DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

May 9, 2023

Ellen V. Sigal
Chair & Founder
Friends of Cancer Research
1800 M St. NW
Suite 1050 South
Washington, DC 20036

Dear Ms. Sigal:

Thank you for your letter and for sharing your thoughts on Medicare's coverage of drugs and biologics approved by the Food and Drug Administration (FDA) under the Accelerated Approval Program. Promoting access to new, innovative and effective treatments is a priority for the Centers for Medicare & Medicaid Services (CMS). And we will continue to work with you and other interested stakeholders to make sure these treatments get to patients who need them as part of President Biden's Cancer Moonshot initiative.

In your letter, you asked whether CMS has changed its approach to drugs and biologics approved by the FDA under the Accelerated Approval Program. We have not. Medicare makes national coverage decisions based on whether an item or service is reasonable and necessary for the treatment of an illness or injury for the Medicare population. While CMS has issued a few National Coverage Determinations (NCD) on a drug or biologic with accelerated approval, it is rare. Most of the decisions when a drug or biologic has accelerated approval continue to be left to the Medicare Administrative Contractor (MAC). Medicare Administrative Contractors are local contractors that pay Medicare fee-for-service claims and decide whether a drug is covered for Medicare beneficiaries on a claim-by-claim basis or through a local coverage determination.

To receive an accelerated approval from the FDA, a drug must address an unmet clinical need and meet the same safety and effectiveness standard as required for traditional approval. The difference is that they can rely on factors that are reasonably likely to predict clinical benefit (for example, proxies such as whether a tumor shrinks) instead of an end result such as survival or improvement in symptoms. These factors are generally referred to as surrogate outcomes or endpoints.

For many accelerated approval drugs for diseases like cancer or human immunodeficiency virus (HIV), there is an established scientific consensus that validated surrogate outcomes are indicators of health outcomes. For example, with respect to cancer, there is scientific evidence as well as wide acceptance by clinicians of the association between shrinking tumors (surrogate outcome) and symptoms or overall patient survival in patients receiving such cancer drugs (health outcome).

Thank you again for your letter and for your concern for the health of Medicare beneficiaries and their access to cancer drugs.

Sincerely,

Chiquita Brooks-LaSure