



FDLI & Clinical Device Group

September 7, 2006

Getting CMS Reimbursement for Medical Technology Products

Reimbursement for Medical Technology, Overview of CMS Coverage

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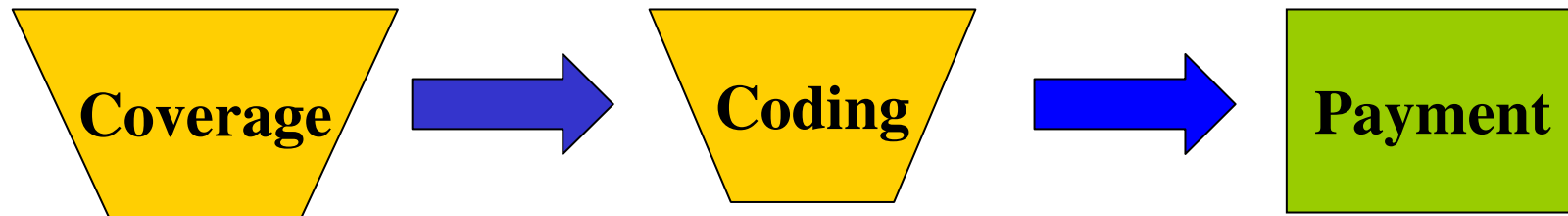
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Difference between FDA and CMS Regulatory Review

- **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





Medicare Benefit Categories

- **Sec. 1812 of Medicare Act, Medicare Part A: Items and services (e.g., supplies, equipment, diagnostic or therapeutic services) provided during covered inpatient hospital stay: inpatient acute hospital, critical access hospital, skilled nursing facility**
- **Sec. 1832 of Medicare Act, Medicare Part B: Outpatient diagnostic and therapeutic services and supplies, items and services provided in physician offices (including “incident to” physician services), durable medical equipment used in the home**



When Is a Device Eligible for Medicare Coverage?

- **FDA cleared Devices are “eligible” for Medicare coverage**
- **IDE or IRB-approved devices; devices used in clinical trials (only routine costs of qualifying trial, but not device)**
- **Class I or II, Category B (non-experimental/investigational)**
- **Class III, Category A, possibly, if used in “diagnosis, monitoring, or treatment of an immediate life-threatening disease or condition”**



Statutory Coverage Standard

- **“Reasonable and Necessary” under Sec. 1862(a)(1) of the Medicare Act: no payment for items and services 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**
- **Statutory Exclusion (Sec. 1862(a)(6) et seq.): no payment for personal comfort items (except in hospice setting), cosmetic surgery (except for prompt repair due to accident)**

What Is “Reasonable and Necessary?”



