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National Coverage Analysis

Introduction to Medicare

drugs, diagnostics, and healthcare services

Objectives

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Disclosures: Katherine B. Szarama, PhD

The Global Cancer Clinical Research, Drug Development and Therapeutic Accessibility Workshop: The Role of Health Authority Insurance on Access

I have no financial relationships to disclose.

I will discuss general off-label and/or investigational use in my presentation.

Summarize the processes used by the Agency to develop coverage determinations, technology assessments, and payment policies.

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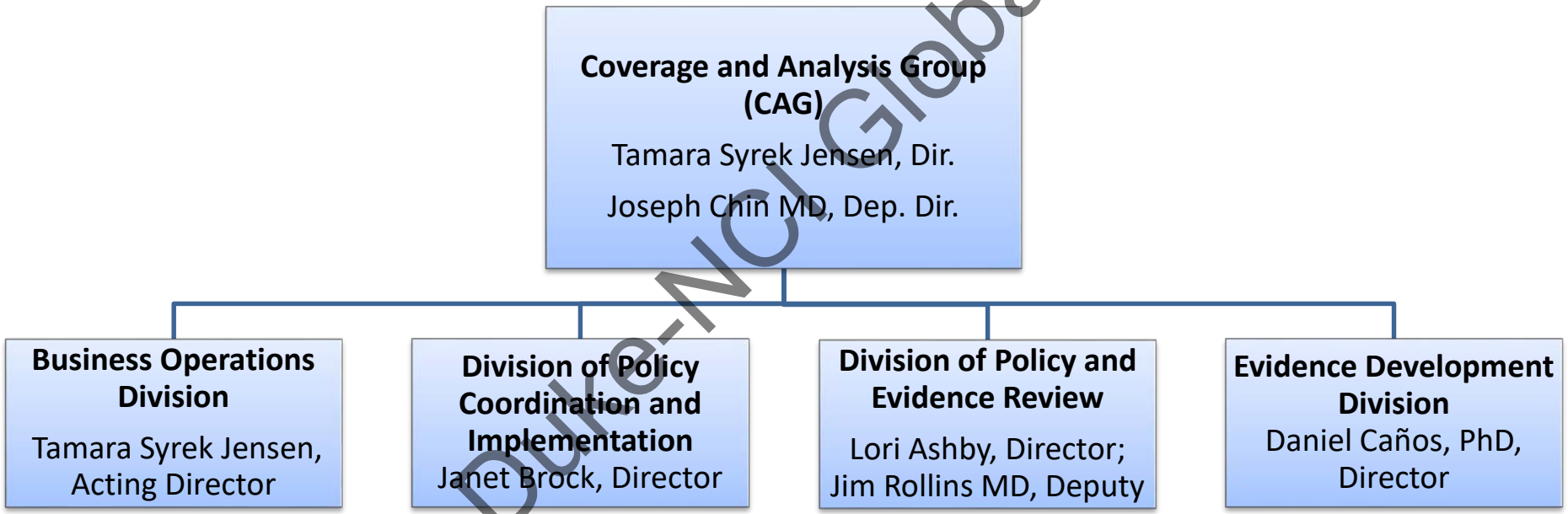

Requirements for Medicare Payment

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1. Item or service must be legal.
2. Congress must have given benefit category for the item or service.
3. Item or service must be reasonable and necessary (coverage).
4. Coding & payment instructions needed.

Benefit Category

Congress defined both specific and broad benefit categories

- 1861(b) Social Security Act: inpatient hospital services

- 1861(t): drugs and biologicals included in
  - US Pharmacopoeia / Homeopathic Pharmacopoeia
  - National Formulary
  - pharmacy approval of the hospital furnishing for use in such hospital.
- any drugs or biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication.

- On December 8, 2003, Congress amended the Social Security Act to provide for a voluntary program for prescription drug coverage.

Coverage

- 1862(a)(1)(A): no payment may be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.

