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Coordination Between FDA and CMS: *Strategic Considerations for Medicare Coverage and Payment, and the Growing Impact of CMS in the Marketplace*

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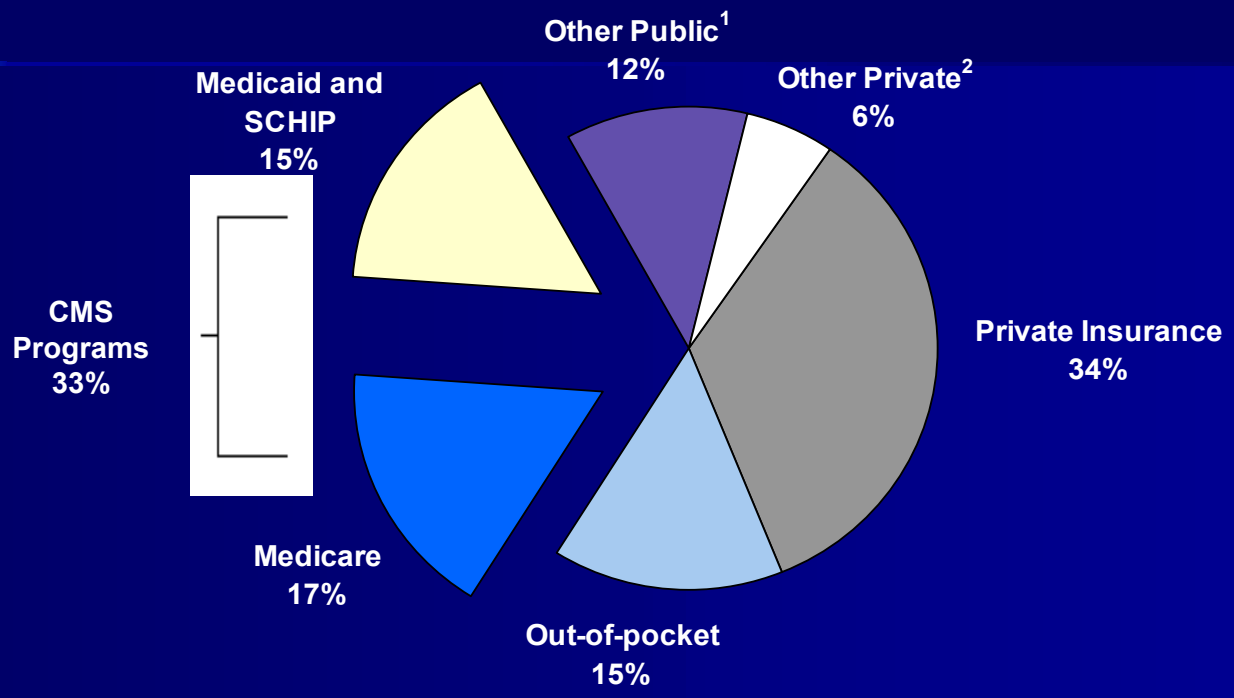
The Nation's Health Dollar, CY 2000

Medicare, Medicaid, and SCHIP account for one-third of national health spending.



Total National Health Spending = $1.3 Trillion

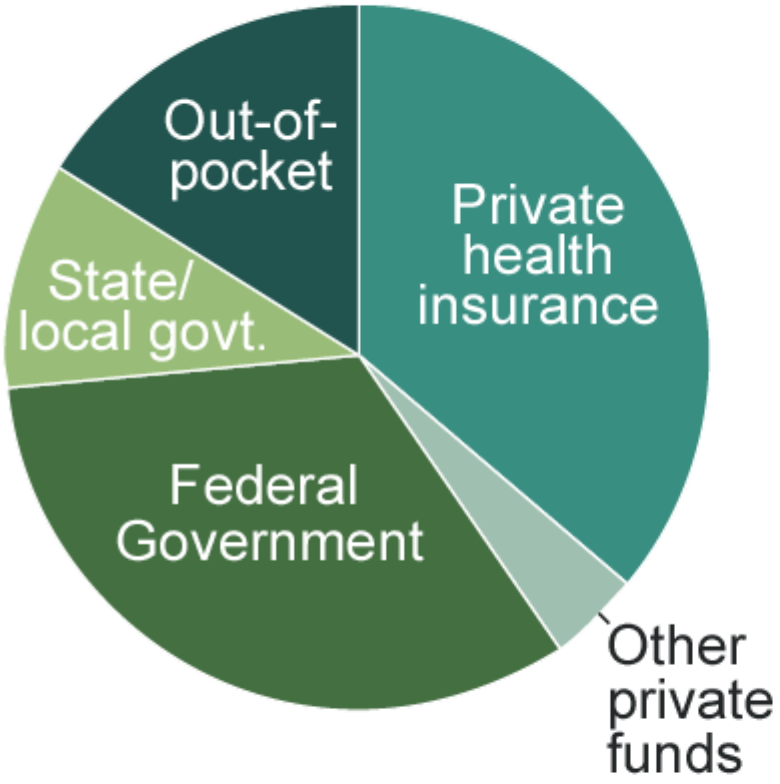
[1] Other public includes programs such as workers' compensation, public health activity, Department of Defense, Department of Veterans Affairs, Indian Health Service, and State and local hospital subsidies and school health.
[2] Other private includes industrial in-plant, privately funded construction, and non-patient revenues, including philanthropy.

