
Medical Technology Reimbursement by the Health Care Financing Administration: Policy Overview¹

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I. Introduction

Introducing innovative technologies into medical practice and achieving maximum clinical impact requires more than solid concepts, good science, and Food and Drug Administration (FDA) marketing approval. In an age where high technology frequently means high cost, it is crucial that physicians and the institutions in which they practice receive appropriate reimbursement from third party payers for new technologies. Arguably the most important of these payers is the Health Care Financing Administration

(HCFA), which administers the federal Medicare and Medicaid programs. Understanding how HCFA makes its coverage decisions is critical to developing strategies that will result in the timely, appropriate reimbursement of new medical therapies.

II. HCFA: Background and Medicare Service Reimbursement Criteria

HCFA was established in 1977 as part of the Department of Health and Human Services (HHS) to administer the Medicare and Medicaid programs, titles XVIII and XIX

of the Social Security Act (the Act), respectively. Although Medicare was originally designed to address the needs of the elderly, coverage expanded in 1973 to include the severely disabled as well as individuals with kidney disease. In administering Medicare, HCFA makes determinations about what medical items and services are covered by the program. Coverage determinations are generally subject to limitations within the Medicare statute, regulations, policy precedent and administrative instructions.

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A. “Reasonable and Necessary” Requirement for Coverage

Medicare law establishes broad categories of covered benefits, general limitations on coverage, and specific exclusions under its coverage policy.² “Covered” benefits are those services, items and procedures available to beneficiaries for which Medicare will pay. Covered services under Part A include inpatient hospital care, skilled nursing facilities (SNF), home health agency care (HHA), and Hospice care.³ Under part B, covered services include physician services, clinical lab testing, durable medical equipment, supplies, diagnostic tests, ambulance services, vaccinations, and certain prescription drugs. Section 1862(a)(1)(A) of the Act addresses only the general nature of coverage, allowing payment for medical items and services under Part A and Part B that are “*reasonable and necessary* for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”⁴ Actual coverage of specific medical devices, surgical procedures and diagnostic or therapeutic services is not made explicit in the Act.

B. Hospital Reimbursement Under Part A

Medicare provides hospital reimbursement under “Part A” of the program. Part A includes inpatient hospital care, skilled nursing facilities, Home Health Agency care, and Hospice care. Initially, reimbursement was on a fee-for-service basis, meaning that the agency based payments on the corresponding reimbursements made by

commercial third-party payers.⁵ This method, based on the institution’s reported costs, proved extremely inflationary.⁶ In response, Medicare began restricting cost-based payments and eventually enacted the diagnosis related group prospective payment system (DRG-PPS), which prospectively established reimbursement levels. This mechanism effectively shifts financial risk to health care providers.

Still in use today, the diagnosis related groups (DRGs) system categorizes patients into groups for reimbursement purposes.⁷ Each predetermined group has corresponding diagnoses and reimbursement rates. Between DRGs, rates will differ according to the level of services and resources needed for particular diagnoses and treatments. Reimbursement may then be adjusted to take into account specific factors affecting particular hospitals, such as regional labor costs, extremely expensive cases, and existence of physician training programs.

C. Physician Reimbursement Under Part B

Medicare reimbursement of physicians’ services is provided under “Part B” of the program. The history of Part B closely parallels that of Part A. Initially, reimbursement was based on a physician’s historical charges.⁸ In response to considerable inflation, a new payment system was implemented in the 1990’s, known as the resource based-relative value schedule (RB-RVS).⁹

The RB-RVS establishes a nominal value for each type of service relative to other services.¹⁰ The RVS is made up of three cost components. The physician work component reflects the time and intensity of the service provided. A practice expense component reflects costs such as office rental, equipment rentals, and salaries. Finally, the malpractice component reflects expenses for professional liability insurance. The value from these three components is then adjusted according to a physician’s geographic location to allow reimbursement to reflect variation in the actual costs of practice.

