

Medicare Reimbursement: Translating Theory into Practice

**Medicare Congress
Pre-Conference Symposium
October 15, 2006**

■■■ Agenda

- **Welcoming Remarks and Introductions**
 - » Perry Bridger, Avalere Health
 - **Coverage Challenge: The Natrecor[®] (nesiritide) Case Study**
 - » Perry Bridger , Avalere Health
 - **The Role of Appropriate Coding**
 - » Chris Mancill, Amgen
 - **Payment Challenges Across Sites of Services**
 - » Jeff Farkas, Medtronic
 - **The Changing Reimbursement System: Interaction Between Medicare Part B and Medicare Part D**
 - » Lauren Barnes, Avalere Health
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■■■ Objectives

- Understand the importance and business impact of the reimbursement process (coverage, coding and payment)
- Recognize how coverage decisions can influence market success
- Understand the significance of various coding systems and importance of coding for new products
- Develop an understanding of payment mechanisms and the challenges for products used across different sites of service
- Explore the impact of Part D on Part B payment
- Use case studies and active discussion to enhance knowledge



An Overview of the Reimbursement Process



The intersection of business
strategy and public policy

■ ■ ■ The Importance of Reimbursement

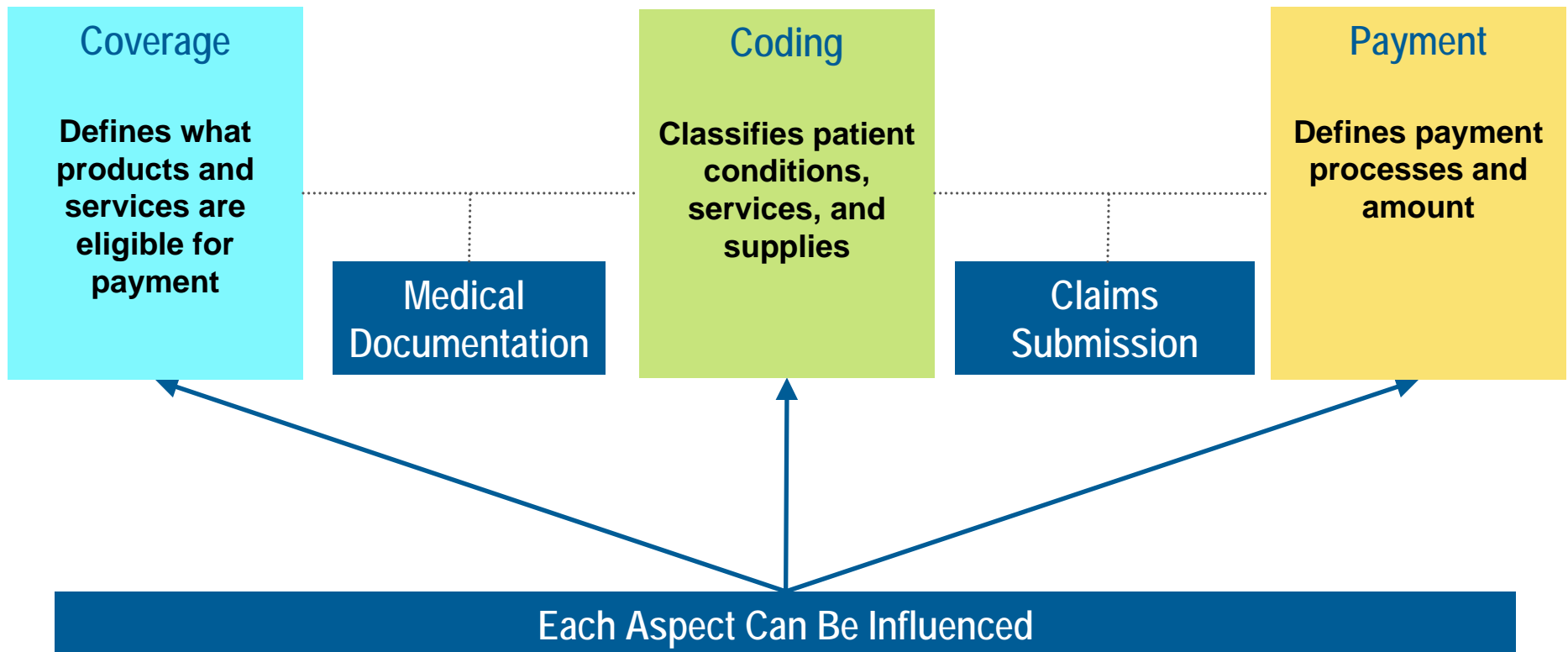
- Reimbursement is the process through which medical technologies and services are assessed for coverage, coding and payment
- Obtaining proper reimbursement is as important as obtaining approval by the U.S. Food and Drug Administration (FDA)
- Different payment systems create varying incentives and disincentives for providers to utilize certain drugs, devices, and procedures
- Lack of coverage or inadequate payment may hinder adoption or patient access to a drug, medical device, or service

