

MEDICARE NATIONAL COVERAGE DETERMINATIONS

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Informational Needs

- Should we pay for this service? = Coverage
- Did we pay for the correct service correctly? = Payment
- Was the service we paid for performed optimally? = Quality

Steps to Coverage Determination and Payment

Outside of CMS:

- FDA approves drugs/devices for market
- Congress determines benefit categories

Within CMS:

- Coverage
- Coding
- Payment

CMS' Legal Authority for Coverage

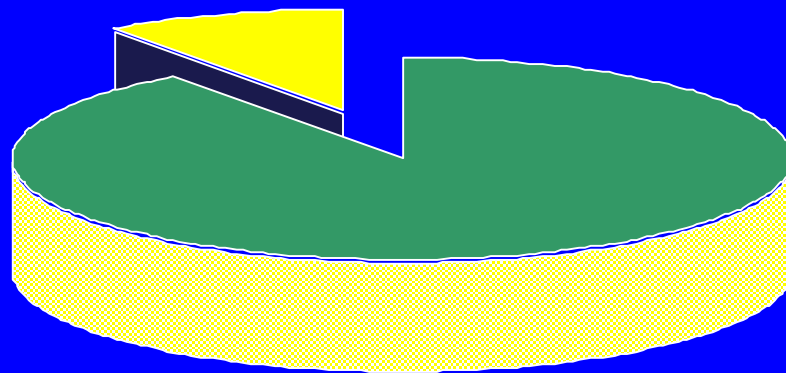
Section 1862(a)(1)(A)

No payment for item or service, unless

- *reasonable and necessary*
 - Diagnosis/treatment of illness or injury, or
 - to improve the function of a malformed body member

