

# ICER SNAPSHOT

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The ICER Snapshot is a summary designed to help the Ulcerative Colitis and Crohn's Disease patient communities learn about the key results and recommendations from ICER's 2026 Special Report to inform CMS Drug Price Negotiations for Vedolizumab (Entyvio®).

The information included is up to date as of March 3, 2026. 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 the Patient Community?

What are the Major Findings of our Report?



## Glossary of Key Terms

**Biologic treatment or “biologics”:** a type of medicine made from living cells and designed to target specific parts of the immune system

**CMS:** Centers for Medicare & Medicaid Services

**Crohn's Disease (CD):** a disease where the immune system mistakenly attacks the digestive tract – anywhere from mouth to bottom – causing deep inflammation, pain, and serious digestive problems that flare over time

**Intravenous (IV) infusion:** when a medicine is delivered directly into your bloodstream through a vein

**Remission:** when the symptoms of a disease calm down significantly or disappear completely, it doesn't mean the disease is gone or cured

**Ulcerative Colitis (UC):** a disease where the immune system mistakenly attacks the colon (main part of large intestine), causing painful sores, inflammation, and digestive problems that come and go over time

## Drug Names

**Entyvio®:**  
brand name for vedolizumab

**ustekinumab:**  
scientific name for Stelara®

**infliximab:**  
scientific name for Remicade®

**adalimumab:**  
scientific name for Humira®

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

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

**Medicare** is a government insurance program that primarily pays for or provides healthcare services for people aged 65 or older but sometimes can cover younger people with certain medical conditions. Similarly, **Medicaid** is a government insurance 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 its third cycle of negotiations in 2028, CMS has selected 15 drugs.

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**.

# How is ICER Participating in the Drug Price Negotiation Process?

ICER wrote a special report to submit to CMS as public input for the 2028 Drug Price Negotiation Process. ICER's special report focuses on **one of the 15 drugs** that will be negotiated in 2028: vedolizumab (Entyvio) made by Takeda Pharmaceutical Co. Ltd. for the treatment of moderate to severe UC and CD.

## What Kind of Information are We Submitting?



ICER's goal is to **compare the evidence for Entyvio to other biologic treatments for UC and CD (ustekinumab, infliximab, and adalimumab)** by answering these questions:

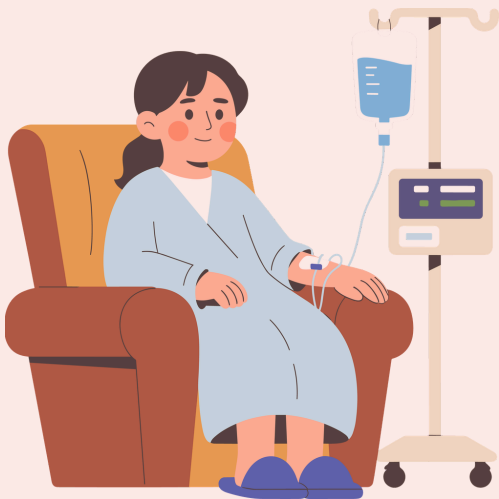
- ➔ Which **clinical outcome measures** should be considered in comparing Entyvio to similar treatments?
- ➔ Which **outcomes are most important to patients** living with UC or CD?
  - How well do these drugs work and how safe are they to use?
  - What type of symptoms are most bothersome for patients?
  - How do patients feel about getting an intravenous (IV) infusion?
- ➔ What is the **impact on quality of life** for people living with UC and CD?
  - Are there any **access or affordability** challenges?
- ➔ 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?

## What Did We Hear From Those Living with UC and CD?

Patients wanted **relief from the diarrhea and bleeding**. The need for frequent bathroom breaks often led patients to be anxious about being outside the home and needing to always be prepared for accidents.

Controlling symptoms often involves **extreme dietary restrictions**. Patients just want to lead a normal life and be able to eat what they want.

