May 21, 2026

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

The Honorable Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 2124

Re: Drug Price Negotiation for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)

Dear Secretary Kennedy and Administrator Oz:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to participate in the Drug Price Negotiation for Initial Price Applicability Year 2028. 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, 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.

As the Centers for Medicare & Medicaid Services (CMS) seeks public input to inform its negotiation process, we would like to underscore that cancer is uniquely complex – it is not just one disease, it is more than 200 different diseases. Cancer patients often require evidence-driven personalized treatment regimens, and medications for cancer treatments are often not interchangeable during the course of a patient's treatment journey. Research and development have also progressed to the point where medications are often targeted to a specific subtype of cancer, driving better patient outcomes.

In addition, it is critical that CMS take into consideration that the modality of cancer treatment significantly matters to cancer patients' outcomes and quality of life. An oral treatment option is essential for patients whose veins cannot handle infusion. Patients also benefit from oral medication as it allows them greater opportunity to engage in their day-to-day activities (such as continuing their work schedule) and reduces access barriers such as transportation. Side effects are also a critical consideration by clinicians as they vary depending on the individual patient – with some patients able to tolerate certain side effects better than others. These important patient clinical and quality experiences should be considered as CMS undergoes the negotiation process.

ACS CAN was pleased to have been selected to participate in three roundtable events concerning Kisqali (used to treat breast cancer), Verzenio (used to treat breast cancer), and Lenvima (used to treat thyroid cancer, endometrial cancer, liver cancer, and kidney cancer). In addition, a representative from the American Cancer Society, Dr. Christina Annunziata, Senior Vice President for Extramural Discovery Science, participated in the town hall event to discuss Kisqali.

Additionally, ACS CAN identified and surveyed 137 patients who had personal experience taking the four cancer drugs on the negotiation list (Kisqali, Verzenio, Lenvima, and Erleada (used to treat prostate

cancer)). During our participation in the roundtable events, we provided a high-level summary of our survey findings. We would like to take this opportunity to share more information about our survey findings for each of the oncology drugs subject to negotiation.[1] Individuals surveyed have a diagnosis of cancer, have Medicare as their primary health care coverage, and have taken or considered taking one of the cancer medications on the negotiation list for treatment of their cancer in the last 18 months.

Experience Across the Selected Therapies

Patients taking these therapies reported some shared experiences. Across all four cancer drugs, patients reported overall quality of life was "much better" while on these therapies, and 97 percent reported that their specific selected therapy had a significant positive impact on their emotional and mental well-being. Patients identified several types of delays and barriers to access, including utilization management by payers (e.g., step therapy and/or prior authorization) and high out-of-pocket costs/affordability. Cost was ranked as among the top three important factors for all selected drugs included in the research, and patients reported that drug affordability impacted treatment adherence.

Kisqali

Overarching Findings: For the 30 patients taking Kisqali, the most important factors in considering this medication as a therapy were: 1) quality of life, 2) impact on survival, and 3) cost. Respondents emphasized overwhelmingly positive outcomes and the important role of Kisqali in their cancer treatment, with 70 percent (21 of the 30) saying Kisqali was very important or critically essential as the only effective therapy for managing their cancer. Sixty-three percent (19 of the 30 Kisqali patients) say there was no other alternative therapy they could have considered instead.

Quality of Life: In terms of patients' day-to-day experiences, 97 percent (29 of 30) say that Kisqali made their daily quality of life much better, and 93 percent (28 of 30) say Kisqali had a significant positive impact on their emotional or mental well-being. Respondents mentioned convenient oral administration as one of the most important attributes of Kisqali, behind its efficacy and impact on quality of life.

Access Challenges: While the efficacy of Kisqali has been critical to many of our respondents, several raise concerns about cost and access. On affordability, seven percent (2) of patients reported skipping doses or taking a partial dose due to cost, and the same number (2) said they did not pick up their prescription for that reason. Seventy percent (21 of the 30) patients tried other therapies first, and about one-third of those (7) were required to do so before Kisqali would be covered (step therapy).

Verzenio

Overarching Findings: For the 29 patients taking Verzenio and 4 who completed the treatment, the most important factors in considering Verzenio as a therapy were: 1) quality of life, 2) impact on survival, and 3) cost. Respondents emphasized overwhelmingly positive outcomes and the important role of Verzenio in keeping their cancer under control, with 70 percent (23 of the 33) saying Verzenio has been very important to their cancer care and treatment and 30 percent (10 of 33) saying it was critically important as the only

[1] A detailed summary of our survey findings is available at https://www.fightcancer.org/sites/default/files/patient_experience_round_3.pdf.

effective therapy for managing their cancer. Eighteen percent (6 of the 33 Verzenio patients) say there was no other alternative therapy they could have considered instead.

Quality of Life: Most critically for our survey respondents, Verzenio slows disease progression while maintaining their quality of life. Ninety-seven percent of the cancer patients we surveyed (32 of 33) say Verzenio made their daily quality of life much better, and 100 percent (33 of 33) also say Verzenio had a very positive impact on their mental or emotional well-being.