Most Coverage is Local

National
10%



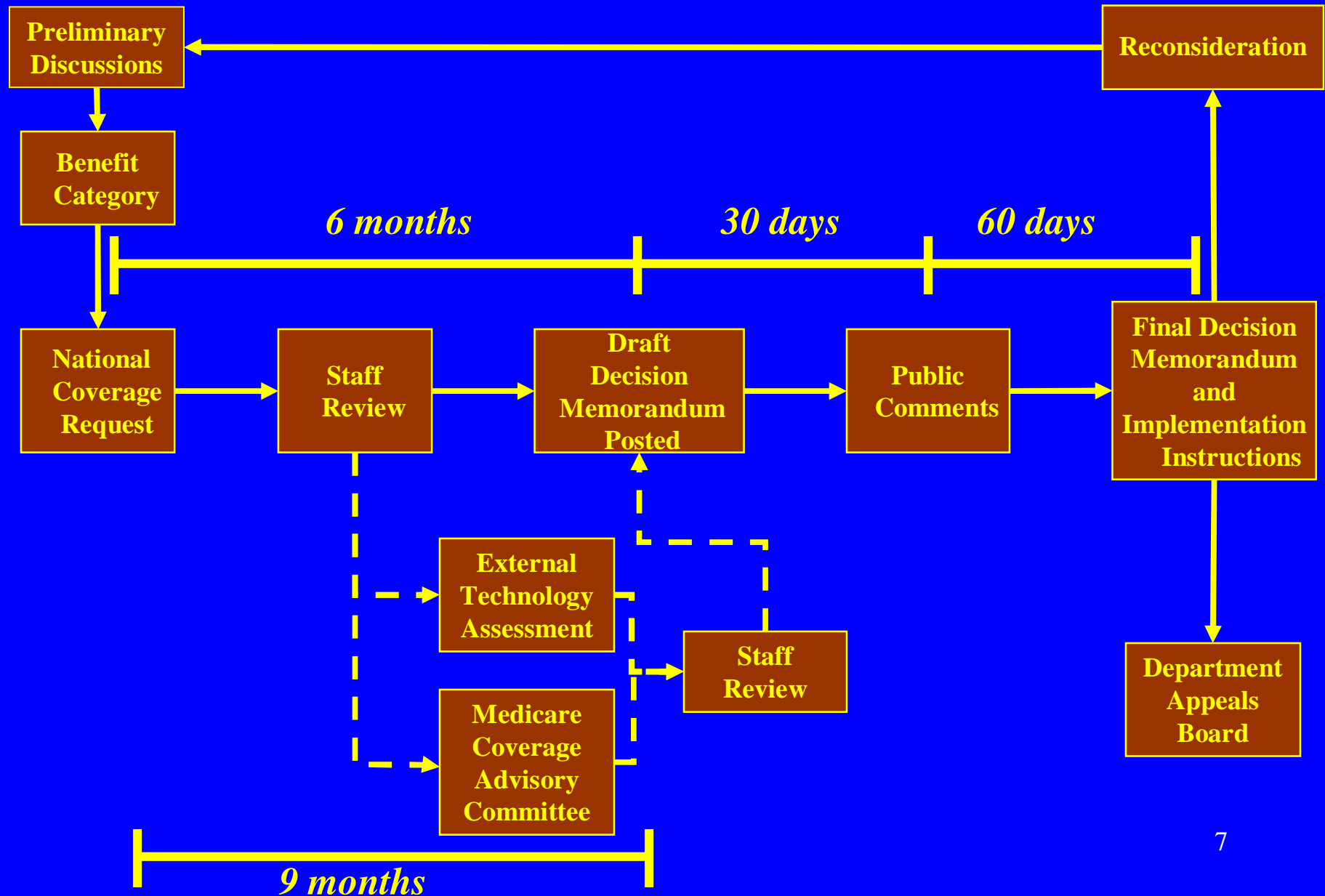
Local
90%

Local
National

What prompts NCDs?

- External request
 - Current national non-coverage policy
 - Substantial variation/disagreement among different Medicare contractors about coverage
- Internally generated
 - Extensive literature or important new study
 - Technological advance with potential major clinical or economic impact
 - Concerns about major inappropriate use

MEDICARE NATIONAL COVERAGE PROCESS



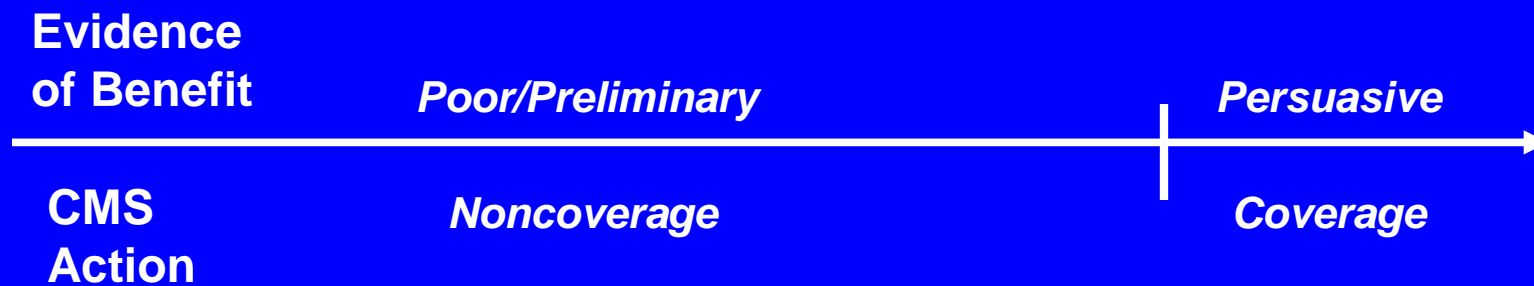
National Decisions

- National Coverage
- National Noncoverage
- National Coverage with restrictions
 - Specific populations
 - Specific providers/facilities

Reasonable & Necessary

- Sufficient level of confidence that evidence demonstrates that the item or service:
 - improves net health outcomes
 - generalizable to the Medicare population
 - generalizable to general provider community

Evidentiary Standard



What standards are used in an NCD?

- Evidence of improved health outcomes
- Appropriate for Medicare population
- Could be replicated in provider community

Evidence Based Medicine Definition

“...Evidence-based medicine de-emphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research.”

Evidence-Based Medicine Working Group, JAMA (1992)

Why base coverage on EBM?

- Lower quality studies are more likely to be wrong
 - e.g. HRT and heart disease, ABMT for breast cancer
- Deductions from basic biology and pathophysiology may be unreliable
- If something doesn't work, we should not spend money on it, even if it is not harmful
- Concentrate resources on things that improve health
- Physicians and patients can make informed choices about treatment
- Allows open, explicit, consistent coverage decisions

Why not rely solely on doctors and experts?

- Assessing effectiveness through intuition has proven unreliable
- Data shows imperfect practice
 - wide geographic variations
 - high rates of inappropriate careFactors other than clinical may influence

National Decisions

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Population
Provider/Facility
Restrictions

Facility Standards

- Lung Volume Reduction Surgery
- Carotid Stents
- Bariatric Surgery
- Left Ventricular Assist Devices (LVADs)

*Coverage with Evidence
Development
(CED)*

CED Objectives

- Goal is to promote innovation while obtaining value in health care
- Prompt coverage serves to speed access to promising new technology
- Studies can improve evidence available to patients, clinicians, policymakers
- Hope to better target treatments to subpopulations with greatest benefit

Recent CED Decisions

- PET scans for Alzheimer
- Colorectal Cancer drugs
- Cochlear implants
- ICDs
- PET scans for oncology indications

CED Status

- Initial draft guidance document – Spring 2005
- Q&A's – Summer 2005
- 2nd draft guidance document – Spring 2006

NCD Process

- Fast decisions
- Transparent process
- Flexible coverage options
- Minimal burden

Contact Information

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