Guide for Submitting Public Input to CMS ICR for IRA

Introduction to submitting input to CMS on Drug Price Negotiation Program
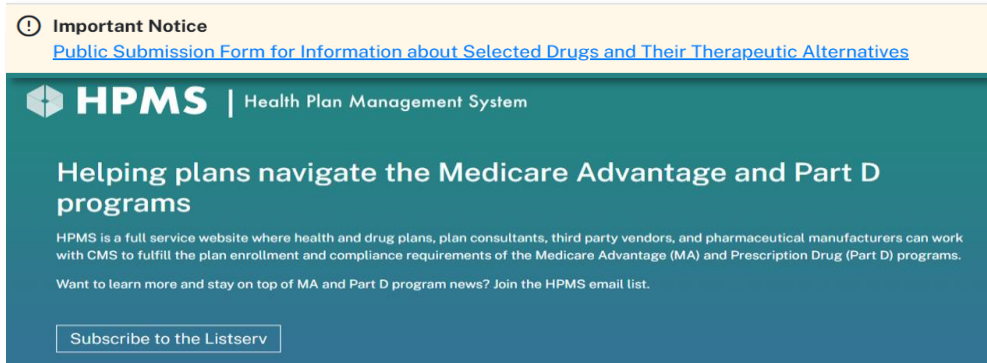
What	CMS is inviting the public to submit data and perspectives to aid in its evaluation of the 15 selected drugs for the Medicare Drug Price Negotiation Program
Who	Patients, Caregivers, Clinicians, Researchers, and other interested members of the public
Where	Submission portal will be available via CMS's Health Plan Management System (HPMS) platform: https://hpms.cms.gov/app/ng/home/
When	Submission portal will close **Saturday, March 1, 2025**

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Detailed guidance for submitting input to CMS (1/2)

Step	Details
1	Navigate to CMS's Health Plan Management System (HPMS): https://hpms.cms.gov/app/ng/home/
	At the top of the home page, you will see a tan banner labeled "**Importance Notice: Public Submission Form for Information about Selected Drugs and Their Therapeutic Alternatives**".
	Click on hyperlink associated with the banner (also here: LINK).
2	On the next page, enter a valid email and click **"Request Email Link"**.
	Check your inbox (and spam folder) for an email from hpms@cms.hhs.gov that gives you a unique URL link.
	Click on the hyperlink or copy/paste the provided URL link into your web browser.
3	You will be redirected to a webpage with a dropdown menu asking you to select 1 of 15 drugs that you would like to provide input on. Choose one and select **"Select Drug"**.
4	At the top of the next page, you will be required to fill out some Respondent Information (Question 28), which will be denoted with an asterisk (*). **Note your name will be redacted when CMS publishes submissions**
5	Next scroll down to the section / question numbers most appropriate to you (see accompanying pages) and copy & paste or enter in your response.
	Click **"Save"** in the bottom right to come back to your response (you come back to the response portal using the link sent initial email from HPMS) or click **"Save and Next"** if you are ready to submit.
6	On the next page, check the box next to **"Check this box to electronically sign…"**
	Next, click **"Submit"** to submit your response to CMS.

FOR BACKGROUND ONLY – REFER TO CMS.GOV FOR OFFICIAL GUIDANCE

Note: Refer to next slide for the screenshots

Detailed guidance for submitting input to CMS (2/2)

1

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

HPMS | Health Plan Management System

Helping plans navigate the Medicare Advantage and Part D programs
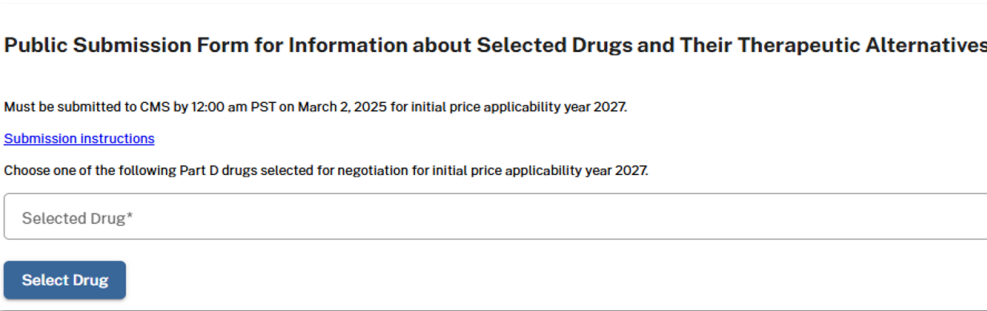
HPMS is a full service website where health and drug plans, plan consultants, third party vendors, and pharmaceutical manufacturers can work with CMS to fulfill the plan enrollment and compliance requirements of the Medicare Advantage (MA) and Prescription Drug (Part D) programs.

