



Chronic Care  
Policy Alliance

State Advocates  
Working Together  
to Bridge the Gaps  
in Chronic Care

# Ensuring Patient Voices Are Heard During Medicare's Drug Price Negotiation Listening Sessions

Wednesday, September 20



# Presenters



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*Chief Executive Officer*  
AiArthritis

## Who is CCPA?

A network of state and regional health care advocacy organizations advancing public policy that improves the lives of those living with chronic conditions and diseases.





**Michael Ward**

*Vice President of Public Policy and  
Government Relations*  
Alliance for Aging Research



**Alliance**  
FOR AGING RESEARCH

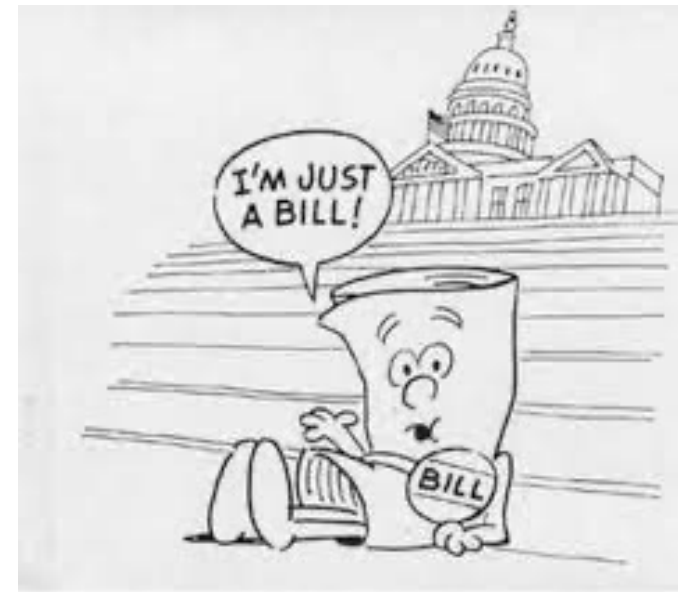
**Catalyzing Innovation  
for Healthy Aging**

# The Inflation Reduction Act and Why Engagement Matters

September 20, 2023

# What is the Inflation Reduction Act?

- The Inflation Reduction Act passed in August 2022 as a budget reconciliation bill, meaning it was not subject to Senate filibuster rules and thus needed only a simple majority to pass. The IRA was signed into law with only Democratic votes.
- The IRA focused on three areas:
  - Budgetary savings / deficit reduction
  - Prescription drug negotiation and addressing Medicare out-of-pocket costs
  - Climate and green energy initiatives





# What are the IRA's healthcare affordability provisions?

- Medicare beneficiary affordability
  - \$2,000 (to grow in future years) annual limit on Medicare beneficiaries OOP costs starting in 2025
  - The ability to pay OOP drug costs in zero-interest installments over the course of a calendar year (Jan-Dec.) starting in 2025
  - \$35/month insulin (codified a CMS pilot project)
  - Elimination of copayments for all CDC-recommended vaccines for Medicare beneficiaries
  - Expanded population (up to 150% of federal poverty level) eligible for premium subsidies starting 2024

# What are the IRA's drug pricing provisions?

- Medicare inflationary rebate
  - If a price for a drug grows faster than the rate of inflation, the manufacturer must provide a rebate to Medicare.
- Medicare price negotiation for drugs
  - Starts with 10 drugs available in Medicare Part D in 2026, then additional 15 drugs in 2027, then 15 drugs from Parts B OR D in 2028, then 20 drugs from either program in 2029 and thereafter
  - Number each year is additive, but selected from the 50 drugs with the highest spend in Part D (and B, starting in 2028)
- What drugs are potentially eligible (partial list of requirements):
  - At least nine years after FDA approval for small molecule
  - At least 13 years after FDA approval for biologics
  - Not have an available generic or biosimilars
  - Not be for a single rare disease indication



# Going deeper on price negotiation



- Voluntary negotiation?
  - Negotiated amount can't exceed the MFP
  - If manufacturer doesn't accept the negotiated price or charges a different price, an excise tax of 65% on all US sales for the product (growing up to 95% - increases by 10% each quarter) is incurred.
  - As an alternative to the tax, a manufacturer would have to withdraw ALL of their drugs from Medicare and Medicaid.