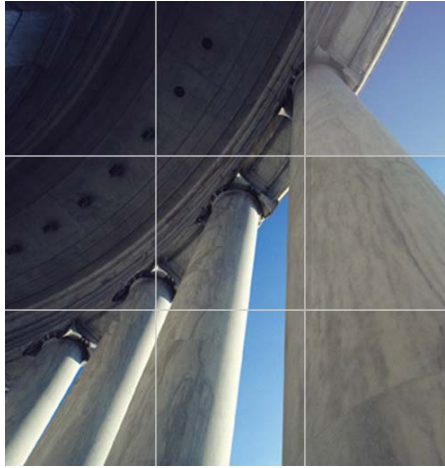


Reimbursement is an Issue for Many New Products and Services



Coverage, Coding, and Payment Are Key to Reimbursement





A Brief Overview of Some Key Trends in the Medicare Coverage Process



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■ ■ ■ CMS National Coverage Trends Signal Higher Medicare Evidence Standards

- Increased transparency of coverage process due to changes in the Medicare Modernization Act (MMA)
- Development of coverage guidance documents, including CED*
- New focus on evidence and data generation beyond FDA requirements, including post-coverage data collection
- Initiative to increase data collection in Parts B and D to use for future coverage decisions or refinements
- Increased collaboration with other government agencies (e.g. National Cancer Institute)
 - » Clinical trial development
 - » Post-market surveillance activities

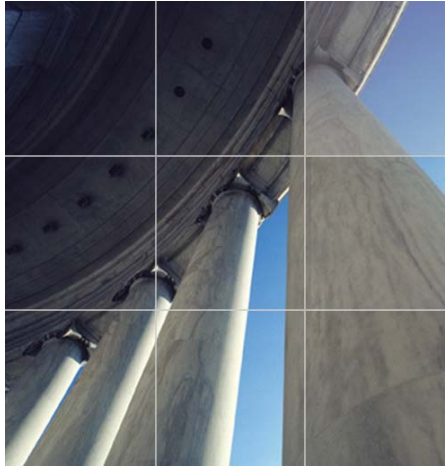
* CED = Coverage with Evidence Development

Medicare and Other Payers are Increasingly Relying on Evidence-Based Medicine (EBM)

- Helps move focus from safety and efficacy to the “value” of health interventions
- Payers and policymakers use evidence to address the cost, access to, and quality of healthcare services
- Patients are becoming sophisticated consumers of information on health and healthcare choices
- Greater investment in health information technology (HIT) may lead to more evidence-based care and accelerate the adoption of pay-for-performance (P4P)

EBM Fundamentally Alters the Generation and Use of Evidence for Coverage Policy Development

	Pre-EBM	Post-EBM
Generation	<ul style="list-style-type: none">Industry largely controls its value proposition	<ul style="list-style-type: none">Government and private sector invest in health technology assessments to obtain information regarding safety and efficacy of drugs/devices
Application	<ul style="list-style-type: none">Payers are administratorsClinicians self-regulate the quality of their clinical practice	<ul style="list-style-type: none">Payers are prudent purchasers of healthcare services and technologySystematic efforts to define, measure, and report on quality within the clinical setting
Implementation	<ul style="list-style-type: none">Resource-based payment systemsCare fragmentationPaternalism in healthcare	<ul style="list-style-type: none">Value-based purchasingCare coordinationConsumerism in healthcare