D. Medicare Plus Choice Organization Reimbursement Under Part C

Medicare reimbursement of organizations participating in one of the risk-based Medicare Plus Choice programs is provided under “Part C” of the program. The three main plans under Part C are (1) coordinated care plans which include Health Maintenance Organizations (HMOs), Provider-Sponsored Organizations (PSOs) and Preferred Provider Organizations (PPOs), (2) private unrestricted fee-for-service plans, and (3) Medical Savings Account plans. Reimbursement for all three types of plans is based on a combination of local and national capitated rates determined by the Secretary pursuant to Section 1853 of the Social Security Act.¹¹

Medicare Plus Choice organizations receive monthly payments in advance for all individuals participating in the program within a predetermined

geographic area based on the annual capitation rate and adjusted for risk factors.¹² The basic risk factors utilized in adjusting such payments include age, disability, gender, and institutional status, factors which take into account variations in health care costs based on the health status of the individuals participating in the program.¹³

III. HCFA Coverage Decision Making Process

The process of making actual coverage decisions under the Medicare program is highly decentralized. Although HCFA is responsible for the administration of Medicare, coverage determinations are generally made by Medicare fiscal intermediaries and carriers, both of which are referred to as “contractors.”¹⁴ These contractors include private insurance companies, and claims-payment contractors located throughout the country.¹⁵ Intermediaries and carriers contract with HCFA to administer the Medicare program at a local level.¹⁶ Peer review organizations (PROs) are also involved in the process, reviewing the medical necessity and quality of care of services provided to Medicare beneficiaries. Apart from national coverage decisions issued by HCFA, intermediaries and carriers hold considerable discretion in making coverage decisions.

A. National Coverage Decision Process

Recently, HCFA instituted a national coverage decision process to address conflicting carrier policies, substantial controversy among experts,

obsolete services or program integrity. All national coverage decisions are binding on Medicare contractors.¹⁷ National coverage decisions are initiated either internally by HCFA, or through external formal requests which normally come from intermediaries and contractors.¹⁸

HCFA will only accept formal requests that comply with the agency’s specific documentation requirements.¹⁹ When HCFA accepts a request, a formal review process begins. The agency must ordinarily respond to the requestor within 90 days of receipt of the completed request.²⁰ Requests for coverage concerning a device or pharmaceutical will only be accepted after official FDA approval.²¹

HCFA’s responses to requests for national coverage decisions vary. The agency may decide not to take action, allowing for local contractor discretion.²² Alternatively, if medical and scientific information on the specific issue is overwhelmingly in favor of, or against coverage, the agency may issue a national non-coverage decision, a national coverage decision with limitations or a national coverage decision without limitations within their ninety day timeframe.²³ If the issue is complex, controversial or very broad, the agency may refer the request to the Medicare Coverage Advisory Committee (MCAC) and possibly to an independent third party technology assessor for further assessment; both HCFA and MCAC are currently formulating criteria which qualify an issue for MCAC review.²⁴ HCFA is free to

accept or reject MCAC recommendations.

HCFA’s intention to issue national coverage decisions are announced in decision memoranda. However, national coverage decisions are not binding on Medicare contractors until they are published in the Federal Register as program instructions or HCFA rulings. Implementation of a national coverage decision regarding medical services will occur after the establishment of code determinations, payment levels and issue claims processing instructions.²⁵ The Center for Health Plans and Providers (CHPP) is responsible for all coding and billing instructions. Generally, implementation will occur within 180 days of the first day of the next full calendar quarter following the date the national coverage decision was issued.²⁶

B. Medicare Contractor Coverage Decision Process

In the absence of national coverage decisions issued by HCFA, Medicare contractors are responsible for deciding coverage issues and adjudicating claims for services within established criteria, employing their individual discretion. HCFA provides guidance in making coverage determinations through Utilization and Quality Control Peer Review Organizations (PROs), and Coverage Issues Manuals, which contain national coverage determinations.²⁷ Contractors may also utilize secondary sources of guidance through advisory groups, contact with regional HCFA representatives and direct contact with the agency. In addition, Medicare contractors may publish local

medical review policies (LMRPs) which explain specific coverage determinations and provide guidance to the general public. However, LMRPs only apply locally.

