FDA Approval + CMS Reimbursement = A Match that *Should* be Made in Device Development Heaven

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Five years from now, FDA regulatory approval decisions and Medicare reimbursement determinations for medical devices will likely occur simultaneously – similar regulatory/reimbursement processes have already begun to be well integrated in Europe and other geographic areas. But in the U.S., few medical device companies have taken advantage of a pilot program announced in September 2010 and launched in October 2011 by both FDA and CMS that enables the parallel pursuit of both FDA approval and CMS national coverage determination (NCD). Intended to alleviate some of the process-heavy FDA and CMS requirements that the industry often views as hampering innovation, the pilot program should be receiving far more attention from medical device companies than it has over the past two years.

At the same time, pursuing both approval to market AND universal reimbursement coverage by Medicare in parallel can seem daunting to device developers. It calls for smarter clinical development strategies and more effective study designs that match the expectations of the FDA, CMS and private payers. That means not only focusing on clinical endpoints that prove the device to be safe and effective, but also demonstrating the device is reasonable and necessary, and potentially superior to others in its category, including current standards of care.

Benefits to the FDA/CMS parallel review pilot program and several key factors device developers need to consider when pursuing a joint approval include the following variables:

1) Advocate for more transparency in the process – Medical device companies often shy away from opening the door to a conversation with FDA, but in this case, dialogue and gathering as much information as possible is critical
2) Establish guiding principles – Timelines and expectations for both the FDA and CMS need to be clearly defined before pre-approval clinical studies begin
3) Know when to call it quits – Device developers can withdraw from the process at any time and need to see and interpret signs for decoupling the pursuit of both milestones.

With these factors in mind, medical device companies could put themselves on a more efficient and effective pathway to bringing new treatments to market with national coverage determination/reimbursement already established – ultimately enabling key devices to reach target patient populations faster and more efficiently.