# So, why should patients and providers care?

- CMS and the Trump Administration tried to implement price setting before. Analysis showed they would have reduced access for patients.
- Under the IRA, drugs are required to be covered, but plans may create disincentives to use drugs included in negotiation. CMS hasn't committed to creating safeguards, only monitoring.
- Important to ensure that CMS values the same things that patients care about when they are thinking about their drugs. Outcomes preferred by payers will guide what is prioritized for development in the future.
- CMS has indicated they may use cost-effectiveness methodologies that discriminate against older adults and people with a disability.
- But wait, won't Medicare beneficiaries save money due to price negotiation? (It depends)

<b>Drug Name</b>	<b>Commonly Treated Conditions</b>
Eliquis	Prevention and treatment of blood clots
Jardiance	Diabetes; Heart failure
Xarelto	Prevention and treatment of blood clots; Reduction of risk for patients with coronary or peripheral artery disease
Januvia	Diabetes
Farxiga	Diabetes; Heart failure; Chronic kidney disease
Entresto	Heart failure
Enbrel	Rheumatoid arthritis; Psoriasis; Psoriatic arthritis
Imbruvica	Blood cancers
Stelara	Psoriasis; Psoriatic arthritis; Crohn's disease; Ulcerative colitis
Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill	Diabetes

# Upcoming Opportunities to Provide Feedback

- Written comments: due October 2<sup>nd</sup>
- Listening sessions (Oct. 30 – Nov. 15): deadline to register is October 2<sup>nd</sup>
  - Limited to 20 participants
- Ad hoc
  - Can request a meeting with CMS staff at any time; helpful if beneficiaries participate





**Michaela Sims**  
*President*  
Sims Strategy

# CMS Engagement

- In revised Negotiation Guidance, CMS announced listening sessions
- Opportunity for:
  - Written Comments
  - Speaking Opportunities at Virtual Listening Sessions
- Details:
  - Focused on Comparative Effectiveness and Therapeutic Alternatives
  - All 10 drugs considered separately



# CMS Engagement

- Keep in mind...
  - This won't be the end of the road for CMS engagement.
  - Plenty of opportunity for future sign on letters, meetings, outreach to CMS.
  - Narrowness of the listening sessions does not mean our future activities will be narrow.

# CMS Engagement

- Speaking Opportunities – Requests to Speak Due October 2, 2023
  - CMS holding 10 virtual 90-minute listening sessions – October 30 – November 15, 2023
  - Approximately 20 randomly selected speakers for each listening session
  - Speakers notified week of October 9
    - *Note – This is after written submission deadline*
  - <https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation-program-patient-focused-listening-sessions>



# CMS Engagement

- Optional Discussion Topics for Speaking Opportunities:
  - *Patients' day-to-day experiences living with the condition(s) treated by the selected drug, including how the experience may differ for different patient populations as well as patient caregivers and families.*
  - *How the selected drug impacts patients, including both benefits and side effects, as compared to the therapeutic alternative(s), and which outcomes matter most to patients with the condition(s) treated by the selected drug.*
  - *Patient experiences of access, adherence, and affordability of the selected drug as compared to therapeutic alternative(s).*
  - *Any other information about the selected drug, the condition(s) it is used to treat, and other treatments used for that condition(s) that the speaker believes is important.*





# CMS Engagement

- CMS will host 10 Listening Sessions this fall, one for each of the 10 selected drugs:
  - Eliquis: Monday, October 30, 2023 at 12:00 – 1:30 PM EST
  - Enbrel: Tuesday, October 31, 2023 at 12:00 – 1:30 PM EST
  - Entresto: Wednesday, November 1, 2023 at 12:00 – 1:30 PM EST
  - Farxiga: Thursday, November 2, 2023 at 12:00 – 1:30 PM EST
  - Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill:  
Friday, November 3, 2023 at 12:00 – 1:30 PM EST
  - Imbruvica: Monday, November 6, 2023 at 12:00 – 1:30 PM EST
  - Januvia: Tuesday, November 7, 2023 at 12:00 – 1:30 PM EST
  - Jardiance: Wednesday, November 8, 2023 at 12:00 – 1:30 PM EST
  - Stelara: Tuesday, November 14, 2023 at 12:00 – 1:30 PM EST
  - Xarelto: Wednesday, November 15, 2023 at 2:00 – 3:30 PM EST
- The Listening Sessions are open to the public, no registration needed, and will be live streamed at <http://www.hhs.gov/live>.



# Commenting Process

- Written Comments – Due October 2, 2023
- CMS Written Submission Instructions Document
  - <https://www.cms.gov/files/document/2023-guide-public-submission-information-about-selected-drugs-and-their-therapeutic-alternatives.pdf>
- Six Total Questions – Don't have to answer them all
  - 1,000-3,000 word limit for each question.
  - Some questions asks if your answer includes a cost-effectiveness measure.
  - Some questions allow for uploading additional materials and adding citations.
- Have to submit the form individually for each drug
- You are not able to save responses – must be entered and submitted at one time for a drug.