Note: Numbers shown may not sum due to rounding.

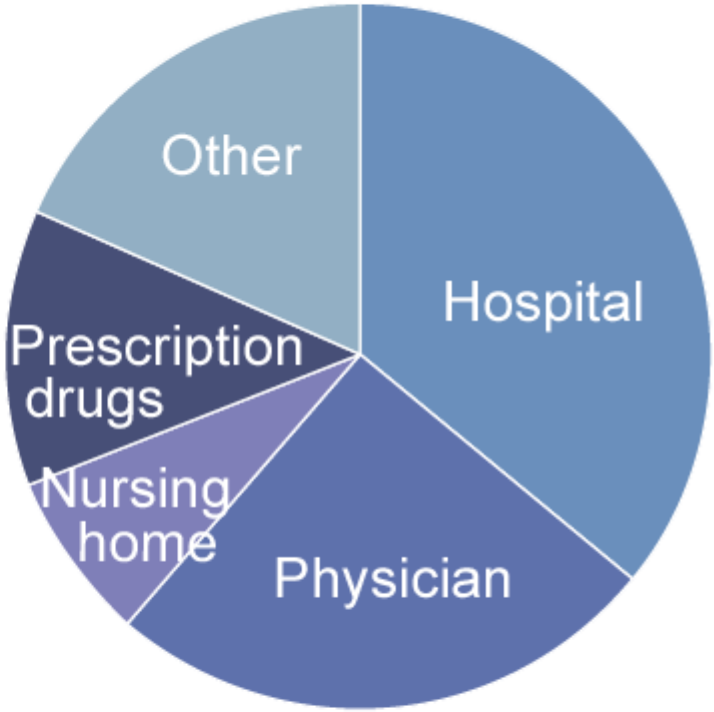
Source: CMS, Office of the Actuary, National Health Statistics Group.

