



Chapter 4

Fundamentals of Reimbursement

Kelli Hallas

VICE PRESIDENT

Field Reimbursement Services

Emerson Consultants, Inc.

Eden Prairie, MN 55344

THE IMPORTANCE OF REIMBURSEMENT

Obtaining optimal reimbursement is critical to the adoption of a new device or technology. Even though a particular device has received regulatory approval to be marketed, there is no guarantee that it will be adopted by surgeons if the practice or hospital cannot obtain reimbursement from third-party payers. The increasing costs of procedures and devices will make some surgeons wary of using a product if the prospect of reimbursement is uncertain. However, as the medical device industry continues to invent and innovate, acquiring reimbursement has become more difficult. Obtaining proper reimbursement for a new device is imperative if device manufacturers hope to make an impact on the market. This is particularly true for orthopedic devices and technologies because payers are responsible for 90% of orthopedic procedures. Understanding the reimbursement process is crucial for medical device companies involved in this market sector.

Companies can make a multitude of mistakes when seeking reimbursement, especially for a groundbreaking treatment such as Nucleus Arthroplasty™ technology. Companies may assume that receiving Food and Drug Administration (FDA) approval will automatically guarantee reimbursement from payers, but this is not necessarily the case. A lack of understanding about the clinical and economic data required to obtain optimal reimbursement can result in the demise of a Nucleus Arthroplasty company. Therefore, Nucleus Arthroplasty companies, especially those seeking new or

additional codes, must be aware of what government and private payers require before granting reimbursement for a new device or technology.

REIMBURSEMENT BASICS

This chapter will review and discuss the basic elements of reimbursement in regard to Nucleus Arthroplasty motion preservation technologies. Most often reimbursement is thought of as a single entity when in actuality it is composed of the following three distinct elements:

- Coverage
- Coding
- Payment

Reimbursement is the end result of the interaction of these drivers.

MOST OFTEN REIMBURSEMENT IS THOUGHT OF AS A SINGLE ENTITY WHEN IN ACTUALITY IT IS COMPOSED OF THE FOLLOWING THREE DISTINCT ELEMENTS: COVERAGE, CODING AND PAYMENT.

COVERAGE

Coverage refers to a third-party payer's decision on whether or not to pay for a particular procedure, device, therapy, or service under the health services or benefits that are arranged, provided, or paid for through a health insurance plan. A coverage determination is based on whether the procedure, device, therapy, or service in question is considered a medical necessity. To be considered medically necessary, the goods or services should meet the following requirements/conditions:

- Appropriate and necessary for the symptoms, diagnosis, or treatment of a medical condition;
- Meet the standards of good medical practice within the medical community in the service area;
- Unbiased regarding convenience to the plan member or plan provider;
- Most appropriate level or supply of service that can safely be provided; and
- Provided for the diagnosis or direct care and treatment of the medical condition.

Note that all of the conditions must be satisfied for the good or service to be considered a medical necessity.

Coverage can be favorable, unfavorable, or limited in nature. It may be issued formally within a policy or granted informally on a case-by-case basis. The coverage of Nucleus Arthroplasty technologies will vary by payer. Whereas some payers may approve the procedure for coverage on an individual basis, others will consider the procedure "investigational" or "experimental" and deny coverage. This increased scrutiny is typical for emerging treatments and technologies.

Obtaining a positive coverage decision is critical to the success of any technology. The following criteria are considered by payers when making coverage decisions:

- The technology must have final approval from the appropriate governmental bodies—the FDA in the U.S.
- Scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
- The technology must improve the net health outcomes.
- The technology must be as beneficial as any currently established alternatives.
- Improvement must be attainable outside of the investigational setting.
- Peer-reviewed data published in a U.S. journal must be available, preferably from a multi-centered, double blind, controlled study conducted in the U.S.

It should also be noted that, although a product may not be intended for significant use in the Medicare population (patients age 65 and older), the coverage policies developed by the Centers for Medicare and Medicaid Services (CMS) heavily influence the coverage decisions of private payers. Therefore, it is important that companies consider the impact the technology will have on the Medicare population during clinical trial design. The final coverage decision made by CMS on any technology may greatly impact the company's overall bottom line sales.

CODING

Coding represents the reimbursement language that payers and providers use to communicate. Codes explain the "why" and the "what," and are universally accepted among physicians, hospitals, and payers. Providers report on procedures by using various types of codes both during clinical trials and after FDA approval. Codes are dynamic and may change even if the product or procedure does not. In the long term, it is critical that companies work closely with CMS, the American Medical Association (AMA), and relevant professional societies to ensure the development of appropriate coding recommendations.

TABLE 1. CODES TO REPORT NUCLEUS ARTHROPLASTY TECHNOLOGIES

CODE TYPE	NUMBER	DESCRIPTION
ICD-9-CM Procedure (hospital)	84.64	Insertion of partial spinal prosthesis, lumbosacral; includes nuclear replacement device lumbar; partial artificial disc prosthesis (flexible) lumbar, and replacement.
ICD-9-CM Procedure (hospital)	84.68	Revision or replacement of artificial disc prosthesis, lumbosacral; removal of (partial or total) spinal disc prosthesis with synchronous insertion of new (partial or total) spinal disc prosthesis lumbosacral; repair of previously inserted spinal disc prosthesis, lumbosacral.
CPT-4 (physician)	22899	Unlisted procedure of the spine.

During a clinical trial, a code that accurately describes a procedure or service may not exist, so an “unlisted” procedure code will be reported. This is most often the case with breakthrough and emerging technologies. However, if the appropriate governing body (CMS or AMA) feels that an existing code can accurately describe the investigational procedure, they may recommend the use of that code during the clinical trial. In such instances, it is highly recommended that companies communicate with CMS, the AMA, and professional societies, prior to making any coding recommendations to providers.