IV. Special Circumstances: Experimental Devices and Conditional Coverage

The Social Security Act provides that Medicare coverage is appropriate only if the proposed treatment is “reasonable and necessary.”²⁸ HCFA has authority to determine the scope of “reasonable and necessary,” which it has defined in the context of devices as a product that is safe and effective, medically necessary, and not experimental.²⁹ The agency considers the term “experimental” to be synonymous with “investigational.”³⁰ Under this reasoning, distribution of a device under an Investigational Device Exemption (IDE)³¹ demonstrated that its use was not reasonable and necessary within the meaning of Medicare.³² Consequently, coverage was denied for IDE-covered devices that otherwise lacked premarket notification clearance under § 510(k) or premarket approval. In the aftermath of a series of investigations of teaching hospitals and Congressional hearings, HCFA has recognized that some IDE-covered devices are actually refinements or replications of existing technologies.³³ Under these circumstances, at least partial evidence exists to support device safety and effectiveness, with IDE-covered clinical trials required to gather additional evidence. Given this partial evidence, HCFA determined

that their use could be viewed as reasonable and necessary for reimbursement purposes, if these products could be identified among the vast number of IDE-covered devices.³⁴

A. Interagency Agreement

On September 8, 1995, FDA and HCFA entered into an interagency agreement, initiating a categorization process that differentiates between novel, first of a kind devices without safety and effectiveness data, and newer generations of legally marketed devices.³⁵ Under this process, FDA assigns each IDE-designated device into one of two categories: category A, experimental/investigational, and category B, non-experimental/investigational. Category A contains innovative class III devices³⁶ for which absolute risk has not been established and initial questions of safety and effectiveness have not been resolved. Products in category A are either completely new class III devices or existing class III devices significantly modified for a new indication(s).

Category B is appropriate for devices in several different regulatory circumstances.³⁷ Initially, it includes products believed to be in class I, II or III and under investigation to establish substantial equivalence to a predicate device, a term used by FDA for legally marketed products to which new devices may demonstrate similarity in operation and clinical use to gain market approval.³⁸ It can include a device believed to be in class III for which incremental risk is unknown, but underlying questions of safety and effectiveness have been

resolved. The latter may be established by demonstrating that the product has similar technological characteristics and clinical indications to a PMA-approved device or has technological changes that represent advances to a device that has already received PMA approval, known as “generational” changes. The classification may also be appropriate where a class III device is comparable to a PMA-approved device but is under investigation for a new indication without significant modification. Finally, Category B includes pre-amendments class III devices covered IDE’s after the FDA required clinical data under the premarket approval process.

Category designation is confidential information between FDA, HCFA, and the device’s sponsor, though the IDE number and device category are public information. However, a health care provider or supplier who knew or could have reasonably known that the device would not be covered will not be reimbursed. Whether the provider could have reasonably known that the device was not covered will depend on whether the provider received notices from HCFA, intermediaries, carriers or PROs. Knowledge can also be imputed from Federal Register publication of national coverage decisions or other decisions indicating noncoverage and from the provider’s knowledge of what are considered acceptable standards of practice by the local medical community.³⁹

Should the sponsor disagree with FDA’s decision to place their device in Category A, it

may petition FDA for a re-evaluation. As the categorization decision is confidential, only the sponsor can make such a petition. Only after FDA has completed its re-evaluation and concludes the device is properly in Category A can the sponsor request review by HCFA, which limits its review to the FDA record. Given FDA's agency expertise in assessing device-related scientific data, HCFA admits that it will rely heavily on FDA's recommendation.⁴⁰ However, HCFA retains the authority to make the final decision concerning Medicare device categorization.

