



March 21, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Administrator Verma:

The College of American Pathologists (CAP) would like to urge the agency to revise its Date of Service (DOS) policy in both the inpatient and outpatient 2019 hospital fee schedule regulations. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the College of American Pathologists serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. Specifically, the CAP urges that the Centers for Medicare and Medicaid Services (CMS) to:

1. Apply all of the recent revisions to Hospital Outpatient Prospective Payment System (HOPPS) laboratory date of service policy to hospital inpatients
2. Expand the exclusions from the OPPS packaging policy to include FISH services

1. Apply all of the recent revisions to Hospital Outpatient Prospective Payment System (HOPPS) laboratory date of service policy to hospital inpatients

The CAP appreciates the improvements to Medicare's laboratory DOS policy to date. However these improvements did not address hospital inpatients and payment for some tests are still problematic.

The CMS and other commenters recognize that these tests have a different pattern of clinical use than the more conventional laboratory tests. Regardless of the location or date of the testing, the services performed during an inpatient or outpatient encounter are typically unrelated to those driven by molecular testing. For example, if blood is drawn at the same time a cancer patient receives chemotherapy during an outpatient encounter (e.g., for the purposes of determining potential metastasis or minimal residual disease) the results of testing completed on that specimen will inform treatment during a future, not the current, encounter.

For these tests, the process of seeking payment from the hospital has long proven burdensome for clinical laboratories, hospitals, treating physicians and Medicare beneficiaries and may have negatively impacted patient care, particularly in the cancer setting where large genomic sequencing panels are increasingly used and timely access to test results can impact the treatments patients receive. The Agency stated in its OPPS Final ruling for 2018 that "adding the laboratory DOS exception for hospital inpatients would have policy and rate setting implications under the IPPS diagnosis related group (DRG) payment". However, close examination of the Medicare program policy documents show a strong history of excluding pathology technical components from the inpatient DRG bundled payment. In fact, agency policy has dictated that such costs were not included in the DRGs for all hospitals utilizing independent laboratories, and in particular these diagnostic services could not, by virtue of their recent emergence, be included in the data on which any prospective payments are based. Furthermore, there has never been a specific adjustment in the DRGs for technical component services.



Laboratory tests ordered for hospital inpatients do not have the specific CPT code tests listed on the inpatient claim. As a result, the hospital and CMS cannot easily track patients who have received these tests using claims data, or evaluate how advanced testing contributes to cancer care and other advanced treatments, or evaluate the total cost of care. If laboratories could directly bill Medicare for molecular pathology tests and ADLTs in the inpatient setting, consistency across places of service, tracking capabilities and patient outcomes could be enhanced.

The CMS and all stakeholders recognize that molecular pathology tests and ADLT's have unique clinical utilization distinct from conventional laboratory tests. As molecular technologies continue to advance, the CAP believes their utility will continue to differ significantly. Molecular testing allows patients and their physicians to make actionable medical decisions based on genomic information. The information and the treatment decisions gleaned from molecular testing are relevant to future patient care, but generally do not impact patient management during the hospital visit. Additionally it is an administrative burden on hospitals that collect specimens, and laboratories that furnish and bill for ADLTs and molecular pathology tests, to track tests ordered for hospital outpatients in a way that is inconsistent with those performed on specimens obtained from hospital inpatients. Reimbursement policy for these services should be consistent across places of service and consistency between the DOS for hospital inpatients and hospital outpatients is important for evaluating data on patient outcomes.

Many hospitals do not perform these types of more technologically advanced laboratory tests in-house. Hospitals therefore, upon receipt of a physician's orders, instead send patient specimens to independent and/or specialized laboratories for testing, regardless of the place of service.

Restricting the DOS policy to only outpatients:

- Restricts patient access to tests and reduces efficacy of treatment plans due to hospitals delaying or foregoing patient testing to avoid financial risk
- Discourages hospitals from utilizing advanced tests because billing for tests not performed by hospitals can create administrative and financial complexities.
- Presents confusion among clinical laboratories and hospitals as to who and when each is responsible for billing of laboratory services.
- Hampers the access of beneficiaries to these results.

Thus, regardless of the place of service, a revised DOS policy that allows the performing laboratory to bill directly for molecular pathology tests and ADLTs, rather than receiving payment from the hospital, would reduce administrative and billing complexity for hospitals, clinical laboratories, treating physicians and Medicare beneficiaries, and promote timely access to patient testing.

Tests on tissue samples acquired from patients during hospital stays are critically important for determining future treatment planning and responsible patient care. The CAP, the AMA, along with other stakeholders believes that molecular pathology testing has rapidly evolved over the past five years, whereas they are performed as a separate set of services in the targeting of treatment and patient care management. Therefore, it is more appropriate that all laboratories performing molecular pathology testing bill Medicare directly. The AMA has recognized this fact and unanimously passed recent policy at its November 2017 House of Delegates meeting that reads:

Elimination of Laboratory 14-Day Rules Under Medicare D-330.903

Our AMA will actively lobby the federal government to change laboratory Date of Service rules under Medicare such that complex diagnostic laboratory services performed on



pathologic specimens collected from a hospital procedure be paid separately from inpatient and outpatient bundled payments

The CAP is eager to work with CMS to ensure that all patients have access to this testing and the personalized medical information it provides. **We urge CMS to allow laboratories to directly bill Medicare for molecular pathology tests and ADLTs in the inpatient setting.**

2. Expand the exclusions from the OPSS packaging policy to include FISH services

Tests on tissue samples acquired from patients during inpatient and outpatient visits are critically important for determining follow-up treatment plans and responsible patient care. The goal is to have all test results in hand prior to the oncologist (or other physicians) making the treatment decision to explore the best quality and value based options for the patients. This supports the Agency's programmatic objectives of providing appropriate use, high value, and personalized patient care.

The CAP supports the direct billing of molecular pathology tests and ADLTs, as both types of tests and other diagnostic modalities are often used to provide critically important diagnostic information to inform follow-up patient treatment plans. Molecular pathology, ADLTs, and Fluorescence In Situ Hybridization (FISH) tests are often used in combination, and with other pathology services, to provide the proper and best patient care. For example, molecular pathology tests and ADLTs (NGS tests) may be used in combination due to limitations in platform capabilities right now. In the case of NGS testing for lung, not all have the robust capabilities to find translocation genes such as ALK and ROS1 so they would use a combination of the NGS and the fluorescence in situ hybridization (FISH) assays. Excluding one would limit capabilities, as well as create unmanageable scenarios within laboratories, to provide comprehensive, guideline based results in a cohesive and timely manner.

FISH technical component services are equally utilized and vital within outpatient and inpatient hospital care in the same ways that molecular and ADLTs are, for clinical guidance of essential clinical decisions in a timely fashion to determine the best course of care. FISH technical component services, associated with CPT codes 88364, 88365, 88366, 88367, 88368, 88369, 88373, 88374, and 88377, have unique clinical utilization distinct from conventional laboratory tests. Laboratories use FISH in combination with other molecular tests as well as independently, to provide critical patient results that inform and guide treatment and patient care. **CAP urges the CMS to expand the exclusions from the OPSS packaging policy to include FISH technical component services in the definition of molecular services provided in the outpatient or inpatient hospital settings: CPT codes 88364, 88365, 88366, 88367, 88368, 88369, 88373, 88374, and 88377.**

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The College of American Pathologists is pleased to have the opportunity to comment on issues and appreciates your consideration of these comments. Please direct questions on these comments to; Todd Klemp (202) 354-7105 / tklemp@cap.org.