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Cancer Policy Institute at the Cancer Support Community
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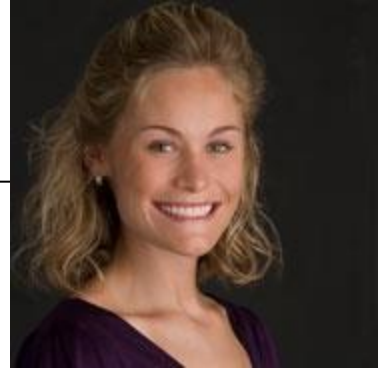
The Medicare Coverage Process 101: Optimizing Your Voice

June 2014

Avalere Health LLC

Jenny Gaffney, Director



Jenny Gaffney advises clients on how to optimize public and private coverage for physician-administered drugs, medical devices, and diagnostics. Jenny has specific expertise in assisting clients engage in Medicare's national and local coverage determination processes. Over the past seven years, she has helped multiple clients optimize Medicare coverage for their items and services. Additionally, Jenny regularly advises clients on how to design their clinical trials and frame their body of evidence to directly respond to Medicare's and commercial payers' evidentiary standards.

Jenny has an AB in Government from Harvard University with minors in Health Policy and Economics.

Presentation Objectives

- Increase understanding of Medicare's coverage determination process for Parts A and B items and services
  - National coverage determination process (focus)
  - Local coverage determination process
- Answer the following questions:
  - What are the engagement opportunities in the national Medicare coverage process?
  - Where do I monitor Medicare coverage activity?
  - How do I optimize my engagement?
- Increase understanding of when and why it is advantageous to proactively engage Medicare at the local and national levels, including the benefits and risks of engaging

Statutorily, Medicare Has Broad National Coverage Authority

> "No payment may be made under [Medicare] for any expenses incurred for items or services [that] are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member"
>
> - Section 1862(a)(1)(A) of the SSA

- To meet the reasonable and necessary qualification, products or services must:
  - Improve health outcomes
  - Be safe and effective
  - Not be deemed experimental or investigational
- In addition, a product or service must:
  - Be approved by the Food and Drug Administration (FDA) (with a few exceptions)
  - Fall into a statutorily-defined benefit category
- Cost or cost-effectiveness is not an explicit factor in determining coverage
  - May be considered in payment policies and decision to initiate formal coverage reviews

This presentation focuses on the coverage process for Medicare Parts A and B items and services

Both CMS National and Local Contractors Make Coverage Determinations at the Class-Level, Not the Product-Level

NATIONAL COVERAGE DETERMINATION (NCD)

- Less than 5% of coverage decisions
- Developed by CMS Central Office/Coverage and Analysis Group (CAG)
- Typically controversial, high-volume, and/or expensive procedures
- Follows set timelines; lengthy public process
- Sets one national policy; binding on all contractors

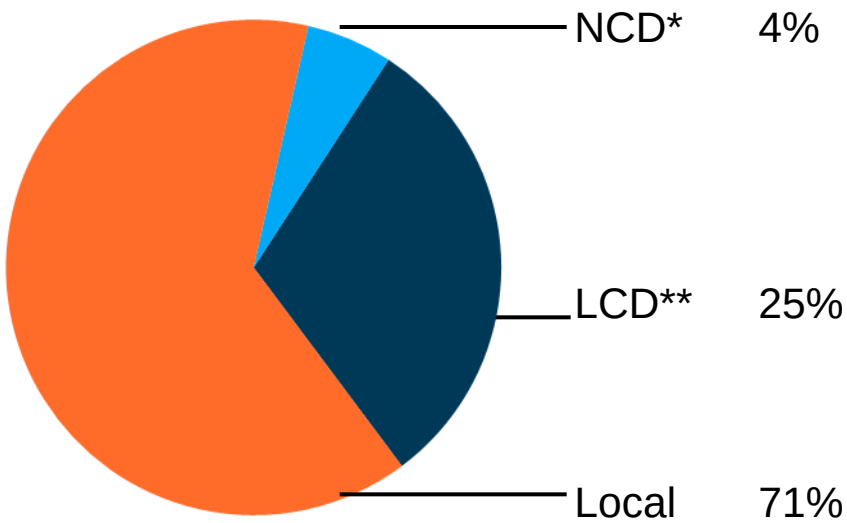
LOCAL COVERAGE DETERMINATION (LCD)

- In the absence of an NCD, Medicare Administrative Contractors (MACs) may develop an LCD
- Historically, more transparent than the NCD process
- Follows set timelines; typically swifter review than NCD process
- Allows for local variation in coverage

In the absence of a formal Medicare coverage policy, claims are generally processed and paid, however documentation of medical necessity is vital in the case of a manual review

