Evaluate Vantage

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BIO 2011 – Diagnostics want barriers to compensation torn down

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The importance of diagnostics in the advancement of personalised medicine is undisputed. However, this growing significance has yet to be fully reflected in the way payers view these worthwhile tools and they can often be reimbursed at rates well below those necessary to recoup the cost of their development, hindering development.

Discussing the reasons behind this disconnect a panel at the *BIO* convention argued that a number of factors were behind the payment shortfall, ranging from an outmoded coding system to price diagnostic tests to varying evidence requirements from payers. Warning that if payment practices and procedures continue to fall short, so too would the promise of personalised medicine was David Parker, vice president of consulting firm Boston Healthcare: “If we don’t get the diagnostic aspects right, we’re not going to get anywhere near where we aspire to be in the personalised medicine realm”.

Coding

Two reports published by industry coalitions in the past year have identified the payment systems and practices that have not evolved sufficiently to recognise the value of some new diagnostics in identifying the best candidates for treatment with targeted therapies - as exemplified by such markers as KRAS, BRCA and EGFR expression - as barriers to commercialisation of companion diagnostics in the US.

The panel said particularly unhelpful was the current procedural terminology (CPT) coding system used by physicians for billing diagnostic tests. Although the American Medical Association, which writes the CPT code book, is refining the codes to take into account new genomic based tests used to identify the best candidates for certain treatments, the fear among companies competing in the space is that revisions will not be sufficiently specific to identify their tests.

This increases the risk that their tests will be coded as “miscellaneous,” which adds administrative burden for both physician and payer and may make physicians reluctant to offer the test.

Return on investment

An even bigger issue, however, is the level of evidence needed to justify reimbursement from payers, along with the actual compensation.

Diagnostic tests sit in a world where many are compensated on their manufacturing costs alone. But in the case of the advanced genetic testing used to identify the best candidates for treatment – for example, the KRAS mutation that identifies poor responders to Erbitux and Vectibix – years of R&D spending may have gone into developing the test.

If investors see such diagnostic tests are insufficiently reimbursed, they will be less likely to back companies doing innovative research, the *BIO* panel argued.

A personalised medicine diagnostic can require a $30m investment through launch, and then $75m in marketing costs to support the launch, which may be excessive for a privately-held venture backed firm, said Kristin Pothier, a partner with consulting firm Health Advances, which published a *BIO*-supported report on companion diagnostics.

“These diagnostics require pharma levels of evidence without pharma levels of return,” said Scott Allocco, president of cancer diagnostics company BioMarker Strategies.

Solutions

Possible solutions may include requiring coverage upon FDA acceptance of a test or bundling of diagnostic testing reimbursement with payment for the pharmaceutical product.

This happens in some cases today, such as Roche's support for a HER2+ companion diagnostic to Herceptin;

other examples have been tests for Amgen’s Vectibix and Bristol-Myers Squibb’s Erbitux. There has also recently been a spate of buy out of diagnostic companies by pharma groups angling to simultaneously fund and develop therapies and tests.

Mr Parker suggested another potential solution to the compensation issue: increasing reimbursement over time as the body of data supports the use of a test. Such a payment strategy would eventually help pay for the R&D necessary to validate a test.

The move toward personalised medicine and biomarkers means that diagnostic tests are no longer an after thought, and reimbursement is shifting. However it seems there is still some way to go before diagnostic companies are comfortable they will see a decent return on their investment.