

CMS: FUNDING THE INNOVATORS OF TODAY AND TOMORROW

A Record of Accomplishment

One of Medicare's primary objectives during its more than four decades of operation has been to make the best of modern medicine available to the older and disabled Americans it covers. In recent years, this has included encouraging the development of new device and biotechnologies which could improve health care for people with Medicare.

As part of this effort to encourage innovation, in August 2008, CMS released the *Innovators' Guide to Navigating CMS*. The *Innovators' Guide* provides a roadmap to Medicare in a single resource document, so that innovators and investors have a predictable path to Medicare coverage, coding, and payment, and Medicare beneficiaries and their health care providers can take advantage of new advances in health care more quickly.

In some cases, where a technological advance is groundbreaking, Medicare may need to make explicit coverage, coding, or payment changes to ensure the coverage of reasonable and necessary new treatment options and the availability of medically appropriate technologies to its beneficiaries.

The *Innovators' Guide* outlines CMS' processes and standards for approving new technology, including which circumstances call for a national or local coverage decision; when a new technology might require a change in coding, and how Medicare determines the level of payment for a drug or device which has only just come to market. For example, the *Guide* provides a detailed explanation of the New Technology Ambulatory Payment Classification (APC) Groups used by CMS to gather cost data about a drug or device before it is placed in an APC with other clinically similar items. The *Guide* details how APCs are determined, the preconditions necessary for a new drug or biological to qualify for an APC, and how new technology payment levels are set.

The *Guide* was developed by the CMS Council for Technology and Innovation (CTI), a CMS-wide working group charged with streamlining and creating a more transparent process to get new technologies to patients more quickly. CTI is composed of senior CMS staff and clinicians, and was established by the Medicare Modernization Act of 2003.

Useful Resources

- The complete ***Innovators' Guide to Navigating CMS***:
<http://www.cms.hhs.gov/CouncilonTechInnov/Downloads/InnovatorsGuide>
- **Information on the CMS Council for Technology and Innovation's initiatives and activities**:
http://www.cms.hhs.gov/CouncilonTechInnov/01_overview.asp
- **Contact information for the CMS Council for Technology and Innovation**: CTI@cms.hhs.gov - for stakeholders with further questions about Medicare's coverage, coding, and payment processes and for further guidance on how to navigate these processes.
- **CMS Website**: www.cms.hhs.gov