The Vast Majority of Medicare Coverage Decisions Occur at the Local Level

Number of Active Coverage Policies/Articles in 2013



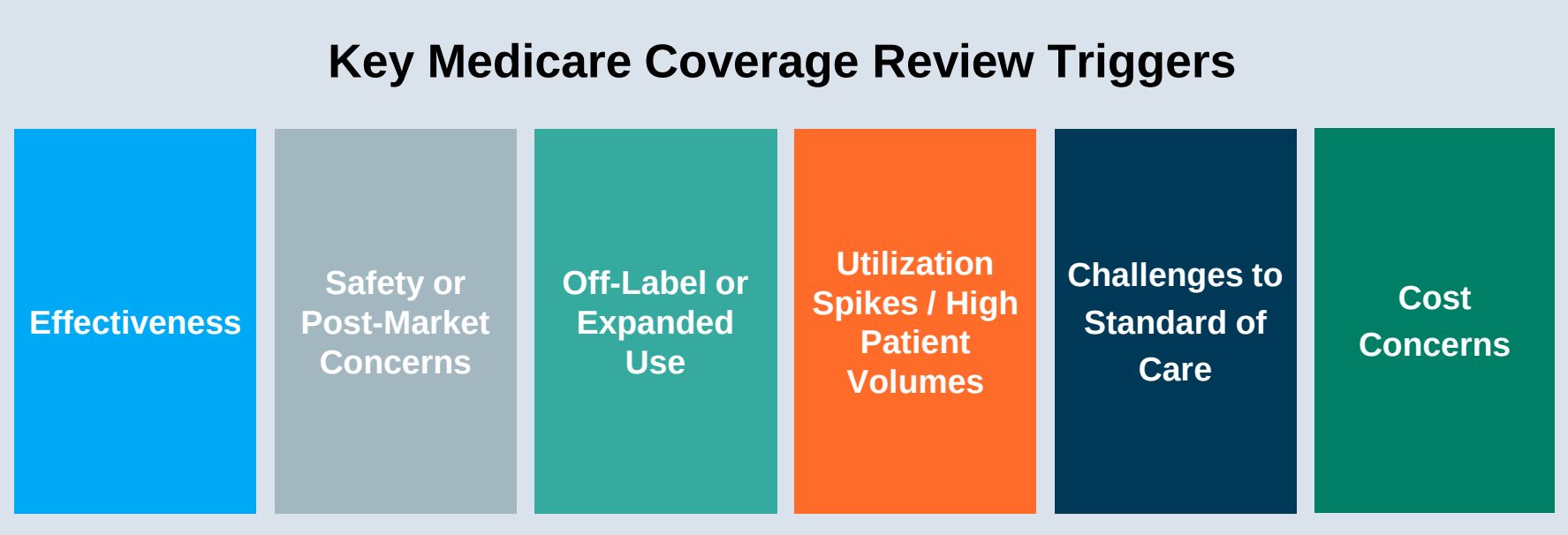
N = 5,895

- **NCD:** Coverage policies issued by the Coverage and Analysis Group within CMS National that are binding for all local Medicare contractors
- **LCD:** Coverage policies issued by local Medicare Contractors that govern a specific part of the country
- **Articles:** Policy updates, coding, and claims processing guidance issued by local Medicare Contractors

Source: ttp://www.cms.hhs.gov/manuals/downloads/pim83c13.pdf
* Avalere analysis CMS' NCD Download Database, last accessed July 3rd, 2013
** Avalere analysis of CMS' LCD Download Database, last accessed July 3rd, 2013
*** Avalere analysis CMS' Article Download Database, last accessed July 3rd, 2013

CMD: Contractor Medical Director

At the National and Local Levels, Medicare Coverage Reviews Are Typically Initiated by One or More Triggers



- Stakeholder groups (e.g., MACs, competitors, providers, beneficiaries, and professional societies) can act on one or more of these triggers to request and NCD or LCD
    - CMS does not act on all formal NCD requests and "prioritizes these requests based on the magnitude of the potential impact on the Medicare program and its beneficiaries and staffing resources"
- Additionally, CMS National and individual MACs can internally generate coverage reviews based on one or more of these triggers

CMS: Center for Medicare & Medicaid Services
NCD: National Coverage Determination
LCD: Local Coverage Determination
MACs: Medicare Administrative Contractors

Source: CMS. Revised NCD Process. http://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/FR08072013.pdf

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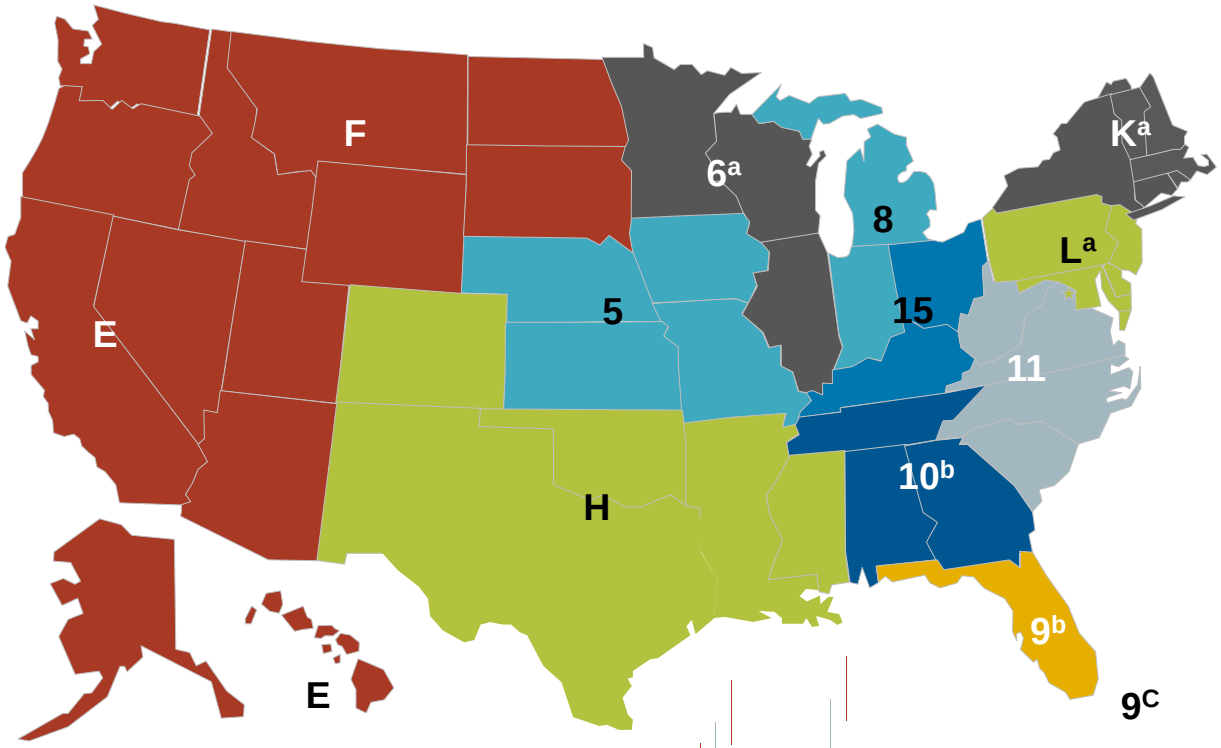
Local Coverage Determination Process