Want to learn more and stay on top of MA and Part D program news? Join the HPMS email list.

Subscribe to the Listserv

1. Navigate to CMS's HPMS System and click on following LINK

2

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.

Email address*

Request Email Link

2. Request Email Link and navigate to the URL via email

3

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

Must be submitted to CMS by 12:00 am PST on March 2, 2025 for initial price applicability year 2027.
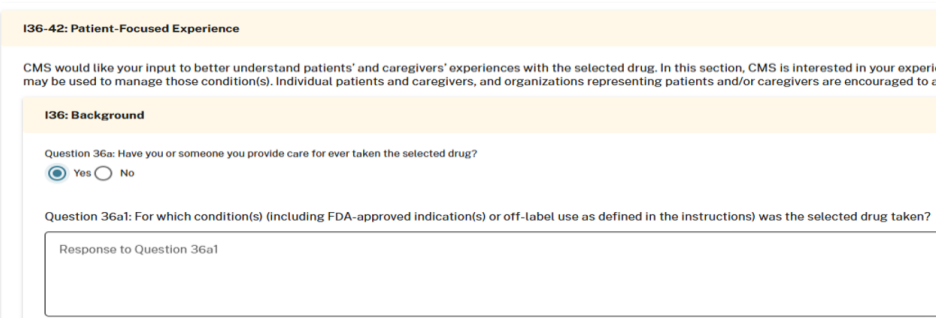
Submission instructions

Choose one of the following Part D drugs selected for negotiation for initial price applicability year 2027.

Selected Drug*

Select Drug

3. Select Drug from drop down menu

4

I28: Respondent Information

Individuals or organizations, including manufacturers, that wish to provide information in this Section I must provide the following information.

Selected Drug *
AUSTEDO; AUSTEDO XR

Respondent Name*

Required

Organization Name (if applicable)

Respondent Email *
dulind@deloitte.com

Which of the following best describes the person completing this form?

