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## Exact Sciences set for US reimbursement after Cologuard approved



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As *EP Vantage's* report into [job numbers](#) in the medtech industry showed last week, Exact Sciences has in the last five years grown faster than any other company in percentage terms, increasing its headcount by 2,500%.

And it is just as well that it has. The group has just won its hard-fought battle to obtain US approval for its DNA-based Cologuard cancer diagnostic, and remarkably it is also on course to score Medicare coverage for a test that is vastly more expensive than the standard faecal blood DNA testing it aims to replace. If the Centers for Medicare and Medicaid Services (CMS) goes ahead with reimbursement, and private insurers follow suit, Exact is going to need all its extra staff.

### Parallel review

The test is the first product to undergo simultaneous assessment by the FDA and the CMS. This pilot parallel review programme is designed to cut the time from study initiation to Medicare coverage by up to six months, the FDA says.

Following a unanimous panel endorsement back in March, approval of Cologuard was more or less a fait accompli ([Colorectal screening set to become a slightly less inexact science](#), March 28, 2014). The CMS's proposal to cover the cost of the test came as more of a surprise, and it is the sales boost this signals that likely accounts for today's 7% rise in Exact's share price.

[The CMS proposes](#) to cover use of the test once every three years to assess asymptomatic patients aged between 50 and 85 with no personal or family history of colorectal cancer or other bowel conditions. The agency is seeking comments on the proposal, and will make a final decision in October or November.

### 20 times more expensive

Until then, Exact can at least sell to patients paying out of pocket, though whether doctors will recommend its use is another question. The test is already on sale in the US, where it is positioned to compete with faecal immunochemical testing (FIT), which costs around \$30 to Cologuard's \$599. With sensitivity of around 92% and specificity of around 87%, Exact's test is not astonishingly more accurate than FIT, which has 74% sensitivity and 95% specificity.

That said, positive diagnoses with both tests have to be confirmed by colonoscopy – still the gold standard and the only colorectal cancer screening method recommended by the US Preventive Services Task Force – so arguably low specificity is less of a problem than low sensitivity, meaning Cologuard has a slight edge.

Edge or not, a 20-fold price differential will surely give some doctors pause. It is interesting that the CMS has not been put off. Even assuming that the company will discount the test for Medicare and Medicaid – if only because the CMS will simply refuse to pay nearly \$600 per patient – it is still vastly more expensive than a test that is nearly as good.

The approval triggers a \$500,000 milestone payment to the Mayo Foundation under a 2009 deal that saw Exact obtain rights to patents covering stool or blood-based cancer diagnostics. If reimbursement under Medicare and by insurance companies does come about, the payment to Mayo will be dwarfed by Cologuard's sales figures. Current forecasts see the test selling \$12m this year and \$548m in 2020, according to *EvaluateMedTech*, but these will not take such early Medicare reimbursement into account, and might therefore be expected to rise.

### Epic

So where does this leave Exact's longtime rival Epigenomics? The latter company's blood-based colorectal cancer diagnostic received a lukewarm verdict from the same panel that waved Cologuard through, and despite Epigenomics' protestations that it was certain of approval anyway, the US regulator turned it down in early July.

Gamely, Epigenomics said yesterday that it was convinced “more than ever” that its Epi proColon assay would gain approval, saying that it was just a matter of time until it completes further trials and wins the FDA over. If it does, and if it charges rather less than \$600, Epi proColon could indeed find a niche. But that will take months if it happens at all. Exact Sciences has won a decisive victory.

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