Personal health care expenditures, 2003

Expenditures $1.4 trillion



Source of funds



Type of expenditures

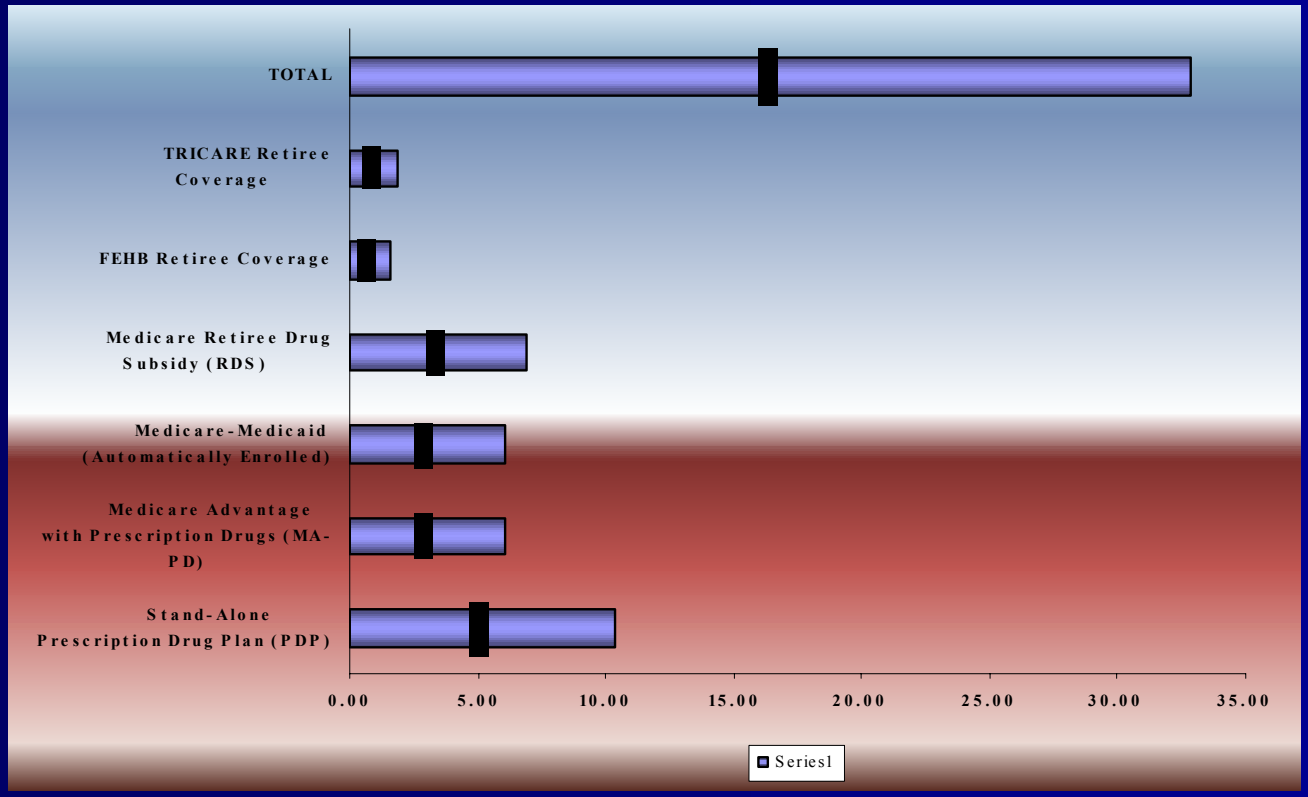
SOURCE: Centers for Disease Control and Prevention, National Center for Health Statistics, *Health, United States, 2005*, figure 9.

Medicare's Impact on the Health Care Market

- **In Fiscal Year 2005, CMS "outlayed" $484.3 billion.**
- **CMS is one of the largest purchasers of health care in the world.**
- **Medicare and Medicaid represent 33 cents of every dollar spent on health care in the United States.**

Source: CMS Financial Report, FY 2005

Medicare Part D Bolsters CMS's Influence on the Health Care Market

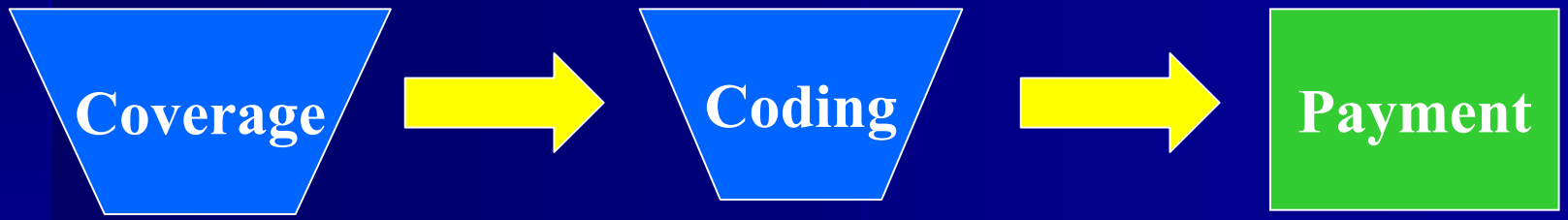


Difference between FDA and CMS Regulatory Review

- **FDA: Safe and Effective**
- **CMS: Reasonable and Medically Necessary for Medicare Population:**

  Data showing improved health outcomes for Medicare beneficiaries over existing treatment or technology
- **CMS: Implicitly looks for value gained from new technology in improving health outcomes for Medicare beneficiaries**

Medicare Coverage, Coding, Payment



When Is a Device or Drug Eligible for Medicare Coverage?

