NATIONAL HEALTH COUNCIL

ICR Cheat Sheet: A Tool for Patient Organizations

Signed into law August 11, 2022, the Inflation Reduction Act establishes a process for Medicare to negotiate the price of prescription drugs. On August 29, 2023, CMS released its first list of 10 drugs to be negotiated.

Included in statute and implementation guidance is a process for external parties to submit information about negotiated drugs and their therapeutic alternatives. Through this process, it is essential patients and patient advocacy groups share their expertise on selected drugs to help CMS understand the patient perspective on key considerations such as patients' views on value, unmet need, and benefits and risks. While technical in nature, patient organizations can choose how detailed they want to be, and it is not required to answer every question.

To guide the process, CMS released the Negotiation Data Elements Information Collection Request (ICR) form for initial price applicability year 2026. However, much of the information in the document is specific to manufacturers and not patient organizations. This document includes suggestions for key themes to include in your response and specific ICR questions where they might be applicable.

The public submission form can be accessed through the submission platform. For more information on how to submit information, see this document from CMS. Organizations who plan to submit data must do so by **October 2, 2023**.

Key Themes

Patient and caregiver experience: Impact on health/wellbeing, side effects, access challenges for the selected drug and therapeutic alternatives.

Unmet medical need: Extent to which the selected drug and its therapeutic alternative(s) address an unmet medical need.

Prescribing information: how selected drug & its therapeutic alternatives are used in course of care.

Therapeutic impact: considerations related to clinical benefit, safety, and patient experience.

Comparative effectiveness: how selected drug compares to existing therapeutic alternatives and to what extent it represents a therapeutic advancement.

Comparative effectiveness within specific populations: focus on individuals with disabilities or terminal illness, the elderly, and children and health equity considerations related to specific populations.

Key ICR Questions

Section I: Question 27 (3,000 word limit and up to 50 citations; up to 10 tables/charts/graphs) Prescribing Information:

- What prescribing information has been approved by the FDA for the selected drug and for therapeutic alternative(s)[1] 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.

Section I: Question 28 (3,000 word limit and up to 50 citations; up to 10 tables/charts/graphs) Therapeutic impact/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).

Section I: Question 29 (3,000 word limit and up to 50 citations; up to 10 tables/charts/graphs) Comparative Effectiveness within 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.

Section I: Question 30 (1,000 word limit and up to 50 citations; up to 10 tables/charts/graphs) 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.

Section I: Question 31 (2,000 word limit) 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.

Section I: Question 32 (1,000 word limit) Executive Summary:

- Provide an executive summary of the information submitted for Section I Questions 27-30.
- Citations/study summaries not required.

1 CMS defines a therapeutic alternative as a product that is clinically comparable to the selected drug. CMS will consider different therapeutic alternatives for each indication, as applicable. Therapeutic alternatives may be a brand name drug or biological product, generic drug, or biosimilar and may be on-label or off label to treat a given indication. CMS will begin by identifying therapeutic alternatives within the same drug class as the selected drug based on properties such as chemical class, therapeutic class, or mechanism of action before considering therapeutic alternatives in other drug classes. In cases where there are many potential therapeutic alternatives for a given indication of the selected drug, CMS may focus on a subset of therapeutic alternatives that are most clinically comparable to the selected drug