

December 19, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Administrator Brooks-LaSure,

The undersigned organizations representing cancer patients and caregivers write to express our concern regarding Humana's recently announced medical coverage policy change for PD-1/PD-L1 non-small cell lung cancer (NSCLC) in Medicare Advantage (MA) plans starting January 1, 2025. This policy is significantly more restrictive than the National Comprehensive Cancer Network (NCCN) guidelines for treatment of NSCLC. We are very concerned that this policy will limit treatment options for patients diagnosed with metastatic PD-1/PD-L1 NSCLC and lead to harmful and unnecessary delays in care. We respectfully ask that CMS use its authority to review Humana's Pharmacy and Therapeutics committee records and evaluate the criteria used for this decision.

In a statement issued on November 6 of this year, Humana indicated that it would apply a step strategy to frontline metastatic NSCLC with a requirement to use the preferred product, cemiplimab-rwlc. Under this policy change, if a physician has recommended a different immunotherapy (IO) or combination IO in consultation with their patient, that patient would have to "fail" on the preferred product before receiving coverage for the recommended treatment – or go through an onerous medical exception process that will inevitably lead to harmful delays in care. We are particularly concerned that this policy contradicts standard practice of care, undermines physician expertise, and will prevent or delay access to life-saving and life-preserving combination IO treatments for those patients whose specific status would suggest this option. This policy undermines the ability of physicians and patients to make treatment decisions tailored to each patient's unique medical needs and desired outcomes.

According to the current NCCN Guidelines, there is no recommendation to go to an IO or IO combination in second line after treatment with an IO in first line. Please see NCCN Guidelines Version 11.2024-October 15, 2024, Non-Small Cell Lung Cancer Section NSCL-J; pages 2 of 6, and 3 of 6ⁱ. The "Preferred" and "Other Recommended" NCCN categories should not be misconstrued as the basis for step therapy, as both NCCN categories remain recommended treatments by NCCN.

For patients, it is vital that payers, including MA and MA-PD plans, include all available medically necessary treatment options in their formularies, without imposing step therapy protocols, so that physicians and patients are able to make treatment decisions based on disease characteristics and what will enable the patient to achieve a durable treatment response while maintaining their quality of life.

In a final rule titled “Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses” (Document Number 2019-10521)ⁱⁱ, CMS noted in response to public comments that the agency “may monitor compliance with (and, as necessary take enforcement and/or compliance action regarding) the P&T committee requirements in § 422.136(b) through requesting written documentation regarding Part B step therapy programs and evaluating whether clinical decisions and criteria are evidence-based and appropriate in terms of safety and efficacy.” Our organizations urge CMS to review Humana’s planned policy change and take action to ensure that all policies are based on current clinical guidelines to serve the best interests of people living with NSCLC.

Please consider our organizations a resource because we work with patients impacted by NSCLC and can share insights related to treatment preferences, outcomes, and needs. If you have any questions, please contact Brandon Leonard, Senior Director of Government Affairs at LUNgevity Foundation, at bleonard@lungevity.org.

Thank you for your consideration on this important topic impacting patient access to care.

Sincerely,

Aimed Alliance

American Lung Cancer Screening Initiative

Biomarker Collaborative

BRAF Bombers

Cancer Support Community

Caregiver Action Network

Caring Ambassadors Program

Citizens for Radioactive Radon Reduction Inc.

Clifton F. Mountain Foundation for Education & Research in Lung Cancer

EGFR Resisters

Exon 20 Group

Free ME from Lung Cancer

GO2 for Lung Cancer

ICAN, International Cancer Advocacy Network

KRAS Cancer Connect | KRAS Kickers

LiveLung

Lung Cancer Connection
Lung Cancer Foundation of America
Lung Cancer Initiative
Lung Cancer Research Foundation
LUNgevity Foundation
MET Crusaders
National Coalition for Cancer Survivorship
PD-L1 Amplifieds
RetireSafe
School Radon Safety
The White Ribbon Project
Upstage Lung Cancer

CC:

Cheri Rice, Deputy Director, Parts C and D, Center for Medicare
Christina Ritter, Director, Medicare Drug Rebate and Negotiations Group
Vanessa Duran, Director, Medicare Drug Benefit and C & D Data Group
Mark Newsom, Deputy Director, Medicare Drug Benefit and C & D Data Group
Brian Martin, Director, Division of Formulary & Benefit Operations
Craig Miner, Deputy Director, Division of Part D Policy

ⁱ NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for Non-Small Cell Lung Cancer V.11.2024, NSLC-J page 2 of 6. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed December 11, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org.

ⁱⁱ Centers for Medicare & Medicaid Services. “Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses.” May 23, 2019. <https://www.federalregister.gov/d/2019-10521>.