- FDA cleared or approved devices or drugs are "eligible" for Medicare coverage
- Class I or II, Category B device (non-experimental/ investigational)
- Class III, Category A device, possibly, if used in "diagnosis, monitoring, or treatment of an immediate life-threatening disease or condition"
- FDA-approved drugs for treatment of covered illness in Medicare benefit category (Part A or B)

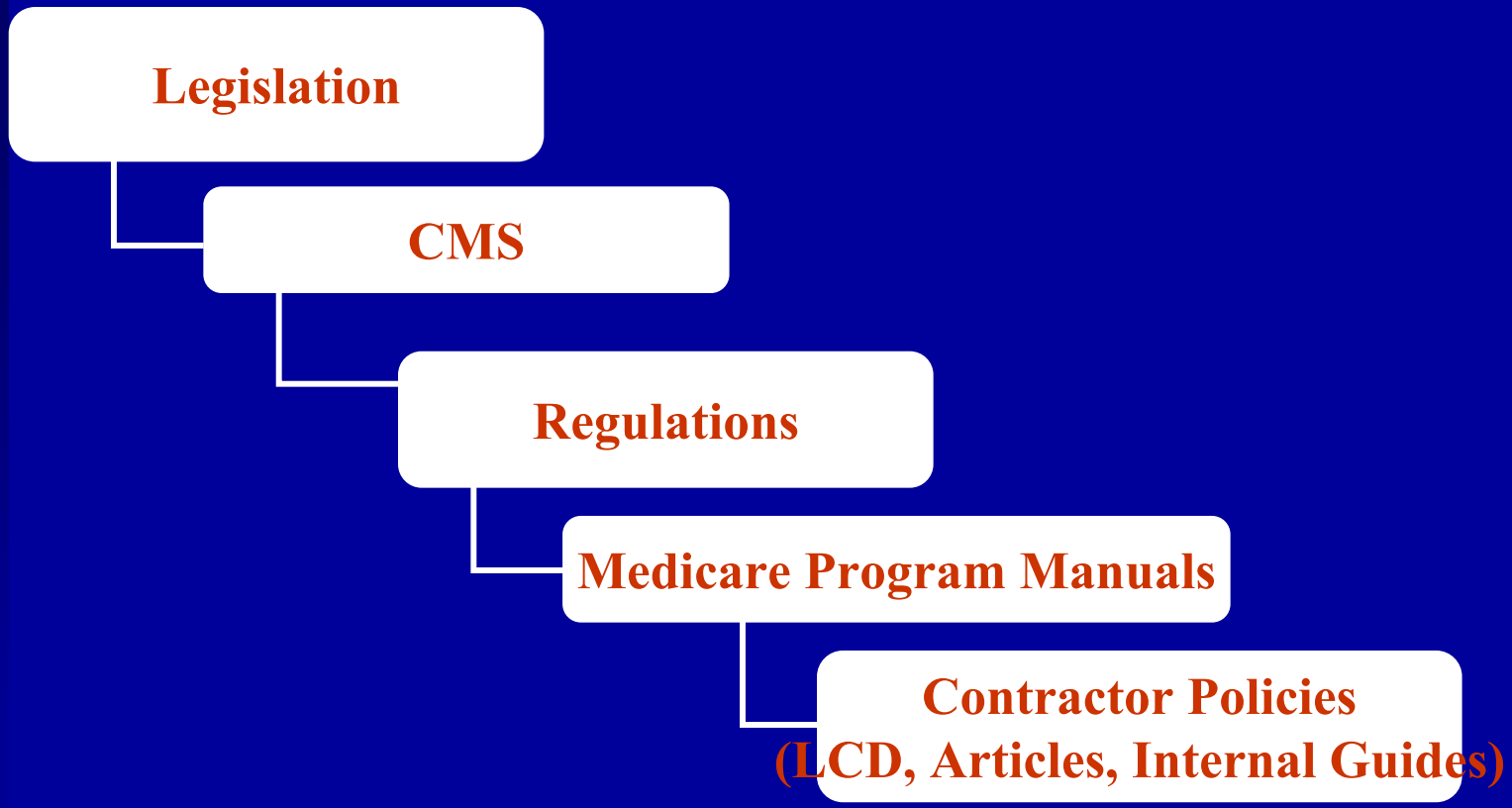
Statutory Coverage Standard

- **"Reasonable and Necessary" (42 USC 1395y(a)): no payment for items . . . which are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member.**

What Is "Reasonable and Necessary?"

