September 14, 2023

The Honorable 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: Selected Drugs for Initial Price Applicability Year 2026

Dear Administrator Brooks-LaSure:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to share our thoughts on the list of Part D drugs selected for the price negotiation program authorized under the Inflation Reduction Act (IRA). ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change, as well as legislative and regulatory solutions, which will reduce the cancer burden. As the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, ACS CAN is more determined than ever to end cancer as we know it, for everyone.

The *Selected Drugs for Initial Price Applicability Year 2026* list includes one oncology drug, IMBRUVICA (ibrutinib), a cancer drug used to treat certain types of leukemia and lymphoma. In future negotiation years, we anticipate that more cancer drugs will be selected for negotiation than drugs in any other therapeutic areas. To that end, ACS CAN wants to ensure cancer patients are not disadvantaged by the new negotiation process. As detailed in our April 14, 2023 letter to CMS found here: Comments to CMS re: Medicare Drug Price Negotiation Program | American Cancer Society Cancer Action Network (fightcancer.org), we support policies that promote innovative, affordable, and accessible treatments for patients, and offer recommendations unique to cancer that we ask CMS to consider as you proceed with implementing the negotiation provision of the Inflation Reduction Act.

Medicare enrollees taking IMBRUVICA, or future negotiated cancer drugs, should benefit from a price negotiation that ensures they pay less for negotiated drugs than they were previously paying.

The affordability of cancer therapies remains a serious obstacle for many cancer patients who face some of the highest disease costs. While the newly enacted cap on Medicare Part D out-of-pocket drug costs will help to make prescription drugs more affordable, ACS CAN encourages CMS to administer the drug price negotiation program in a manner that ensures savings directly reach beneficiaries, and not result in just overall savings for the program.

Cancer patients require access to the specific drug that works for treating their cancer so protected class drugs must remain protected.

Notwithstanding the need for patients taking negotiated drugs to benefit from the savings, ACS CAN is concerned about the extent to which beneficiaries could be steered towards negotiated drugs. Because plans will bear more risk under the IRA's Part D benefit redesign, there is a financial incentive to steer beneficiaries toward a drug with the lowest price the plan is able to negotiate by imposing more rigorous prior authorization or step therapy requirements on non-negotiated drugs. Access to a full range of prescription drug therapies is a key determinant in successful cancer outcomes. Cancer patients need access to the most clinically appropriate treatments and should not be "stepped through" other, potentially less effective, drugs. ACS CAN urges CMS to monitor Part D plan formularies to determine the extent to which plans are using more utilization management tools for non-negotiated drugs.

The consequences of these restrictions are particularly detrimental for cancer patients, and for that reason antineoplastics are considered one of the six protected classes. ACS CAN also urges CMS to maintain the protected class policy to ensure access to non-negotiated cancer drugs is not hindered.

Non-oncology negotiated drugs are also important to cancer patients

It is worth noting that the *Selected Drugs for Initial Price Applicability Year 2026* includes non-oncology drugs that are prescribed to cancer patients for certain health conditions. For example, Eliquis (apixaban), an anticoagulant medication, is prescribed for cancer-associated thrombosis. According to a study published in the American Society of Hematology BLOOD[1], the incidence of venous thromboembolism (VTE) in cancer patients is 3% after cancer diagnosis, which is ninefold higher than in the general population. This means that thousands of cancer patients will rely on drugs like Eliquis annually so ensuring access is not disrupted is paramount.

Innovation is needed to address the unmet needs in cancer care.

While the overall cancer mortality rate continues to decline, there is still an enormous unmet need for the development of therapies to treat cancer. In monitoring manufacturer response to the IRA government negotiation provision, there is a growing narrative surrounding the downstream impact on cancer research and development.

ACS CAN is concerned that additional, potentially life-saving indications for new therapies will not be pursued. 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. Many expanded indications are for rare cancers.

We also want to ensure that the different negotiation eligibility timelines for drugs and biologics do not disincentivize the development of small-molecule oncology products. Oral drugs are especially important tools in the treatment of cancer. These therapies can be taken by patients at home which can reduce patient time and transportation burdens.

[1] https://ashpublications.org/blood/article/137/14/1959/474129/Venous-thromboembolism-in-cancer-patients-a

To mitigate unintended consequences on innovation, we ask that CMS work with the FDA to monitor potential implications and consider the impact on long-term research, investment, and unique characteristics of indication sequencing when determining Maximum Fair Prices for these cancer products.

Conclusion

Thank you for your consideration of our recommendations in response to the first selection of a cancer drug for negotiation. Ensuring affordability while at the same time investing in innovation and cancer discovery are critical to address the unmet needs in cancer care and provide patients access to the specific drug that best treats their unique cancer. ACS CAN is hoping to provide further comments during the CMS-hosted listening session for Imbruvica on November 6, 2023. If you have any questions or need additional information, please feel free to contact me directly or Kirsten Sloan, Managing Director, Public Policy at Kirsten.Sloan@cancer.org.

Sincerely,

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