B. Application of the Interagency Agreement

HCFA continues to view experimental/investigational devices as falling short of the "reasonable and necessary" threshold for reimbursement, and excludes coverage for category A devices under this rationale.⁴¹ HCFA's acceptance of a category A designation constitutes a national coverage decision and is binding on all HCFA's contractors. In addition to non-coverage of the device itself, services related to the use of a category A device are also not covered. This includes care rendered in preparation for use, actual device use, and in patient recovery and follow-up. Complications arising from noncovered device use may be reimbursed, provided they meet all other Medicare requirements.

Placement of a device in category B does not ensure Medicare coverage. Rather, HCFA uses FDA's

categorization as a factor in making coverage decisions.⁴² HCFA reserves the right to conduct an independent assessment to determine whether it will extend coverage.⁴³ In addition, the agency may restrict coverage to a limited number of patients participating in a FDA-approved clinical trial.⁴⁴ For example, HCFA has issued non-coverage instructions on category B devices such as carotid stents. Should HCFA elect coverage of a category B device, the rate of reimbursement is based on, and may not exceed, that currently applied to products employed for the same medical purpose.⁴⁵ For devices requiring inpatient treatment, the diagnosis related group (DRG) prospective payment system will ordinarily be applied. If the device is used in an outpatient setting, then the government either will pay charges or will establish a fee schedule.⁴⁶

Ultimately, coverage decisions will be made according to the existing process and criteria used by Medicare contractors when making coverage decisions for legally marketed devices. Contractors are directed to review the instructions HCFA issues to determine if the category B device is potentially covered. After determining that a device is potentially covered, the contractor must apply HCFA's long-standing criteria and procedures for making coverage decisions. These criteria include whether the device is: 1) medically necessary in the particular case and whether the amount, duration, and frequency of the use or application of the service

is medically appropriate; 2) furnished in accordance with accepted standards of medical practice; 3) furnished in a setting appropriate to the patient's medical needs and condition.⁴⁷

V. Conclusion

HCFA has established a Medicare reimbursement system that is largely decentralized and difficult for the casual observer to fully comprehend. Regardless of complexity, its reimbursement decisions have the potential to significantly affect clinical acceptance of new technologies, and with it, patient care. It is incumbent on the provider community to better understand the system's operations, as well as its intrinsic strengths and weaknesses. Only through such knowledge may timely, appropriate reimbursement decisions be predictably obtained and systemic reimbursement issues adequately addressed. By learning more about HCFA and its process, physicians and other providers will not simply be schooling themselves in policy and procedure, but ultimately improving the care of their patients.

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² Medicare Program; Procedures for Medical Services Coverage Decisions, 52 Fed. Reg. 15560, 15560 (1987).

³ Inpatient hospital care includes the cost of a semi-private room, meals, operating and recovery room, intensive care, inpatient prescription drugs, and laboratory tests. SNF care is covered only in the event it follows within thirty days of hospitalization of three or more days. The services covered are the same as inpatient care, but also include rehabilitation services and appliances. HHA care includes care provided to home-bound beneficiaries if part time skilled nursing and/or other therapy is necessary. Hospice care includes pain relief, supportive medical and social services, physical therapy, nursing services, symptom management, and all covered services for unrelated conditions that arise for the terminally ill patient.

⁴ 42 U.S.C. § 1395y (1999).

⁵ See E.D. Kinney, *Medicare Managed Care From the Beneficiary Perspective*, 26 Seton Hall L. Rev. 1163, 1169 (1996).

⁶ See *id.* at 1165.

⁷ See *id.* at 1171.

⁸ See *id.* at 1170.

⁹ See *id.* at 1172.

¹⁰ 42 U.S.C. § 1395w-4 (1999).

¹¹ 42 U.S.C.A. s 1395w-23.

¹² 42 U.S.C.A. s 1395w-23(a)(1)(A).

¹³ *Id.*

¹⁴ Medicare Program; Procedures for Making National Coverage Decisions, 64 Fed. Reg. 22619, 22621 (general notice April 27, 1999).

