
Medicare Coverage for Non-FDA Approved Devices Used in Conjunction with FDA-Approved Products in Medically Indicated Procedures*

John J. Smith, M.D., J.D.¹

Jennifer A. Agraz, B.A.²

Tony R. Maida, B.A.³

¹Assistant Radiologist
Massachusetts General
Hospital Assistant Professor
of Radiology Harvard School
of Medicine Director of
Regulatory Affairs/CIMIT*

²Research Assistant in
Regulatory Affairs, CIMIT;
Boston University School of
Law, School of Public Health
(combined J.D.-M.P.H),
Class of 2002.

³Research Assistant in
Regulatory Affairs, CIMIT;
Boston University School of
Law, Class of 2001

Correspondence Information
for All Authors:

c/o Dr. Smith
Department of Radiology
Massachusetts General
Hospital
55 Fruit Street
Boston, MA 02114

* This work was supported in
part by a grant from CIMIT,
a non-profit consortium
comprised of Massachusetts
General Hospital, Brigham
and Women’s Hospital,
Massachusetts Institute of
Technology and Draper
Laboratory.

I. Introduction

Development of new medical technologies often requires demonstration of ‘proof of concept’ prior to full scale product development and testing for Food and Drug Administration (FDA) marketing approval. When such demonstrations are conducted in the course of medically-indicated patient treatment that normally qualifies for third-party payer reimbursement, the question arises whether reimbursement may be legally sought. This question is particularly important in the setting of the Health Care Financing Administration (HCFA), the administrator of the Medicare program, and the nation’s largest third party payer. Improperly billing Medicare in the setting of non-FDA approved devices may result in accusations of fraud, charges that carry significant civil and even criminal sanctions. Avoiding these pitfalls requires a working knowledge of HCFA coverage and reimbursement policies and how these policies may be applied to the limited use of non-FDA approved devices.

Table of Contents

I. Introduction.....	1
II. Medicare Coverage and Reimbursement Policies	2
A. Policy Overview	2
B. Medicare Organization	2
C. Conditional Coverage for Certain Experimental Devices	3
III. Coverage and Reimbursement of Medically-Indicated Procedures Using non-FDA Approved Devices	3
A. HCFA Policy	3
1. Coverage and Reimbursement Under Fee-for-Service Models	3
2. Treatment Under Prospective Payment Systems	4
3. President Clinton’s Executive Order	4
B. Analysis: HCFA Reimbursement for Non-FDA Approved Products	4
1. Reimbursement Generally	4
2. Reimbursement in a Fee-for-Service Setting	5
3. Reimbursement Under Prospective Payment Systems	5
Conclusion.....	6
References	6

II. Medicare Coverage and Reimbursement Policies

A. Policy Overview

HCFA divides Medicare payment for medical products and services into two broad determinations: coverage and reimbursement. Coverage addresses whether Medicare may legally pay for a product or service. Reimbursement determines the level of payment made for products and services that are covered.

To be eligible for coverage, a product or service must be “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” [1]. The Social Security Act, in which the statutory law governing Medicare is found, does not delineate coverage of specific products or services. Rather, it is HCFA and various contractors under the agency’s control, that determine the specifics of coverage.

Medicare coverage decisions may be either national or local. Should HCFA make a coverage determination, this decision applies nationally to all beneficiaries. The agency itself does not administer Medicare on the local level, instead contracting this responsibility to various contractors [2]. These contractors include entities such as private insurance companies and claims-payment contractors. In the absence of a national coverage decision, contractors enjoy considerable discretion in making local coverage decisions, though these determinations are applicable only in the geographic area in which that contractor operates. The vast majority of coverage decisions are local,

often resulting in non-uniform coverage for products and services.

HCFA maintains a number of policies that govern coverage decisions both nationally and locally. Currently, these policies are undergoing agency review with the ultimate outcome probably still years away. At the present time, the agency interprets its statutory mandate that products and services be “reasonable and necessary” to require that medical devices used in procedures be safe, effective, medically necessary and not experimental [3]. Furthermore, HCFA considers the term “experimental” to be synonymous with “investigational” [4].

Following a positive coverage determination, HCFA must determine reimbursement levels for the product or service. This is a fairly involved and elaborate process, which differs according to the type of product or service provided, and the setting in which it is provided, i.e., inpatient or outpatient, hospital or non-hospital. Often, this involves establishment of new codes to identify a procedure for appropriate billing.

B. Medicare Organization

Covered products and services are separated into groupings, known as ‘parts’ [5]. Hospital Insurance, or “Part A,” includes inpatient hospital care, skilled nursing facilities, home health agency care, and hospice care. Supplemental Medical Insurance, or “Part B,” covered services include physician services in both hospital and non-hospital settings, clinical lab testing, durable medical equipment, supplies, diagnostic tests, ambulatory services,

vaccinations, and certain prescription drugs. When these services are provided by hospitals in an outpatient setting, ambulatory surgical center, or by a home health agency, they are also included in Part B.

