



# Understanding the Negotiation Process

WHY PATIENT VOICES ARE NEEDED



# THANK YOU

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# WELCOME

Medicare drug price negotiation is now being implemented, and the decisions being made will directly affect patient access to treatments and care.

This patient-focused briefing provides a clear explanation of how Medicare drug price negotiation works, what it does—and does not—do, and what patients should understand as this policy moves forward.

# WHAT WE PLAN ON COVERING



What negotiation actually is

What CMS is evaluating

Where patients fit

What has changed since  
last year

Emerging structural issues  
(biosimilars, valuation)

# WHAT NEGOTIATION MEANS UNDER IRA

This is a structured price setting, not open-ended bargaining.



**CMS SELECTS DRUG**



**CMS SETS MAXIMUM FAIR PRICE**



**MANUFACTURER MUST COMPLY OR FACE EXCISE TAX**



# HOW CMS DETERMINES VALUE

- MANUFACTURER-SPECIFIC DATA
- THERAPEUTIC ALTERNATIVES
- R&D CONSIDERATION
- REVENUE DATA
- CLINICAL BENEFIT
- PUBLIC INPUT (LIMITED)



# High-Level Market Considerations

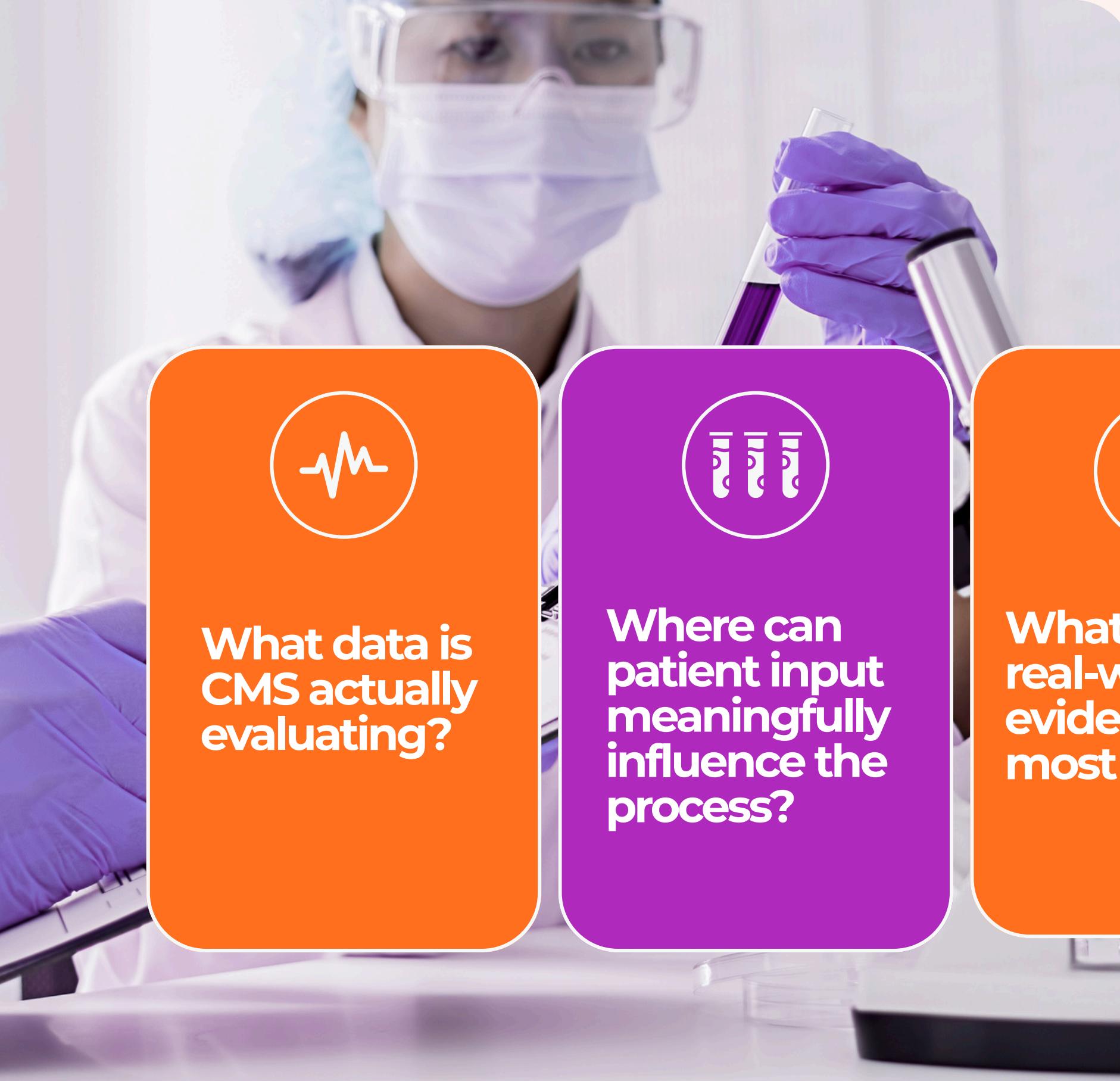


How CMS evaluates value across therapeutic alternatives

How plans may respond through formulary design and utilization management

How government price setting interacts with broader market competition — including biosimilars

