

Bringing New Medical Technology to Market:  
Understanding CMS Coverage and Payment Determinations\*

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**I. Introduction**

The Centers for Medicare and Medicaid Services (CMS), by virtue of its administration of the Medicare Program, is the largest third-party payer of medical services in the United States. Beyond Medicare, CMS' coverage and payment determinations are often adopted by other third party payers, further increasing these decisions' importance and impact. In a healthcare environment where institutions and providers can simply not afford to provide large-scale access to medical products and services without third-party reimbursement, CMS' actions play a crucial role as to whether and how quickly innovative, new technologies achieve broad clinical impact. Understanding how CMS makes these decisions is key to developing strategies that will result in the timely, appropriate payment of new medical therapies, ultimately achieving improved patient care.

**II. Background**

Medicare was established in 1965 as a public insurance program for elderly Americans, though its scope has been broadened to include the disabled and those with end stage renal disease. CMS, formerly known as the Health Care Financing Administration (HCFA), is an administrative agency within the Department of Health and Human Services with broad discretion to administer the Medicare Program under the provisions of the Social Security Act.<sup>1</sup> As part of its administrative duties, CMS makes

determinations concerning which medical services and products will be covered, subject to provisions found in the Medicare statute and applicable regulations. Beyond a positive coverage determination, Medicare reimbursement also requires assignment of a billing code and determination of an appropriate level of payment.

The Medicare Program is broken down into discrete categories, known as “parts.” Part A is the Hospital Insurance Program which governs reimbursement of hospital covered services and includes inpatient hospital care, skilled nursing facilities, home health agency care, and hospice care.<sup>2</sup> Part B is the Supplementary Medical Insurance Program which covers reimbursement for physicians’ services as well as medical services provided in the hospital setting, clinical laboratory testing, durable medical equipment, supplies, diagnostic tests, ambulance services, vaccinations, and some prescription drugs. Part B also includes these services when performed on an outpatient basis such as in ambulatory surgical centers and home health agencies. Finally, Part C encompasses the Medicare Plus Choice managed care program.

### **III. Medicare Coverage**

#### **A. Medicare Coverage Criteria**

Coverage, the initial step in obtaining Medicare payment, examines whether a product or service is part of the defined group of benefits covered by Medicare. This question is addressed in two parts. Initially, it must be determined whether a product or service falls within the roughly fifty broad benefit categories found within the Medicare statute, and is not specifically excluded or limited by other statutory provisions.<sup>3</sup> Second, the product or service must be “reasonable and necessary,” as Medicare covers only those products or services that are deemed “reasonable and necessary for the diagnosis or

treatment of illness or injury or to improve the functioning of a malformed body member.”<sup>4</sup> This language has been interpreted by CMS as requiring that medical products and services demonstrate clinical effectiveness, where reliable clinical evidence supports a finding that the benefits of the service or technology outweigh the harms.<sup>5</sup> In practice, Medicare coverage is rarely an issue for new drugs that have undergone FDA’s rigorous approval process and otherwise fall within program benefit categories, though the treatment of medical devices is more complex.

In the case of new medical devices, CMS has defined the scope of *reasonable and necessary* to include only those products that are safe and effective, medically necessary, and not experimental.<sup>6</sup> In terms of the “safe and effective” requirement, Medicare will generally not cover medical technologies that are not FDA-approved for at least one indication, though the program may cover off-label use of approved technologies.

Historically, for most Medicare coverage purposes, the term “experimental” has been used synonymously with “investigational,” a position that traditionally precluded a finding that a product distributed under an FDA investigational device exemption (IDE) was reasonable and necessary to a beneficiary’s care.<sup>7 8</sup> However, due to increasing recognition that some IDE-covered devices do have at least partial evidence to support safety and effectiveness, as these products are refinements or replications of already-existing and approved technologies, CMS subsequently decided to consider coverage for devices with an FDA-approved IDE that have been categorized as nonexperimental/investigational.

In recognition of this distinction, CMS entered into an interagency agreement with FDA, creating a categorization process: IDE-covered devices that represent newer generations of existing, legally-marketed devices for which data are available on safety and efficacy are placed into “Category B,” while IDE-covered devices that are truly novel and lack safety and effectiveness data are placed into “Category A.”<sup>9</sup> This framework allows Category B, IDE-covered devices to be found “reasonable and necessary” and thus eligible for Medicare coverage, though this determination is not automatic.<sup>10</sup> While CMS ultimately determines category designation, the agency relies heavily on FDA’s recommendation for categorization, implicitly recognizing FDA’s expertise in assessing device-related scientific data.