# Commenting Process

- Per CMS, full question text is available:
  - *All questions, instructions and definitions are available in the Information Collection Request Form for the Negotiation Data Elements. You only need to look at Sections I and J, Questions 26 through 32 starting on page 36.*
  - <https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pralisting/cms-10847>



# Questions Overview

Question	Topic	Word Limit	Notes
#26	Respondent Information		
#27	Prescribing Information	3,000	
#28	Therapeutic Impact and Comparative Effectiveness	3,000	
#29	Comparative Effectiveness on Specific Populations	3,000	
#30	Addressing Unmet Medical Needs	1,000	
#31	Patient and Caregiver Experience	2,000	Only available if answer to #26 indicates patient or caregiver
#32	Executive Summary	1,000	Only available if answer to #26 is NOT patient or caregiver

# Request A Submission Link

- [https://hpms.cms.gov/app/ng/pblc\\_cmt/](https://hpms.cms.gov/app/ng/pblc_cmt/)

## Requested Link - Medicare Drug Price Negotiation Program Public Submission Form

Enter your email address and then click the "Request Email Link" button. You will receive an email from "HPMS@cms.hhs.gov" with a link to access the public submission form.

Request Email Link

# Completing the Public Submission Form

## Public Submission Form for Information about Selected Drugs and Their Therapeutic Alternatives

Must be submitted to CMS by 12:00 a.m. PST on October 3, 2023 for initial price applicability year 2026.

[Submission instructions](#)

Choose one of the following Part D drugs selected for negotiation for initial price applicability year 2026.

Active Ingredient / Active Moiety\*



Select Drug



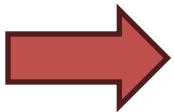
# # 26 – Your Information

**I26: Respondent Information** ^

Provide the following information for the individual completing this form.

**Selected Drug \***  
APIXABAN

**Respondent Email \***  
*youraddress@email.com*



## # 26 – Your Information

- Which of the following best describes the person completing this form?
  - Representative of a manufacturer that does not manufacture the selected drug or its therapeutic alternative(s)
  - Representative of a manufacturer of the selected drug or its therapeutic alternative(s)
  - Representative of a trade association
  - Representative of a patient advocacy organization
  - A health care provider who has experience prescribing, dispensing, or administering the selected drug or its therapeutic alternative(s)
  - A patient who has experience taking the selected drug or its therapeutic alternative(s)
  - A caregiver for an individual who has experience taking the selected drug or its therapeutic alternative(s)
  - Academic researcher or other subject matter expert not affiliated with a manufacturer of the selected drug or its therapeutic alternative(s)
  - Academic researcher or other subject matter expert affiliated with a manufacturer of the selected drug or its therapeutic alternative(s)<sup>33</sup>
  - Other

Note: Brings up definitions and instructions for that question, in upper right margin of page

# #27 – Prescribing Information

## I27: Prescribing Information

- What prescribing information has been approved by the FDA for the selected drug and for therapeutic alternative(s) to the selected drug?
- Please provide information about how the selected drug and its therapeutic alternative(s) are used in the course of care for the condition or disease treated by each indication.
- If the selected drug is used off-label to treat a certain disease or condition, please indicate this and provide evidence from nationally recognized, evidence-based guidelines and recognized by CMS-approved Part D compendia, as applicable.

Response to Question 27

//  
1/3000 words

Does the evidence submitted include a cost-effectiveness measure: 



# #28 – Therapeutic Impact and Comparative Effectiveness

## I28: Therapeutic Impact and Comparative Effectiveness

- Please provide information on the therapeutic impact of the selected drug compared to existing therapeutic alternatives. What is known about the comparative effectiveness of the selected drug and its therapeutic alternative(s)? Please discuss for each indication of the selected drug, as applicable. Consider discussing outcomes (including patient-reported outcomes) and patient experience for each indication, as applicable.
- Please provide key outcomes for each indication of the selected drug, as applicable, and explain why each outcome was chosen.
- To what extent does the selected drug represent a therapeutic advance as compared to existing therapeutic alternatives? Please discuss for each indication of the selected drug, as applicable.
- Please provide information on the risks, harms, or side effects, and any unique scenarios or considerations related to clinical benefit, safety, and patient experience related to the selected drug and its therapeutic alternative(s) for each indication, as applicable. Please describe any differences in the safety profile of the selected drug and its therapeutic alternative(s) for each indication, as applicable.
- Please provide current costs of such existing therapeutic alternatives (if known).