Hospitals and physicians use different coding systems (ICD-9-CM and CPT-4® codes) to report on their work. Each of these systems will be described separately along with the codes to report Nucleus Arthroplasty technologies.

Hospitals use ICD-9-CM procedure codes to describe inpatient surgical, diagnostic, and therapeutic procedures (admitted >24 hours). ICD-9-CM codes are controlled by CMS. During a clinical trial, requests can be submitted to CMS for the creation or modification of an ICD-9-CM code to allow for accurate classification of a new procedure. Formal applications are accepted twice a year. FDA approval is not required to obtain an ICD-9-CM code for an inpatient procedure.

CPT-4 codes are used by both physicians and hospital outpatient departments to describe surgical, non-surgical, and diagnostic procedures. CPT-4 codes are controlled by the AMA. If the AMA decides that a procedure is closely related to an existing procedure in consumption of resources, it may recommend use of the existing code to report the procedure. If the procedure is different and distinct from any current coding descriptions, it will recommend use of an unlisted procedure code during the clinical trial for tracking and reporting purposes. In the case of Nucleus Arthroplasty technology, the unlisted procedure code is reported by the surgeon and will encompass all resource utilization to perform the procedure inclusive of the discectomy.

After the clinical trial has been completed, either a professional society or an external party can file a formal request for either a new code or modifications to an existing code if the product or procedure has:

- Received FDA approval
- Published U.S. peer-reviewed data
- Documented widespread use
- Support of the professional society

The codes used to report Nucleus Arthroplasty technologies are listed above in Table 1.

PAYMENT

Payment is determined by contractual terms between healthcare providers and payers. These arrangements can take different forms. Examples of hospital payment methodologies include:

- *Case rate* – A payment is arranged to cover a specific procedure, technology, or diagnosis.
- *Discounted fee for service* – The payment equals the amount billed less a pre-negotiated discount.
- *Fee schedule* – The facility is paid a flat payment for the patient’s admission regardless of resources used or length of stay (DRG) involved.
- *Per diem* – The facility is paid a flat rate per day.

Examples of physician payment methodologies include:

- *Capitation* – The physician is paid a certain amount per member per month to cover the costs of care.
- *Case rate* – The surgeon has contracted a fixed fee for a specific procedure.
- *Discounted fee for service* – The payment equals the amount billed less a pre-negotiated discount.
- *Fee schedule* – The physician receives a pre-determined payment for a particular service.

TABLE 2. DRG ASSIGNMENT FOR NUCLEUS ARTHROPLASTY TECHNOLOGIES

DRG	DESCRIPTION
499	Back and neck procedures, except spinal fusion with complications.
500	Back and neck procedures, except spinal fusion without complications.

In the hospital environment, Medicare pays hospitals according to the DRG (Diagnostic Related Group) methodology. The DRG system is intended to classify patients into clinically cohesive groups that demonstrate similar patterns of consumption of hospital resources and length of stay. According to the Medicare payment system, Nucleus Arthroplasty technology will be assigned to one of the DRG’s listed above in Table 2.

REIMBURSEMENT FOR NEW DEVICES

When a groundbreaking device is substantially more expensive than devices that are already on the market, companies will usually seek a new code to receive proper reimbursement. However, because claims information does not yet exist, many companies will apply for an add-on payment, which is a temporary provision for new technologies. This additional payment gives hospitals and surgeons in private practices in the U.S. an incentive to use products that have recently received FDA approval. In order to receive an add-on payment, the product must be:

- New,
- Substantially improved relative to the existing technology, diagnosis, or treatment, and
- Of sufficient cost.

Add-on payments are difficult to obtain and require sufficient clinical and economic data in order to prove to payers that such a payment is justified.

THE CURRENT REIMBURSEMENT STATUS OF NUCLEUS ARTHROPLASTY TECHNOLOGY

It is helpful to consider the status of Nucleus Arthroplasty technology in order to gain a better appreciation of the current reimbursement environment for this new technology. Nucleus Arthroplasty motion preservation technologies are continuously emerging. Unlike other spine procedures, this breakthrough technology was not recognized by CMS until October 2004. It was at this time that CMS created a new subcategory of procedure codes to classify spine disc replacement technologies including total and partial replacements.

Although codes were created to enable tracking of Nucleus Arthroplasty procedures, CMS has collected little claims data specific to this ICD-9-CM code and technology. This is because, until recently, no nucleus replacement technologies have received approval to begin an Investigational Device Exemption (IDE) clinical trial in the U.S. Due to several recent approvals, patient outcomes impacting coverage decisions can now be tracked, and economic data can be collected to ensure appropriate payment.

Ultimately, it is the responsibility of the industry and health care providers to assist CMS in making critical coverage and reimbursement decisions impacting this technology. Industry must ensure that economic data is collected and a solid reimbursement strategy is integrated into the early stages of clinical trial design and product development. Hospitals and physicians must adhere to coding guidelines set forth to report the procedures.

All activities that take place during the clinical trial phase will directly impact payer decisions made after FDA approval and will ultimately affect the economics of this new technology. CMS requires data to assist payers in making appropriate decisions. To ensure positive coverage and payment decisions, this data must be concise, compelling, and show substantial clinical improvement over the current gold standard. Therefore, design and execution of a clinical trial can either make or break a technology.

CONCLUSION

The reimbursement landscape for Nucleus Arthroplasty technologies will continue to evolve. Although a hospital procedure code exists for the technology; coverage, payment, and physician CPT-4 codes have yet to be determined. In the end, having a well-designed reimbursement strategy that engages the efforts of physicians, professional societies, and industry will have a positive impact on reimbursement for this technology.