Respondent Description*

Required

4. Provide Respondent Information (will be redacted during submission)

5

I36-42: Patient-Focused Experience

CMS would like your input to better understand patients' and caregivers' experiences with the selected drug. In this section, CMS is interested in your experie may be used to manage those condition(s). Individual patients and caregivers, and organizations representing patients and/or caregivers are encouraged to a
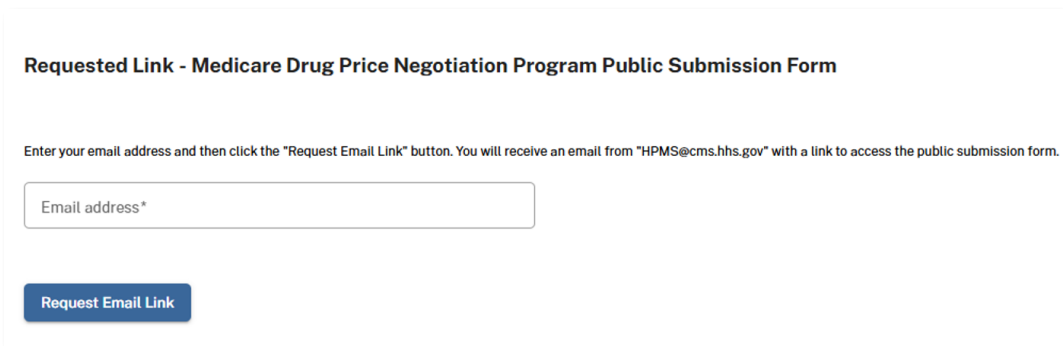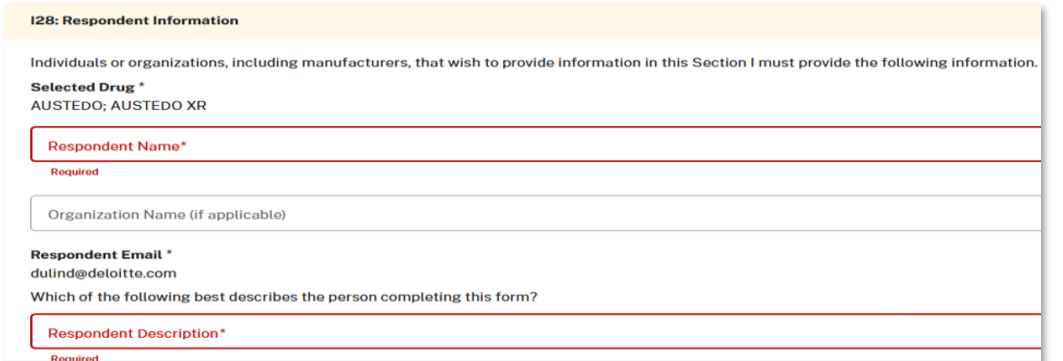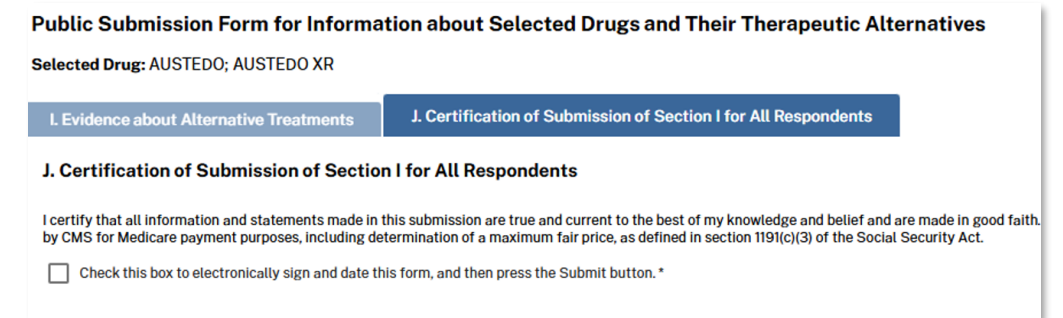
I36: Background

Question 36a: Have you or someone you provide care for ever taken the selected drug?
◉ Yes ○ No

Question 36a1: For which condition(s) (including FDA-approved indication(s) or off-label use as defined in the instructions) was the selected drug taken?

Response to Question 36a1

5. Provide responses to the questions

6

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

Selected Drug: AUSTEDO; AUSTEDO XR

I. Evidence about Alternative Treatments | J. Certification of Submission of Section I for All Respondents

J. Certification of Submission of Section I for All Respondents

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. 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. *

6. Provide electronic signature

For questions and issues in submitting input to CMS

HPMS Help Desk

For: Technical assistance on submitting input via HPMS

Contact: hpms@cms.hhs.gov or 1-800-220-2028

IRA Rebate and Negotiations Team

For: Questions on terms in the questions

Contact: IRARebateandNegotiation@cms.hhs.gov

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Questions for Patients

IRA Information Collection Request (ICR) | Questions for Patients

Q36: Background Questions

- Experience with the selected drug and/or condition(s) it treats
- Date of diagnosis for condition(s)
- Condition(s) treated by the selected drug that you would like to provide input on

Q37: Info on Your Condition(s)

- Impact of the condition(s) listed in Q36 on your daily life and well-being
- Change or progression in your condition(s) over time
- What is important to you in managing your condition(s)
- Challenges faced in managing your condition(s)

Q38: Info on Medication(s) for Your Condition(s)

- Status of taking medication(s) for the condition(s) you listed in Q37
- Medication(s) that you are taking to manage the condition(s) listed in Q36
- How you decided to start taking medication(s) to manage the condition(s)
- Your experience with the medication(s)
- Your satisfaction with the medication(s)