LCDs are Under the Jurisdiction of Different MACs And Can Be Issued in the Absence of an NCD

MAC Jurisdictions, Each Responsible for Issuing LCDs

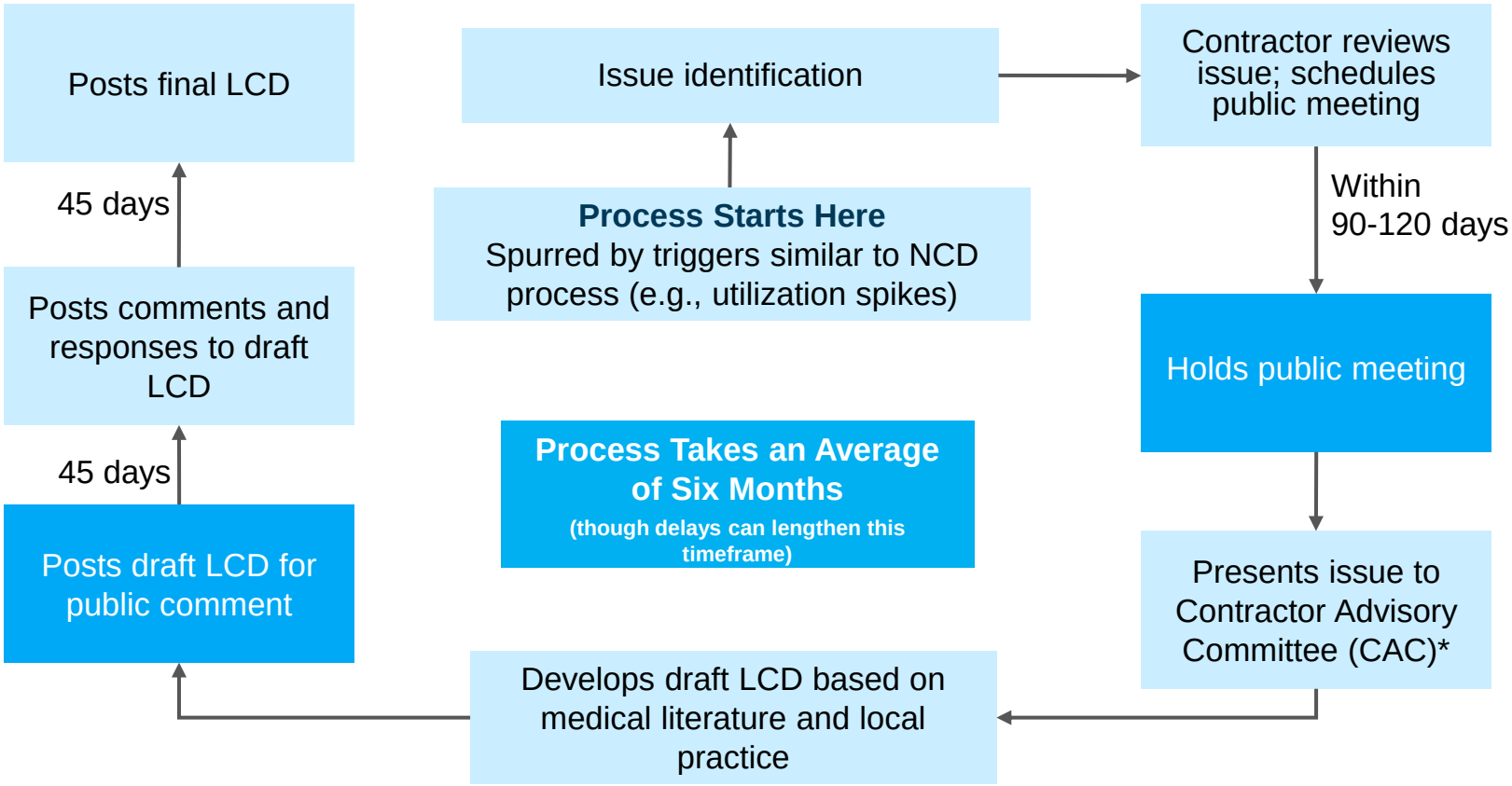


Cahaba Government Benefits Administrator (GBA), LLC
First Coast Service Options, Inc. (FCSO)
Novitas Solutions, Inc. (Novitas)
National Government Services (NGS)

