THE COMMONWEALTH FUND

In the Literature

Highlights from Commonwealth Fund-Supported Studies in Professional Journals

Medicare's National Coverage Decisions for Technologies, 1999–2007

November 10, 2008

Authors: Peter Neumann, Sc.D., Maki S. Kamae, M.D., M.P.H., and Jennifer A. Palmer, M.S.
Journal: *Health Affairs,* November/December 2008 27(6):1620–31
Contact: Peter Neumann, Tufts Medical Center, pneumann@tuftsmedicalcenter.org, or Mary Mahon, Senior Public Information Officer, The Commonwealth Fund, mm@cmwf.org
An abstract is available at: http://content.healthaffairs.org/cgi/content/abstract/27/6/1620

Synopsis

A multiyear analysis of Medicare's "national coverage decisions"—policies for reimbursing health care providers for particular medical services—shows that the program considers the available evidence "fair" or "poor" for most medical technologies it reviews. Nonetheless, Medicare issues favorable decisions in 60 percent of cases.

The Issue

Although Medicare covers broad categories of hospital, physician, and other health services, it is prohibited from paying for items and services deemed "not reasonable and necessary." The process by which Medicare determines whether and how it will pay for new services, technologies, and treatments is a fragmented one, with many decisions made by local contractors. In the case of technologies that are considered controversial or are projected to have a major impact on the program, the Centers for Medicare and Medicaid Services (CMS) issues national coverage decisions (NCDs). Decisions consider whether the item or service is safe, effective, and appropriate, and whether it leads to improved health outcomes. CMS also considers the quality of the available evidence. In 2004, as part of the Medicare Modernization Act, a time limit on reviews was instituted, and in 2005, CMS initiated a "coverage with evidence development" policy, allowing coverage contingent upon data collection to allow greater flexibility in cases where sufficient evidence may not yet be available.

> "Cost-effectiveness analysis offers **a powerful technique to help CMS improve the value of its spending.**"

Key Findings

- The 119 technologies considered for NCDs between 1999 and 2007 pertained mostly to medical procedures, medical devices, or laboratory/diagnostic tests.

- For most of the technologies it evaluated, CMS considered the evidence only fair or poor. In only 15 percent of the cases was the evidence considered good.
- CMS made favorable coverage decisions in about 60 percent of cases, although these were almost always qualified—for example, by placing restrictions based on disease severity.
- Technologies with good evidence were more likely to be covered than those with fair or poor evidence. The strength of evidence and rate of favorable decisions were somewhat higher for drugs than for other categories.
- Mean review times declined after the review time limit was instituted, from 312 days during 1999–2003 to 243 days during 2004–2007.

Addressing the Problem

CMS should continue to explore ways to enact flexible coverage policies, the authors say. In addition to the coverage with evidence development policy, which has challenges of being resource- and time-intensive, CMS should consider "risk-sharing" or "outcomes agreement" strategies, under which manufacturers agree to link reimbursement to actual results. Efforts to improve the evidence base regarding the comparative effectiveness of alternative strategies could also help CMS make decisions. Finally, Congress and Medicare officials should revisit CMS's policy to exclude use of cost-effectiveness criteria in its coverage decisions, since such information could help improve value in Medicare spending.

About the Study

The researchers reviewed all complete Medicare NCDs from 1999 through 2007, based on publicly available materials posted on the CMS Web site. After excluding several NCDs for various reasons (e.g., decisions that only involved minor coding changes or instances of incomplete decision information), they included 119 decisions in the study. Review times, strength of evidence, and the nature of the final decision were included in the assessment. Using CMS' reporting on the evidence base, strength of evidence was classified using U.S. Preventive Services Task Force criteria of "good" if evidence included consistent results from well-designed, well-coordinated studies in representative populations; "fair" if evidence was sufficient to determine the effect on health outcomes but limited by the number, quality, or consistency of individual studies; or "poor" if evidence was insufficient to assess the effect on health outcomes because of flaws in design or conduct or lack of information on important health outcomes.

The Bottom Line

CMS issues favorable coverage decisions in the majority of the cases it takes on—albeit with conditions placed on coverage—despite limited evidence available for most of the technologies considered.

Citation

P. Neumann, M. S. Kamae, and J. A. Palmer, Medicare's National Coverage Decisions for Technologies, 1999–2007, *Health Affairs*, November/December 2008 27(6):1620–31.

This summary was prepared by Deborah Lorber.