New Tests That Can Back Up Promises with Clinical Studies Prosper

Kalorama Information

In vitro diagnostic test products that can provide clinical validation of their performance have a better chance obtaining reimbursement status, according to Kalorama Information. The report studied some recent products and their success at the critical task of clearing payor standards and found that those with clinical studies backing up their effectiveness did far better. The finding was made in its new research report on the topic, Reimbursement for IVD Tests.

“No new product, anywhere, can expect to be reimbursed simply because it provides a technological improvement over existing products,” said Bruce Carlson, Publisher of Kalorama Information. “Successful IVD demonstrate cost benefits over alternative approaches; and have strong clinical validation of test results through rigorous, published clinical studies.”

In the United States, the Centers for Medicare and Medicaid Services (CMS) determines and implements payment methodologies for specific types of healthcare services covered by Medicare and Medicaid. These federal plans, which combined cover almost 100 million persons, represent the largest health care plans in the nation by a wide margin and thus most other public and private health plans defer to CMS regarding coverage decisions. Decision-makers focus on cost-savings, according to Kalorama’s analysis, and reward products that save the healthcare system money and prove results. This is not easy for IVD products, but some form of trial is the preferred way.

“Trials aren’t easy and don’t always apply to IVD products the way they would for pharmaceuticals, said Carlson. “There are more variables, because when a test is performed it’s not as simple as work or not work. There’s a variety of actions a physician could take.”

Kalorama says that while randomized controlled trials remain the preferred study design for establishing the causal effects of medical interventions on patient outcomes, other study designs can sometimes substitute for them, particularly in the evaluation of diagnostic products. Well-designed, non-randomized observational studies like patient cohort studies, case control studies, registries, and surveillance studies may all provide evidence that is sufficiently strong to inform payers making coverage and payment determinations.

The report cites three examples of test products that obtained reimbursement status:

AlloMap Developed by privately held XDx Inc., is thus far the only non-invasive gene expression test that assists physicians in identifying the absence of heart transplant

rejection.

Agendia's MammaPrint test for lymph node negative breast cancer patients is used to estimate a woman's recurrence risk for early-stage (Stage I or II) breast cancer, and can help patients and physicians make a more informed decision about whether to use chemotherapy to reduce recurrence risk.

OncotypeDX, developed by publicly traded Genomic Health and introduced in 2004, quantifies the likelihood of disease recurrence in women with early-stage ER positive breast cancer and assesses the likely benefit from certain types of chemotherapy.

In all cases, the report said, these products were able to demonstrate effectiveness in clinical studies and that they produced cost-savings over other test products or in reduction of treatment costs.

Kalorama's report, Reimbursement for IVD Tests contains detailed case studies of successful products, a complete explanation of the reimbursement process, statistics and relevant codes. The report can be found at http://www.kaloramainformation.com/Reimbursement-IVD-Tests-7852349/ [1]

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