Noridian Administrative Services, LLC (NAS)
Palmetto GBA, LLC
Wisconsin Physicians Service (WPS)
CIGNA Government Services (CGS)

MMA: Medicare Prescription Drug, Improvement, and Modernization Act of 2003
Source: http://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Spotlight.html
Note: This map represents the MAC contracts as of 7/11/2013. NGS received the contract award for JK (formally J13 and J14) on 2/22/2013, however National Heritage Insurance Corporation (NHIC) will continue to be a legacy contractor for JK until the transition is complete. NGS will be subcontracting several significant functions to NHIC under the new JK MAC contract. Additionally, NGS received the contract award for J6 on 1/16/2013, but WPS and Noridian will continue to be a legacy contractors for J6 until the transition is complete.
a. Implementation in progress
b. Recompete in progress

Triggers for Initiation of Local Coverage Policies are Identical to Those at the National Level



*CACs are transitioning to be called jurisdiction advisory committees (JACs) in the future
Source: Medicare Program Integrity Manual, Chapter 13 – Local Coverage Determinations, 2008, https://www.cms.gov/manuals/downloads/pim83c13.pdf

MACs Use the Following Evidence in Developing Coverage Determinations

While the FDA approved label and peer-reviewed, published literature are the gold standard for coverage decision-making, contractors frequently utilize other information sources:

- Local/Regional Contractor Advisory Committees (CACs)
  - CACs are composed of physicians representing a range of medical and surgical specialties who advise Contractor Medical Directors (CMDs) about coverage policies
  - CAC members hold certain sway over many Medicare reimbursement decisions made at the local level
- Opinions of community physicians who are key opinion leaders (KOLs) and early adopters
  - Other local contractors and their policies
  - State and national professional societies and position statements
  - Evidence-based treatment guidelines
  - Unpublished literature (e.g., posters from society meetings, clinical abstracts, articles submitted for publication) when published literature is not available
  - Advocacy groups
  - Expert opinions

While the FDA label and peer-reviewed articles are essential in developing both NCDs and LCDs, the LCD process allows for more expert and KOL input than the NCD process. Expert and KOL support will be essential for a successful local coverage strategy