Part A payments are made under a prospective payment system based on diagnosis related groups, known as “DRGs” [6]. This system prospectively determines reimbursement based on a beneficiary’s diagnosis within the DRG classifications, with payment based on the level of services and resources needed for that particular diagnosis and its treatment. Though actual reimbursement may be adjusted to allow for factors affecting specific hospitals, the DRG system largely pays the same fixed rate for a given diagnosis, regardless of the actual resources required by the beneficiary.

Physician compensation under Part B is also paid on a set fee schedule, known as the resource-based relative value schedule (RBRVS) [3]. Similar to DRG’s, the RBRVS establishes a nominal value for each type of service relative to other services [7]. It includes various components, including physician work, practice expense, and professional liability coverage. Actual payments are adjusted for geographic variation in expenses.

Outpatient services provided to Medicare beneficiaries are somewhat more complicated. On August 1, 2000, HCFA implemented a hospital outpatient prospective payment system which prospectively determines reimbursement levels for procedures and services based on an ambulatory payment classification (APC) value [8]. This bundled payment reflects the cost of devices, durable

medical equipment, and other items used to perform diagnostic and therapeutic procedures and services [9]. Though there are some exceptions for newly developed devices and services, items are no longer separately billable [8].

C. Conditional Coverage for Certain Experimental Devices

Medicare does not ordinarily cover medical devices that are considered investigational or experimental. Under HCFA's original interpretation of Medicare law, devices undergoing clinical testing under an FDA Investigational Device Exemption (IDE)-covered protocol were considered experimental and thus not covered. In the 1990's, the agency realized that a portion of IDE-covered devices were refinements or replications of existing technologies, with at least partial data supporting their safety and effectiveness [4]. Under these circumstances, HCFA concluded that use of the IDE-covered product could be viewed as reasonable and necessary and potentially eligible for Medicare coverage and reimbursement.

To identify Medicare-eligible devices covered by IDE's, HCFA and FDA instituted a product categorization process that differentiates between novel, first of a kind devices and newer generations of legally marketed products [4]. Under this system, innovative, new devices for which absolute risk has not been established and initial questions of safety and effectiveness have not been resolved are placed in Category A. Category B designation is given to products for which there is some evidence of safety or effectiveness, or which are undergoing testing to

demonstrate similarity in operation and use to a legally-marketed device. FDA makes the initial determination of product categorization, though HCFA retains final categorization authority.

Placement of an IDE-covered product in Category A constitutes a national coverage decision that precludes Medicare coverage and reimbursement [10]. In addition to the device itself, services related to its use are not covered, including care rendered in preparation for use, actual product use, and patient recovery and follow-up. However, complications arising from a non-covered device may be reimbursed, provided they meet all other Medicare requirements.

Category B designation does not ensure Medicare coverage. Rather, HCFA uses FDA's categorization as a factor in making coverage decisions, the ultimate decision being an independent one on the part of HCFA for national coverage decisions, or its contractors for local decisions [10]. HCFA reserves the right to conduct an independent coverage assessment and may restrict coverage to a limited number of patients participating in an FDA-approved clinical trial. Should HCFA or a contractor cover 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 [10]. For devices requiring inpatient treatment, the diagnosis related group (DRG) prospective payment system will ordinarily be applied.

III. Coverage and Reimbursement of Medically-Indicated Procedures Using non-FDA Approved Devices

Early in the development of new medical technologies, there is often need to establish 'proof of concept', that is that a medical device functions in the manner it is intended. Often, physicians will use these products in the course of providing medically indicated treatments. More commonly, physicians and other health care providers use non-FDA approved products in the same medically indicated procedure as approved devices.

There are numerous examples of both circumstances. For example, interventional cardiologists may employ an experimental vascular imaging catheter during a medically indicated cardiac catheterization, or employ an experimental stent if the approved product fails to provide favorable results. Vascular surgeons and interventional radiologists may fabricate custom covered stents to treat aneurysms. Non-FDA approved software and hardware may be used along with approved, commercially available products in the operating room and other patient care areas. All such uses raise issues of coverage and reimbursement not only for the non-approved product, but also for the procedure itself and any approved devices that may be employed.

A. HCFA Policy

1. Coverage and Reimbursement Under Fee-for-Service Models

Circumstances where Medicare permits fee-for-service billing are growing progressively more

limited as HCFA institutes the hospital outpatient prospective payment system into an environment that features long-standing prospective payment methodologies under the DRG and RBRVS systems. Under remaining fee-for-service systems, medical products and services are billed separately, allowing for relatively easy identification of a non-approved device. Generally, products lacking FDA approval are not covered, nor are any medical services related to their use. Category B devices which have received positive coverage determinations are an exception to this rule and may be legally billed.