## **B. Medicare Coverage Determination Process**

Medicare coverage decisions are made both locally and nationally. Local coverage decisions, which comprise over 90% of all coverage decisions, are made by entities contracted by Medicare to administer the program (“contractors”) and apply only in the region administered by that contractor.<sup>11</sup> National coverage decisions (NCDs) are made by CMS itself, and apply nationally to all contractors in all regions.

### **1. Local Coverage Decisions**

CMS contracts with fiscal intermediaries and local carriers across the country to administer Medicare at the local level. These contractors, which include private insurance companies and claims-payment contractors, are responsible for deciding coverage issues and adjudicating claims for services. Though subject to a variety of program controls, including CMS Coverage Issues Manuals, Utilization and Quality Control Peer Review Organizations (PROs) oversight, and local medical review policies,

in practice these contractors retain considerable discretion in actual coverage determinations.

## **2. National Coverage Decisions**

In an effort to improve program integrity, CMS recently established a National Coverage Decision (NCD) process, which addresses instances of conflicting local coverage decisions, discrepancies among experts, and obsolete services.<sup>12</sup> NCDs may be initiated either internally by the agency or externally through receipt of a formal request from beneficiaries, providers or industry, and result in a variety of agency actions.<sup>13</sup> CMS may elect to leave the coverage decision with local contractors, in which case the contractors maintain their usual coverage discretion. Alternatively, CMS may decide to take action based on available medical and scientific evidence. This may lead to a national coverage decision which covers the product or service under all circumstances, a limited national coverage determination which provides explicitly circumscribed coverage, or a national non-coverage decision.<sup>14</sup> Where coverage issues are complex or controversial, CMS may refer the request to the Medicare Coverage Advisory Committee (MCAC) or to an independent contractor for a technology assessment prior to any coverage determination.<sup>15</sup> Notably, CMS is not bound by recommendations from the MCAC committee or third party assessors.

## **IV. Assignment of Procedural Codes**

Following a CMS positive coverage determination, CMS and its Medicare contractors require a method to identify the covered product or service, allowing a provider or institution to indicate to Medicare that it was provided or performed. In the case of a new product or service, this requires establishment of a new procedural code.

The various coding methods and the processes by which these methods establish new codes is a complex subject, a comprehensive discussion of which is beyond the scope of this article. Still, a brief overview of the Current Procedural Terminology (CPT) coding system, developed by the American Medical Association (AMA) and the most commonly used coding system today, provides considerable insight as to how coding is conducted.<sup>16</sup>

Oversight of the CPT process is provided by an Editorial Panel, which includes representatives nominated by the AMA, other third-party payer organizations such as the Blue Cross and Blue Shield Association, and other interested parties, such as the American Hospital Association. Initially, requests for new codes are reviewed by the AMA, which makes an initial determination as to whether the procedure at issue is covered by existing codes. If, in the determination of AMA staff, with the assistance of the CPT/Health Care Professionals Advisory Committee (HCPAC), a new or modified code should be issued, the matter is referred to the CPT Editorial Panel. The Editorial Panel meets quarterly, determining whether a particular request should result in a new code or whether existing coding nomenclature should be modified, tabled until additional information is obtained, or rejected.

## **V. Medicare Payment Process**

### **A. Process Overview**

The final step in Medicare's coverage and payment system is determining the payment levels for a specific code. Again, the method used to value a particular CPT code is illustrative of the process by which codes generally are linked to payment levels.

Following approval of a CPT code by the CPT Editorial Panel, a survey process is undertaken to determine its value, a process which polls health care providers as to the

level of expense and effort required to provide the product or service. Information from this process is used by the AMA's Relative Value Update Committee (RUC), which recommends a particular value to a product or service expressed as "relative value units" or RVUs.<sup>17</sup> With the RUC recommendation in hand, CMS then makes a final determination as to the RVUs to be assigned in the Medicare Fee Schedule. Notably, a Congressional mandate requires that these valuation levels be reviewed every five years. To realize payment levels in dollars, assigned RVUs are multiplied by a so-called "conversion factor," a figure determined annually by CMS and expressed in dollars per RVU.