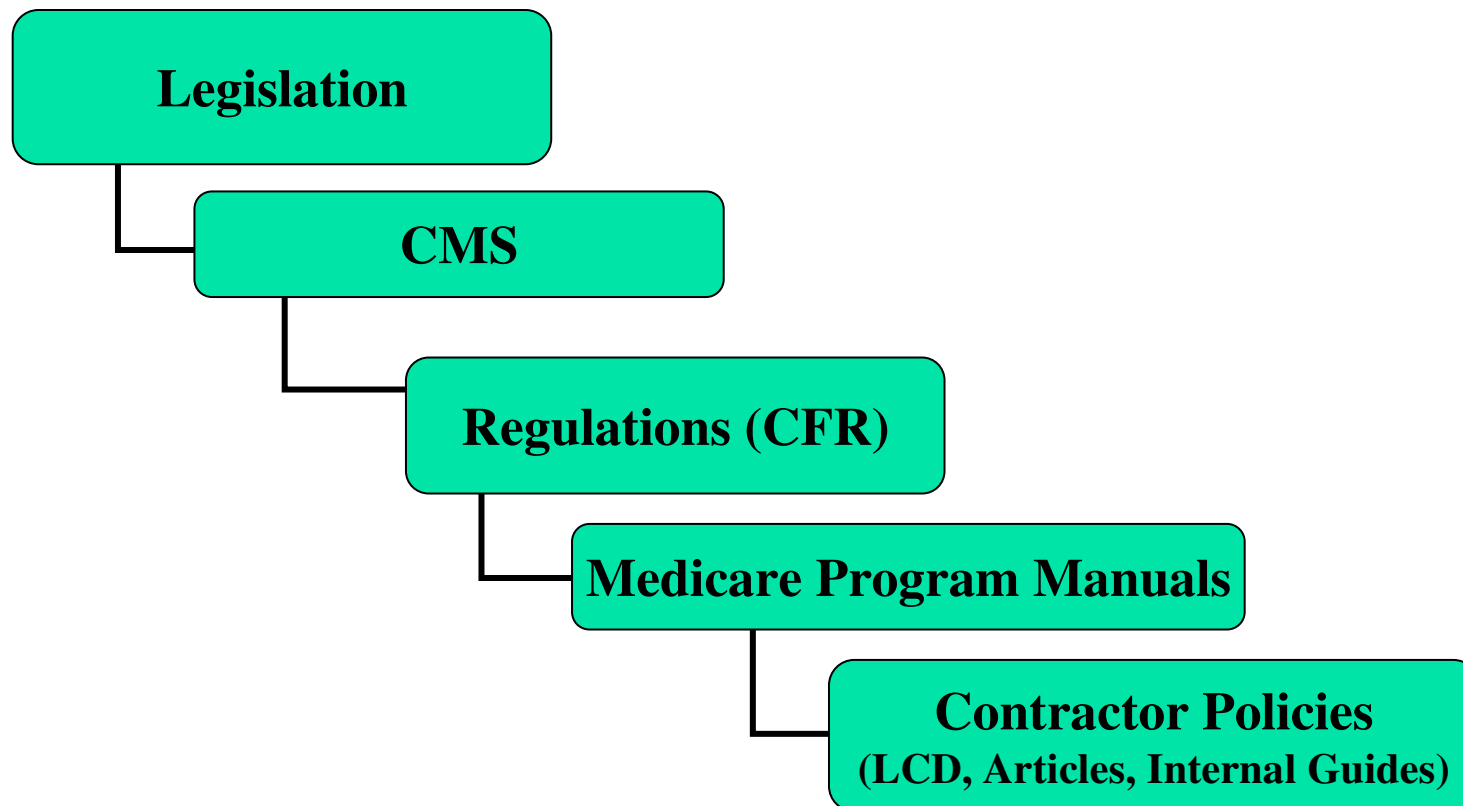
- **No statutory or regulatory definition, but CMS has generally interpreted “reasonable and necessary” to mean that the item or service should improve health outcomes overall for Medicare beneficiaries.**



Who Decides What Is Reasonable and Necessary?

- **CMS and Medicare contractors**
Medicare contractors: Fiscal Intermediaries, Carriers and others

What Guides these Decisions?