Response to Question 28

1/3000 words

- Can submit additional materials and citations related to this question

# #29 – Comparative Effectiveness on Specific Populations

## I29: Comparative Effectiveness on Specific Populations


- What is known about the comparative effectiveness of the selected drug and therapeutic alternatives to the selected drug with respect to specific populations, such as individuals with disabilities, the elderly, individuals who are terminally ill, and children?
- Are there other specific populations not noted in the question above that use the selected drug that could be considered? If so, please explain.
- As applicable, for other specific populations that use the selected drug, what is known about comparative effectiveness of the selected drug and its therapeutic alternative(s)?
- What health equity considerations should CMS consider related to specific populations taking the selected drugs? This may include, but is not limited to, challenges or advantages accessing the drug compared to therapeutic alternatives, differences in clinical or other outcomes, or differences in disease or condition symptoms for a specific population that the drug does or does not adequately address.
- In addition to comparative effectiveness, please discuss any differences in the safety profile of the selected drug compared to its therapeutic alternative(s) for each applicable specific population.

Response to Question 29

1/3000 words

- Can submit additional materials and citations related to this question

# #30 – Addressing Unmet Medical Needs

I30: Addressing Unmet Medical Needs 

- Does the selected drug address an unmet medical need for any indications; and if so, which indications?
- To what extent do the selected drug and therapeutic alternative(s) to the selected drug address an unmet medical need for an indication, as applicable?
- If unmet medical need is determined based on inadequate therapeutic alternative(s), please explain why therapeutic alternative(s) do not meet the medical need of individuals with the disease or condition for an indication, as applicable.

Response to Question 30

1/1000 words

- Can submit additional materials and citations related to this question

# #31 – Patient and Caregiver Experience

**I31: Patient and Caregiver Experience** ⓘ ^

- What is your experience taking the selected drug and/or its therapeutic alternative(s)? How long have you been taking the selected drug and/or its therapeutic alternative(s)?
- How did treatment with the selected drug and/or its therapeutic alternative(s) impact your health, including your symptoms?
- Please describe any side effects that you have experienced, and the impact of these side effects have had on you.
- How did treatment with the selected drug and/or its therapeutic alternative(s) impact your quality of life and wellbeing?
- Have you had challenges accessing or taking the drug? For example, challenges affording the drug, gaining coverage through your health insurance, or taking the drug as prescribed.

Response to Question 31

1/2000 words

- Can submit additional materials and citations related to this question

# #32 – Executive Summary

## I32: Executive Summary ^

- Please provide an executive summary of the information submitted for Section I Questions 27-30.
- Citations and study summaries do not need to be included in this question.

Response to Question 32

1/1000 words



# Ready to Submit?

## Confirm Navigation

Are you sure you want to continue to certify your responses? You will not be able to go back and make changes.

Cancel

Yes



# Submitting Your Responses

## Public Submission Form for Information about Selected Drugs and Their Therapeutic Alternatives

I. Evidence about Alternative Therapies

J. Certification of Section I

### J. Certification of Section I

I certify that all information and statements made in this submission are true and current to the best of my knowledge and belief and are made in good faith. I reviewed the submission and made a reasonable inquiry regarding its content. I understand the information contained in this submission is being provided to and will be relied upon by CMS for Medicare payment purposes, including determination of a maximum fair price, as defined in section 1191(c)(3) of the Social Security Act.

Check this box to electronically sign and date this form, and then press the Submit button. \*



**Tiffany Westrich-Robertson**  
*Chief Executive Officer*  
AiArthritis





# AiArthritis CMS Engagement



September 10, 2023

To Whom It May Concern:

The International Foundation for Autoimmune and Autoinflammatory Arthritis (AiArthritis) would like to thank the Centers for Medicare and Medicaid Services (CMS) for the opportunity to offer comments on the CMS proposed HOPPS policy changes for diagnostic radiopharmaceuticals payments (CMS-2023-0120-0002).

AiArthritis is a leader in advancing education, advocacy, and research for those impacted by AiArthritis diseases through peer-led guidance, collaboration, and resources that are driven by patient-identified issues and patient-infused solutions.

