Drug negotiations have been advertised as a victory for patients and a way to lower their out-of-pocket costs. However, healthcare is complicated. Patient costs may go down, but they also might not go down, and and there could also be unintended consequences of the program. We don't know yet, which is why we need patients to share their experiences related to these drugs AND the diseases treated by these drugs.



Since the negotiation process is still under construction, we (the patients) MUST make sure we participate and, in turn, help shape their work and make sure what we need is addressed as a priority.

It is a pilot project. So we need patients to be pilots.

How does the drug negotiation work?

Drug Name	Commonly Treated Conditions*			
Ozempic; Rybelsus; Wegovy	Type 2 diabetes; Type 2 diabetes and cardiovascular disease; Obesity/overweight and cardiovascular disease	10514921		
Trelegy Ellipta	Asthma; Chronic obstructive pulmonary disease			
Xtandi	Prostate cancer			
Pomalyst	Kaposi sarcoma; Multiple myeloma			
Ibrance	Breast cancer			
Ofev	Idiopathic pulmonary fibrosis			
Linzess	Chronic idiopathic constipation; Irritable bowel syndrome with constipation			
Calquence	Chronic lymphocytic leukemia/small lymphocytic lymphoma; Mantle cell lymphoma			
Austedo; Austedo XR	Chorea in Huntington's disease; Tardive dyskinesia			
Breo Ellipta	Asthma; Chronic obstructive pulmonary disease			
Tradjenta	Type 2 diabetes			
Xifaxan	Hepatic encephalopathy; Irritable bowel syndrome with diarrhea			
Vraylar	Bipolar I disorder; Major depressive disorder; Schizophrenia			
Janumet; Janumet XR	Type 2 diabetes			
Otezla	Oral ulcers in Behçet's Disease; Plaque psoriasis; Psoriatic arthritis			



CMS selects a handful of drugs that have high costs to them and starts a formal negotiation process with manufacturers. These are not drugs identified based on patient-reported needs.



CMS asks all groups who are part of the complex prescription drug system to submit information to them about the drug under review.

Some include drug companies, insurance/Pharmacy Benefit Managers (PBMs) who pick the drugs on your drug lists, pharmacists, doctors, patient organizations, and PATIENTS/CAREGIVERS. roundtables, and a townhall. Currently, VERY, VERY few patients are participating in these sessions and CMS is making decisions WITHOUT OUR INPUT.











How does drug negotiation work?



CMS wants to know about patient/caregiver experience with this drug, including experience with any "therapeutic alternatives". Other questions they ask will be reviewed later!



CMS proceeds with negotiation and publishes a list of final prices to establish the Maximum Fair Price (MFP) for each selected drug.

It is a pilot project. So we need patients to be pilots.

CMS defines Therapeutic Alternatives as "drugs that are used to treat the same condition or disease state as the selected drug; the Inflation Reduction Act (IRA) directs CMS to consider how the selected drug compares to therapeutic alternatives when negotiating.

What does this mean for me?

- It's possible savings will be passed on to the patient, which is good for those on this drug.
 - **However,** CMS expects plans may switch patients away from the negotiated drugs, possibly because plans won't be able to gain as much profit from a low cost drug.
 - Plans may adjust their formularies (preferred drug lists) to drive doctors/patients to other drugs that treat the same condition or disease (therapeutic alternatives).

• This could mean:

- Medicare patients taking the drug under review could see changes to how those drugs are prescribed to them
 OR
- if a patient is diagnosed with a condition the drug under review treats, if that drug becomes the cheapest for Medicare, others could be asked to switch to it.

"CMS is concerned that Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs by placing selected drugs on less favorable tiers compared to non-selected drugs, or by applying utilization management that is not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs."

Potential Outcomes

- Negotiated prices are price caps to the health insurance plans.
- Plan savings might or might not not be passed on to patients.
- Plans still will be able to adjust how each medication is treated on their plans.

Outcome Options:

Patient Costs Improve
Or
Patient Costs Do Not Improve

Concerns, having a voice is the best way to ensure great outcomes!

Diagnosis/Not on Drug -Asked to Switch to Negotiated Medication

On Drug - Drug not chosen - Asked to Switch to an Alternative Medication

The impact of Medicare drug negotiations on individual patients still largely depends on their individual plan and how insurers/PBMs decide to handle the new pricing.

Potential Patient Impact: Reported Savings - Advertising

Drug Name	Participating Drug Company	Commonly Treated Conditions	Agreed to Negotiated Price for 30- day Supply for CY 2026	List Price for 30-day Supply, CY 2023	Discount of Negotiated Price from 2023 List Price	Total Part D Gross Covered Prescription Drug Costs, CY 2023	Number of Medicare Part D Enrollees Who Used the Drug, CY 2023
Januvia	Merck Sharp Dohme	Diabetes	\$113.00	\$527.00	79%	\$4,091,399,000	843,000
Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill	Novo Nordisk Inc	Diabetes	\$119.00	\$495.00	76%	\$2,612,719,000	785,000
Farxiga	AstraZeneca AB	Diabetes; Heart failure; Chronic kidney disease	\$178.50	\$556.00	68%	\$4,342,594,000	994,000
Enbrel	Immunex Corporation	Rheumatoid arthritis; Psoriasis; Psoriatic arthritis	\$2,355.00	\$7,106.00	67%	\$2,951,778,000	48,000
Jardiance	Boehringer Ingelheim	Diabetes; Heart failure; Chronic kidney disease	\$197.00	\$573.00	66%	\$8,840,947,000	1,883,000
Stelara	Janssen Biotech, Inc.	Psoriasis; Psoriatic arthritis; Crohn's disease; Ulcerative colitis	\$4,695.00	\$13,836.00	66%	\$2,988,560,000	23,000

Let's Review 2024 List

You probably saw this table circulating around election time this year. It demonstrates the negotiated costs of the first 10 drugs selected for negotiation.

However, while this looks
GREAT, this is not actually about
patient costs. It's about
Medicare's costs (savings to the
system).

YOUR VOICE MATTERS!

CMS has established a couple opportunities to provide feedback on the 15 drugs:

Written Comments

Submitted through an Information Collection Request (Form) - Due March 1

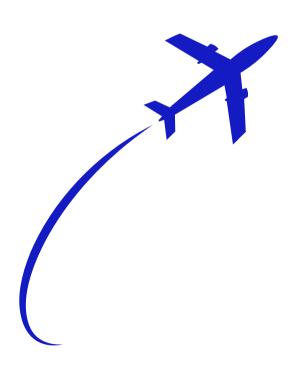




- Are you interested? Example of questions (in simple terms):
 - **Disease impact.** How your condition impacts your life: daily life, how has your condition changed over time?
 - Challenges faced managing your condition?
 - **Medication:** Why did you start taking it? Experience with it? Stopped, if so, why? Benefits? Side effects?







Participating in Events

Patient/Caregiver Roundtables

- CMS will hold up to 15 roundtables for patients to share about their drugs
- Will ask questions and allow discussion among participants
- Patient organizations and patients/caregivers will both be invited to participate
- Roundtable events will be held virtually
- They will be recorded, but not "live"
- By signing up to the PIC, you'll have us to help you prepare!

Opportunities from the PIC

- Let us help guide you to make sure your experiences are counted
- Take our survey!
- Communicate with CMS through our efforts
- Patient-led, leave opinions at the door, focus on sharing your truth and being a pilot!









THANK YOU

Be a pilot for your own health outcomes. Let us help you get there.

Interested in participating in anything we talked about today?



eachpic.org/pic-voices/

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