Q39: Info on Medication(s) Used in Past for Your Condition(s)

- Status of having taken other medication(s) in the past to manage the condition(s) listed in Q38
- Medication(s) that you have taken in the past for the condition(s)
- How you decided to start taking the medication(s) that you used in the past to manage the condition(s)
- Experience with the medication(s) used in the past
- Why you stopped taking the medication(s) used in the past

Q40: Additional Information

- Additional information about the condition(s) and the medication(s) you identified that you think CMS should consider while evaluating the selected drug

Q42: Demographic Questions

- Your age
- Your race/ethnicity
- Your regional location
- Status of Medicare coverage

CONSIDERATIONS

- **Not required** to answer all questions – answer any that you wish to

- **Answer each question in narrative form**

- **Not required** to maximize character or citation count

- **Do not** provide personally identifiable information (PII)

(Q41) Respondents may also submit up to 10 tables, charts, and/or graphs that support the responses to questions Q36 – Q42

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Questions for Patients	Type	Character Max	Citation Max
Q36: Background Questions			
Q36a: Have you or someone you provide care for ever taken [the selected drug]?	Yes / No	N/A	N/A
Q36a1: [If YES] For which condition(s) (including FDA-approved indication(s) or off-label use as defined in the instructions) was [the selected drug] taken?	Text	6,000	N/A
Q36a2: [If YES] When were you or someone you provide care for given a diagnosis related to this condition or conditions? You may write an approximate date, or if you never received a diagnosis write "N/A."	Text	6,000	N/A
Q36a3: [If NO] What condition(s) (including FDA-approved indication(s) or off-label use as defined in the instructions) treated by [the selected drug] would you like to provide input on?	Text	36,000	N/A
Q36a4: [If NO] What is your experience with this condition or conditions?	Text	36,000	N/A
Q37: Information on Your Condition(s) or Condition(s) of Someone You Care For			
Q37a: How do the condition(s) you listed in Q36a1 impact your daily life and well-being or the daily life and well-being of someone you provide care for?	Text	36,000	N/A
Q37b: How has the condition(s) you listed in Q36 changed or progressed over time?	Text	36,000	N/A
Q37c: What is important to you or those you provide care for in managing the condition(s) you listed in Q36?	Text	36,000	N/A
Q37d: What challenges do you, or someone you care for, face in managing this condition(s)?	Text	36,000	N/A
Q38: Information on the Current Medication to Treat Your Condition			
Q38a: Are you, or someone you care for, currently taking medication(s) to manage the condition(s) you listed in Q37?	Yes / No	N/A	N/A
Q38a1: [If YES] What medication(s) are you, or someone you provide care for, currently taking to manage the condition(s) you listed in Q36?	Text	36,000	N/A
Q38a2: [If YES] How did you or someone you care for decide to start taking the medication(s) currently used to manage the condition(s) you listed in Q36?	Text	36,000	N/A
Q38a3: [If YES] What has been your experience, or the experience of someone you provide care for, with the medication(s) currently used to manage the condition(s) you listed in Q36?	Text	36,000	N/A

