PIRC

PROTECTING INNOVATION IN RARE CANCER

REBALANCE THE IRA

Engage Together – What to Prepare For

Negotiation of Drug Prices was a high priority on surveys to date

- CMS will release list of 10 drugs by Sept. 1
- Three cancer drugs expected
  - Xtandi (prostate)
  - Ibrance (breast)
  - Imbruvica (lymphoma/leukemia/graft vs host)
- Thirty days patient participation window
- Listening Sessions
- Written submissions
- List of data elements requested
  - Specific or broad comments
- Work together? How?

CMS Process/Questions to Prepare For

Info from entities other than manufacturers can be submitted on “Section I” -- Evidence About Alternative Treatments

All respondents who are not Primary Manufacturers will use a **separate user-friendly web application to access the questions in Sections I and J**. This application will be:

- accessible from an entry point on CMS.gov,
- accessible on CMS HPMS landing page at https://hpms.cms.gov.

Expect the following “steps” to gain access and submit information:

- Patient group (respondent) provides an email address
- A confirmation email message from CMS will be sent to the respondent-provided email address
- Respondent must follow steps in CMS’ email message to obtain access to the questions in Sections I and J.
- Submissions may not be saved for work completed in progress.

Additional instructions to access this public web application will be made available on CMS.gov.
Technical assistance for Primary Manufacturers and other interested parties will also be made available.

First question = info about commenter, i.e., which drug, whether commenter is patient, advocacy org, manufacturer of therapeutic alternative, trade association, etc.

Questions to Prepare For

Prescribing Information (3000-word limit)

- 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.
- Does evidence include cost-effectiveness measure? If so, does it use QALY?

Therapeutic Impact and Comparative Effectiveness (3000-word limit, up to 50 citations and 10 tables)

- 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[1]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).
- Does evidence include cost-effectiveness measure? If so, does it use QALY?

Questions to Prepare For

Comparative Effectiveness on Specific Populations (3000-word limit, up to 50 citations and 10 tables)

- 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.
- Does evidence include cost-effectiveness measure? If so, does it use QALY?

Addressing Unmet Medical Needs (3000-word limit, up to 50 citations and 10 tables)

- 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[1]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).
- Does evidence include cost-effectiveness measure? If so, does it use QALY?

Questions to Prepare For

Patient and Caregiver Experience (2000-word limit)

- 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.