

FDA-CMS parallel review for medical devices: shaping the future

The findings of the US Food and Drug Administration/Centers for Medicare & Medicaid Services pilot programme for parallel review of medical products will have implications on how the broader life sciences community grapples with the evolving evidence requirements of the two agencies, *Tanisha Carino* says.

On 11 October, the US Food and Drug Administration and the Centers for Medicare & Medicaid Services (CMS) announced the launch of a pilot programme for parallel review of medical devices^{1,2}. The long-awaited pilot has the stated goal of promoting innovation; but it also uniquely positions the Medicare programme to shape the medical technology industry's post-market research investments and stem the diffusion of technologies it deems as lacking sufficient evidence.

As companies contemplate whether parallel review is an opportunity or a threat, it is worthwhile to look at the history of intensity modulated radiation therapy (IMRT). In the mid-late 1990s, IMRT, a technology that enables radiation oncologists to attack cancerous tumours with beams of highly focused radiation doses, was rapidly adopted to manage localised prostate cancer. The use of IMRT grew exponentially; in 2008 alone, the Medicare programme spent an estimated \$1 billion on IMRT³. The growth of IMRT, along with other treatments for prostate cancer, gave rise to increased payer interest in this area. According to Avalere Health's EBM Navigator, since 2007 there have been 44 comparative effectiveness research studies examining the relative effectiveness and costs of the common management options for prostate cancer, including IMRT. A recent report found little high-quality evidence to distinguish the relative effectiveness of the various treatment options and concluded that IMRT has low comparable value⁴. As the US faces increased budget pressures, IMRT has become a prominent example for the need to expand Medicare's ability to stem the growth of technologies that fail to demonstrate relative value⁵.

In the case of IMRT, CMS did not open a national coverage determination (NCD) at the outset to assess the merit of IMRT for Medicare beneficiaries. No NCD for IMRT exists today, leaving its coverage at the discretion of local Medicare contractors. Because IMRT has become entrenched as an option for management of localised prostate cancer, CMS may have little appetite to withdraw payment and restrict beneficiary access. In addition, Medicare has limited ability, and there is little market incentive to require additional studies of IMRT. So what parallel review offers the Medicare programme is a new means to define the type of evidence needed to ensure favourable Medicare coverage even before a

technology receives FDA approval. It also allows the agency the ability to stem the entrant into the Medicare programme of technologies that it does not believe have sufficient evidence, thus avoiding a repeat of what has been experienced with IMRT.

The pilot creates a pathway for concurrent review of medical devices seeking FDA marketing approval or clearance and CMS coverage through the NCD process with the goal of reducing time to market. The two-year pilot is expected to be available to a handful of devices. However, the findings will have implications on how the broader life sciences community grapples with the evolving and, oftentimes obscure, evidence requirements of the FDA and CMS.

The pilot will elucidate two important lessons in technology evaluation. First, the pilot will shed light on the ideal scenario for when a company should decide to pursue FDA-CMS parallel review. There are two clear scenarios where this pathway may be appealing to manufacturers. The first is where there is an existing NCD that prohibits Medicare payment for the device that is coming to market. This is the circumstance facing Exact Science's molecular diagnostic colorectal cancer screening test, with the company announcing to its investors that a critical component of their commercial strategy will be to seek parallel review⁶. The second scenario is if manufacturers anticipate facing significant hurdles to market entry by Medicare's local contractors. Palmetto GBA, a Medicare administrative contractor, issued a draft coverage policy that would deny payment for molecular diagnostic tests unless they meet a specific set of regulatory and coding criteria. The proposed Palmetto policy essentially represents a de facto national policy because the majority of molecular diagnostic labs are based in California⁷. Success of the pilot will be gauged on how aggressively CMS reduces its NCD timeframe and the approach CMS uses in working with local Medicare contractors to facilitate quick adoption.

Second, the pilot may provide more concrete guidance on the type of evidence that industry needs to produce for both agencies. Over the past few years, Medicare has increasingly used its coverage with evidence development (CED) policy, where Medicare requires additional data collection often through a clinical trial or registry in exchange for coverage. Since 2007, CMS has issued 38 national coverage determinations; 21% of which have ended with

CED⁸. Manufacturers have largely viewed CED negatively because of both the additional hurdles it creates for providers and beneficiaries and the significant financial burden that it places on the manufacturers who are often the sponsors for the additional data collection.

FDA-CMS parallel review is not for everyone and will need to be approached strategically. Gaining Medicare coverage has increasingly become a requirement for market success for many companies as fewer technologies will be granted the same level of unrestricted entry as an IMRT in the future. The increasing financial pressures on the Medicare programme and potential new authorities to hold down costs will likely result in a more challenging coverage environment. If approached the right way, the new FDA-CMS parallel review pilot will offer an opportunity to shape the future.

References

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