- No statutory or regulatory definition of "reasonable and necessary."
- CMS has generally interpreted "reasonable and necessary" to mean that the item should improve health outcomes overall for Medicare beneficiaries.

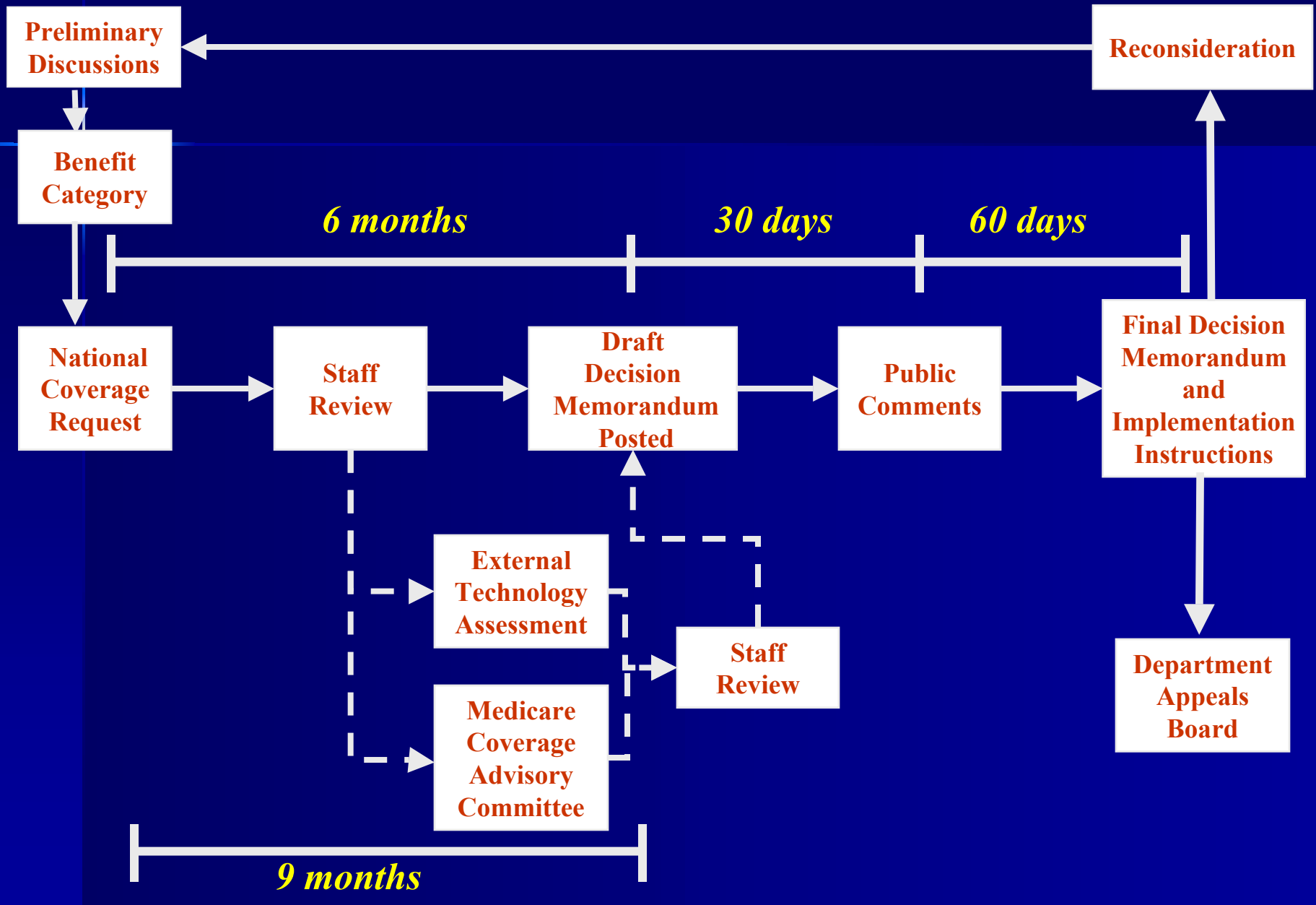
What Guides Coverage and Payment Decisions?



Strategic Considerations for Medicare Coverage

- National Coverage Determination (NCD) versus Local Coverage Determination (LCD)
- Evidence/Clinical Data that shows improvement in health outcomes for Medicare beneficiaries
- Show “value” to Medicare
- Early planning for Medicare coverage
- Assess current Medicare coverage, coding and payment

MEDICARE NATIONAL COVERAGE PROCESS



NCD Versus LCD: Which Is Better?