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Questions for Patients	Type	Character Max	Citation Max
Q38: Information on the Current Medication to Treat Your Condition			
Q38a4: [If YES] How satisfied are you, or someone you care for, with the medication(s) you take now to manage your condition(s)?	Text	36,000	N/A
Q39: Information on the Medication(s) Used in the Past to Treat Your Condition			
Q39a: Have you, or someone you care for, taken other medication(s) in the past to manage the condition(s) you listed in Q38?	Yes / No	N/A	N/A
Q39b1: [If YES] What medication(s) have you, or someone you care for, taken in the past to manage the condition(s) you listed in Q36?	Text	36,000	N/A
Q39b2: [If YES] How did you, or someone you care for, decide to start taking the medication(s) used in the past to manage the condition(s) you listed in Q36?	Text	36,000	N/A
Q39b3: [If YES] What was your experience, or the experience of someone you provide care for, with the medication(s) used in the past to manage the condition(s) you listed in Q36?	Text	36,000	N/A
Q39b4: [If YES] Why did you, or someone you provide care for, stop taking the medication(s) used in the past to manage the condition(s) you listed in Q36?	Text	36,000	N/A
Q40: What other information about the condition(s) you have identified or the medication(s) used to manage these condition(s) do you think CMS should consider while evaluating [the selected drug]?	Text	36,000	50
Q41: Provide up to 10 visual representations, if any, such as tables, charts, and/or graphs that support the responses to Questions 36 through 40. Indicate which question each file corresponds to.	PDF	Up to 10 PDF Files	
Q42: Demographic Questions			
Age (i.e.,. 18-24 years, 25-34 years, … , 100 years or older)	Range	N/A	N/A
Race/Ethnicity (i.e., American Indian or Alaska Native, Asian, … , Other not Listed)	Select	N/A	N/A
Regional Location (i.e., New England: CT, ME, MA, NH, RI, VT; … ; Other)	Select	N/A	N/A
Medicare Beneficiary	Yes/No	N/A	N/A

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Questions for Clinicians

IRA Information Collection Request (ICR) | Questions for Clinicians

Q43: Background Questions

- Your area of specialization
- Experience with the selected drug
- Indication(s) for the selected drug you would like to provide input on

Q45: Treatment Questions Cont.

- Placement of the selected drug in current treatment paradigm
- Line of treatment of the selected drug for the condition(s) it treats
- Therapeutic alternatives of the selected drug that you consider
- Considerations that drive your treatment selection for the indication(s) of the selected drug
- Notable differences between the selected drug and its therapeutic alternatives
- Your characterization of risks / benefits of the selected drug
- Side effects, risks, or other safety concerns you consider in selecting a treatment option for indication(s)
- How you think the benefits and risks of the selected drug differ from its therapeutic alternatives
- Specific populations that derive greater benefit or harm from the selected drug
- How you assess the tolerability and effectiveness of the selected drug or its therapeutic alternatives for a patient

Q44: Treatment Questions

- Treatment goals for condition(s) treated by the selected drug
- Outcome measures you use for indication(s) of the selected drug
- How you constitute meaningful improvement or treatment response for these outcomes
- How you assess these improvements in certain subpopulations
- Clinical guidelines indication(s) and how they support your decision making

Q46: Health Equity and Patient Experience

- Health equity or access issues that you consider relevant for the selected drug and its therapeutic alternatives

Q47: Therapeutic Advance and Unmet Medical Need

- Extent to which the selected drug represents (or does not) a therapeutic advance compared to its therapeutic alternatives
- Extent to which the selected drug addresses (or does not) an unmet medical need
- Unmet medical needs that persist for patients with the condition(s) treated by the selected drug

Q48: Additional Information

- Additional info on the selected drug, its therapeutic alternatives, or the indication(s) that you think CMS should consider

CONSIDERATIONS

- **Not required to answer all questions – answer any that you wish to**
- **Answer each question in narrative form**
- **Not required to maximize character or citation count**
- **All declarative statements should be supported by evidence with a citation (NLM style format) unless you are sharing a personal experience**
- **CMS prefers publicly available peer-review literature rather than poster abstracts and non-peer reviewed literature**
- **When providing non-peer reviewed literature, provide sufficient information on these studies**
- **CMS will not consider cost-effectiveness measures that assumes a lower value of life for an elderly, disabled, or terminally ill patient**
- **Do not provide any patient personally identifiable information (PII)**

(Q49) Respondents may also submit up to 10 tables, charts, and/or graphs that support the responses to questions Q43 – Q48

