October 2, 2023

Chiquita Brooks-LaSure Administrator
Centers for Medicare and Medicaid
Services 200 Independence Avenue
S.W. Washington, D.C., 20201

Re: Medicare Drug Price Negotiation Program: Considerations for Selected Oncology Drugs

Dear Administrator LaSure:

On behalf of the American Cancer Society Cancer Action Network (ACS CAN) and the undersigned patient advocacy organizations, we appreciate the opportunity to offer input on how the Agency should consider pharmaceutical therapeutic alternative(s) to selected oncology drugs for Initial Price Applicability Year 2026.

Our organizations represent millions of cancer patients. We encourage CMS to implement the negotiation of selected drugs in a way that encompasses the many unique oncology considerations. In determining therapeutic alternatives to negotiate a Maximum Fair Price (MFP), we recommend CMS consider the following for selected oncology products:

- Prioritize evidence from, and validate identified therapeutic alternative(s) with, experts in cancer treatments and oncology-specific features;
- Account for health equity considerations to address cancer disparities;
- Consider the potential consequence of plan "steering" on beneficiary health outcomes; and
- Ensure that the initial offer based on the therapeutic alternative price, and the eventual MFP, do not discourage future innovation in cancer therapies.

We urge CMS to prioritize evidence from, and validate identified therapeutic alternative(s) with, experts in cancer treatments

We appreciate the Agency's solicitation of public input on therapeutic alternatives and understand CMS will use this input, as well as its research, to identify a selected drug's therapeutic alternatives to generate an initial offer price. As therapeutic alternatives are considered for selected oncology drugs, we recommend CMS give credence to input from organizations with expertise in cancer treatments, to include the patient perspective.

We support comparative effectiveness research because it provides clinicians with information regarding the relative clinical effectiveness of a given intervention and potential differences in side effects, but at the same time recognize that in oncology, there are very few drugs that are truly equivalent with respect to the FDA approved label indication and the scientific evidence supporting the efficacy of a given drug.

The National Comprehensive Cancer Network's Drug and Biologics Compendium and treatment guidelines are examples of science-based resources from which CMS can gain information on the comparative effectiveness of selected oncology drugs and their therapeutic alternatives. We also support CMS considering health

outcomes such as cure, survival, progression-free survival, or improved morbidity when comparing a selected drug to therapeutic alternatives.

Importantly, drugs may also have multiple indications and the therapeutic alternatives may vary greatly from indication to indication. This is quite common in oncology, and CMS should clarify how it intends to address the issue of multiple indications with widely varying alternatives.

In addition to provider-focused evidence, we also encourage CMS to use both patient-reported outcomes and patient experience data. Patients have first-hand knowledge of the effectiveness of a treatment, as well as the impact on their quality of life. It is particularly important for cancer patients that CMS considers whether a selected drug fills an unmet medical need through its on- or off-label use, such as treating a disease or condition in cases where extremely limited or no other treatment options exist. Evidence-based off-label use of oncology drugs is not only common, but it is supported by statutory requirements for CMS coverage as well.

To increase transparency and bolster support from the cancer community, we recommend that CMS engage provider and patient experts to validate the identified therapeutic alternatives throughout the negotiation process and beyond the limited public submission and patient-focused listening session opportunities.

CMS should account for health equity considerations to address cancer disparities

Disparities persist despite efforts to address equity in cancer diagnosis and treatment. We appreciate CMS's solicitation of input on how the effectiveness and safety of a selected drug or its therapeutic alternatives may vary across different populations. We strongly support a negotiation approach that does not assess a drug's benefit for the average person without considering its benefit for specific populations. We offer the following oncology-specific considerations:

Oral selected drugs should have oral therapeutic alternatives
Small-molecule oral oncology drugs are particularly important tools in the treatment of cancer. These therapies can be taken by patients at home, which can reduce patient time and transportation burdens. Accordingly, it may be more difficult for certain populations to receive physician-administered infusions, including, but not limited to, individuals with disabilities, the elderly, individuals who are terminally ill, lower-income individuals, individuals without transportation, working individuals, and individuals who live in rural areas. For this reason, we urge CMS to identify oral therapeutic alternatives for oral selected drugs in oncology.

Safety and effectiveness of selected drugs and their therapeutic alternatives should be stratified by race/ethnicity

CMS identified individuals with disabilities, the elderly, individuals who are terminally ill, and children as specific populations for which there may be challenges or advantages to access, differences in clinical or other outcomes, or differences in disease or condition symptoms, and asks if there are other specific populations not noted that could be considered. Racial disparities are observed in many different cancer measures, including screening and diagnosis rates, incidence and prevalence, and overall outcomes including survival and mortality.[1] For this reason, we recommend the comparative effectiveness of selected

[1] National Cancer Institute, Cancer Disparities, 2022. https://www.cancer.gov/about-cancer/understanding/disparities

oncology drugs and their therapeutic alternatives be evaluated with respect to non-white populations. To the extent that a selected drug or its therapeutic alternatives represents a therapeutic advantage for a specific race or ethnicity, that value should be reflected in the negotiation process.

Cancer is a specific population that requires special consideration

As CMS looks at the comparative effectiveness on specific populations, it should also consider people living with cancer as a patient population that requires special consideration, given the chronic, progressive nature and high mortality.

