October 5, 2020

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

RE: CMS-1736-P: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-owned Hospitals

Dear Administrator Verma:

As organizations that represent hundreds of thousands of patients and health care providers, we appreciate the opportunity to offer our comments on the proposed changes to the "Laboratory Date of Service Policy" (DOS) in the Centers for Medicare and Medicaid Services Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule for Calendar Year 2021. We are pleased to see the work CMS has done to improve access to precision medicine and ensure that patients receive the best possible care to suit their needs. As a result, we write to strongly support the agency's proposal to except cancer-related protein-based Multianalyte Assays with Algorithmic Analyses (MAAAs) from the laboratory DOS policy at §414.510(b)(5), and we urge finalization of this policy change.

Certain clinical diagnostic laboratory tests that are considered integral, ancillary, supportive, dependent, or adjunctive to the primary services provided in a hospital outpatient department are packaged. While this is the general policy for many laboratory tests, CMS has said there are tests that have distinct patterns of clinical use that make them relatively unconnected to a patient's hospital encounter. For these unique tests, our organizations supported CMS's previous packaging policy exclusions and the exceptions to the Laboratory DOS policy, which would allow laboratories to bill Medicare directly.

As organizations representing patients, we are encouraged that CMS has proposed to exclude certain cancer-related protein-based MAAAs from the OPPS packaging policy, allowing them to be paid separately under the Clinical Lab Fee Schedule (CLFS) and be billed by laboratories through the DOS policy exception. We have previously supported extending the exception to MAAAs asking that CMS contemplate all advanced diagnostics when considering related policy modifications. We appreciate the recognition by CMS that "treatments that are based on the result of cancer-related protein-based MAAAs are typically furnished after the patient is no

longer in the hospital, in which case they are not tied to the same hospital outpatient encounter during which the specimen is collected."[1] However, we encourage CMS to apply the same rationale to other diseases that are similar when considering additional modifications in future rulemaking.

Importantly, we also note that allowing these tests to be billed to Medicare directly by laboratories can reduce delays and improve patient outcomes. When the date of service is the date of the specimen collection rather than the date the test is performed, the test may not be ordered when it could be the most critical for a patient. As referenced in the proposed rule, there have been concerns that hospitals may delay ordering tests for 14 days or more after the hospital outpatient encounter to bypass the DOS policy.

Delaying treatment can have severe implications for cancer patients. For example, in a study published in 2019, researchers found that time to treatment initiation "has lengthened significantly and is associated with absolute increased risk of mortality ranging from 1.2–3.2% per week in curative settings such as early-stage breast, lung, renal and pancreas cancers. Studies of interventions to ease navigation and reduce barriers are warranted to diminish potential harm to patients."[2]

Delays in testing, and subsequent initiation of treatment, are especially problematic because cancer patients can benefit significantly from targeted therapies. Timely access to comprehensive biomarker testing can prevent harm by ensuring that the most appropriate treatment plan is identified for each individual's unique needs. A study published in 2018 found that "precision oncology may improve overall survival for refractory cancer patients while lowering average per-week healthcare costs, resource utilization and end-of-life costs."[3]

Therefore, we believe that the exceptions in this proposed rule will reduce delays in ordering of these tests and improve the prognosis for cancer patients, but we encourage CMS to apply the same reasoning to diseases that are similar to cancer in future rulemaking. Thank you again for the opportunity to provide comments on this important issue. As organizations that promote policies that support patients, we strongly urge finalization of the proposed policies related to cancer-related protein-based MAAAs.

Please contact Kristen Santiago, Senior Director of Public Policy for the LUNGevity Foundation at ksantiago@lungevity.org if you have any questions or if you would like us to provide additional information.

Sincerely,

Active Surveillance Patients International (ASPI)
American Cancer Society Cancer Action Network (ACS CAN)

[1] 85 Fed. Reg. 48772 (August 12, 2020).
[2] Khorana AA, Tullio K, Elson P, Pennell NA, Grobmyer SR, et al. (2019) Time to initial cancer treatment in the United States and association with survival over time: An observational study. PLOS ONE 14(3): e0213209. https://doi.org/10.1371/journal.pone.0213209
[3] Haslem DS, Chakravarty I, Fulde G, et al. Precision oncology in advanced cancer patients improves overall survival with lower weekly healthcare costs. *Oncotarget*. 2018;9(15):12316-12322. Published 2018 Feb 2. doi:10.18632/oncotarget.24384. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5844748/

American Lung Association
Answer Cancer Foundation d/b/a AnCan
AONN+
CancerCare
Cancer Support Community
Cholangiocarcinoma Foundation
Clearity Foundation
Dusty Joy Foundation (LiveLung)
Fight Colorectal Cancer
Free ME from Lung Cancer
Friends of Cancer Research
FORCE: Facing Our Risk of Cancer Empowered
Go2 Foundation For Lung Cancer
ICAN, International Cancer Advocacy Network
International Myeloma Foundation
Lung Cancer Action Network (LungCAN)
Lung Cancer Initiative
Lung Cancer Foundation of America
LUNGevity Foundation
Mountain Foundation for Research & Education in Lung Cancer
National Alliance of State Prostate Cancer Coalitions
National Coalition for Cancer Survivorship
Pancreatic Cancer Action Network
Prevent Cancer Foundation
Prostate Cancer Foundation
Rexannas Foundation
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