

Policy Brief: Fair and Rational Medicare Payment for Molecular Diagnostic Tests

In vitro tests represent less than 5% of the nation's health care cost but leverage up to 70% of critical health care decisions, according to a recent Institute of Medicine study. Molecular diagnostic tests, while more costly than the tests they replace, do provide significantly more useful clinical information that permits doctors to intervene with targeted therapy and literally change the course of disease.

It is essential to have health care payment policy that supports patient access to these DNA-based laboratory tests. Financial incentives need to be aligned to ensure that there are no barriers to providing clinicians and patients with the best information that technology has to offer. Providers of laboratory services deserve fair and rational payment for these highly sophisticated molecular tests.

FDA labeling requires that a pathologist perform specific steps in the pre and post analytic phases of many molecular tests... which means that they are placed on the physician fee schedule and paid according to the resource based relative value scale, (RBRVS), which is a true reflection of the cost of quality controlled results.

The Personalized Medicine Coalition was concerned when in July 2004, Medicare proposed moving certain surgical pathology tests from the physician fee schedule to the clinical laboratory fee schedule, which has been frozen for ten of the last thirteen years and, under the Medicare Modernization Act will remain frozen through 2009.

Such a move is inconsistent with the Social Security Act and Medicare's rules, which state, "The law requires that physician pathology services be treated like other physician services under the fee schedule." Under widespread protest, Medicare did assign the new surgical pathology codes to the physician fee schedule, as required by law.

Thus these new codes will be paid fairly and patients will receive the benefit of the information the new tests provide. The Personalized Medicine Coalition will remain vigilant about molecular test reimbursement issues and in discussions with CMS and lawmakers will use this as an example of health payment policy making that could have had an adverse impact on access and quality of care.

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