- **It depends . . . .**

National Coverage Decision

- Medicare Program Integrity Manual, Chapter 13
- National scope/jurisdiction
- NCD (+ or -) = no contractor discretion
- May be initiated internally by CMS or on request
- NCDs binding on: contractors, providers, and ALJs on claims appeals

Local Coverage Decision

- Medicare Program Integrity Manual, Chapter 13
- Focus on what is "reasonable and necessary"
- Limited Scope/Jurisdiction (several states)
- Often reactive rather than proactive: utilization, denial of claims or new technology
- Can Be Overruled by Administrative Law Judge

Premarket Considerations for Medicare Coverage

- **Early Planning: Phase I-III**
  - **Include Medicare population in clinical studies**
  - **cost effectiveness endpoints**
- **FDA Clearance or Approval: 510(k) versus Premarket Approval Application (PMA) review**
- **Meet with CMS**

Premarket Considerations for Medicare Coverage

- 510(k) may: preclude new HCPCS code; place device in existing payment categories; significantly limit payment; or preclude coverage
- PMA may allow you to get separate code, which may lead to better reimbursement
- Informal meeting with CMS may provide guidance: clinical trials and data should show efficacy for Medicare population

Other Coverage Considerations

- Even if no data on effectiveness for Medicare population, there are options:
  - Coverage with Evidence Development:
    - New Coverage Pathways:
    - Coverage with Appropriateness Determination
    - Coverage with Study Participation
  - FDA Phase IV

Coding Considerations

- Healthcare Common Procedure Coding System (HCPCS) Codes: Level I and II
- HCPCS Level I: AMA (five digit code)
- Category III Current Procedural Terminology (CPT-4) Codes: medical procedures and services performed by physicians and other healthcare providers
- CPT Coding Process By AMA : 1+ year process unless your product is covered by an existing code

Coding Considerations

- HCPCS Level II: CMS (five position alphanumeric code)
- Certain medical equipment, drugs, and services when used outside physician's office and not otherwise described in CPT-4 codes
- Examples: C-codes (C2625) (stent); L-codes (L8699) (prosthetic implant n.o.c.); J-codes (J3499)
- Fairly well-defined applications process, but need three months of marketing experience prior to requesting code; exemption for drugs
- HCPCS Application Process by CMS: strategic timing issues

Payment

CMS Payment Systems:

- **Prospective Payment Systems**
- **Fee Schedules**
- **New Technology Considerations**

Payment

- Inpatient Hospital Prospective Payment System (IPPS)
- Diagnosis Related Groups (DRGs)
- Drugs included in DRG
- New technology add-on

Payment

- **IPPS special add-on for new technology:**
  - **CMS must determine that new device is a substantial clinical improvement over current treatments.**
  - **Significant changes likely due to proposed changes to DRGs.**

Payment

- **Hospital Outpatient Prospective Payment System (OPPS) transitional pass-through payment or new APC category for new devices:**
  - **CMS must determine that new device is a substantial clinical improvement over current treatments.**

Payment

- **New Technology APC:**
  - **Intended to provide payment under the OPPS for complete services or procedures that cannot be appropriately billed under an existing HCPCS code or APC.**
  - **Must be "truly new," i.e., inability to describe appropriately, and without redundancy, the complete service with a current individual HCPCS code or combination of codes.**
  - **Must be distinct procedure with a beginning, middle, and end.**

Payment

- New outpatient prescription drugs:
  - Pass-through payment (generally ASP + 6%, unless covered by competitive acquisition contract)
  - Pass-through for 2, but no more than 3 years
  - News drugs that do not qualify for pass-through payment, i.e. nonpass-through, (95% average wholesale price)

Payment

- Medicare Part B: Average Sales Price Methodology for outpatient prescription drugs (generally, ASP + 6%)
- Specified Covered Outpatient Drugs (generally ASP + 6%)
  - Radiopharmaceuticals
  - Drug receiving pass-through payments prior to 2003
- Part D voluntary prescription drug benefit:
  - Government payment to plans
  - Premiums paid by Medicare beneficiaries
  - Part D effect on prescription drug market

Conclusion


Effective Early Planning
Coverage, Coding
Medicare Payment

Thank you!

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