



**Working with Regulators: A Focus on CMS**  
An Educational Program of the  
Cancer Policy Institute at the Cancer Support Community  
in Partnership with Uniting a Community (UaC):  
Policy, Advocacy, Education and Action Network



# Medicare's National Coverage Determination Process

<http://www.cms.gov/medicare-coverage-database/>

# NCD Definitions in SSA

1862(l)(6) National and local coverage determination defined.—For purposes of this subsection—

(A) National coverage determination.—The term “national coverage determination” means a determination by the Secretary with respect to whether or not **a particular item or service** is covered nationally under this title

# What is a Covered Service?

Generally, an item or service:

- which, if subject to FDA review, has been approved or cleared for at least one indication;
- which falls within a Medicare Benefit Category (generally found in §1861 of the Act);
- which is not statutorily excluded based on §1862(a)(2)-(15) of the Act;
- which is reasonable and necessary based on §1862(a)(1)

# Reasonable & Necessary

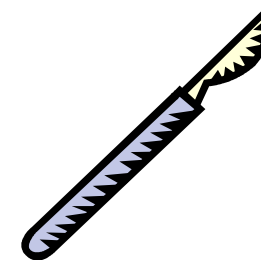
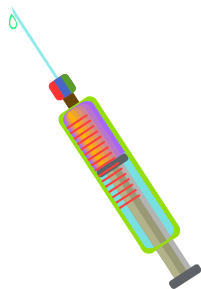
- Sufficient level of confidence that the evidence is adequate to conclude that the item or service:
  - Improves health outcomes
  - Is generalizable to the Medicare population
  - Is generalizable to general provider community

PATIENT



Usual Workup

Workup + New Test



Usual Therapy

Different Therapy

Better Outcome

Usual Outcome

Worse Outcome

# The Preferred Road to Diagnostic and Therapeutic Coverage

## Diagnostic

- ✓ Provide adequate evidence that
- ✓ The incremental information obtained by new diagnostic technology compared to alternatives
- ✓ Changes physician recommendations
- ✓ Resulting in changes in therapy
- ✓ That improve clinically meaningful health outcomes
- ✓ In Medicare beneficiaries

## Therapeutic

- ✓ Provide adequate evidence that
- ✓ The new therapeutic intervention compared to alternatives
- ✓ Results in improve clinically meaningful health outcomes
- In Medicare beneficiaries

# Health Outcomes of Interest

## *More Impressive*

- Longer life and improved function/participation
- Longer life with arrested decline
- Significant symptom improvement allowing better function/participation
- Reduced need for burdensome tests and treatments

## *Less Impressive*

- Longer life with declining function/participation
- Improved disease-specific survival without improved overall survival
- Surrogate test result better
- Image looks better
- Doctor feels confident

*Medicare has stated publicly that as a matter of policy that it does not generally consider cost in making national coverage determinations.*