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Questions for Clinicians	Type	Character Max	Citation Max
Q43: Background Questions			
Q43a: Are you a health care provider (i.e., a person who is trained and licensed to give health care)?	Yes / No	N/A	N/A
Q43a1: [If YES] What is your area of specialization? If you are currently practicing, provide a brief description of the type of practice and your practice site.	Text	6,000	N/A
Q43b: Do you have experience prescribing or managing the use of [the selected drug]?	Yes / No	N/A	N/A
Q43b1: [If YES] For which indication(s) (which includes off-label use(s) per the definition provided in the instructions) have you prescribed or managed use of [the selected drug] that you would like to provide CMS information on?	Text	6,000	N/A
Q43b2: [If NO] On which indication(s) (which includes off-label use(s) per the definition provided in the instructions) would you like to provide input?	Text	6,000	N/A
Q44: Treatment-related Questions			
Q44a: What are goals of treatment for the condition(s) treated by the [selected drug]? (e.g., disease remission, symptom management)	Text	36,000	N/A
Q44b: What outcomes do you use to assess improvement or treatment response for this indication(s)?	Text	36,000	50
Q44b1: What would you consider to be a meaningful improvement or treatment response for the outcomes listed in Q44b?	Text	36,000	50
Q44b2: Would you assess improvement or treatment response differently in certain patient subpopulations? If so, which subpopulations and why?	Text	36,000	50
Q44c: Are there widely used evidence-based clinical practice guidelines for the condition(s) treated by [the selected drug]? If so, please cite these guidelines and explain how they are used to support clinical decision-making.	Text	36,000	50
Q45: Additional Treatment-related Questions			
Q45a: How does [the selected drug] fit into the current treatment paradigm for patients with the conditions(s) treated by [the selected drug]?	Text	36,000	50
Q45b: At what point in treatment might [the selected drug] be considered as a treatment option for patients with the condition(s) treated with [the selected drug]? What other treatments might be considered before [the selected drug] is considered a clinically appropriate treatment option, if any?	Text	36,000	50
Q45c: What medications would you consider to be therapeutic alternatives for [the selected drug] for treatment of the condition(s) treated with [the selected drug]?	Text	36,000	50
Q45d: What considerations drive treatment selection among [the selected drug] and its therapeutic alternatives for the indication(s)? (e.g., relative efficacy, safety profile, route of administration, patient characteristics, patient preferences, cost, formulary placement, etc.)	Text	36,000	50

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Questions for Clinicians	Type	Character Max	Citation Max
Q45: Additional Treatment-related Questions (cont.)			
Q45e: Are there notable differences between how [the selected drug] or the therapeutic alternatives identified in Q45c are prescribed or managed in your practice setting and how these drugs are used in broader clinical practice and/or treatment recommendations in current clinical guidelines for the condition(s) treated with [the selected drug]?	Text	36,000	50
Q45f: How would you characterize the benefits and risks associated with [the selected drug]?	Text	36,000	50
Q45f1: What side effects or risks, common or serious, or other safety concerns would you take into consideration when selecting a treatment option from among [the selected drug] or its therapeutic alternatives for the condition(s) treated with [the selected drug]?	Text	36,000	50
Q45f2: In your opinion, how do the benefits and risks associated with [the selected drug] differ from the benefits and risks associated with its therapeutic alternatives for the indication(s)?	Text	36,000	50
Q45f3: What specific populations or patient subgroups may derive greater benefits or be at risk for greater harms by using [the selected drug] or any of its therapeutic alternatives for the indication(s)?	Text	36,000	20
Q45g: How would you assess whether a patient is tolerating and/or responding to [the selected drug] or any of its therapeutic alternatives when used for each indication(s)?	Text	36,000	20
Q46: Health Equity and Patient Experience (What health equity or access issues would you consider relevant to an evaluation of [the selected drug] and its therapeutic alternatives for the condition(s) treated by [the selected drug]?)	Text	36,000	50
Q47: Therapeutic Advance and Unmet Medical Need			
Q47a: For the condition(s) treated by [the selected drug], describe the extent to which [the selected drug] currently represents (or does not represent) a therapeutic advance as compared to its therapeutic alternative(s).	Text	36,000	20
Q47b: For the condition(s) treated by [the selected drug], describe the extent to which [the selected drug] currently addresses (or does not address) an unmet medical need.	Text	36,000	50
Q47c: What unmet medical needs do you believe persist among patients with the condition(s) treated by [the selected drug], if any?	Text	36,000	50
Q48: What other information about [the selected drug], its therapeutic alternative(s), or the indication(s) do you think CMS should consider in its evaluation of [the selected drug]?	Text	36,000	50
Q49: Provide up to 10 visual representations, if any, such as tables, charts, and/or graphs that support the responses to Questions 43 through 48. Indicate which question each file corresponds to.	PDF	Up to 10 PDF files	

