How Changes In The Medicare Coverage Process Have Facilitated The Spread Of New Technologies

A high Medicare official explains the reasons for the changes and offers examples of how the process has become more firmly grounded in evidence.

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ABSTRACT: The Medicare coverage decision process can affect the availability and use of new technologies. The Centers for Medicare and Medicaid Services (CMS) has recently made advances in making its coverage decision process speedier, predictable, and more transparent. The CMS recently issued draft Coverage with Evidence Development (CED) guidance to assure that Medicare beneficiaries have access to new technologies through expanded coverage criteria, while gathering information that can be helpful to the doctors who care for them. The CMS continues these efforts with the goal of improving the evidence used for high-quality care, while avoiding unnecessary risks and costs.

The interview with Ron Dollens outlines several important issues pertaining to technology and innovation in health care. Speeding the availability of new medical technologies that can save and improve lives, and supporting their effective use in patients who can benefit, is one of the principal goals of the Medicare program. One of the many areas of Medicare policy that could affect the availability and use of new technologies is coverage decisions for the benefits covered under Medicare Part A (hospital and many postacute services) and Part B (outpatient and ambulatory services). Coverage decisions under Medicare Part D (drugs) will be made by prescription drug plans, subject to oversight by Medicare. Medicare’s statutory standard for coverage under Parts A and B is whether the item or service is “reasonable and necessary” for the beneficiary’s health care within a set of broad benefit categories. The decision as to which items and services are “reasonable and necessary” is made by the Centers for Medicare and Medicaid Services (CMS) and the medical directors of the contractors that are responsible for Medicare claims processing, review, and adjudication in each region of the country. National coverage decisions (NCDs) are made by the CMS at the national level, while local coverage decisions (LCDs) are made by its contractors at a local level. Only around 10 percent of all coverage decisions are NCDs; fully 90 percent are LCDs. Most LCDs are appropriately done with relatively little variation from locality to locality. NCDs are undertaken when there is variation in the locality decisions, or when the coverage issue is com-
plex or controversial. The vast majority of NCD requests come from outside the CMS, mainly from product developers.

The CMS has endeavored to improve and streamline its NCD process during the past few years, stressing increased speed of the decision-making process as well as its predictability and transparency, including the publication of a detailed description of the NCD process in September 2003. As a result of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, timelines for NCD processing were shortened to six months for most NCDs not requiring technology assessment and nine months for those with technology assessment. The law also required standard opportunities for public input in the NCD process, starting at the time of the initial request, as well as a thirty-day public comment period after a draft decision is published. The CMS is tracking the performance of the NCD process and has met the timeline and public comment requirements for finalizing NCDs in 100 percent of cases. Once an NCD is issued, requests for reconsideration of the decision are possible. The CMS uses expert clinical and academic advice in its NCD process and increasingly uses outside technology assessment by independent technology review organizations and experts when NCD analysis is complex or controversial. One of these outside bodies, the Medicare Coverage Advisory Committee (MCAC), is a 100-member panel of experts that provides both clinical expertise and public participation and input simultaneously to the CMS. The NCD process is documented publicly on the CMS Web site, www.cms.hhs.gov/coverage, throughout the process, and electronic comments are now used to simplify and accelerate public input.

The CMS continuously seeks ways to improve the overall NCD process. For example, it has recently issued guidance documents that educate the public on how its NCD process applies to specific items and devices, on when and how technology reviews are implemented, as well as other important areas of the NCD process. The public process of issuing and then finalizing written guidance is an important way to promote predictability and to make sure that our processes are based on the latest science and the most efficient approaches. The CMS also regularly uses public Open Door Forums, which combine in-person meetings and teleconferencing, to obtain public input and to provide clarification of its coverage policies. Further, as Dollens mentions in the interview, the CMS has recently been working with the U.S. Food and Drug Administration (FDA) to develop a parallel process for both FDA approval and Medicare coverage, so that product developers can benefit from a more efficient process.

As the interview implies, FDA approval of an item or device as “safe and effective” for a population of people is a different standard from “reasonable and necessary” for Medicare coverage. The difference in definitions implies that under certain circumstances, a safe and effective item or device may not always be necessary or reasonable to treat an illness in a specific patient. Conversely, in many cases, CMS coverage extends to much broader populations than those included “on the label” approved by the FDA for the drug or device. In such cases, new clinical evidence might have been developed since the initial FDA coverage decision, so that there is good reason to suspect important clinical benefits in additional patients beyond those on the FDA label.

■ The ICD example. An example of the uncommon situation where Medicare coverage was initially narrower than the FDA label involves implantable cardioverter defibrillators (ICDs). Following FDA approval in the 1980s, the CMS originally issued an NCD in 1986 providing limited coverage of the devices. Following a request by Guidant Corporation in May 2002 for expanded indications for ICDs, the CMS performed an internal technology assessment with an extensive review of
available medical literature, as well as obtaining an external technology assessment commissioned through the Agency for Healthcare Research and Quality (AHRQ) and an MCAC review. Analysis of all of this information led the CMS to conclude in June 2003 that there was insufficient evidence to expand ICD coverage at that time. Between August 2003 and January 2005, with additional medical evidence available, the CMS processed three re-considerations for ICDs. That evidence indicated that some patients with severe heart disease benefit from ICDs. However, not all patients at risk benefited, and some patients’ deaths were reported.

In the January 2005 decision, the CMS expanded ICD coverage broadly while providing for the collection of clinical patient data and information related to the treating physician and facility, as part of its recently published Coverage with Evidence Development (CED) guidance policy. Under this policy, more Medicare beneficiaries can obtain earlier access to ICDs (or similar technology) through the expanded coverage criteria, while the clinical data registry can provide insights into the use and experience of subpopulations of patients receiving ICDs. One benefit is better information for doctors and patients to use in making decisions about ICD placement, which helps achieve the goal of getting more rapid use of important new technologies in patients who can benefit from them. CMS coverage policy, therefore, is achieving the goal of making ICD technology more widely available, while better defining for which Medicare beneficiaries ICDs are most appropriate.

**The stent example.** Another recent example pertains to carotid artery stents, where the CMS recently expanded coverage to many patients with carotid artery stenosis included in the FDA-approved indications. However, more recent studies raised concerns about complications in patients with asymptomatic carotid artery stenosis greater than 80 percent. Further studies involving these patients are now under way in the CARESS Phase II trial, and the CMS already covers alternative treatments to carotid stenting for these patients. In the past, CMS analysis would likely have resulted in noncoverage for these patient subgroups. Currently, however, Medicare has expanded coverage for carotid stents more broadly using CED principles—that is, covering carotid artery stents while gathering information to assure that they are reasonable and necessary for these additional types of patients. The increasing opportunities for developing better evidence on treatments in actual practice not only allow for additional coverage expansions; they also provide a stronger foundation for well-informed, evidence-based decisions by doctors and patients.

**Impact of changing the coverage process.** These and other recent NCDs that more quickly expanded coverage to broader populations of patients reflect the impact of both the increasing transparency and timeliness of the NCD process, and the increasing opportunities to develop more evidence to help improve medical practice. The CMS will continue to take steps to increase transparency, public input, and responsiveness, with the goal of making prompt coverage decisions using the best scientific principles, and to improve the evidence available to doctors and patients to help them get the greatest benefits while avoiding unnecessary risks and cost.

**NOTES**

3. Iglehart, “Grasping the Role of Technology.”