Coverage Challenge: The Natreacor[®] (nesiritide) Case Study



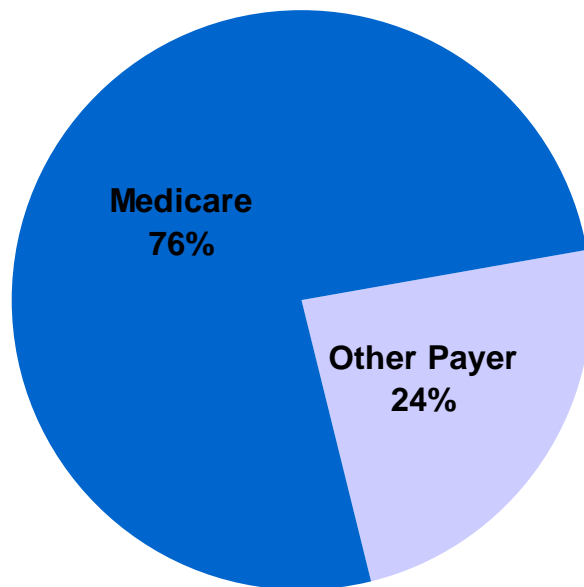
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Natrecor®

Manufacturer	Scios (Johnson & Johnson)
Date of FDA Approval	August 10, 2001
Route of Delivery	Intravenous infusion
Indication	Acutely decompensated heart failure (ADHF) in patients who have dyspnea at rest or with minimal activity
Complications & Risks	Renal complications, hypotension, increased mortality
Black Box Warning?	No

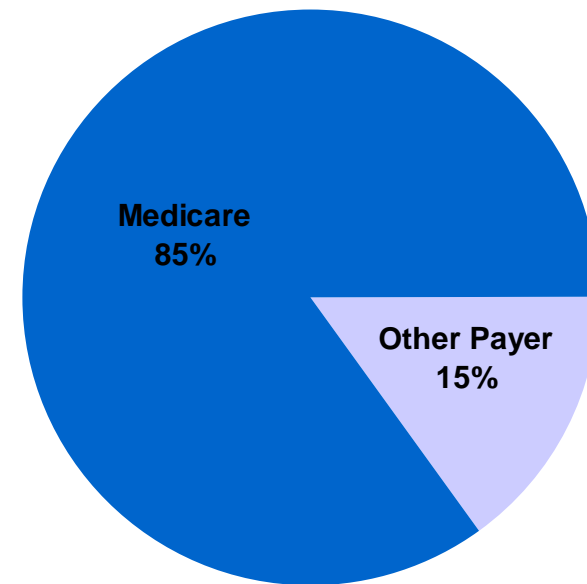
Medicare is the Primary Payer for Heart Failure and Natrecor in the Inpatient Setting

All Discharges with Heart Failure Diagnosis



An analysis of the 2003 National Hospital Discharge Survey (NHDS) demonstrates that 76% of all inpatient stays for some form of heart failure* have Medicare as their primary payer**

Patients Receiving Natrecor



Within the subset of patients receiving Natrecor, 85% have Medicare as their primary payer**

* ICD-9-CM diagnosis code 428.XX, denoting various heart failure diagnoses.

** ICD-9-CM procedure code 00.13

FDA Approval

- April 27, 1998 – Scios submitted a New Drug Application (NDA) to the FDA for Natrecor
- FDA had concerns about study design, safety, and clinical results
 - » An FDA Advisory Panel meeting was held on January 29, 1999
- January 10, 2001 – Scios submitted a substantially amended NDA for Natrecor addressing the concerns raised by the FDA
 - » A second FDA Advisory Panel convened on May 25, 2001, to review the amended NDA
- August 1, 2001 – FDA approves Natrecor

Additional Safety Concerns Led to an Independent Advisory Panel and a Physician Education Campaign in 2005

- Scios convened the independent Nesiritide Advisory Panel (NAP) to review safety and efficacy data in June 2005
 - » Of particular concern was the use of Natrecor in the outpatient setting
- The NAP made three recommendations based on their review:
 - » Natrecor should be strictly limited to patients presenting with ADHF with dyspnea at rest in the hospital (FDA labeled indication)
 - » Natrecor should not be administered intermittently in the outpatient setting, on a repetitive basis, to improve renal function, or to enhance diuresis
 - » Scios should proactively educate physicians on the proper use of Natrecor and its risks
 - Drug marketing should be consistent with the education program
- The NAP endorsed the manufacturer's plan to conduct further clinical trials

Questions About the Use, Safety, and Marketing of Natrecor began to appear in Medical Journals and the Popular Press