¹⁵ A comprehensive list of Medicare contractors with appropriate contact names and numbers can be accessed through <http://www.hcfa.gov/medicare/ncardir.htm#1>.

¹⁶ Generally, fiscal intermediaries administer Part A of the Medicare program while carriers administer Part B. In some cases, carriers will administer Part A claims for physician services performed on an inpatient basis.

¹⁷ See Procedures for Medical Services Coverage Decisions, 52 Fed. Reg. at 15561.

¹⁸ See Procedures for Making National Coverage Decisions, 64 Fed. Reg. at 22621.

¹⁹ See *id.* at 22622.

²⁰ See *id.*

²¹ See *id.* HCFA's internal timeframes will not begin until official FDA approval of the device or pharmaceutical. However, interested parties may contact HCFA before official FDA approval for discussions and informal requests.

²² See *id.* HCFA will provide guidance as to the deficiencies in evidence or the type of information the agency needs in order to make or withdraw a national coverage decision.

²³ See Procedures for Making National Coverage Decisions, 64 Fed. Reg. at 22622-22623.

²⁴ See *id.* at 22623.

²⁵ See *id.* at 22624.

²⁶ *Id.*

²⁷ See Procedures for Medical Services Coverage Decisions, 52 Fed. Reg. at 15561.

²⁸ See 42 U.S.C. § 1395y (1999).

²⁹ See Medicare Program; Criteria and Procedures for Extending Coverage to Certain Devices and Related Services, 60 Fed. Reg. 48417, 48418 (1995) (to be codified at 42 C.F.R. Parts 405 and 411).

³⁰ See *id.*

³¹ An Investigational Device Exemption (IDE) is a regulatory mechanism that allows for the clinical evaluation of devices that are not cleared for marketing. It is generally used where a device lacks FDA marketing approval under either 510(k)/substantial equivalence or premarket approval pathways, though it may be used for clinical trials to gain additional indication(s) for products that are already legally marketed. See Food, Drug and Cosmetic Act (FDCA) § 520(g); Center for Devices and Radiological Health, FDA, Investigational Devices Exemptions Manual, HHS Publication FDA 96-4159 (1996).

³² See Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices Memorandum 9/15/95 (D95-2). Center for Devices and Radiological Health, FDA, at 1.

³³ See *id.* at 1.

³⁴ See Criteria and Procedures for Extending Coverage to Certain Devices and Related Services, 60 Fed. Reg. at 48418.

³⁵ See *id.* at 48419.

³⁶ The Food, Drug and Cosmetics Act regulates medical devices using a stratified, risk-based classification scheme. Class I contains low risk products, class II contains medium risk devices, and class III contains high risk medical devices or devices for which data is lacking to make an accurate determination of patient risk. *See* FDCA, § 513(a).

³⁷ *See* 42 C.F.R. § 405.201(b).

³⁸ FDCA allows legal marketing of devices which are “substantially equivalent” to predicate devices, which are certain products that are legally

marketed. This pathway is generally not available for genuinely new devices marketed after 1976 that remain in class III. *See* FDCA § 510(k).

³⁹ *See* 42 C.F.R. § 411.406 (e).

⁴⁰ *See* Criteria and Procedures for Extending Coverage to Certain Devices and Related Services, 60 Fed. Reg. at 48421.

⁴¹ *See id.* at 48420.

⁴² *See* 42 C.F.R. § 405.201 (a)(1), 205 (a)(2).

⁴³ *See* Criteria and Procedures for Extending Coverage to Certain Devices and Related

Services, 60 Fed. Reg. at 48420.

⁴⁴ *See id.*

⁴⁵ *See id.* at 48421.

⁴⁶ *See* John B. Reiss, Ph.D., *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, 102 (1997).

⁴⁷ *See* Criteria and Procedures for Extending Coverage to Certain Devices and Related Services, 60 Fed. Reg. at 48422.