

# CMS Coverage Perspective Diagnostic Tests

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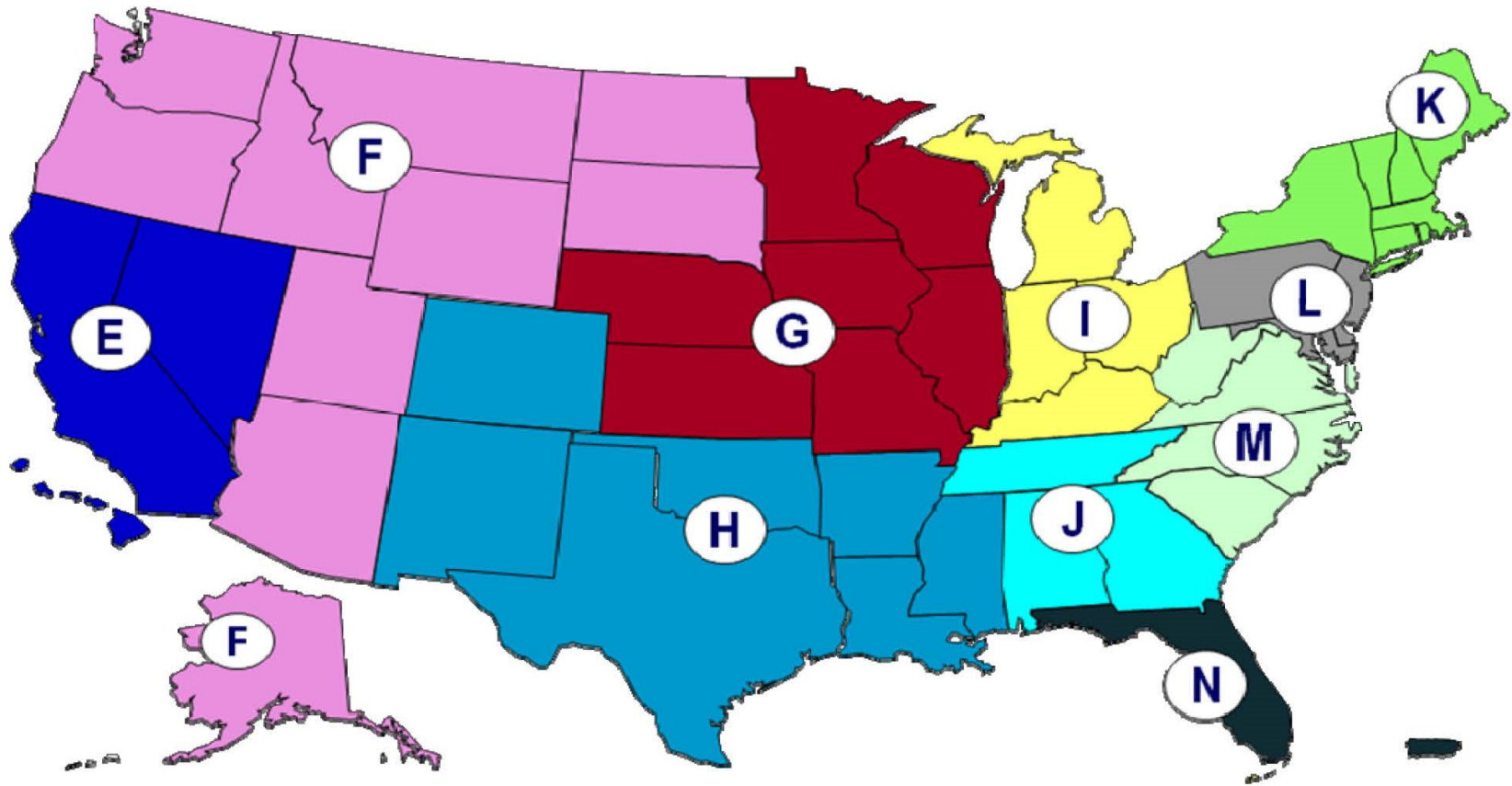
Coverage and Analysis Group



## Overview

- A national program with local administration
  - Medicare Administrative Contractors (MACs)
  - Other contractor types (e.g. RACs, appeals)
- Coverage decisions
  - Local Decisions
    - Claim by claim at the local level
    - Local coverage determination (LCD)
      - Articles
  - National Decisions
    - National coverage determination (NCD)
    - Regulation

# Consolidated A/B MAC Jurisdictions



# Coverage Process Comparison

## Local

- Process in CMS manual
- Publishes proposed LCD (45 public comment)
  - Open Meeting
  - Carrier Advisory Committee at least 3x/year (part B only)
- Final LCD (45 days notice prior to effective date)
- Claim by claim adjudication

## National

- Statutory and Federal Register Notice
- Tracking Sheet (30 day public comment)
- Proposed decision (30 day public comment)
- Final Decision (effective immediately)

### OPTIONAL (+ 3 months)

- Medicare Evidence Development & Coverage Advisory Committee (MEDCAC)
- External Technology Assessment

## Statutory Differences

### LCDs

**Definition:** Determination by a Medicare Administrative Contractor (MAC) respecting whether or not a particular item or service is covered on an MAC-wide basis, in accordance with section 1862(a)(1)(A).