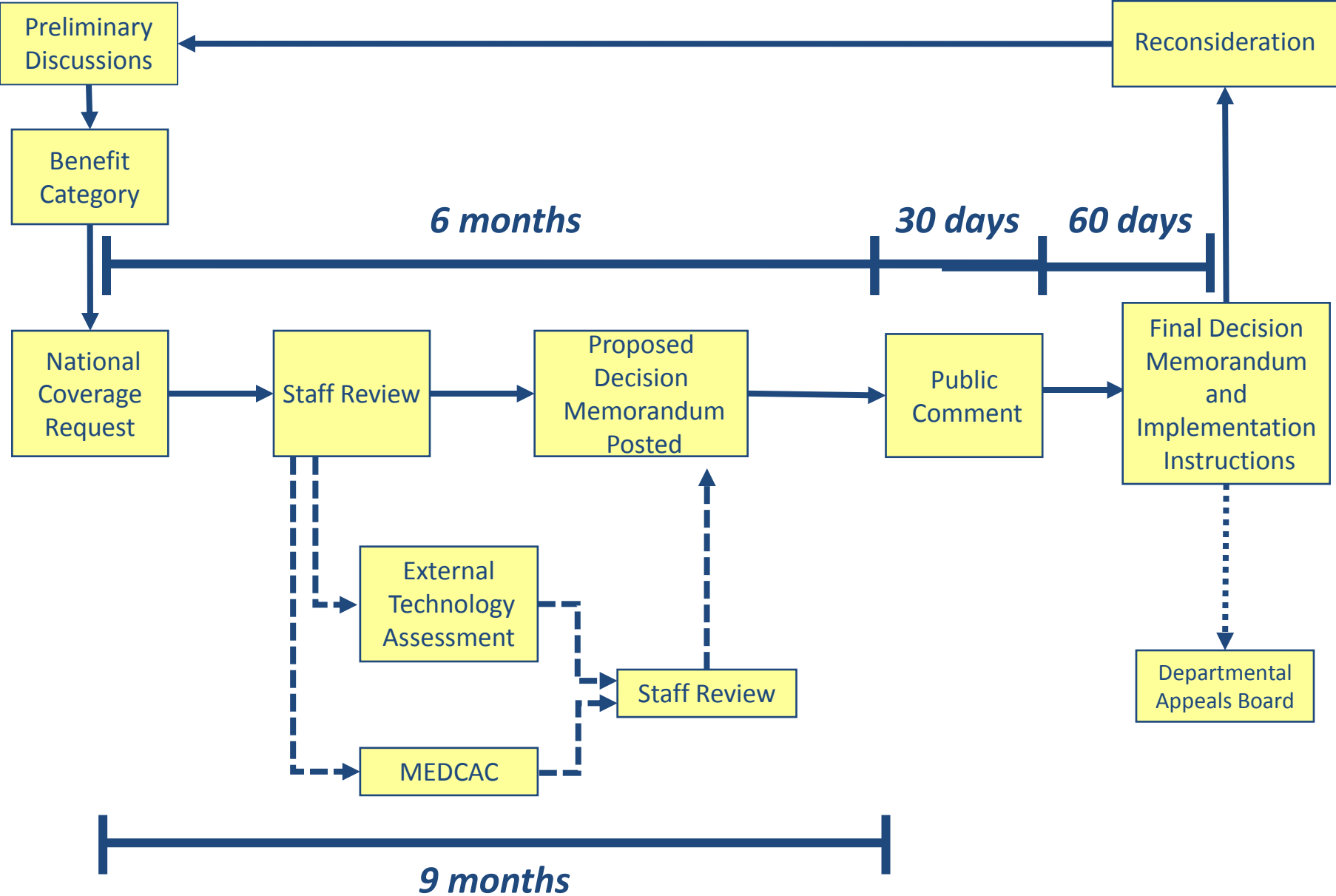
# What prompts NCDs?

- External request (statutory)
  - Current national non-coverage policy
  - Substantial LCD variation
- Internally generated
  - Extensive literature or important new study
  - Technological advance with potential major clinical or economic impact
  - Major concerns about inappropriate use

# NCD Process

- Formal Request (30 day comment period)
- Benefit Category Determination
- Review of evidence by CMS
- Technology Assessment/MEDCAC
- Proposed Determination (30 day comment period)
- Final Determination posted on CMS Web site 60 days later

# MEDICARE NATIONAL COVERAGE PROCESS



# Evidence for NCDs

- **Medical Literature**

  - Peer Reviewed Journal

  - Medical texts

- **Technology Assessments thru AHRQ**

  - Evidence Based Practice Centers

- **Medicare Evidence Development and Coverage Advisory Committee (MEDCAC)**

# **MEDCAC**

## **Medicare Evidence Development Coverage Advisory Committee**

- **Meets on controversial issues**
- **Votes only on the quality of the evidence  
and not on a coverage determination**
- **Not necessarily on NCDs**
  - **Usual Care of Chronic Wounds 2006**

# Evidence Deficits

- No evidence
- Standard measures missing
- Short term follow-up to studies
- Lack of comparative effectiveness
- Generalizability for Medicare beneficiaries

# National Coverage Determinations

- National Coverage
- National Non-Coverage
- National Coverage with Limitations
- Contractor Discretion

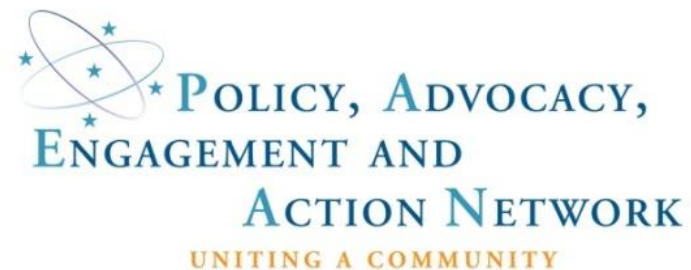
# Reconsideration of NCD

- An NCD Reconsideration may be requested when:

An NCD currently exists, any individual or entity may request that we reconsider any provision of that NCD by filing an acceptable request for an NCD reconsideration.

- 1) Additional material medical and/or scientific information that was not considered during the initial review, that is, results from new clinical trials, new scientific or medical publications, or studies supporting the request
- 1) Arguments that our conclusion materially misinterpreted the existing evidence at the time the NCD was made.





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