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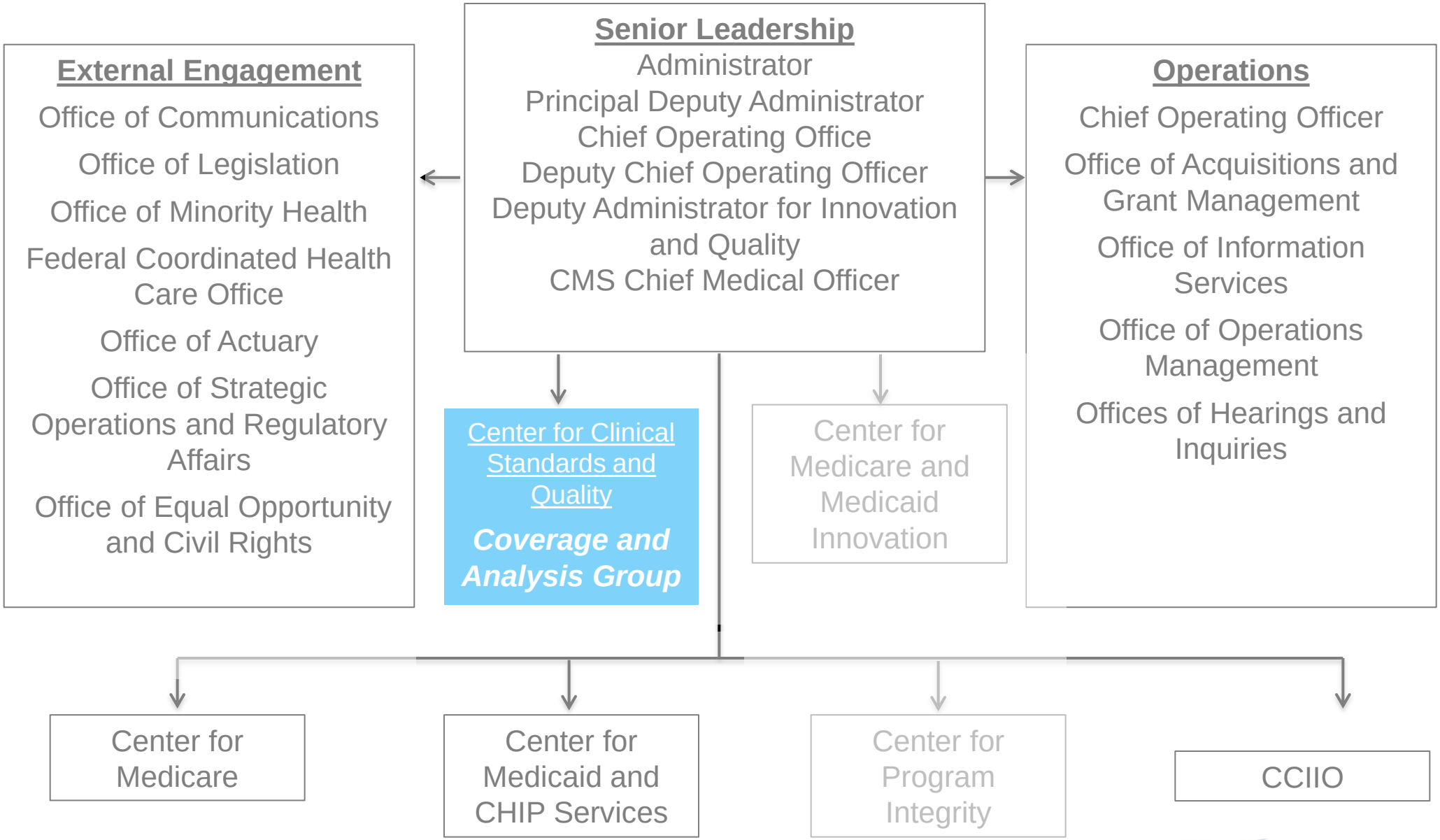
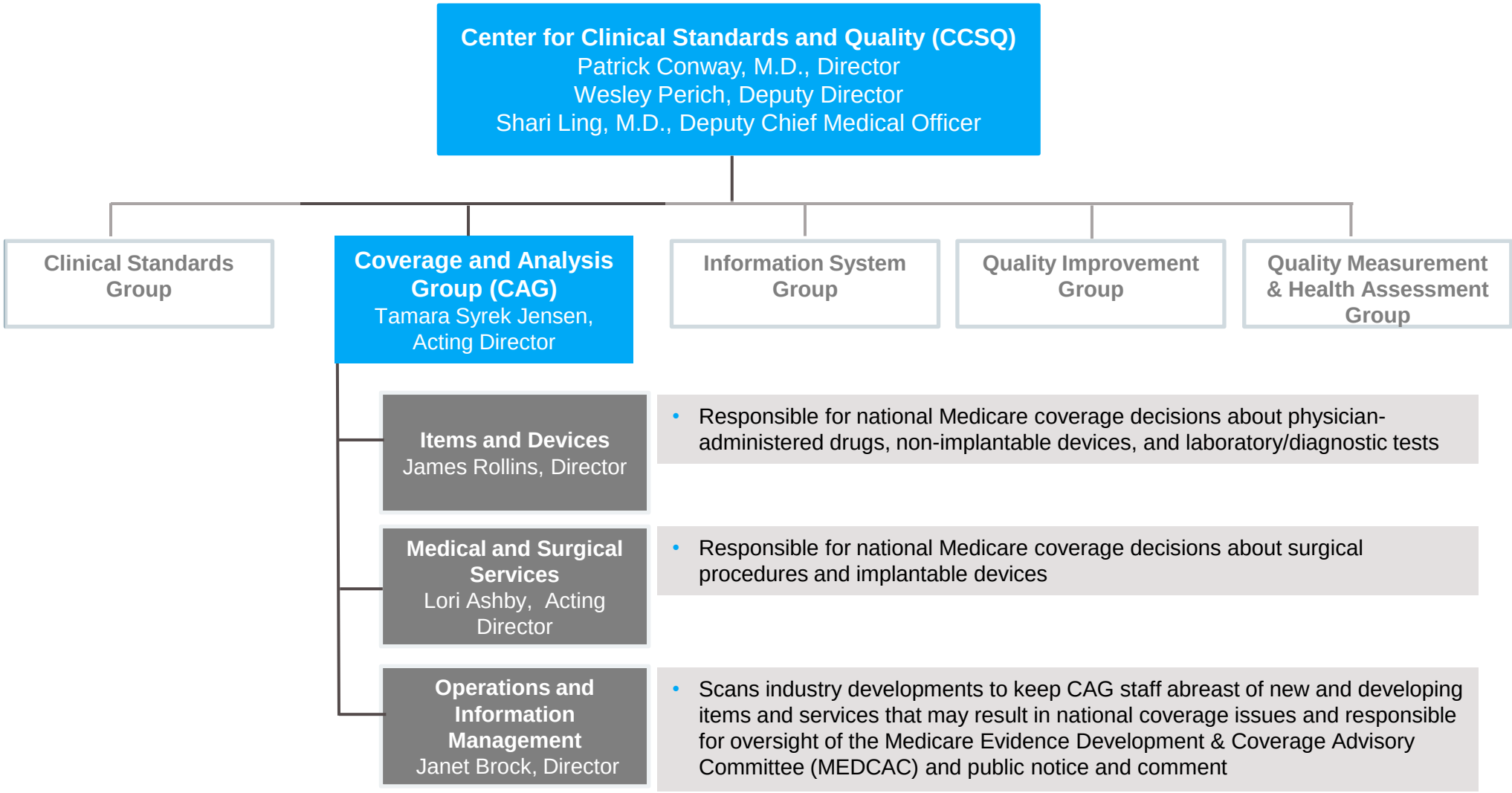
National Coverage Determination Process

The Coverage and Analysis Group is Housed Under the Center for Clinical Standards and Quality