JAMA

- April 20, 2005
Short-term Risk of Death After Treatment With Nesiritide for Decompensated Heart Failure
- August 24 – 31, 2005
Risk of Death With Nesiritide



- June 14, 2005
J&J Should Restrict Use of Drug For Heart Failure, Experts Say
- July 21, 2005
J&J Unit Gets Subpoena On Natrecor® Marketing

Circulation

- March 29, 2005
Risk of worsening renal function with nesiritide in patients with acutely decompensated heart failure



The NEW ENGLAND JOURNAL of MEDICINE

- July 14, 2005 (response October 6, 2005)
Nesiritide — Not Verified

The New York Times

- May 17, 2005
The Marketing and Success of Natrecor®
- August 9, 2005
Expert Panel Gives Advice That Surprises A Drug Maker
- August 23, 2005
Guidance to Doctors on a Coronary Drug

Trailblazer Requested a National Review for Natrecor Based on Spending for Off-Label Use and Safety Concerns

- Trailblazer Health Enterprises, an influential Part B contractor, requested a national coverage determination (NCD) review in May 2005
- Utilization data illustrated rapid increase in number of services allowed and dollars paid by Medicare Part B contractors
- Trailblazer attributed increased utilization to off-label use in the outpatient setting
 - » Chronic congestive heart failure (CHF) and maintenance therapy (i.e “tune-up therapy”) were thought to be the most common off-label uses
- The NCD request also referenced reports indicating serious adverse consequences associated with Natrecor

■■■ NCD Request also Cited “Aggressive Marketing Practices” by Scios as a Cause for the Increase in Sales

- Allegations that Natrecor was inappropriately marketed for off-label use by the manufacturer
 - » Physicians encouraged to start outpatient infusion centers
- Natrecor Reimbursement Support telephone line had coached providers on filing claims for outpatient Natrecor infusions, spurring accusations that Scios was promoting Natrecor for an unapproved use*

* Saul, Stephanie, “Expert Panel Gives Advice That Surprises A Drug Maker,” The New York Times, August 9, 2005.

■ ■ ■ The Natrecor Decision Resulted in Non-Coverage of Natrecor for “Chronic” CHF

- CMS acknowledged that some studies suggested Natrecor may reduce days of hospitalization and improve symptoms of chronic CHF
 - » However, CMS found that this was not a consistent finding in the clinical literature
- CMS weighed the weaknesses of the literature against “substantial” safety concerns
 - » Determined that the benefits of Natrecor for the treatment of chronic CHF benefits do not outweigh the risks in the Medicare population
- CMS’ decision applies only to off-label use of Natrecor as a treatment for chronic CHF
 - » Does not address current FDA indication of ADHF

Subsequent Local Decision Issued to Assure Adherence to National Policy

- Trailblazer Health Enterprises issued an LCD to define coverage further in its jurisdiction
- The LCD defines the five ICD-9-CM* diagnosis codes for which Natrecor will be covered as reasonable and necessary:
 - » 428.0 – congestive heart failure unspecified
 - » 428.21 – acute systolic heart failure
 - » 428.23 – acute on chronic systolic heart failure
 - » 428.41 – acute combined systolic and diastolic heart failure
 - » 428.43 – acute on chronic combined systolic and diastolic heart failure
- If one of the above ICD-9-CM diagnosis codes does not appear on the claim form, Natrecor will not be covered

* ICD-9-CM = International Classification of Diseases, Ninth Revision, Clinical Modification

Key Takeaways

- Trailblazer requested the NCD based on the following factors:
 - » Increased spending on off-label indications
 - » Concerns over use in the outpatient setting
 - » Safety
- Insufficient data demonstrating clinical benefit, combined with safety profile, were key considerations in CMS' decision to accept the NCD
 - » These factors also led to the final non-coverage decision for chronic CHF
- CMS did not make a reasonable and necessary ruling for the on-label indication, or for other off-label indications
 - » Coverage for these uses remains at contractor discretion
- Scios recently announced selection of the Duke Clinical Research Institute (DCRI) to lead the Acute Study of Clinical Effectiveness of Nesiritide in Decompensated Heart Failure Trial (ASCEND-HF)
 - » Randomized, double-blind, placebo-controlled trial to enroll 7,000 patients at 600 sites worldwide