While HCFA policy precludes coverage and reimbursement of non-approved devices whose use is the primary objective of a procedure and which are separately billed, this policy is much less clear when use of a non-approved product is ancillary to a medically-indicated and otherwise covered procedure. This is particularly true for devices that are not billed separately and whose use does not appreciably alter procedural length or the professional resources required.

2. Treatment Under Prospective Payment Systems

Prospective payment systems, such as DRGs, APCs, and the RBRVS, prospectively fix payment based on either patient diagnosis or the type of service involved. Itemized billing for individual devices is not generally possible, with the cost of medical products included in the fixed reimbursement. At first glance, this appears to allow the practitioner far greater latitude in device use, provided he or she is

willing to accept the reimbursement level provided. However, even under such systems, there are limitations on billing Medicare for non-FDA approved devices.

Importantly, the application of a prospective payment system does not alter the statutory requirement that treatment provided Medicare beneficiaries be reasonable and necessary. Non-FDA approved devices, with the exception of Category B products that have received positive coverage decisions, are considered experimental or investigational and do not meet this requirement. Accordingly, any non-approved product whose use is the primary purpose of a medical procedure cannot be legally billed under the various Medicare prospective payment systems.

As with fee-for-service models, HCFA policy becomes less clear when use of a non-approved product is ancillary to a medically-indicated procedure. Specifically, the prohibition on billing for procedures using non-approved devices appears to become less applicable the more ancillary the use of the non-approved product becomes, or in instances where a non-approved product is used following the failure of an approved device.

3. President Clinton's Executive Order

A recent executive memorandum further complicates coverage and reimbursement of procedures where non-approved devices are employed. On June 7, 2000, President Bill Clinton, citing the low enrollment of the elderly in clinical trials, announced that he would order Medicare to reimburse routine patient care

costs associated with clinical trials [11]. This action, apparently taken without extensive consultation with HCFA, reverses long-standing agency policy, and will no doubt require a significant level of administrative attention to fully implement.

Facially, this new policy will presumably allow providers and institutions to legally bill Medicare for medically necessary care provided as part of clinical trials. However, there are at least two major issues with this initiative. Importantly, its application is limited to clinical trials, presumably including IDE-covered clinical trials and their enrolled patients. Though the spirit of the initiative may suggest broader application, the executive order does not appear to extend to instances where non-FDA approved devices are employed outside of the clinical trial setting. Furthermore, there is the very basic question of scope, i.e., how is "routine" care going to be defined by HCFA. Given these and other issues that are sure to arise, it will probably be quite some time before the true impact of this executive order can be determined.

B. Analysis: HCFA Reimbursement for Non-FDA Approved Products

1. Reimbursement Generally

Statutory law and HCFA policy clearly preclude billing for non-FDA approved devices outside of Category B products that have received positive coverage decisions, where use of those devices is the primary purpose of a procedure. While billing for the devices themselves is not possible, there is the strong possibility that a provider or institution could legally bill for

services provided in the setting of non-approved device use where the use of that product is not the primary purpose of the treatment provided. To qualify for such reimbursement, there are two primary requirements. Initially, the product must be ancillary to the medical care provided. The more ancillary the product, the better, as a strong argument may be made that the billable procedure would have been performed regardless of the use of the non-approved device. Finally, the treatment provided must meet all Medicare requirements, such as being medically necessary and appropriate for the beneficiary.

There are numerous examples of potentially billable procedures using non-approved devices. For instance, a procedure performed to place an experimental cardiac stent may be non-reimbursable, conditional coverage notwithstanding, while a medically-indicated procedure where the same experimental product was placed after an unsatisfactory result with an approved device may qualify. Should a non-approved device be completely ancillary to a medically-indicated procedure, such as use of an experimental anesthesia monitor used in conjunction with approved equipment in the setting of a major operation, few problems in billing Medicare for the procedure should arise.

Even where a non-FDA approved product is employed in an ancillary fashion in a medically necessary procedure, Medicare reimbursement would be limited to that for the identical procedure performed with FDA-approved products. In the setting of a prospective payment system, there may also be the need to adjust billed fees such that costs

related to the non-approved device are not actually reimbursement.

2. Reimbursement in a Fee-for-Service Setting

Where a non-approved device is employed in an ancillary fashion during a medically-indicated procedure in the fee-for-service setting, the procedure itself could be billed in the usual fashion, along with any FDA-approved products employed. However, the cost of the non-approved product could not be included, unless that product is a covered Category B device. These billing limitations may result in inadequate provider reimbursement, with Medicare payment potentially failing to cover the real costs of performing the procedure. In an environment where medical devices often cost hundreds if not thousands of dollars, it is very unlikely that a given provider or institution could absorb the expense of routinely employing consumable, non-approved, unreimbursable devices, even if Medicare assumed the costs of the procedure itself.

