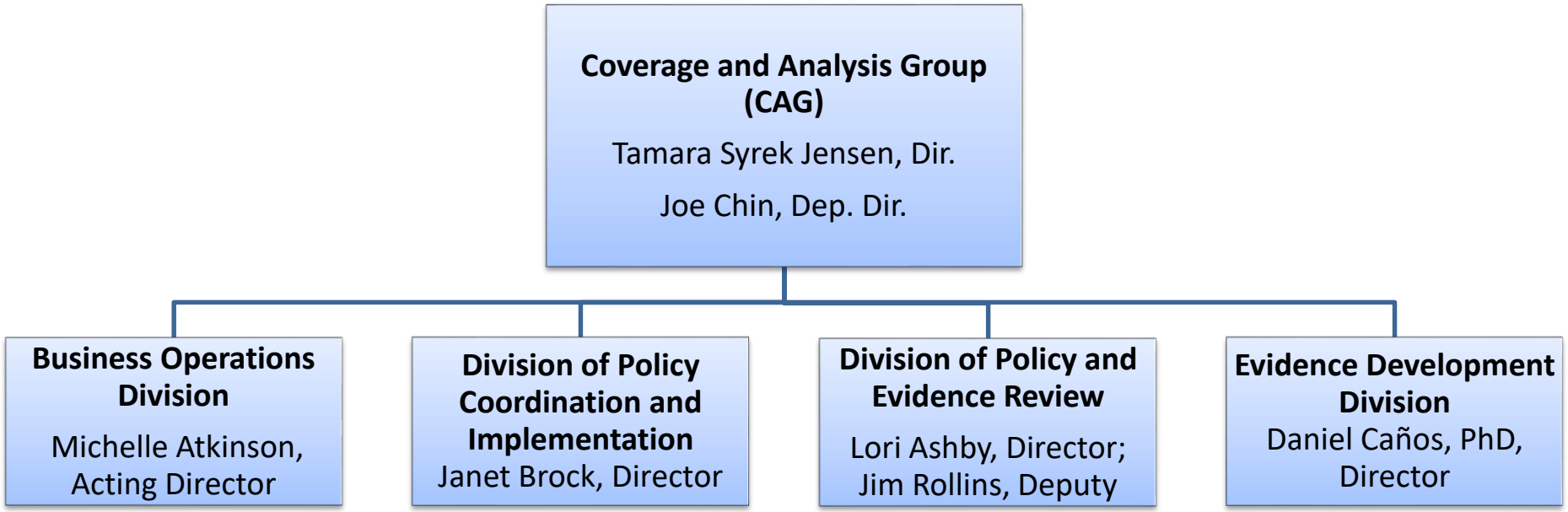
National Coverage Analysis and Medicare National Coverage Determination

Diagnostic Laboratory Tests using Next Generation Sequencing

Coverage and Analysis Group, CCSQ



National Coverage Determination: a discretionary decision by the Secretary of the Department of Health and Human Services to determine whether or not a particular item or service is covered nationally under Title XVIII of the Act as controlling authority for Medicare contractors and adjudicators.

In the absence of an NCD, Medicare contractors may establish a local coverage determination (LCD) (defined in section 1869(f)(2)(B) of the Act) or adjudicate claims on a case-by-case basis.

Requirements for Medicare

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(s)(3) of the Social Security Act: other diagnostic tests.

- Screening refers to the application of a test to people who as yet have no symptoms of a particular disease.

- 1861(ddd)(1): additional preventive services that are:
  A. reasonable and necessary for prevention or early detection of illness/disability;
  B. recommended with a grade of A or B by the USPSTF.