- 1862(a)(1)(E): items or services which are reasonable and necessary for research conducted with respect to
  - outcomes, effectiveness, and appropriateness
  - health care services and procedures
  - identify the diseases, disorders, and other health conditions that can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically

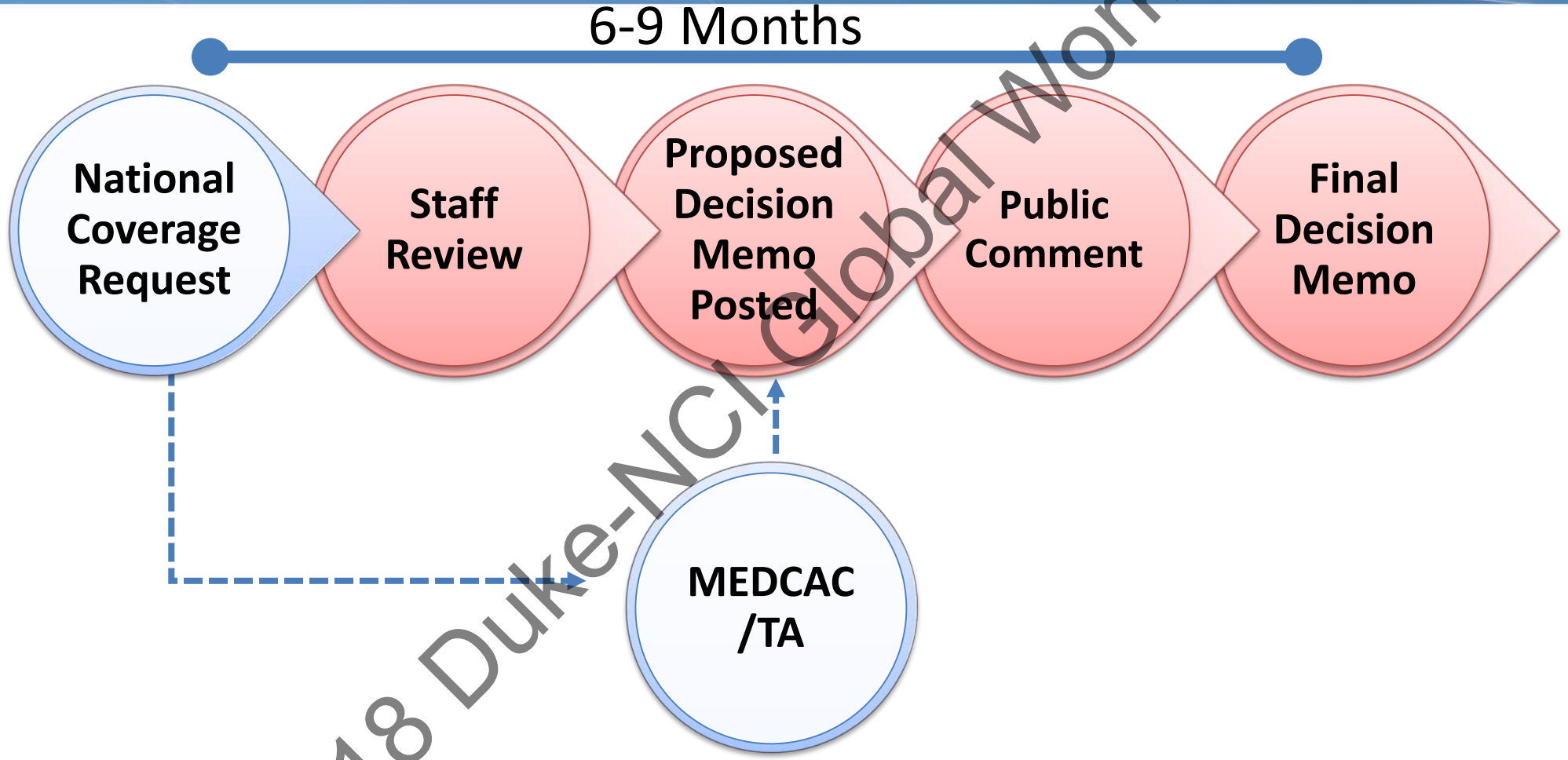
Coverage

- Healthcare services: Adequate evidence to conclude that the item or service improves health outcomes.
  - Emphasis of outcomes experienced by patients
  - Generalizable to the Medicare population

  – Drugs: any use approved by the Food and Drug Administration, and another use supported by authoritative compendia.

