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From Research to Revenue: Coverage and Reimbursement for Life Sciences Products - When Parallel Review Is Right for You



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Drug and device manufacturers now have two procedural options when seeking formal approval and coverage for their products under Medicare. Under the traditional framework, the manufacturer first submits a new drug application to the Food & Drug Administration (FDA) for approval, then seeks a Medicare coverage determination from the Centers for Medicare & Medicaid Services (CMS). Alternatively, the product may undergo what is called "parallel review," under which the product faces review by both agencies simultaneously, potentially expediting what can be a lengthy process. The agencies first announced that they would establish a formal voluntary parallel review process for medical devices on Sept. 17, 2010.[1] On Oct. 11, 2011, the agencies released a notice outlining the procedure for parallel review.[2]

FDA and CMS conduct different types of review, using different criteria, so the agencies require manufacturers to provide them with different types of data.[3] FDA approval requires that a product be "safe" and "effective," while Medicare coverage requires items or services to be "reasonable and necessary." Thus, during product development and clinical trials, manufacturers will likely want to ensure that they have performed the trials and analysis necessary to generate the types of data required by both agencies. A study that is designed solely to obtain FDA approval may not suffice to obtain a positive Medicare coverage decision, to the extent one is required. Formal decisions regarding Medicare coverage are made through either National Coverage Decisions (NCDs), which determine coverage for a product on a nationwide basis, or Local Coverage Decisions (LCDs) by Medicare Administrative Contractors (MACs), which determine coverage only within the geographic region covered by that MAC.[4] Because Medicare is the single largest health care payor in the nation and many other payors look to Medicare for guidance on coverage decisions, obtaining Medicare coverage can be as practically important as FDA approval.

Parallel review allows for CMS to undertake the NCD process at the same time that FDA regulatory review is taking place, reducing or eliminating the delay between the two processes and thus the overall time it takes for a product to get through both.[5]

Though the agencies have talked about parallel review processes as far back as 2005, this latest notice creates a formal program for such review.[6] Manufacturers have long been able to seek informal parallel review by engaging with both agencies simultaneously and asking CMS what data the manufacturer should gather in order to expedite the review process.

Several important issues must be resolved before the new formal process can be successfully implemented. Stakeholders and the agencies themselves should give these issues consideration, or the parallel review process could end up being even more time-consuming for some manufacturers, rather than expediting approval and medical progress, as it is intended to do. In the meantime, some manufacturers may find that parallel review is an appropriate avenue for them, while others may not benefit from it as much.

Situations with Important Potential Disadvantages to Parallel Review

Most products do not require an NCD in order to be covered by Medicare. Manufacturers have the option to request an NCD, or CMS may undertake one on its own initiative. However, the majority of new products may be covered under an existing code or receive coverage under an LCD. Thus, if a manufacturer's product is likely to be covered by Medicare in the absence of an NCD, to undergo parallel review would actually delay the product's reaching the market, as FDA review unaccompanied by CMS review would likely be faster. Furthermore, requesting an NCD leaves open the possibility that the decision could be adverse, thus eliminating the possibility of Medicare coverage for the device on a nationwide basis.

Often, the data required to obtain a favorable NCD are not available during the FDA approval process. Such data may come from such sources as post-approval studies. In these cases, submitting premature or incomplete data may result in an adverse coverage decision in a situation where a more careful and thorough development of data could have yielded a favorable decision. It is more difficult to convince CMS to reverse a negative NCD than to issue a favorable NCD upon first consideration of a product. Furthermore, some products obtain Medicare coverage for off-label (that is, non-FDA-approved) uses. If the agencies conduct their reviews at the same time, even if unintentional, FDA may place greater scrutiny on products that it knows will be used off-label, or CMS may hesitate to provide Medicare coverage for off-label uses that have been specifically and simultaneously rejected by FDA.

Some products, such as clinical laboratory tests, do not generally require FDA approval in order to gain Medicare coverage, thus making parallel review especially unnecessary for these products. Going through both the FDA and CMS approval processes at the same time could be more time-consuming, as any agency collaboration is likely to be more complicated than single-agency action. Further, conducting clinical trials that meet both FDA and CMS standards could be more expensive and difficult than conducting them only for one purpose. For these reasons, such manufacturers seem unlikely to choose to put their new products through parallel review.