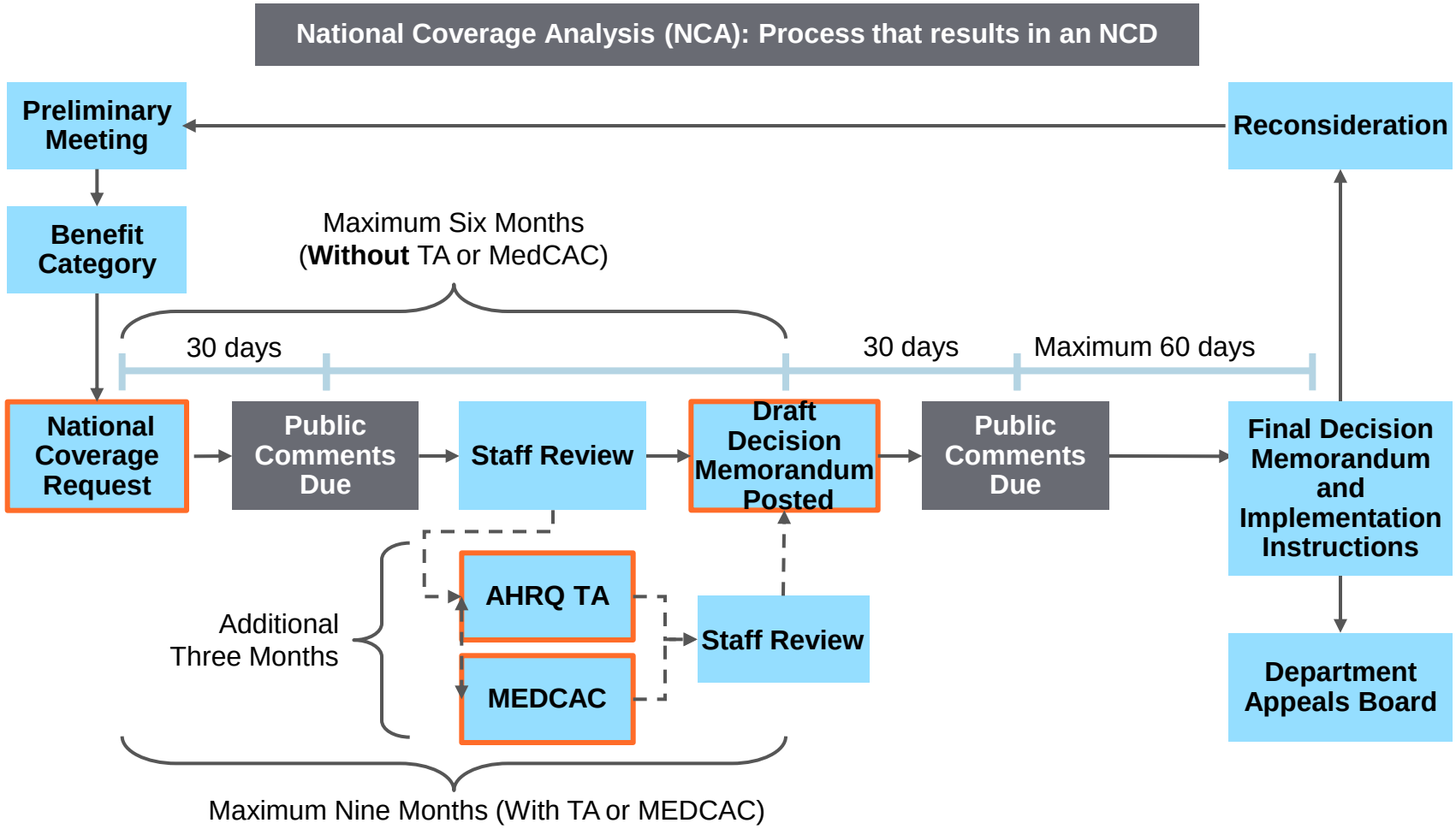
Source: https://www.cms.gov/About-CMS/Agency-Information/CMSLeadership/Office_CCSQ.html (Page last updated 6/2/2014)

CCSQ Oversees National Quality Initiatives and Includes the Coverage and Analysis Group



Sources: https://www.cms.gov/About-CMS/Agency-Information/CMSLeadership/Office_CCSQ.html (Page last updated 6/2/2014) and http://cms.hhs.gov/Medicare/Coverage/CouncilonTechInnov/Downloads/InnovatorsGuide5_10_10.pdf (Document last update Spring 2010)
CCSQ: Centers for Clinical Standards and Quality

Medicare's NCD Process Involves Multiple Steps and Opportunities for Comment



Medicare requests MEDCAC meetings and/or AHRQ TAs for a subset of NCDs when they feel an additional review of the evidence by other experts would be helpful

Denotes public comment opportunity

AHRQ: Agency for Healthcare Research and Quality
MEDCAC: Medicare Evidence Development & Coverage Advisory Committee (formerly the Medicare Coverage Advisory Committee, or MCAC)
TA: Technology Assessment

CMS Leverages Several Types of Evidence to Inform its Coverage Analyses

Clinical Trials

All pre- and post-market data generated through manufacturer sponsored or other pivotal trials

Health Technology Assessments

Systematic reviews of available data on the safety, efficacy, and cost-effectiveness of a drug or device

Clinical Guidelines

Consensus recommendations issued by professional societies regarding the routine clinical use of a drug/device

Real-World Evidence

Data on the safety/efficacy of a drug or device generated in a non-controlled environment (e.g., registry, EHR data)

MEDCAC Recommendations

Insights from an independent panel of experts regarding the value of a product for Medicare beneficiaries

An NCA Can Result in a Variety of Outcomes, Ranging From Benign to Detrimental for Patient Access

