

New Law Promotes Development of and Access to New Diagnostic Tests

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Only 1% of all marketed drugs have a companion diagnostic to determine which patients will benefit from a specific treatment, and this lack of clinically useful diagnostics is hindering growth in personalized medicine.^{1,2}

Once a new diagnostic test is approved by the FDA, it can take anywhere from 18 months to several years before the diagnostic has an assigned code for prescribing and billing. This means precious treatment time is lost for the patient.

Take the example of the human epidermal growth factor receptor 2 (HER 2) diagnostic test to identify breast cancer patients for Herceptin drug therapy (Figure). The test received FDA approval in 1999, but the code for HER 2 was not established until 5 years later. That meant women with breast cancer had to gamble on whether to undergo Herceptin therapy, not knowing if it was the right treatment option for them, because there was no assigned code for ordering or paying for the HER 2 test.

On April 1, 2014, President Obama signed into law HR 4302: the Protecting Access to Medicare Act of 2014, a momentous step toward promoting the development and use of advanced diagnostics.³

The bill received extensive media coverage because it was the latest effort to temporarily delay both a planned cut to physician reimbursements under Medicare and the implementation of the next-generation medical coding system known as the *International Classification of Diseases, Tenth Revision (ICD-10)*.^{4,5}

Also tucked inside this legislation were 2 game-changing provisions for which the patient advocacy community has been fighting since 2011:

- A means for getting advanced diagnostic tests to patients more quickly, and
- A process to promote high-value advanced diagnostics that truly personalize care for patients.

These provisions were first proposed in Section 102 of the Modernizing our Drug and Diagnostic Evaluation and Regulatory Networks (MODDERN) Cures Act, a bill crafted by the National Health Council.⁶

Improving Patient Access to Advanced Diagnostics

It is rare for a drug to be safe or effective for everyone and under all circumstances.⁷ This inherent variability in response to a particular treatment has a significant effect on the quality and cost of healthcare.⁸ To ensure the best care, we need diagnostics to target the treatment that meets the specific needs of the patient. After such tests have been approved by the FDA, there needs to be a way to quickly get them into the market and to the patients who need them.

Section 216 of HR 4302 creates a temporary Healthcare Common Procedure Coding System (HCPCS) code that can be assigned after tests are cleared or approved by the FDA. Also under the new law, existing approved tests that have not yet been assigned a Medicare reimbursement code must have a temporary HCPCS code assigned by January 2016.

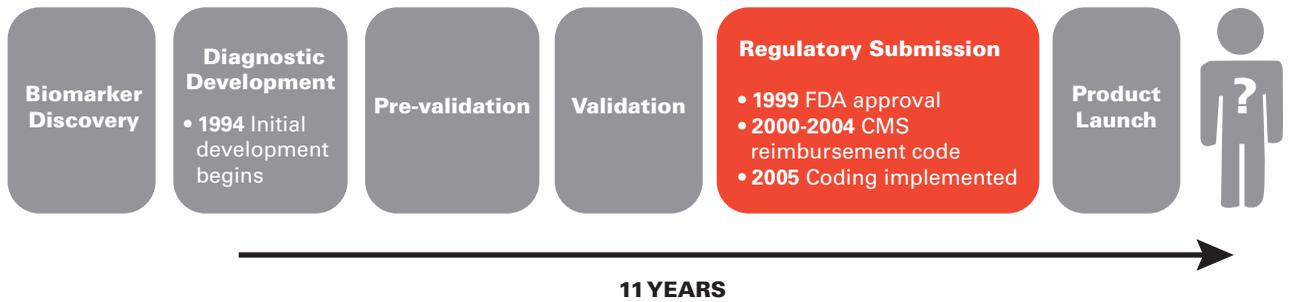
This temporary code will be used until a permanent code has been assigned, but not for longer than 2 years, ensuring that patients receive immediate access to these diagnostic tests and increasing the likelihood of establishing more effective treatment plans.

Promoting the Development of Advanced Diagnostics

In addition to enhancing access to approved diagnostics, the new law changes how the reimbursement rate is set for such tests in order to promote the development of high-value advanced diagnostics that truly personalize the delivery of care for patients.

When a new advanced diagnostic gets approved under the current system, CMS assigns the test a Medicare reimbursement rate that is comparable to that of the most

Figure. PathVysion: HER 2 DNA Test to Identify Candidates for Herceptin Breast Cancer Therapy



HER 2 indicates human epidermal growth factor receptor 2.
Source: National Health Council.

similar test currently on the market. However, since the new diagnostics are innovative, there is no apples-to-apples comparison by which to determine a payment level.

Section 216 of HR 4302 creates an expert advisory panel that will use a more comprehensive approach to recommend the Medicare reimbursement rate for new diagnostics. This panel will take into consideration factors such as the improvement in patient care and the differential between the cost of developing and administering the new test compared with an existing test that is being used as the payment benchmark. Placing greater emphasis on the value of advanced diagnostics will encourage the development of such tests, which will improve the ability of health-care providers to appropriately treat individual patients.

The Secretary of HHS is directed to create the advisory panel no later than July 1, 2015, and the law states that the panel should be “composed of an appropriate selection of individuals with expertise, which may include molecular pathologists, researchers, and individuals with expertise in laboratory science or health economics.” As originally conceived, this panel would also include patient representatives, including a patient representative for rare disorders; clinicians; experts in the area of pharmacoeconomics or health technology assessment; and individuals with expertise regarding the impact of new tests on quality of patient care, including genetic counselors.⁹ Since the precise makeup of the expert advisory panel is not articulated in the law, the patient advocacy community will seek to ensure that the patient voice is part of the decision-making process.

For many people with chronic conditions, their health care history is a drawn-out trial-and-error process to find the treatment plan that meets their unique needs. There must be a better way to determine which therapy will be the most effective for an individual. The changes in the nation’s Medicare diagnostic system as enacted by Congress and signed into law by the president are 2 major steps toward meeting this goal.

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