  – Diagnostics: assess clinical utility.
    - Hierarchical framework of Fryback and Thornbury (1991)
    - Evaluate using ACCE Model Process (2003)

Medicare National Coverage Process



MEDCAC

Medicare Evidence Development & Coverage Advisory Committee

- Provide independent guidance and expert advice to CMS on specific clinical topics.
- Topics referred when CMS would like independent expert advice in making decisions based upon the reasoned application of scientific evidence.

- All meetings (4-6/yr.) are public.
- 13-15 members serve at any one meeting.
- one consumer representative, one industry representative, and one patient advocate to participate at every meeting.

Public Comment Period

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The Medicare Prescription Drug, Improvement, & Modernization Act:

- Proposed decision shall be made available for public comment.
- Comment period shall last 30 days.
- Final decision issued not later than 60 days after the conclusion of the comment period.
- A summary of the public comments received and responses to the comments included in the final NCD.

Decision Summary

A. Coverage

- The Centers for Medicare & Medicaid Services (CMS) has determined that Next Generation Sequencing (NGS) as a diagnostic laboratory test is reasonable and necessary and covered nationally, when performed in a CLIA-certified laboratory, when ordered by a treating physician and when all of the following requirements are met:

Decision Summary

A. Coverage

1. Patient has:
   a. either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer; and
   b. either not been previously tested using the same NGS test for the same primary diagnosis of cancer or repeat testing using the same NGS test only when a new primary cancer diagnosis is made by the treating physician; and
   c. decided to seek further cancer treatment (e.g., therapeutic chemotherapy).

Decision Summary

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A. Coverage

2. The diagnostic laboratory test using NGS must have:
   a. FDA approval or clearance as a companion in vitro diagnostic; and
   b. an FDA approved or cleared indication for use in that patient's cancer; and
   c. results provided to the treating physician for management of the patient using a report template to specify treatment options.

Decision Summary

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B. Other

Medicare Administrative Contractors (MACs) may determine coverage for patients with cancer only when the patient has:

- either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer; and
- either not been previously tested using the same NGS test for the same primary diagnosis of cancer or repeat testing using the same NGS test only when a new primary cancer diagnosis is made by the treating physician; and
- decided to seek further cancer treatment (e.g., therapeutic chemotherapy).

Coding & Payment

- Payments are made based on fee schedules and payment systems.
- Priced codes are necessary for payment.
- Example, diagnostic laboratory tests may be paid using the
  - Physician Fee Schedule (PFS); or
  - Clinical Laboratory Fee Schedule (CLFS).

Clinical Laboratory Fee Schedule

- Payment is lower of the amount established in contractor region, the national price if established, or the billed amount.

- Contractor pricing includes:

  – Crosswalking – Use price of an existing code that is conducted using the same or a similar methodology

  – Gapfilling – For codes that are truly novel and dissimilar to other codes already being paid under the CLFS. Requires data on actual costs.

Updating Payment Rates

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Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), requires laboratories performing clinical diagnostic laboratory tests to report the amounts paid by private insurers for laboratory tests. Medicare will use these private insurer rates to calculate Medicare payment rates for laboratory tests paid under the Clinical Laboratory Fee Schedule (CLFS) beginning January 1, 2018.

PAMA and ADLTs

- Per statute, Medicare will pay actual list charge for a special category of advanced diagnostic laboratory tests (ADLTs)

1. an analysis of RNA, DNA or proteins; include a unique algorithm; produce a result that predicts the probability a specific individual patient will develop a certain condition or respond to a particular therapy; and provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests.

2. cleared or approved by the U.S. Food and Drug Administration.

For more information

- https://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center.html
- https://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=290
- https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Advanced-Diagnostic-Laboratory-Tests.html