THE MAJORITY OF NCAS END IN COVERAGE WITH RESTRICTIONS OR CED

	National Coverage	National Coverage with Restrictions	Coverage with Evidence Development (CED)	National Non-Coverage
National Decision	• Consistent with FDA-approved label	• Specific indications • Patient sub-populations • Provider requirements • Approved clinical sites	• Post-market data collection requirements • Clinical trial participation • Registry participation	• Access to item or service is restricted
No National Decision	**Coverage left to local contractor discretion**			

High-Level Overview of Components of an NCD for an Innovative Technology

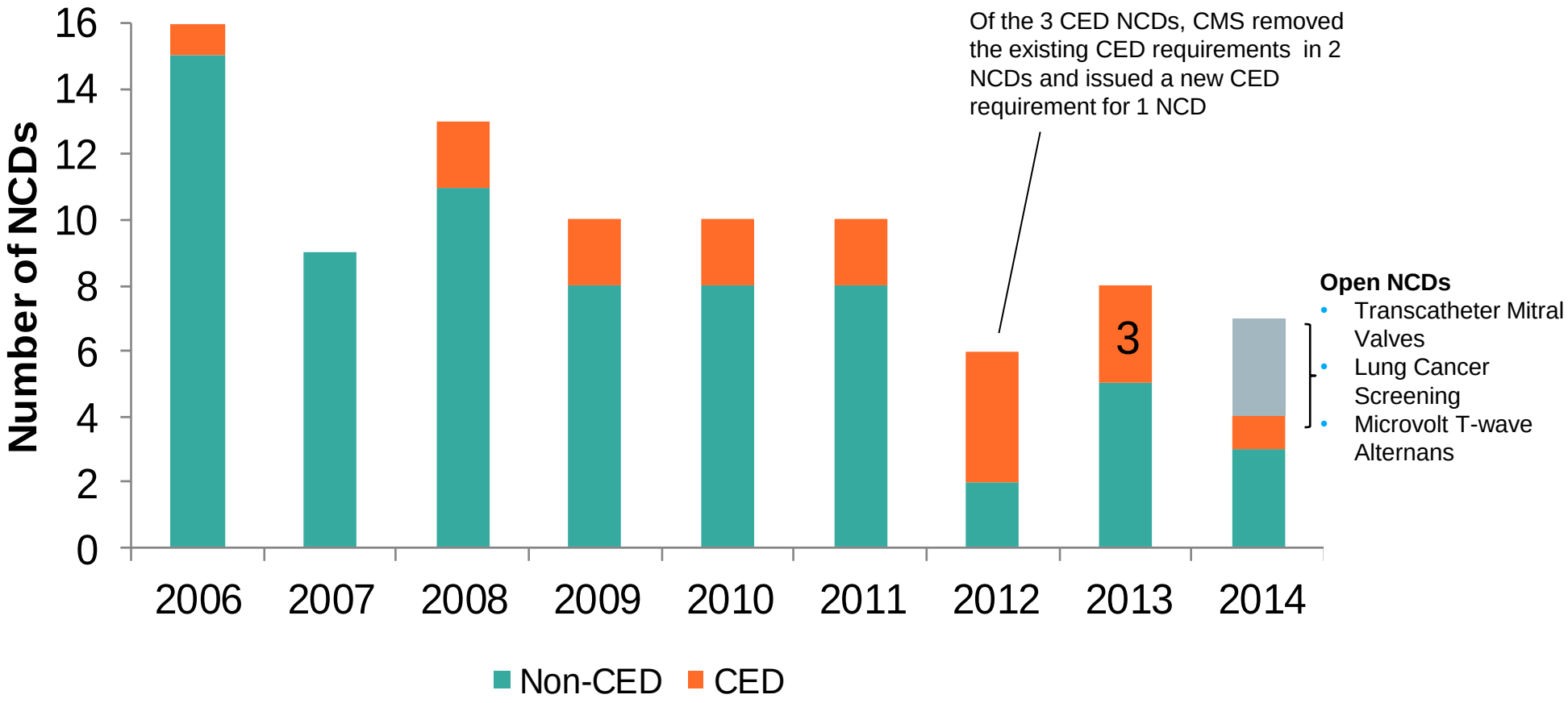
Benefit Category	• Delivery site for class of products or service being evaluated (e.g., *Inpatient Hospital Services* for MT)
Item Description	• Description of the class of products and the specific condition the item or service is intended to treat

Indications and Limitations of Coverage	• States CMS' ruling regarding whether item is covered nationally, locally, with restrictions, or not covered at all
	• If covered, CMS typically restricts coverage to the FDA label *and* additional coverage restrictions
	• Potential coverage restrictions:
	  ○ Patient selection criteria
	  ○ Facility and operator certification requirements
	  ○ CED: item must be used in a CMS-approved clinical trial or registry to be covered

NCDs for highly technical procedures typically include patient selection criteria and operator requirements that are narrower than the FDA label

CMS is Increasingly Deploying CED in its Medicare Coverage Determinations

UNDER CED, MEDICARE MAKES COVERAGE CONTINGENT ON ADDITIONAL EVIDENCE COLLECTION THROUGH A REGISTRY OR PROSPECTIVE TRIAL



Source: Avalere Analysis using the Tufts Medicare NCD Database and Medicare Coverage Database. Analysis conducted May 28, 2014.

While CED is Better Than Non-Coverage, There Are Several Concerns with the Policy

CED can be financially burdensome for participating providers and manufacturers, which can lead to geographic inequalities in patient access

Medicare only reimburses for the item or service(s) explicitly dealt with in the NCD. Medicare does not cover the cost of evidence collection or evaluation; these activities are typically funded by participating providers or affected manufacturers. For example, hospitals pay an initial fee of $25,000 and an annual renewal fee of $10,000 to participate in the transcatheter aortic valve replacement (TAVR) CED registry.