(1862(a)(1)(A)): reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member 8\*\*\*

Coverage with Evidence Development (CED):  
??

Prevention/Screening: No authority

### NCDs

**Definition:** determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title.

1862(a)(1)(A) +

CED: 1862(a)(1)(E) in the case of research conducted pursuant to section 1142, which is not reasonable and necessary to carry out the purposes of that section, \*\*\*

Prevention/Screening: Reasonable and necessary for the prevention or early detection of illness or disability

## LCDs and NCDs – Similarities

- Eligible for Medicare coverage: 1) FDA approval/clearance; 2) statutory category (i.e., benefit category (1861); not statutorily excluded (e.g., eyeglasses, hearing aids)
- Statutory Authority (1862(a)(1)(A)): reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member .....
- **Part A and Part B** (FFS Medicare): Binding.
- **Part C** (Medicare Advantage plans): Covers any items and services covered under NCDs and LCDs (in jurisdiction).
- **Part D**: Self-administered drugs. Generally not applicable.

## Social Security Act 1862(a)(1)

Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—

(A) which, except for items and services described in a succeeding subparagraph or additional preventive services (as described in section 1395x(ddd)(1) of this title), are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,

\*\*\*

(E) in the case of research conducted pursuant to section 1142, which is not reasonable and necessary to carry out the purposes of that section,

\*\*\*



## What is the definition of R&N?

- Congress has not defined it in statute.
- Attempted unsuccessfully to define via rulemaking in 1989 and 2000.
- Explored attempting rulemaking again, but there has been no traction.
- For practical uses, CMS has operationalized the following definition:

*Adequate evidence to conclude that the item or service improves clinically meaningful health outcomes for the Medicare population*





## Local vs. National Coverage Differences

### Local

- Apply only in MAC jurisdiction
- LCDs can be overturned by ALJs
- Allow initial diffusion of innovations
  - learning curve with new tech
- Responsive to community care standards
- Allow regional flexibility / variation in policy

### National

- Applies nationally
- ALJs have no jurisdiction
- Departmental Appeals Board
- Less flexibility

## CMS Challenge

- NIH voluntary registry
  - 12,000 tests/4,000 diagnosis
- Current system
  - Not clear what Medicare was paying

## Diagnosics Coverage Criteria

- Screening tests
  - Unique statutory requirements
  - Only via a national coverage determination (NCD)
  - Reasonable and necessary for the prevention or early detection of illness or disability.
  
- Diagnostic tests:
  - Results of test must be used in the management of beneficiary specific medical problem (42 CFR 410.32)
  - reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member

## Some Diagnostic Questions

- What data does it generate?
- What clinical information do the data provide?
- (How) Have we gotten this information before (from other sources) ?
- What (different) decisions are made based on this information?
- What are the advantages/disadvantages of basing decisions on this new test?

## What we tried : Palmetto Molecular Diagnostic pilot project

- Under the MOLDx program, Palmetto GBA requires that labs obtain a unique identifier (Z-code™) for each molecular assay. The Z-code will be applied in the claim line narrative/comment field for each code stack or NOC code.
- Clinical laboratories are required to submit the scientific data to support “reasonable and necessary.” Palmetto GBA will review and approve all molecular diagnostic tests with the help of subject matter experts, and publish a tech assessment summary.

## Where that got us

- Lots of complaints
  - No public comment
  - No appeals
  - No transparency
  - Screening non-coverage – what about the diagnostic aspect?

## The Protecting Access to Medicare Act (PAMA)

- Signed into law: April 1, 2014
- Beginning January 1, 2015, a Medicare Administrative Contractors (MAC) shall only issue a coverage policy for a clinical diagnostic laboratory test in accordance with the **local coverage determination (LCD)** process.
  - This does not change the ability to obtain coverage through the national coverage determination (NCD) process.
- Additionally, the Secretary may designate one or more (not to exceed 4) MACs to establish coverage policies and/or payment processes.

## Future?

- Process must be:
  - Open and transparent process
    - Public comment on proposed decision
  - Preserve Appeal rights
- Need appropriate evidence
  - Clinical utility
    - What should that mean for Medicare?
  - Lab developed tests vs. FDA approved/cleared tests
    - Easier CMS path for one?