Actual payment levels determined by CMS are further broken down into so-called "professional" and "technical" components, attached to each CPT code.<sup>18</sup> The professional component, which largely represents physician's services, includes compensation for the service itself, as well as the expenses incurred in providing the service, such as office overhead and malpractice. The technical component includes reimbursement for the physical and personnel infrastructure associated with providing the product or service, such as hospital facilities and the salaries of non-physician professionals such as nurses and technologists. For example, when a patient has an x-ray taken at a non-hospital owned outpatient facility, the professional component compensates the radiologist interpreting the study and his or her practice expenses, while the technical component provides reimbursement for use of the x-ray equipment and x-ray technologist salaries.

**B. Complicating Factors: Prospective Payment and Other Specialized Systems**

While it is fairly straightforward to conceptualize a paradigm whereby a medical product or service is provided, subsequently billed under the appropriate code, with the appropriate professional and technical payment components applied for ultimate reimbursement, the existence of a variety of Medicare payment systems makes actual reimbursement much more complex in practice. These systems vary depending on the type of service and the environment in which it is provided.

For example, Part A payments to hospitals for inpatient services are made under a diagnosis-related group (DRG) prospective payment system. Under this system, hospitals are reimbursed a prospectively determined, fixed amount for all services and medical products provided to diagnose and treat the beneficiary-patient's diagnosis, though adjustments may be made for factors including regional labor costs, extremely complex cases, and medical education programs.<sup>19</sup> A somewhat similar prospective payment system, the hospital outpatient prospective payment system, was recently instituted to reimburse hospital outpatient services under Part B.<sup>20</sup> This payment mechanism is based on an ambulatory payment classification (APC) system that bundles medical products, services and procedures that are clinically similar and require similar levels of resources into an APC that is reimbursed at a single, predetermined reimbursement rate.

Notably, the reimbursement of new medical technology is an issue under the hospital outpatient prospective payment system, given the high costs of innovative devices and drugs. As such, various payment adjustments have been established, such as transitional "pass-through" payments for innovative devices, drugs, and biologics - a mechanism to allow for more accurate reimbursement of these innovations and improved

access of new technologies for Medicare beneficiaries.<sup>21</sup> Another example is establishment of a special temporary APC group for new technology services or procedures that cannot be incorporated into existing APC groups.<sup>22</sup> Reimbursement under the new technology APCs is based solely on the cost of the service. Thus, newer medical devices may be placed into a special APC category with associated higher reimbursement rates.

## **VI. Obtaining Medicare Coverage and Payment: An Illustration**

As outlined in the preceding sections, obtaining Medicare coverage and payment is not a simple or straightforward process. Accordingly, a hypothetical example of a new medical technology is useful to illustrate how the system works in practice.

Suppose that a brilliant cardiologist has partnered with a leading manufacturer to develop a novel catheter/stent combination that reliably crosses and opens completely occluded coronary arteries, a commonly encountered clinical issue which no existing interventional cardiology technology adequately addressed. Furthermore, the FDA has approved the device for market. However, the new combination device is considerably more costly than traditional technology and requires substantially more operator time per procedure. Given these factors and current Medicare reimbursement for traditional stenting procedures, providers and institutions are reluctant to use the device, despite its clinical benefit.

The initial step in ultimately gaining Medicare reimbursement is a positive coverage determination. A costly, potentially beneficial technology that may be widely used in Medicare beneficiaries is typical of products and services that are subject to the

NCD process. Assuming that the manufacturer believes an NCD to be desirable, that manufacturer would typically petition CMS for a coverage determination.

While CMS retains the right to make an NCD on the basis of available scientific information, it rarely makes such a decision on new technology without additional information in the form of an external technology assessment, obtaining a recommendation from an MCAC panel, or both. A purely internal CMS determination may be made rather quickly, usually within 90 days. However, obtaining an external technology assessment and/or an MCAC panel recommendation adds considerably to time involved, typically taking 6 months or more. Even after a positive coverage determination is made and coverage instructions issued, it typically takes 120 to 270 days for Medicare coverage to become effective.

With a positive coverage determination, a new technology involving substantially higher costs will require a new CPT code. The AMA notes that at least three months of preparation and processing is required before the new code request is ready for review by the CPT Editorial Panel, which makes the ultimate decision as to whether a code will be assigned. Should a code be assigned, it must then be valued, a process that typically requires a survey to assess the resources and effort entailed in providing the new service to patients. Using this data, the RUC provides a recommendation in the form of RVUs to CMS, which then makes the ultimate decision as to payment level.