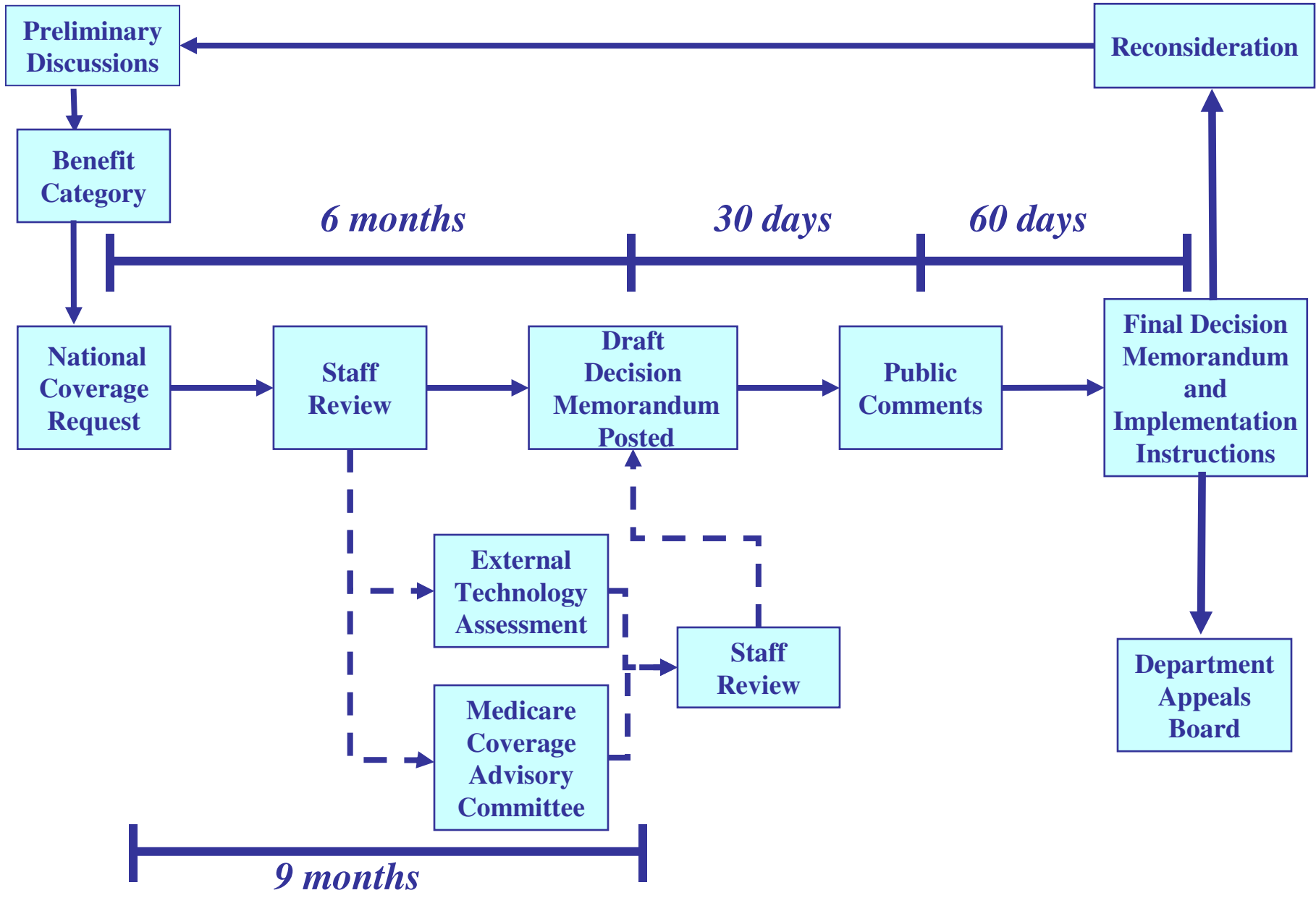




Strategic Considerations for Medicare Coverage

- **National Coverage Determination (NCD) versus Local Coverage Determination (LCD)**
- **Importance of clinical data showing effectiveness in improving health outcomes for Medicare beneficiaries**
- **Importance of early planning if you want Medicare coverage**

MEDICARE NATIONAL COVERAGE PROCESS



NCD Versus LCD: Which Is Better?

- It depends





National Coverage Decision

- **Medicare Program Integrity Manual, Chapter 13**
- **National scope/jurisdiction**
- **No NCD = contractor discretion**
- **NCD (+ or -) = no contractor discretion**
- **May be initiated internally by CMS or on request**



National Coverage Decision

- **May address large or small issues, new technology**
- **NCDs binding on: carriers, providers, and ALJs on claims appeals**
- **Review under 42 CFR Part 426 (by aggrieved party, i.e., Medicare beneficiary)**
- **Medicare Coverage Database**



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
- Review under 42 CFR Part 426 (by aggrieved party, i.e., Medicare beneficiary)



Local Coverage Decision

- **Evidence Considered for LCD new technology:**
 - **Evidence from randomized clinical trials or other definitive studies**
 - **General acceptance by the medical community (standard of practice); however, acceptance by individual health care providers, or even a limited group of health care providers may not suffice**
 - **Scientific data or research studies published in peer-reviewed medical journals**
 - **Consensus of expert medical opinion**

Premarket Considerations for Medicare Coverage

- **Early Planning: Phase I-III**
- **FDA Approval: 510(k) versus Premarket Approval Application (PMA) review**
- **Informal Meeting 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, it's not too late:**
 - **NCD with Restrictions**
 - **Coverage with Evidence Development**
 - **Contractor discretion under LCD if no NCD**
 - **FDA Phase IV**

Payment

- **CMS Payment Systems:
Prospective Payment
Systems, Fee Schedules**
- **New Technology
Considerations**





Payment

- **Inpatient Hospital Prospective Payment System (IPPS)**
- **Diagnosis Related Groups (DRGs)**
- **New technology add-on**
 - **42 CFR Part 412**
 - **CMS Guidance**