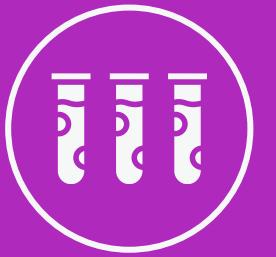
Balancing immediate savings with long-term sustainability



# KEY STRUCTURAL QUESTIONS



**What data is CMS actually evaluating?**



**Where can patient input meaningfully influence the process?**



**What types of real-world evidence are most helpful?**



**How should patients frame treatment impact?**



**What mistakes should advocates avoid in public comments?**

# WHAT CMS IS LOOKING FOR

You don't have to be a policy expert to participate. CMS is looking for clear, real-world insight into how medications are actually used and how access affects health and daily life. The value information that explains how a treatment functions outside of clinical trials, which outcomes matter to patients, what happens when access is delayed, restricted or lost and how treatment influences quality of life, independence and day-to-day functioning.

# WHAT ARE LISTENING SESSIONS?

Listening Sessions, sometimes referred to as patient roundtables, are structured conversations in which patients share their experiences verbally. During these conversations, CMS staff may ask questions for participants to explain how access to treatment affects real life beyond what can be captured in written feedback.



# HOW TO PARTICIPATE

## Step 1: Learn the Basics

Understand which drugs have been selected and what participation options are available.

## Step 2: Prepare Your Story

Outline your experience clearly and honestly. Focus on what matters most to you.

## Step 3: Submit Written Comments

Written comments are submitted through CMS's official process and become part of the public record.

## Step 4: Register (if available)

Some patients may be invited or able to register to participate in listening sessions or roundtables.

## Step 5: Participate with Confidence

You're sharing your experience. There are no "right" or "wrong" answers.



# WHAT'S HELPFUL



- **Your condition or diagnosis** (in general terms is acceptable)
- **Your treatment journey**, including how you arrived at your current therapy
- **Your experience with the medication**, including benefits and challenges
- **What access means to you**, or what losing access would mean
- **Any disruptions** you've experienced (delays, switches, denials)

You don't need to submit medical records, include scientific citations or use legal or technical language.

# WHAT'S PERSUASIVE



- **Why a medication works** for you when others did not
- **If you experience side effects**, describe how side effects affect daily functioning
- **What stability on treatment** allows you to do (work, caregiving, independence)
- **The real consequences** of switching or delaying treatment

Clear, specific examples are more helpful than general statements.

# **SUBMITTING WRITTEN COMMENTS**

CMS invites patients, caregivers and members of the public to share written feedback about the drugs selected for negotiation. This input can include information about how a medication is used in real life, what treatment options exist or do not exist, where needs remain unmet and how different patient populations are affected. CMS is also interested in hearing directly from patients and caregivers about their experiences managing care, accessing treatment and living with these medications day to day.

**SUBMIT YOUR COMMENTS BY MARCH 1**



## DATES + DEADLINES

The roundtable events will be held April 6 – April 17, 2026.

Registration will be open until March 6, 2026.

The public engagement events are subject to change, including postponement and/or cancellation.

***All times are Eastern Standard Time.***

# ROUNDTABLE DISCUSSION DATES

- **Anoro Ellipta**: April 6 from 11 a.m. – 1 p.m.
- **Biktarvy**: April 6 from 2:30 – 4:30 p.m.
- **Botox, Botox Cosmetic**: April 8 from 11 a.m. – 1 p.m.
- **Cimzia**: April 8 from 2:30 – 4:30 p.m.
- **Cosentyx**: April 9 from 11 a.m. – 1 p.m.
- **Entyvio**: April 9 from 2:30 – 4:30 p.m.
- **Erleada**: April 10 from 12 – 2 p.m.
- **Kisqali**: April 13 from 11 a.m. – 1 p.m.
- **Lenvima**: April 13 from 2:30 – 4:30 p.m.
- **Orencia**: April 14 from 11 a.m. – 1 p.m.
- **Rexulti**: April 14 from 2:30 – 4:30 p.m.
- **Trulicity**: April 15 from 11 a.m. – 1 p.m.
- **Verzenio**: April 15 from 2:30 – 4:30 p.m.
- **Xeljanz; Xeljanz XR**: April 16 from 11 a.m. – 1 p.m.
- **Xolair**: April 16 from 2:30 – 4:30 p.m.
- **Tradjenta**: April 17 from 12 – 2 p.m.





# THANK YOU!

[www.patientsrising.org](http://www.patientsrising.org)