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Questions for Researchers

IRA Information Collection Request (ICR) | Questions for Researchers

Q50: Background Questions

- Status of having possessed research experience with the selected drug or its therapeutic alternative(s)
- Indication(s) of the selected drug that you would like to provide input on

Q53: Specific Populations and Patient Experience

- Relevant evidence on the patient experiences with the selected drug, its therapeutic alternatives, and the condition(s) that the selected drug treats
- Impact of the selected drug and/or its therapeutic alternatives on specific patient populations or subgroups
- Access and health equity considerations for the selected drug, its therapeutic alternatives, and condition(s) the selected drug treats

Q55: Additional Information

- Other information or evidence you think CMS should consider in the evaluation of the selected drug

Q51: Potential Therapeutic Alternatives

- Medications that you consider to be therapeutic alternatives for the selected drug for each indication(s)

Q52: Comparative Clinical Evidence

- Recommended approach for evaluating the clinical effectiveness of the selected drug and its potential therapeutic alternative(s)
- Relevant outcome measures for evaluating the clinical effectiveness of the selected drug and its therapeutic alternative(s)
- Relevant evidence on the clinical comparative effectiveness of the selected drug and its potential therapeutic alternative(s)

Q54: Prevalence, Utilization, and Cost Estimates

- Estimate of the prevalence of each indication(s) among the Medicare population
- Estimate of the utilization of the selected drug and/or therapeutic alternatives by indication(s) among Medicare population
- Relevant evidence regarding the relative health care resource utilization of patients who take the selected drug and its therapeutic alternatives

CONSIDERATIONS

- **Not required to answer all questions – answer any that you wish to**
- **Answer each question in narrative form**
- **Not required to maximize character or citation count**
- **All declarative statements should be supported by evidence with a citation (NLM style format) unless you are sharing a personal experience**
- **CMS prefers publicly available peer-review literature rather than poster abstracts and non-peer reviewed literature**
- **When providing non-peer reviewed literature, provide sufficient information on these studies**
- **CMS will not consider cost-effectiveness measures that assumes a lower value of life for an elderly, disabled, or terminally ill patient**

(Q55) Respondents may also submit up to 10 tables, charts, and/or graphs that support the responses to questions Q50 – Q54

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Questions for Researchers	Type	Character Max	Citation Max
Q50: Background Questions			
Are you: (1) An individual or representative of an entity that has conducted research (including clinical trials or data analyses) related to use of [the selected drug] or its potential therapeutic alternative(s)? (2) Familiar with methods used to evaluate use of [the selected drug] or its potential therapeutic alternatives? (3) Aware of research-based evidence CMS should consider regarding [the selected drug], its potential therapeutic alternatives and/or the indication(s) it treats?	Yes / No	N/A	N/A
Q50a: On which indication(s) (which includes off-label use(s) per the definition provided in the instructions) of [the selected drug] would you like to provide input?	Text	6,000	N/A
Q51: Potential Therapeutic Alternatives (What medications would you consider to be therapeutic alternatives for [the selected drug] for each indication(s)? Provide supporting rationale and citations where applicable.)	Text	36,000	50
Q52: Comparative Clinical Evidence			
Q52a: What methodology, framework, or other analytic approach would you recommend CMS consider for use in its evaluation of the clinical comparative effectiveness (e.g., clinical efficacy, real-world effectiveness, or safety) of [the selected drug] and its potential therapeutic alternatives for the indication(s)? Provide supporting rationale and citations where applicable.	Text	36,000	50
Q52b: What relevant clinical outcome measures should CMS consider in its evaluation of clinical comparative effectiveness (e.g., clinical efficacy, real-world effectiveness, or safety) of [the selected drug] and its potential therapeutic alternatives for the indication(s)? Provide supporting citations where applicable.	Text	36,000	50
Q52c: For the indication(s) of the selected drug, identify any relevant evidence evaluating the clinical comparative effectiveness (e.g., clinical efficacy, real-world effectiveness, or safety) of the selected drug and potential therapeutic alternatives. Relevant comparative evidence may include but is not limited to: head-to-head randomized controlled trials, pragmatic clinical trials, network meta-analyses, observational studies, and real-world evidence. Provide supporting citations.	Text	36,000	50