**Fatigue** greatly impacts the daily activities and quality of life for these patients. It can feel very limiting and also lead to serious mental health challenges.

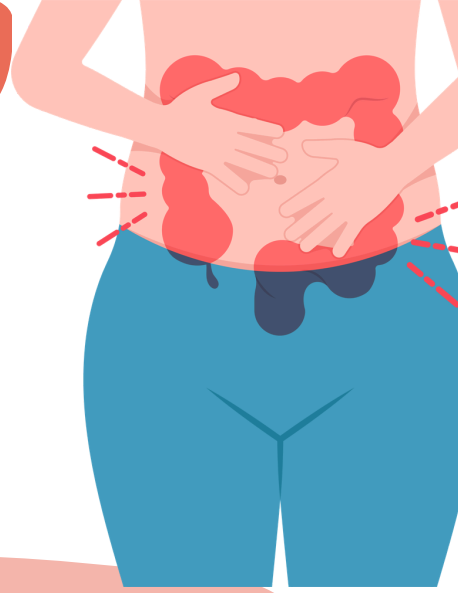


Patients shared that intravenous (IV) **infusions were time-consuming** and also took a toll on their veins.

The **new form of self-injectable pens were preferred by patients**, but easier to forget to take the treatment at home, leading to disease flares.

The **affordability and access challenges** for these patients were burdensome. In addition to fighting **insurance barriers**, patients were also impacted by **co-pays**, and the **cost of blood draws and special diets** to manage their disease.

We heard from patient groups that **when patients can't access certain treatments, their disease can get worse** and may lead to serious complications requiring hospitalization or surgery. They also shared that UC and CD can affect people differently, so doctors need to consider things like other health conditions, side effects, cost, and symptoms beyond the gut – **like joint pain, fatigue, and mental health struggles** – when deciding on treatment.



# Clinical Results

## What Were the Major Findings from Our Report?

### Outcomes of Interest

- How well patients responded to treatment
- Whether they reached remission
- How many patients stopped treatment due to serious side effects

## Entyvio compared to ustekinumab

### C-

#### Ulcerative Colitis

**ICER rated Entyvio as similar to or slightly worse than ustekinumab for treating UC.** For the outcomes of interest, there were no major differences between the two drugs. However, ustekinumab did show a slight edge, with more patients responding and reaching remission with fewer participants stopping treatment due to side effects.

### C

#### Crohn's Disease

**ICER rated Entyvio as comparable to ustekinumab for treating CD.** For the outcomes of interest, there were no major differences between the two drugs.

## Entyvio compared to infliximab and adalimumab

### C+

#### Ulcerative Colitis and Crohn's Disease

**ICER rated Entyvio as equal to or better than infliximab and adalimumab for treating both UC and CD.** For the outcomes of interest, there were no major differences between the drugs. However, Entyvio had fewer serious infections in real-world data, and unlike Entyvio, both infliximab and adalimumab carry serious warnings about the risk of severe infections and cancer.

# Economic Results

ICER calculated price premiums for Entyvio to show how much more Medicare (CMS) should pay for Entyvio when compared to two other drugs, infliximab and ustekinumab, for treating both UC and CD.

For UC, Entyvio showed some advantages over infliximab in keeping patients in remission and reducing the need for surgery. For CD, Entyvio did not show clear advantages over infliximab. When these results were combined to reflect the proportion of Medicare patients (mostly 65 years and older) with UC and CD, an **overall price premium of \$210 to \$230 for Entyvio** was supported.

**Compared to ustekinumab**, Entyvio did not show better health outcomes for either condition, so **the evidence does not support charging a higher price for Entyvio**.

## Conclusion

ICER's special report on Entyvio found that it works about as well as similar treatments for UC and CD. The economic model supports a slight premium increase for Entyvio when compared to infliximab but not when compared to ustekinumab. The full report was submitted to CMS on February 27th, 2026 as public input to inform the 2028 drug price negotiations between Medicare and the drug companies.