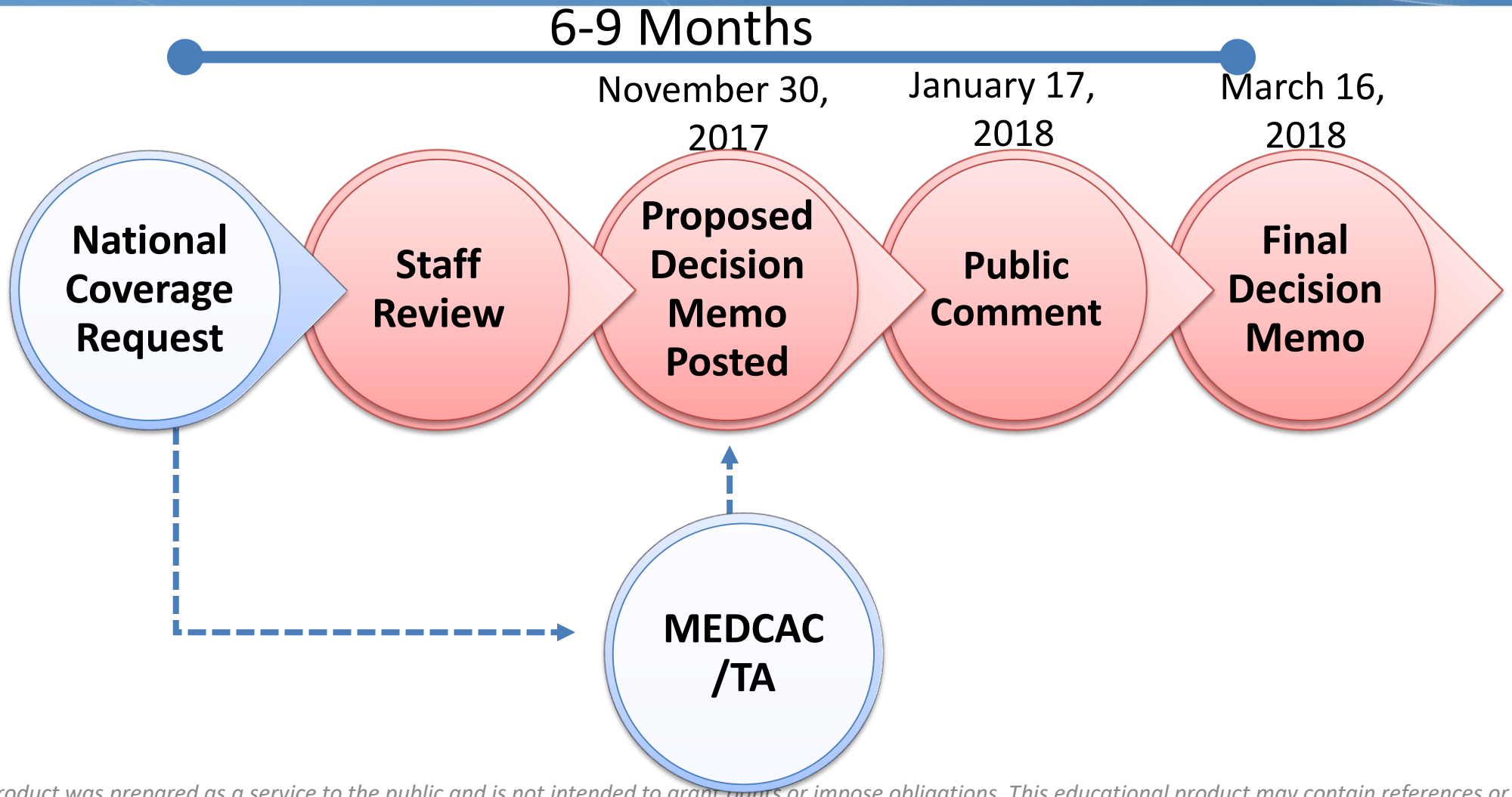
Coverage

- 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.
  - Adequate evidence to conclude that the item or service improves health outcomes. For diagnostic tests = clinical utility
    - Emphasis of outcomes experienced by patients
    - Generalizable to the Medicare population

Coverage

- 1862(a)(1)(E): no payment may be made for items or services which are not reasonable and necessary in the case of research.
  - Research under authority vested with the Administrator of the Agency for Healthcare Research and Quality (AHRQ) with respect to the outcomes, effectiveness, and appropriateness of health care services and procedures.

Medicare National Coverage Process



MEDCAC

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- The Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) established to provide independent guidance and expert advice:
  - Supplements CMS' internal expertise.
  - Reviews and evaluates medical literature, technology assessments, public testimony and information on the benefits, harms, and appropriateness of medical items and services.
  - Judges strength of the available evidence and makes recommendations to CMS based on that evidence.

Public Comment Period

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November 30, 2017 to January 17, 2018

- Proposed questions in an effort to prompt substantive input.
- Include supporting documentation, peer-reviewed evidence, and a detailed analysis of view.
- How can the information in this proposed NCD be clearly communicated to health care practitioners, patients, and their caregivers?

Decision Summary

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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

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR CLINICAL STANDARDS & QUALITY

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

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR CLINICAL STANDARDS & QUALITY

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

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

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

Clinical Laboratory Fee Schedule

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- 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

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

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- 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