



ASSOCIATION FOR MOLECULAR PATHOLOGY

Providing global expertise in molecular testing that drives patient care
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October 5, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1736-P
P.O. Box 8016
Baltimore, MD 21244-8013

Re: CY 2021 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 Proposed Rule (CMS-1736-P)

Dear Administrator Verma:

The Association for Molecular Pathology (AMP) appreciates the opportunity to provide comments on the CY 2021 Hospital Outpatient Prospective Payment System (OPPS) proposed rule. AMP is an international medical and professional association representing approximately 2,500 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from academic medicine, hospital-based and private clinical laboratories, the government, and the in vitro diagnostics industry.

We look forward to working with CMS as this proposed rule moves toward implementation and offer the following comments regarding the proposed revisions to the OPPS packaging policy and the laboratory date of service (DOS) rule.

AMP supports CMS' proposal to exclude cancer-related protein-based Multianalyte Assays with Algorithmic Analyses (MAAAs) from the OPPS packaging policy and to create an exception to the laboratory DOS rule for these services. We agree with the agency that cancer-related protein based MAAAs are typically used to guide and manage the patient's care after the patient is discharged from the hospital outpatient department, since the test results are used to determine potential future oncologic surgical and chemotherapeutic interventions. These tests, like the others that have already been excluded from the OPPS packaging policy, almost never impact the treatment regimen during the same hospital outpatient service where the specimen is collected, even if the results are immediately available. Therefore, it is appropriate to exclude these services from the OPPS packaging policy and have Medicare pay for them on the Clinical Laboratory Fee Schedule (CLFS) instead of the OPPS.

CMS identified the following five cancer-related protein-based MAAAs that would be excluded from the OPPS under this proposal: CPT codes 81500 (Onco (ovar) two proteins), 81503 (Onco (ovar) five proteins), 81535 (Oncology gynecologic), 81536 (Oncology gynecologic), and 81539 (Oncology prostate prob score). These are critical tests for patients, and currently patients are waiting for extended periods of time to have testing done.

This has led to increased time to diagnose cancer patients, which in turn delays treatment and care for patients. Excluding these services from the OPPS and creating an exception to the DOS rule will improve patient access to clinically appropriate testing and the treatment decisions that result from it.

Thank you for the opportunity to submit recommendations for CMS to consider while revising the DOS policy. We are happy to answer any questions about our recommendations and provide further information. Please direct your correspondence to Tara Burke, PhD, AMP Senior Director of Public Policy and Advocacy, at tburke@amp.org.

Sincerely,

Karen E. Weck, MD FCAP
President, Association for Molecular Pathology