Access Challenges: Many respondents indicated challenges related to affordability and access while taking Verzenio, including high out-of-pocket costs, insurance coverage barriers, and prior authorization or administrative delays. Twenty-seven percent (9) of patients reported skipping doses or taking only part of a dose due to cost, and the same number (9) said they did not pick up their prescription for that reason. Forty-two percent (14 of 33) say they experienced treatment delays or interruptions in accessing Verzenio. More than half (18) of patients were required to try other therapies first before Verzenio would be covered.

Lenvima

Overarching Findings: For the 31 patients actively taking Lenvima and 3 who completed the treatment, the most important factors in considering Lenvima as a therapy were: 1) quality of life, 2) impact on survival, and 3) cost. Respondents emphasized that Lenvima works to effectively manage their cancer after other therapies stopped working and, in some cases, delays the need for more intensive treatments. Ninety-one percent (31 of 34) say Lenvima has been very important to their cancer care and treatment or critically essential as the only effective therapy for managing their cancer. Forty-four percent (15 of 34 Lenvima patients) say there was no other alternative therapy they could have considered instead.

Quality of Life: Respondents emphasized the importance of Lenvima in improving their quality of life. Ninety-four percent (32 of 34) of the cancer patients we surveyed said Lenvima made their daily quality of life much better. Ninety-seven percent (33 of 34) also say Lenvima had a very positive impact on their mental or emotional well-being.

Access Challenges: Many of our respondents raise concerns about cost and access to Lenvima. Eighteen percent (6) of patients reported skipping or taking only part of a dose due to cost, and the same number (6) said they did not pick up their prescription for that reason. Forty-four percent (15 of 34) reported experiencing delays or interruptions in accessing Lenvima, and 32 percent (11) reported being required to try other therapies first before Lenvima would be covered.

Erleada

Overarching Findings: For the 38 patients actively taking Erleada and 2 who completed the treatment, the most important factors in considering this medication as a therapy were: 1) quality of life, 2) impact on survival, and 3) cost and lack of side effects, which patients rated equally important. Respondents stressed how Erleada is clinically effective and has improved their likelihood of survival, with 50 percent (20 of 40) saying Erleada has been very important to their cancer care and treatment and one-fourth (10 of 40) saying it was the only effective therapy for managing their cancer. Forty-five percent (18 of the 40) say there were no alternative therapies they could have considered instead.

Quality of Life: Regarding the day-to-day experience taking the treatment, 98 percent (39 of 40) of the cancer patients we surveyed said Erleada made their daily quality of life much better. Our survey respondents emphasized quality of life as the most important attribute of Erleada, including preserving physical strength, avoiding the need for painful treatment, and improving mental well-being. Ninety-eight percent (39 of 40) also say Erleada had a very positive impact on their mental or emotional well-being.

Access Challenges: Many respondents indicated challenges in access to Erleada and noted that its cost impacted treatment adherence and persistence. Half of patients (20 of 40) say they experienced treatment delays or interruptions in accessing Erleada. Twenty-five percent (10) say they skipped or split doses due to cost, and 30 percent (12) say they did not pick up their Erleada prescription for the same reason. Patients also reported Erleada frequently being subject to step therapy – about 40 percent (16) were required to try other therapies first before Erleada would be covered.

Feedback on Public Engagement Process

ACS CAN values the opportunity to participate in the public engagement process for the 2028 initial price applicability year. We have taken part in each year's public engagement process and appreciate CMS's ongoing efforts to improve the experience for patients and engagement of patient organizations. We recognize that the proposed rule for the Medicare Drug Price Negotiation Program is still pending; in the meantime, we wanted to offer our initial feedback on the public engagement process. We recommend that CMS:

- Revise the Information Collection Request form to make the process more accessible for patients and patient organizations by making it separate from the manufacturer form. This change would allow stakeholders to submit to CMS information pertinent to patient experience rather than being constrained by the form's rigid question-and-answer-box format and enable stakeholders to comment on multiple drugs.
- Allow patient organizations to register at the organizational level rather than as individual representatives so they have flexibility to designate a substitute speaker if a last-minute conflict arises.
- Share the questions in advance so participants can prepare thoroughly and provide CMS with the most relevant data on patient experience.
- Tailor the questions to the specific drug and disease state being discussed. While we understand that CMS must meet its statutory responsibilities, the process should also reflect that different drugs address distinct clinical needs.
- Revise the patient roundtable questions so that they focus more on patient experience rather than clinical details. The separate clinical town halls are the more appropriate setting for clinical discussions.

Conclusion

Thank you for the opportunity to provide comments. If you have any questions or need additional information, please feel free to contact me directly or Allie Babyak, Public Policy Fellow, Access to Care and Prescription Drugs, at Allie.Babyak@cancer.org.

Sincerely,

Lisa A. Lacasse, MBA
President
American Cancer Society Cancer Action Network

cc: Lara Strawbridge, Acting Director, Medicare Drug Rebate and Negotiations Group, Center for Medicare