3. Reimbursement Under Prospective Payment Systems

Under the various Medicare prospective payment systems, it may be possible to bill for procedures where a non-approved device is used. However, as with the fee-for-service model, it is crucial that use of the non-approved product be ancillary to a procedure that otherwise qualifies for Medicare reimbursement.

Strictly speaking, the process of billing for a non-approved device

under a prospective payment system would not be straightforward. Initially, the cost of the product could not be included, a complicated exercise in circumstances where individual devices are not billed separately. In addition, physician time using the non-approved product should be factored out. However, where use of a non-approved device is wholly ancillary, such as a new anesthesia monitoring unit whose use is not separately billed and which does not add any appreciate time to the procedure, it is likely that the standard DRG, APC, or RBRVS could be billed without such adjustments. Still, problems exist where an established prospective payment system is billed for procedures using non-FDA approved devices.

Under the DRG system, patients are categorized into diagnoses with predetermined reimbursements rates for each diagnosis group. Only FDA-approved devices are considered in the DRG calculation, meaning that additional costs for non-approved devices are not reflected in payments. Furthermore, HCFA requires institutions to report the use of non-approved devices, including their IDE numbers and cost. When institutions perform procedures that are not specifically covered or employ non-FDA approved devices, whether or not related to research, the "unlisted" service code is commonly used to bill Medicare. Use of this code often results in an audit by the local Medicare contractor. In the absence of a national coverage decision, local contractors generally reimburse only on a case-by-case basis.

HCFA's new hospital outpatient prospective payment system, implemented on August 1, 2000, assigns each procedure a fixed APC reimbursement. However, APC rates only include the cost of FDA-approved products. In the short term, hospitals will have a two- to three-year transitional period where they may receive additional pass-through payments for certain drugs and devices, including new medical devices [12]. To qualify for this additional reimbursement, devices must receive FDA approval or category B designation under an IDE and be integral to a medically-necessary procedure. As with the DRG system, the APC system makes no allowance for additional costs associated with non-approved products, and the actual exercise of billing for a procedure using such devices may be difficult.

The RBRVS establishes a service-based prospective payment system for physicians similar to DRG's and APC's. In the setting of procedures which are medically necessary and use of the non-approved device is ancillary, the provider is likely to be reimbursed for the RBRVS amount. However, as with other prospective payment systems, there is no mechanism to address the additional resources that may be required by non-approved devices, creating the potential for substantial differences between real provider costs and actual reimbursement levels.

Conclusion

Establishing proof of concept for a new medical device often requires limited clinical testing in actual patient care settings. In addition, cutting edge medical care does not always respect FDA-regulatory status of medical

devices. Both situations may create considerable confusion for Medicare coverage and reimbursement for the medically-necessary services provided which employed these non-approved products.

Under current law, providers and institutions can probably bill for procedures using non-approved products, providing that the products employed are ancillary to an otherwise Medicare-reimbursable procedure. However, care must be taken not to bill for the non-approved device itself, or any additional resources required for its use. Unfortunately, this policy may not fully compensate providers and institutions using the non-approved product, a reality that will inevitably impact that device's use.

References

1. Social Security Act, Exclusions from Coverage and Medicare as Secondary Payer, 42 U.S.C. § 1395y (1999).
2. Medicare program; procedures for making national coverage decisions, 64 Federal Register 22619-22625 (1999).
3. Kinney ED. Medicare managed care from the beneficiary perspective, Seton Hall L Rev 1999;26:1163-94.
4. Center for Devices and Radiological Health, Food and Drug Administration. Implementation of the FDA/HCFA interagency agreement regarding reimbursement categorization of investigational devices memorandum. Rockville: Food and Drug Administration; September 15, 1995.
5. Medicare program; procedures for medical services

coverage decisions, 52 Federal Register 15560-15563 (1987).

6. Health Care Financing Administration, Medicare: A brief summary, available at <http://www.hcfa.gov/medicare/or/medmed.htm>. Accessed July 3, 2000.
7. Social Security Act, Payment for Physician Services, 42 U.S.C. § 1395w-4 (1999).
8. Prospective payment system for hospital outpatient services, 63 Federal Register 47552-48030 (1998).
9. Prospective payment system for hospital outpatient department services, 42 C.F.R. § 419.2 (1999).
10. Medicare program; criteria and procedures for extending coverage to certain devices and related services, 60 Federal Register 48417-48425 (1995).
11. White House press release: Taking new action to encourage participation in clinical trials, available at <http://www.whitehouse.gov/wh/work/060700.html>. Accessed July 26, 2000.
12. Transitional pass-through for additional costs of innovative devices, drugs, and biologics, 42 C.F.R. s. 419.43(e)(1)(C) (1999).