One area we strongly focus on is expediting detection, diagnosis, and treatment, as missing an early window of opportunity to treat lessens the chance to ever achieve remission. Today, 1 in 10 people live with at least one AiArthritis disease, but due to delayed diagnosis and uncontrolled inflammation, approximately 70% of these people will develop comorbidities - including dual diagnosis, heart disease, and even Alzheimer's disease. Due in part to delays, remission is not always possible. Therefore, access to advanced and innovative diagnostic radiopharmaceuticals is vital for people with these diseases.<sup>1</sup>

The current practice of considering diagnostic radiopharmaceuticals as "supplies" through a packaged payment system can prevent patients from accessing tools which can impact diagnosis. By averaging the higher cost of specialized products with more general and widely used low-cost radiopharmaceuticals, CMS overpays for the lower cost products while reducing the reimbursement for higher-cost products. This uneven reimbursement policy deters providers from offering these services to Medicare patients. By providing a fair reimbursement to healthcare providers, imaging can be utilized more often, leading to early detection of diseases like AiArthritis.

Furthermore, we would like to see CMS separate payments for diagnostic radiopharmaceuticals in the hospital outpatient setting. This rule change, along with Congress passing the FIND Act, will support our mission to improve patient outcomes and quality of care for Medicare beneficiaries and, in turn, help all Nevadans have the best possible quality of life.

We are thankful that CMS is looking at this issue. AiArthritis encourages CMS to implement a solution for Calendar Year 2024 to foster a healthcare environment that prioritizes patient-centered care and medical progress specifically for patients in need of diagnostic radiopharmaceutical treatments.

Thank you for your consideration of our comments. If you have any questions or require further information please contact me at [tiffany@aiarthritis.org](mailto:tiffany@aiarthritis.org).

Tiffany Westrich-Robertson

Chief Executive Officer  
Person Living with Non-Radiographic Axial Spondyloarthritis

1. Ziegeler K, Eshed I, Diekhoff T, Herrmann KG. Imaging of Joints and Bones in Autoinflammation. J Clin Med. 2020 Dec 17;9(12):4074. doi: 10.3390/jcm9124074. PMID: 33348664; PMCID: PMC7766736.

TAX ID - 27-1214308

[info@aiarthritis.org](mailto:info@aiarthritis.org)

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



April 14, 2023

Chiquita Brooks-LaSure  
Administrator  
Center for Medicare  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Sent Electronically to [IRARebateandNegotiation@cms.hhs.gov](mailto:IRARebateandNegotiation@cms.hhs.gov)

RE: Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments

Dear Administrator Brooks-LaSure:

We are leaders in advancing education, advocacy, and research for those impacted by autoimmune and autoinflammatory arthritis (AiArthritis) diseases through peer-led guidance, collaboration, and resources that are driven by patient-identified issues and patient-infused solutions. As we are led by patients we understand the importance of ensuring better health outcomes and lower costs for patients, particularly those with chronic, degenerative diseases like Psoriatic Arthritis, Rheumatoid Arthritis, Lupus, Spondyloarthritis, and over a dozen other AiArthritis Diseases.

We thank the Centers for Medicare & Medicaid Services (CMS) for the opportunity to submit comments on the Medicare Drug Price Negotiation Program Initial Guidance for the initial price applicability year of 2026. We understand that this step was not explicitly required in the Inflation Reduction Act (IRA) and it is appreciated by patient groups. The Maximum Fair Price (MFP) provisions within the IRA provide CMS with significant new authority to reduce drug prices for Medicare beneficiaries. As your guidance recognized, the MFP provisions of the law also include requirements to protect patients and support patient-centered action. With this new authority, CMS has the opportunity to advance the crucial goal of ensuring better outcomes and reducing costs for patients throughout the implementation of the Medicare Drug Price Negotiation Program. It is imperative that CMS center its decisions around patients and key components that may impact their access to optimal care.

We believe AiArthritis and CMS aim to achieve better health outcomes for patients. While there are several areas we could address, the following considerations focus on key points considerate of heterogeneous diseases where one-size-fits-all treatments do not exist. We respectfully suggest CMS refines its negotiation process to consider: 1) The welfare of patients must be in the forefront of the implementation, and their input should be considered 2) There must be incentives for innovation by the

International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis) Tax ID 27-1214308  
Headquarters - St. Louis, MO 63109 [www.aiarthritis.org](http://www.aiarthritis.org)



# Q&A



# Thank You!

Learn more on our blog (<https://chroniccarealliance.org/category/blog/>)

[CCPA's statement on Medicare drug price negotiations](#)  
[CCPA's letter to CMS on negotiations and listening sessions](#)

For additional questions or inquiries,  
please contact Liz Helms at [lizh@chroniccarealliance.org](mailto:lizh@chroniccarealliance.org)