Special Report to Inform CMS Drug Price Negotiations: Trelegy Ellipta® and Breo Ellipta® for Patients with COPD

ICER SNAPSHOT

Reviewed by: COPD Foundation

The COPD Foundation is not responsible for the final contents of ICER's Report or Snapshot, nor should their review be assumed to support any part of ICER's findings.

The ICER Snapshot is a summary designed to help patients and the broader community learn about the key results and recommendations from ICER's Special Report to inform CMS Drug Price Negotations for Trelegy Ellipta® and Breo Ellipta® for patients with COPD.

The information included is up to date as of March 2025. New information may become available, but is not captured here.

Let's Take a Look

- **What is the CMS Drug Price Negotiation Program?**
- **What is ICER's Role in this?**
- **What Kind of Information are We Submitting?**
- **What Did We Hear From Those Living with COPD?**
- **What are the Major Findings of our Report?**



Glossary of Key Terms

CMS: Centers for Medicare & Medicaid Services

Comparator: a similar treatment for the same medical condition used to compare to the drug of interest

Drug company: the company that makes the drug and chooses a price for it; also known as the drug manufacturer

Exacerbation: a sudden major increase or worsening of symptoms

Out-of-pocket costs: the amount of money you pay for medical services that your health insurance doesn't cover

Persistence: continuing to take a medication over time (even without perfect adherence, which is taking it exactly as prescribed)

Respiratory: related to breathing; impacting the nose, mouth, and lungs

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What is the Centers for Medicare & Medicaid Services (CMS) Drug Price Negotiation Program?

The **Centers for Medicare & Medicaid Services (CMS)** is a federal department in the United States (US). This department manages major healthcare programs such as **Medicare, Medicaid, and the Children's Health Insurance Program (CHIP)**. In combination, these programs provide healthcare to more than **160 million people** across the US.

Medicare is a national program that primarily provides healthcare services for people aged 65 or older but sometimes can cover younger people with certain medical conditions. Similarly, **Medicaid** is a national program that provides healthcare services, but for low-income individuals and families.

The **Inflation Reduction Act (IRA)** was signed into law in 2022. There are many goals of this law, but the one we are focusing on for this report is the Drug Price Negotiation Program. The goal of this program is to **bring financial relief to millions of people who use Medicare by improving access and affordability to various drugs.** Currently, drug prices in the US are among the highest in the world. **This program allows Medicare to directly negotiate with drug companies on the prices of certain high-cost drugs.** For 2027, CMS has selected 15 drugs to negotiate.

As a part of the Drug Price Negotiation process, CMS is asking for public input. Drug companies, patient groups, clinicians, research institutions, and others are invited to provide relevant information about any of the 15 drugs on CMS' list. Specifically, **CMS wants public information to support their understanding of how well the selected drugs work compared to similar treatments.**

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How is ICER Participating in the Drug Price Negotiation Process?

ICER is writing a special report to submit to CMS as public input for the 2027 Drug Price Negotiation Process. ICER's special report will focus on **two of the 15** drugs that will be negotiated in 2027: **Trelegy Ellipta® and Breo Ellipta®**. These drugs were produced by the same drug company for the treatment of **chronic obstructive pulmonary disorder (COPD)**. Breo Ellipta® is a combination of two drugs (dual therapy) and Trelegy Ellipta® is a combination of three drugs (triple therapy).



What Kind of Information are We Submitting?

ICER's goal is to compare the evidence for both Breo Ellipta and Trelegy Ellipta to their comparators (other similar treatments for COPD) by answering these questions:

- Which **clinical outcome measures** should be considered in comparing Breo Ellipta® and Trelegy Ellipta® to similar treatments?
- Which **outcomes** are most important to patients living with COPD?
  - Things like; how well do these drugs work, how safe are they to use, and what happens if people are not able to continue taking the available medications?
- What are people living with COPD saying about their use of inhalers and how it impacts their **quality of life**?
  - What type of **symptoms** are patients experiencing?
  - Are there any **health equity considerations** we need to keep in mind?
- What are the **expected health benefits and harms** from these drugs compared to similar treatments?
- What is the **highest price** at which these drugs are still considered cost-effective when compared to similar treatments?