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Questions for Researchers	Type	Character Max	Citation Max
Q53: Specific Populations and Patient Experience			
Q53a: What evidence are you aware of regarding patient experiences related to use of [the selected drug], its potential therapeutic alternatives, and/or condition(s) treated by [the selected drug]? This may include but is not limited to evidence regarding patient priorities and preferences related to treatment of the condition(s), treatment burden, burden of disease, or other patient experience data. Provide supporting citations.	Text	36,000	50
Q53b: What specific populations or patient subgroups are impacted by [the selected drug] and/or its potential therapeutic alternatives for the condition(s) treated by [the selected drug]? How are these populations or subgroups impacted? Identify studies focused on the impact of [the selected drug] and its therapeutic alternatives on the specific populations. Provide supporting citations where applicable.	Text	36,000	50
Q53c: What considerations related to access, health equity, and/or health disparities are relevant to [the selected drug], its potential therapeutic alternatives, and/or or this condition(s) treated by [the selected drug]? Provide supporting citations where applicable.	Text	36,000	50
Q54: Prevalence, Utilization, and Cost Estimates			
Q54a: For each indication(s), provide an estimate of prevalence among the Medicare population. Provide citations and/or brief methodology to support the estimate.	Text	36,000	50
Q54b: For each indication(s), provide an estimate for Medicare utilization of [the selected drug] and/or its potential therapeutic alternatives. Estimates of Medicare utilization can include estimates of total number of patients treated, estimated share of [selected drug] prescriptions dispensed to patients for a given indication, or similar measures. Provide citations and/or a brief methodology to support the estimate.	Text	36,000	50
Q54c: For each indication(s), identify or provide evidence relevant to Medicare regarding relative health care resource utilization of patients who take [the selected drug] and its potential therapeutic alternatives. Relevant evidence of relative health care resource utilization may include but is not limited to: disease burden or cost-of-illness analyses, cost-effectiveness or cost-utility analyses, and/or other analyses of health care resource utilization relevant to [the selected drug] and any therapeutic alternatives. Provide citations and/or a brief methodology to support the assessments.	Text	36,000	50
Q55: What other information or evidence do you think CMS should consider in the evaluation of [the selected drug]? Provide citations when applicable.	Text	36,000	50
Q56: Provide up to 10 visual representations, if any, such as tables, charts, and/or graphs that support the responses to Questions 51 through 57.	PDF	Up to 10 PDF files	

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Questions for 'Other Public'

IRA Information Collection Request (ICR) | Questions for 'Other Public'

Q57	Indications(s) of the selected drug you would like to provide input on
Q58	Experience with the selected drug or the condition(s) it treats
Q59	Additional information that you think CMS should consider as it evaluates the selected drug

CONSIDERATIONS

- **<u>Not required</u> to answer all questions – answer any that you wish to**

- **<u>Not required</u> to maximize character or citation count**

- **Do not provide personally identifiable information (PII)**

(Q60) Respondents may also submit up to <u>10 tables, charts, and/or graphs</u> that support the responses to questions Q57 – Q59

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Questions for 'Other Public'	Type	Character Max	Citation Max
Q57: For which indication(s) (which includes off-label use(s) per the definition provided in the instructions) would you like to provide input?	Text	6,000	N/A
Q58: What is your experience with [the selected drug] or the condition(s) it treats?	Text	36,000	N/A
Q59: What information or evidence do you think CMS should be aware of as it evaluates [the selected drug] for each indication(s)? Provide citations when applicable.	Text	36,000	50
Q60: Provide up to 10 visual representations such as tables, charts, and/or graphs that support the responses to Questions 56 through 58.	PDF	Up to 10 PDF files	