From this brief overview, it is easy to see the complexity and time involved in obtaining broad Medicare reimbursement for a new, clinically useful medical technology.

## **VII. Conclusion**

Coverage under the Medicare program, essential for obtaining Medicare reimbursement, is widely followed in the third-party payer community, and is a major factor in whether a new medical technology achieves broad clinical impact. In its current form, the process is quite complex, requiring interaction between CMS, outside medical and insurance organizations, and product sponsors on a number of levels over an extended period of time. Despite this complexity, product sponsors, medical organizations and other parties interested are well served by a thorough knowledge of the system, and a willingness to partner with CMS to productively address the inevitable issues that arise. By doing so, stakeholders may eliminate unnecessary delays in Medicare coverage and payment determinations, bringing safe and effective new technologies to patients in need.

## Endnotes

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<sup>1</sup> Social Security Amendments of 1965, Pub. L. No. 79-97, 79 Stat. 286 (1965) (codified as amended at 42 U.S.C. §§ 1395-1395ccc (1988 & Supp. V 1993).

<sup>2</sup> 42 U.S.C. § 1395i (1988).

<sup>3</sup> *See id.*; *see also* Medicare Program; Procedures for Medical Services Coverage Decisions, 52 Fed. Reg. 15560, 15563 (1987).

<sup>4</sup> Social Security Act, Exclusions from Coverage and Medicare as Secondary Payer, 42 U.S.C. § 1395y (1999).

<sup>5</sup> Sean R. Tunis, Jeffrey L. Kang, “Improvements in Medicare Coverage of New Technology,” 20 *Health Affairs* 83 (2001): 83, 83-84.

<sup>6</sup> Medicare Program: Criteria and Procedures for Extending Coverage to Certain Devices and Related Services, 60 Fed. Reg. 48417-48425 (1995) (to be codified at 42 C.F.R. Parts 405 and 411).

<sup>7</sup> *See id.*

<sup>8</sup> Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices Memorandum 9/15/1995 (D95-2), Center for Devices and Radiological Health, Food and Drug Administration, at 1.

<sup>9</sup> *See id.*; *see also* Medicare Program: Criteria and Procedures for Extending Coverage to Certain Devices and Related Services, 60 Fed. Reg. 48418.

<sup>10</sup> While placement of an IDE-covered device into category B designates the device as nonexperimental/investigational, such placement does not guarantee Medicare coverage. Rather, CMS considers Category B designation as just one factor out of many factors in making coverage determinations.

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<sup>11</sup> John B. Reiss, “Commentary on Payment and Reimbursement Issues Affecting the Marketing of Drugs, Medical Devices, and Biologics, with Emphasis on the Anti-Kickback Statute and Stark II,” 52 Food Drug L.J. 99, 101 (1997).

<sup>12</sup> Medicare Program: Procedures for Making National Coverage Decisions, 64 Fed. Reg. 22619-22625 (1999).

<sup>13</sup> *See id.* at 22621-22624.

<sup>14</sup> *See id.* at 22622.

<sup>15</sup> *See id.* The Medicare Coverage and Advisory Committee was chartered on November 24, 1998 to advise CMS on whether medical items or services under review at the agency for coverage are reasonable and necessary under Medicare law. Centers for Medicare & Medicaid Services, Medicare Coverage Policy – MCAC Charter, available at <http://www.cms.gov/mcac/default.asp> (last accessed March ,10 2003).

<sup>16</sup> American Medical Association, CPT Process: How a Code Becomes a Code, *available at* <http://www.ama-assn.org/ama/pub/category/3882.html> (last accessed March 10, 2003).

<sup>17</sup> American Medical Association, RVS Updating Process, *available at* <http://www.ama-assn.org/ama/pub/category/3121.html> (last accessed March 10, 2003).

<sup>18</sup> Social Security Act, Payment for Physician Services, 42 U.S.C. § 1395 (1999).

<sup>19</sup> 42 U.S.C. 1395i (1988).

<sup>20</sup> Prospective Payment System for Hospital Outpatient Services, 65 Fed. Reg. 18434, 18436 (2000).

<sup>21</sup> 42 C.F.R. § 419.22.

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<sup>22</sup> Office of Inspector General; Medicare Program; Prospective Payment System for Hospital Outpatient Services, 65 Fed. Reg. At 18434, 18476-78 (to be codified in scattered sections of 42 C.F.R.).