MedTech Patient Access Improvements for America's Seniors

For medical technology companies, it can be difficult to know what type of evidence or clinical studies CMS wants to see in order to show improved outcomes. Often, studies conducted for the FDA do not meet CMS's expectations. FDA and industry have a "Pre-submission Meeting" process that allows for a discussion of evidence requirements that dictate the methods for conducting the clinical study/trial and review metrics for determining safety and effectiveness. This creates certainty that if a company meets the pre-determined metrics and no other issues are of concern, the technology is likely to be approved/cleared.

No such process[1] exists for the majority of technologies seeking Medicare coverage – making the coverage process uncertain and volatile in the eyes of companies and investors. And this can especially be a challenge for "breakthrough" technologies that receive accelerated treatment by FDA.

Cover FDA Breakthrough Devices. — The FDA's Breakthrough Device Program is intended to provide patients more timely access to a limited set of the most innovative and disruptive medical technologies by expediting their development, assessment, and review while still meeting statutory standards for safety and effectiveness. Yet the medical technologies that FDA determines are most important for patients can languish at CMS without Medicare coverage – defeating the purpose of accelerating their FDA approval. Changes to ensure that Medicare patients actually have timely access to breakthrough technologies are needed to leverage the benefits of FDA's breakthrough program.

Two key administrative changes can dramatically improve patient access these technologies and remove unnecessary regulatory red tape that is bogging down the process. First, breakthrough technologies should be automatically covered for Medicare patients and, secondly, as breakthrough technologies represent new and substantial improvements over existing care options, they also should receive automatic approval for inpatient New Technology Add-on Payments (NTAP) and hospital Outpatient Passthrough payments if they are high cost.

CMS should consider all such technologies eligible for New Technology Add-on Payments (NTAP) and/or outpatient Passthrough and provide immediate three-year coverage with additional data collection as may be required to make a long-term coverage determination.

Expand Medicare's Coverage with Evidence Development Process —For FDA approved or cleared technologies that don't receive "breakthrough" automatic access to Medicare coverage (described above) or that do not already have an established payment pathway, a new process should be created to provide coverage with evidence development (without issuance of a national coverage determination). This process would allow CMS and the manufacturer to specify desired evidence expectations for a new technology, including study outcomes and metrics. Once agreed upon, transitional Medicare coverage and reimbursement should be available to help support the post-FDA evidence development process for at least three years. Upon successful completion of the study with positive outcomes, CMS would determine a long-term coverage option.

[1] The FDA/CMS Parallel Review program allows CMS to participate in the FDA process and presubmission meeting but there has been limited participation since 2011.