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What Did We Hear From Those Living with COPD?

1

Inhaled medications are one of the main forms of treatment for COPD. However, many people have **trouble using prescribed inhalers correctly**. Using inhalers incorrectly can **decrease** how well they work. People with COPD also expressed frustration that **clinicians do not always show them how to use inhalers correctly**, especially new ones.

2

We heard that it is much easier to consistently take inhaled medications when it is required only once a day. Even if this requires multiple 'puffs' in one sitting, **people prefer a once-a-day treatment over taking 'puffs' at multiple times during the day**.

3

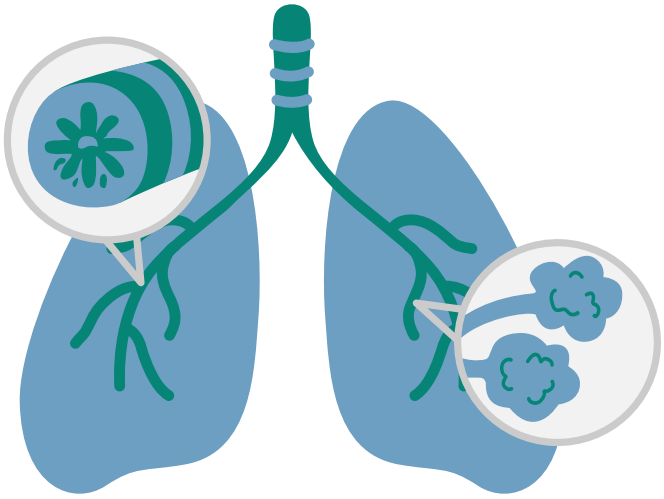
People with COPD shared that **both preventing exacerbations and managing them** if they happen are very important. COPD can get permanently worse after these flare-ups (sudden worsening symptoms), so it often helps when people **work with their clinician to understand their condition and potential treatments for when symptoms get worse**.



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Clinical Results

What Were the Major Findings from Our Report?



Trelegy Ellipta®

Trelegy Ellipta® works just as well as other triple therapy drugs when the treatments are used correctly as prescribed. However, one benefit of Trelegy Ellipta® is that **it only requires one 'puff', once a day,** while the comparators usually involve **multiple inhalers and are typically used twice a day**. There is some evidence suggesting that once-daily treatments like Trelegy Ellipta® lead to greater persistence which likely results in **fewer COPD exacerbations** compared to other treatments taken more often. Therefore, Trelegy Ellipta® is about the **same or slightly better than its comparators.**

Breo Ellipta®

Breo Ellipta® was found to offer **more benefit** when compared to existing inhaled dual therapy options. Furthermore, it offers the advantage of **requiring only one puff, once a day,** leading to greater persistence while its comparators require a **twice-daily use**. In conclusion, Breo Ellipta® is about the **same or slightly better than its comparators.**

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Economic Results

Our economic results aim to inform CMS about the prices they should negotiate with drug companies. These results are calculated based on the prices of the comparator drugs and how well Trelegy Ellipta® and Breo Ellipta® work compared with similar treatments. The results show that Trelegy Ellipta® and Breo Ellipta® **resulted in fewer COPD exacerbations** likely due to greater persistence in taking the drugs **when compared to similar treatments.**

CMS predicts that the savings to come from the negotiation process will lower out-of-pocket costs for those enrolled in Medicare by an estimated **$1.5 billion in 2026.***

Source: *https://www.cms.gov/files/document/factsheet-medicare-negotiation-selected-drug-list-ipay-2027.pdf

Conclusion

ICER's special report on two new drugs for COPD found that **both drugs work at least as well** as similar treatments because of greater persistence, thereby reducing COPD exacerbations. The full report was submitted to CMS on February 26th, 2025 as public input to inform the 2027 drug price negotiations between Medicare and the drug companies.

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