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FRIENDS of CANCER RESEARCH

Overview of CMS' National Coverage Decision

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Wifi Code: FCR18

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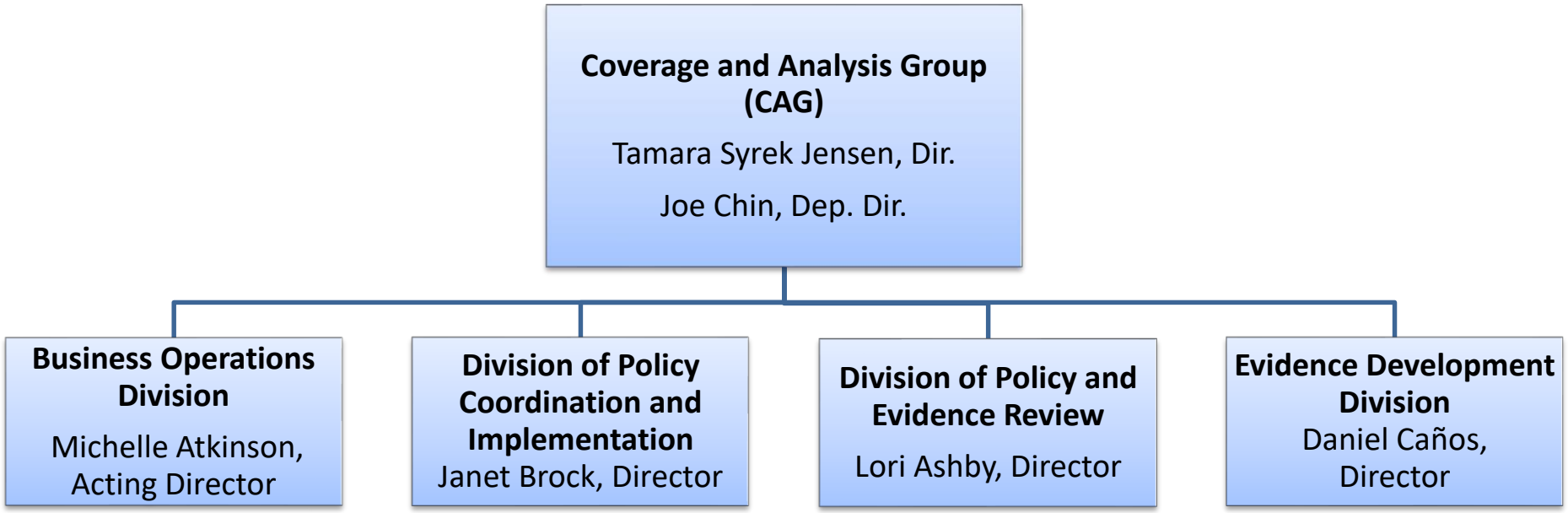
#ProgressForPatients

National Coverage Analysis and Medicare National Coverage Determination

Diagnostic Laboratory Tests using Next Generation Sequencing

Coverage and Analysis Group, CCSQ



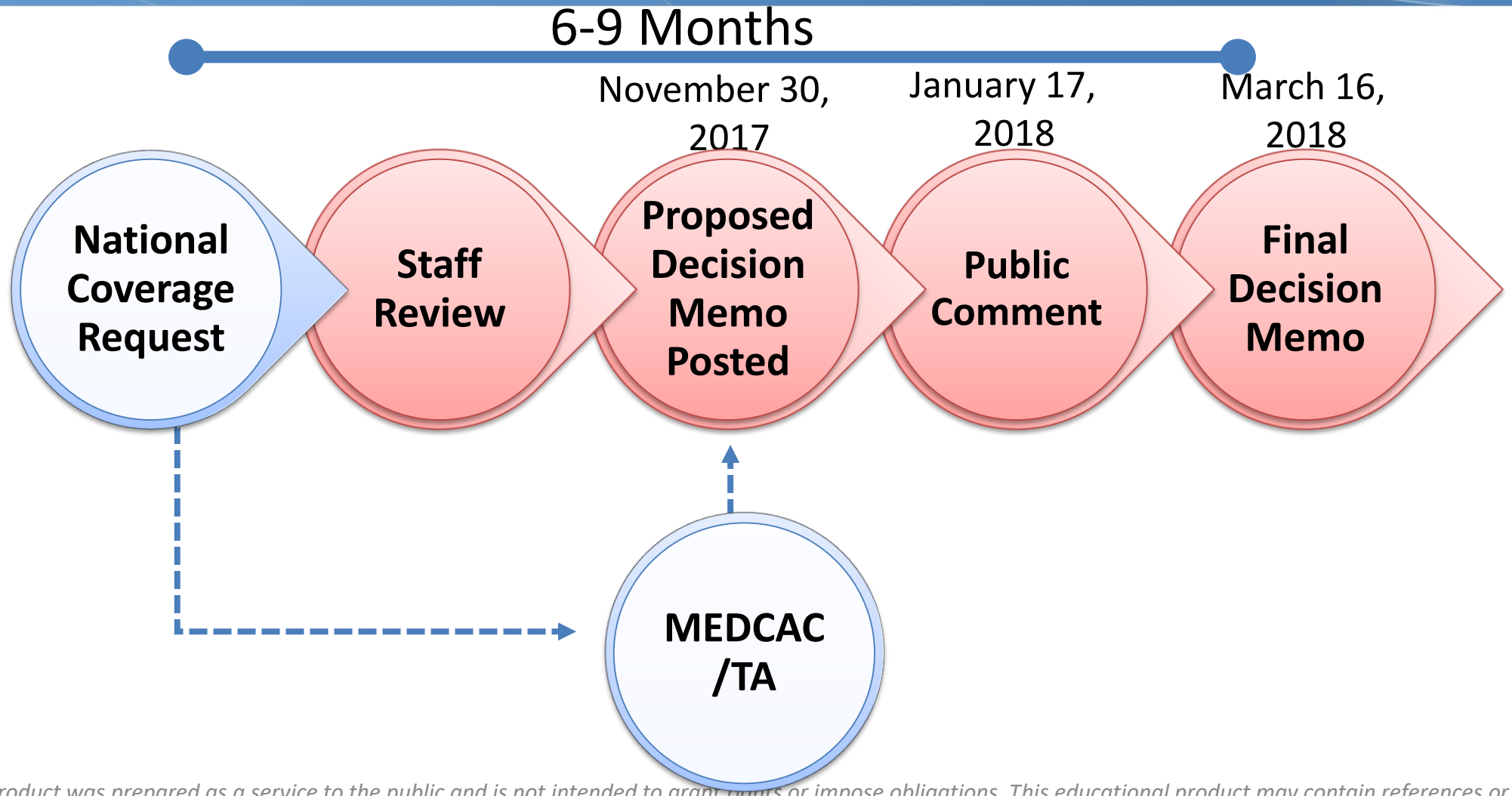
National Coverage Determination: a discretionary decision by the Secretary of the Department of Health and Human Services to determine whether or not a particular item or service is covered nationally under Title XVIII of the Act as controlling authority for Medicare contractors and adjudicators.

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.

Medicare National Coverage Process



Public Comment Period

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

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

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

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).

For more information

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

- 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