FDA Approves Cancer Screening Test as First Device Under Parallel Review Pilot

On August 11, 2014, the Food and Drug Administration (FDA) issued a premarket approval (PMA) for Exact Sciences' Cologuard, a colorectal cancer screening test, and the Centers for Medicare & Medicaid Services (CMS) issued a proposed national coverage determination (NCD) for Cologuard on the same day. Cologuard is the first device to be approved under CMS and FDA's Pilot Program for Parallel Review of Medical Products (the Pilot Program), a voluntary program for companies to coordinate with FDA and CMS to reduce the time between FDA marketing approval and NCDs.

Although begun in 2011 with much fanfare, and extended for an additional two years in December 2013, no devices had successfully navigated the process.[1] Because participation is confidential, it is difficult to know exactly how many devices have joined the pilot. Exact Sciences is one of few companies that has publicly announced its participation in the program. This result may encourage additional companies to consider the advantages of this combined path for FDA approval and Medicare coverage of a new device. The direct impact of this development is likely to be limited (for the reasons discussed below), but it is nonetheless an important milestone and could put some momentum behind efforts to coordinate FDA and CMS reviews.

There are several reasons that Cologuard's approval and NCD may have limited implications. To begin with, most medical devices enter the U.S. market under a 510(k) substantial equivalence clearance, rather than a new-device PMA. In addition, few devices go through the NCD process. NCDs, which affect Medicare payments nationally, carry significant costs for the manufacturer, as well as significant consequences from an adverse decision. Instead, many manufacturers seek local coverage determinations (LCDs), which are coverage decisions made at the discretion of local Medicare contractors in the absence of an NCD. Finally, the Pilot Program is a limited program with few participants. When the Pilot Program launched in October 2011, FDA stated that the Pilot Program expected to accept only three to five device candidates per year.

The key issue addressed by the Pilot Program is the timing of CMS involvement. The Pilot Program does not affect review standards for device approval by FDA or for a coverage determination by CMS. The Pilot Program was created as a response to the lag time that exists between when FDA permits a device to be legally marketed and when CMS is able to make a national coverage decision. Generally, medical device review by FDA and CMS proceeds serially; FDA first determines whether the device meets applicable safety and effectiveness standards. After FDA approval or clearance, the company seeks coverage from third-party payors, including CMS, who determine the payment rate for the product. This process can be inefficient for several reasons. Administratively, materials submitted for FDA review are generally not available to CMS or other payors. More fundamentally, CMS is concerned with issues that may not have been emphasized by FDA for device approval (*e.g.*, community and home use; generalizability of results to other populations; incremental clinical utility compared to currently available technology), which may require device sponsors to perform additional clinical trials.

Cologuard is a colorectal cancer screening test that evaluates DNA in stool for specific DNA markers and fecal hemoglobin using a proprietary analytic algorithm. Under CMS's coverage decision, CMS will cover Cologuard once every three years for beneficiaries aged 50-85 years who are asymptomatic and at average risk of developing colorectal cancer. CMS is currently seeking comments on its proposed coverage decision.

---

[1] 76 Fed. Reg. 62808, 63809 (October 11, 2011); 78 Fed. Reg. 76628 (Dec. 18, 2013).

Results from Exact Sciences' pivotal trial with 9,899 patients comparing Cologuard to fecal immunochemical tests was published online in the *New England Journal of Medicine* on March 19, 2014. On March 27, 2014, FDA's Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee determined by a unanimous vote of 10 to zero that Cologuard demonstrated safety, effectiveness and a favorable risk benefit profile.

Ropes & Gray will continue to monitor developments in this area. If you have any questions, please contact any member of Ropes & Gray's FDA regulatory practice or your usual Ropes & Gray Advisor.