Payment

- **IPPS special add-on for new technology:**
 - **CMS must determine that new technology is a substantial clinical improvement relative to current or previous diagnosis or treatment**
 - **Data reflecting the cost of new technology must not yet be available in the data used to recalibrate the DRGs**
 - **DRG payment rate otherwise applicable to the new technology would be inadequate (i.e., average charges for cases using the new technology will be in excess of the amount determined by CMS formula)**



Payment

- **Cost Criteria**
- **Threshold: charges for new technology exceed the lesser of:**
 - **75 % of standardized amount for DRG or**
 - **75% of one standard deviation for DRG involved.**



Payment

- **New Technology Add-On Payment Amount:**
 - **Full DRG payment, plus the lesser of:**
 - **50 % of the amount by which the hospital costs to use new technology exceed standard DRG; or**
 - **50% of the costs of new technology**



Payment

- **Hospital Outpatient Prospective Payment System (OPPS) transitional pass-through payment for drugs, biologics or devices, or new APC category for new devices:**
 - **42 CFR Part 419**
 - **CMS must determine that there is a substantial clinical improvement over current treatments**



Payment

- **Transitional pass-through payment for new technology (at least 2, no more than 3 years):**
 - **Must meet “new” criteria**
 - **Must meet “not insignificant” cost criteria**



Payment

Cost Criteria

- **Drugs and biologics**

- **Estimated average reasonable cost > 10% of applicable APC payment amount**
- **Estimated average reasonable cost exceeds drug or biologic portion of APC payment amount by at least 25%**
- **Difference between estimated average reasonable cost and APC payment amount > 10% of APC payment amount for related service**



Payment

Cost Criteria

- **Medical Devices**
 - **Estimated average reasonable cost of devices in APC > 25% of applicable APC payment for relevant procedure, and exceeds cost of device-related portion of APC payment by at least 25%**
 - **Difference between estimated average reasonable cost of devices in APC and device portion of APC payment amount > 10% of APC payment amount for related service**
- **Exclusion of certain items**



Payment

Amount of Pass-through payment

- **Drugs or Biologics:**

- **Generally, ASP + 6%, minus drug or biologic portion of APC payment amount**

- **Medical Devices:**

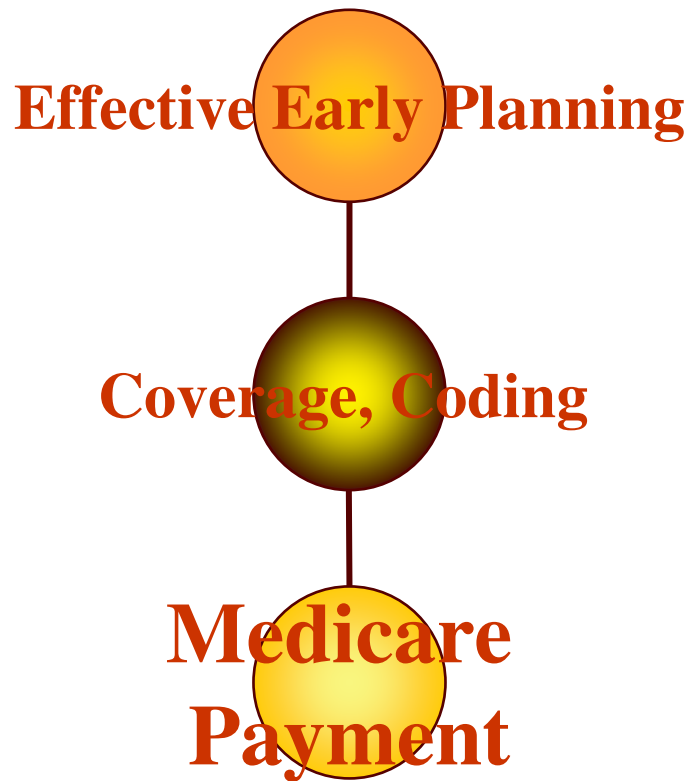
- **Hospital's charge, adjusted to actual cost, minus APC payment amount for device**



Payment

- **New Technology APC category:**
 - **Intended for complete services/procedures that cannot be appropriately billed under an existing HCPCS code or APC**
 - **Must be “truly new”**
 - **Must be distinct procedure with a beginning, middle, and end**
 - **Not appropriate for drugs, biologics or devices that could qualify for pass-through payment under OPPS**

Conclusion





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Thank you!

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