Cancer is not just one disease; it is hundreds of diseases. For example, lung cancer is subdivided into small cell lung cancer and non-small-cell lung cancer, which is further defined by up to ten distinct biomarker driven subtypes. Each cancer patient and his or her disease is distinct and requires a tailored treatment approach.

The benefit of a cancer drug can vary across conditions, being curative in some and palliative in others. We reiterate our suggestions that CMS consider real-world evidence and patient experience data to determine the comparative effectiveness, and further recommend that comparative effectiveness reviews be determined for each on- and off-label use of a selected drug, with consideration being given to any use that represents an unmet need.

CMS should consider the potential consequence of plan "steering" on beneficiary health outcomes

As CMS negotiates selected drugs with the aim to achieve "the lowest maximum fair price for each selected drug," we want to ensure that beneficiaries are not steered towards a particular drug.

As Part D plans will bear more risk under the IRA's Part D benefit redesign, plans have a financial incentive to steer beneficiaries toward a drug with the lowest price the plan is able to negotiate. While it is possible that negotiated drugs would represent the lowest price, non-negotiated drugs may cost less due to rebate dynamics. It is possible that Part D plans could steer beneficiaries toward negotiated drugs or non-negotiated drugs and may impose barriers (such as more rigorous prior authorization or step therapy requirements) on others in the class.

Cancer patients should have uninhibited access to the full range of treatment options available to best address their specific needs. For cancer patients who have found a specific drug that works for treating their cancer, and for patients who may benefit from a novel therapy, being steered towards another – potentially less effective drug – could be detrimental.

CMS should bear these dynamics in mind when determining the MFP for oncology products, and monitor plan formularies to determine the extent to which plans are using more utilization management tools that can hinder access to the medications initially prescribed by an oncologist.

Ensure that the initial offer based on the therapeutic alternative price, and the eventual MFP, do not hinder innovation in cancer therapies

The U.S. cancer death rate has declined 33 percent since 1991 due in large part to access to new drug therapies.[2] There has been a remarkable increase in the number of new cancer drug therapies in recent years, with 10 out of the 37 new drug therapies approved by the Food and Drug Administration (FDA) in 2022 for the treatment of cancer.[3] We urge CMS to carefully balance the need to lower the cost of drugs offered through Medicare with the need to incentivize the development of new treatments and cures.

Implementation of the negotiation process is expected to have a downstream impact on research and development. While the overall cancer mortality rate continues to decline, there is still an enormous unmet need for the development of therapies to treat cancer, and we encourage CMS to approach the MFP negotiation process in a way that does not impede future innovation in cancer drugs.

A growing number of manufacturers have announced decisions to deprioritize small molecule drug development due to the shorter period before IRA negotiation eligibility compared to biologics. For example, several oncology drug manufacturers have noted strong disincentives to pursue small molecule drugs (e.g., Alkermes, Eli Lilly, Novartis, Pfizer/Seagen) and smaller indications (e.g., Astellas, AstraZeneca, Genentech, Merck, Mirati, Seagen), while others have announced discontinued pursuits of cancer treatments (Alkermes, BMS, Eli Lilly).

Many oncology medicines approved a decade ago also received approvals for additional indications in later years, and most of those were seven or more years after initial FDA approval. These indications are often for earlier-stage cancers when cancer is more treatable, and many expanded indications are for rare cancers.

We want to ensure that overall investment in small molecule cancer drug development and the pursuit of follow-on indications is not put at risk. To mitigate this potential unintended consequence of government negotiation, we request the following:

- CMS should work with the FDA to monitor and report the implications of the negotiation program, including:
    - The submission of applications for new indications of existing therapies; and
    - Trends in the number of new cancer therapies brought to market.
- If a majority of drugs subject to negotiation pertain to one disease or condition, CMS should consider the impact on long-term research, investment, and unique characteristics of innovation for that disease when determining the Maximum Fair Price for negotiated drugs.
- CMS should examine any potential increase in launch prices in a disease area as a result of negotiation, including the overall impact on beneficiary costs, and determine the extent to which higher launch prices potentially negate some of the potential beneficiary savings from negotiation.

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[2] ACS Journals, Cancer statistics, 2023, https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21763

[3] U.S Food and Drug Administration, New Drug Therapy Approvals 2022, https://www.fda.gov/drugs/new-drugs-fda-cdersnew-molecular-entities-and-new-therapeutic-biological-products/new-drug-therapy-approvals-2022.

Conclusion

We appreciate the opportunity to provide input on the negotiation process for the Initial Price Applicability Year 2026 selected drugs. If you have any questions or need additional information, please feel free to contact Kirsten Sloan, Managing Director, Public Policy at Kirsten.Sloan@cancer.org.

Sincerely,

ACS CAN
Association of Community Cancer Centers
Brem Foundation to Defeat Breast Cancer
Cancer Help Desk
CancerCare
Caregiver Action Network
CLL Society
Colon Cancer Coalition
Color of Crohn's and Chronic Illness
Fight Colorectal Cancer
FORCE: Facing Our Risk of Cancer Empowered
Global Colon Cancer
Association HealthTree
Foundation Health Men Inc.
LUNGevity Foundation
Melanoma Research Foundation
National Brain Tumor Society
Partnership to Fight Chronic Disease
Sharsheret | The Jewish Breast & Ovarian Cancer Community
St Baldrick's Foundation
Support For People With Oral And Head And Neck Cancer (SPOHNC)
ZERO Prostate Cancer