Coverage under Medicare Part B is another area in which parallel review is unlikely to be very useful. Drugs reimbursed under Part B are likely to be covered by MACs for at least their on-label indications, making an NCD unnecessary in those cases. For off-label indications, in order to have enough evidence to obtain a favorable NCD, a product would likely have been in clinical use for so long that an NCD would be superfluous anyway (either because coverage by the MACs is well established under LCDs or otherwise or because the evidence, if available, would be sufficient to also gain FDA approval for the indication). The same considerations that apply to Part B drug products likely apply to devices, which are the focus of the new parallel review policy.

Situations with Important Potential Benefits to Parallel Review

Parallel review, though perhaps not helpful to some manufacturers, will likely be helpful to manufacturers in certain circumstances. Manufacturers that create products that are unusually expensive or likely to have difficulty with Medicare coverage may benefit from parallel review. Difficulty with Medicare coverage may include an existing adverse NCD or adverse LCDs, or a very limited NCD. Putting a product through parallel review may garner sufficient CMS attention to warrant revisiting an NCD and reverse an adverse coverage decision or series thereof. For screening technologies, which must be approved using an NCD, parallel review would likely expedite CMS review and increasing access to the new technology.

Further Issues with Parallel Review

Other issues affect the potential benefit that parallel review may offer to manufacturers and the agencies. Some manufacturers may wish to obtain Medicare coverage through LCDs rather than risking an adverse NCD. Parallel review provides for only FDA approval and Medicare coverage of a product. However, even after a product is covered, in many cases true market access still requires some change or decision on coding and reimbursement. The formal parallel review process does not, unfortunately, address coding and reimbursement. The gulf between theoretical coverage and true access is especially pronounced within the inpatient and outpatient prospective payment systems, where until a technology is widely adopted, its cost is not factored into the overall Medicare payments made for certain treatments. The exceptions are when new technologies are paid for through an add-on or pass-through payment, but these are difficult to obtain.[7]

Parallel review also raises issues with regard to collaboration between FDA and CMS. If the agencies are working together to approve the same product, even in their different capacities, there is the possibility that the standards each must use could become blurred together, resulting in an unfair denial by one agency or the other that would not have happened had that agency been properly applying its own standard. Also, proprietary information held by one agency or the other, or both, is at more risk of being discussed inappropriately simply by virtue of being in more hands simultaneously, though the agencies do have safeguards in place to protect such information.[8] Furthermore, the agencies have

different timelines for their review of new products.[9] In particular cases, these may conflict or operate such that parallel review does not actually offer more efficient approval of new products.

Though FDA and CMS have engaged in parallel review in the past, the pilot program established in late 2011 creates for the first time a formal parallel review process. As described above, many manufacturers may decline to participate in parallel review unless certain improvements or changes are made. Manufacturers should consider carefully the benefits and risks of engaging in the parallel review process before making the decision to do so. If properly implemented, the parallel review process may be a significant step toward improving quick access to new medical technology.

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[1] Parallel Review of Medical Products, 75 Fed. Reg. 57045 (Sept. 17, 2010).

[2] Pilot Program for Parallel Review of Medical Products, 76 Fed. Reg. 62808 (Oct. 11, 2011).

[3] *See* 21 U.S.C. § 355(b)(1) (2006); 42 U.S.C. § 1395y(l)(1) (2006).

[4] *See* 42 U.S.C. §§ 1395ff(f)(1)(B), 1395y(l)(6)(A) (2006).

[5] 75 Fed. Reg. at 57045.

[6] Secretary Tommy Thompson, Moving Medical Innovations Forward ~~-~~New Initiatives from HHS (Jan. 2005), available at http://archive.hhs.gov/reference/medicalinnovations.shtml.

[7] *See* 42 C.F.R. §§ 412.87-.88, 419.66 (2009).

[8] Factors CMS Considers in Opening a National Coverage Determination at 9-10 (Apr. 11, 2006); *see also* 42 U.S.C. § 1395y(a) (2006).

[9] *See* 42 U.S.C. § 1395y(l)(2)-(3) (2006); CMS, Medicare National Coverage Process, available at www.cms.gov/DeterminationProcess/Downloads/8a.pdf.