CMS does not typically set timelines to reevaluate Medicare's coverage for an item or service studied under CED

Of all of the CED decisions, there has been only a few cases in which CMS expanded coverage based on data generated from CED. CMS has yet to change its coverage parameters on prior CED decisions, even for decisions implemented over 5 years ago.

The NCD timeframe does not allow sufficient time or enough stakeholder input to develop well-considered methods for CED implementation

Stakeholders have argued that the six to nine month NCD timeframe does not allow sufficient time to appropriately design and implement CED

Medicare Typically Looks to Professional Societies for Advice on How to Structure Its Coverage Decisions

Generating Evidence to Fill Evidence Gaps

- At 2012 MEDCAC on DME, AAO called the panel's attention to a new NIH-sponsored CER study comparing the effectiveness of the anti-VEGF agents under question as a means to fill key evidence gap

Initiating NCDs and Reconsiderations

- In 2011, CMS accepted a request from the ACC and STS to initiate a NCD on TAVR
- In 2012, CMS accepted a request from MITA to reconsider its existing PET NCD

Informing Content of Decisions

- In 2012, CMS modeled TAVR CED policy after the registry that ACC and STS established
- CMS largely adopted the facility and operator requirements outlined by the professional societies in the TAVR NCD

It is critical to ensure alignment across professional societies and understand what registry vehicles and/or appropriateness criteria may be put forward to Medicare for a topic undergoing NCD review

AAO: American Academy of Ophthalmology
DME: Diabetic Macular Edema
VEGF: Vascular Endothelial Growth Factor
NIH: National Institutes of Health
TAVR: Transcatheter aortic valve replacement

ACC: American College of Cardiology
STS: Society of Thoracic Surgeons
MITA: Medical Imaging & Technology Alliance
PET: Positron Emission Tomography

Key Questions Medicare Asks When Developing an NCD

- **Are there distinct patient populations for which the therapy is clinically effective?**
  - Medicare typically establishes different coverage restrictions for distinct patient populations (e.g., with different risk profiles)
- **How does the therapy in question compare to the standard of care in improving health outcomes?**
  - Medicare weighs evidence on health outcomes (e.g., mortality, stroke rate) more heavily than evidence on surrogate endpoints (e.g., recanalization rate)
  - Medicare wants evidence on the durability of health outcomes (≥1 year)
- **Is the evidence generalizable to the Medicare population?**
  - Medicare wants evidence on the clinical effectiveness of the therapy for the >65 population
- **Is the evidence generalizable to real-world settings?**
  - For high-risk or highly technical procedures in particular, Medicare will want assurances that the therapy will work as good as it does in a controlled clinical study
  - To mitigate its concerns, Medicare could restrict coverage to accredited facilities and/or require registry participation to track outcomes and ensure compliance with facility and operator requirements

Key Evidence Medicare Uses to Answer These Key Questions

FDA Approval

- Medicare often ties coverage of a therapy specifically to its FDA-approved indication so that it does not have to reopen the NCD with every label expansion

Published Clinical Trial Evidence with a Preference for U.S. Based Studies

- Medicare does not give much weight to unpublished evidence or studies that are exclusively performed outside of the U.S.

U.S. and ex-U.S. Health Technology Assessments

- Medicare strongly considers both U.S. and ex-U.S. systematic reviews of the clinical evidence

Professional Society Consensus Statements and Guidelines

- Medicare relies heavily on the input of proactive professional societies particularly when determining patient selection, facility and operator criteria
    - It is critical for the HPAB to identify whether there is existing criteria that the group support that could be leveraged to inform a coverage policy

Mandated Evidence Collection Through CED

- When Medicare identifies key evidence gaps, it will consider whether to issue CED
    - If it does, Medicare will mandate coverage through an approved clinical registry or clinical trial

Medicare Coverage Decision-Making Often Directly Informs Private Payer Policies

- CMS is a leader in defining evidence necessary for coverage and payment
  - CMS' process for evaluating an item or service often sets the standard for many payers
  - Medicare payment systems, rates, and quality measures are frequently benchmarks for private payers and Medicaid
- Since CMS' processes are publicly accountable and transparent, private payers can easily reference NCDs and the evidence evaluated to get to get to the determination
- In turn, private payers can influence Medicare decision-making on an issue by directly commenting on national coverage analyses or by publicly posting their coverage policies on the topic of interest

It is important to recognize that Medicare NCDs and LCDs for drugs typically have a ripple effect throughout the private payer community especially when the majority of the affected patient population is 65 and older

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Opportunities for Engagement in the NCD Process

There Are Three Key Engagement Opportunities

1	Request an NCD be Opened or Reconsidered
2	Get Early Input on a Trial Design of a Therapy Likely to Be Reviewed by Medicare National Prior to Launch
3	Respond to an Open NCD to Inform Coverage Parameters

1 There Are Only Select Circumstances Where It Might Be Advantageous to Request an NCD

Existing national coverage decision or legislative language denies or restricts coverage for beneficiaries

OR

Existing national coverage decision is outdated, not representative of the current data and needs to be retired

OR

Coverage policies at the local level are negative or significant variation in extent of coverage at the local level

AND

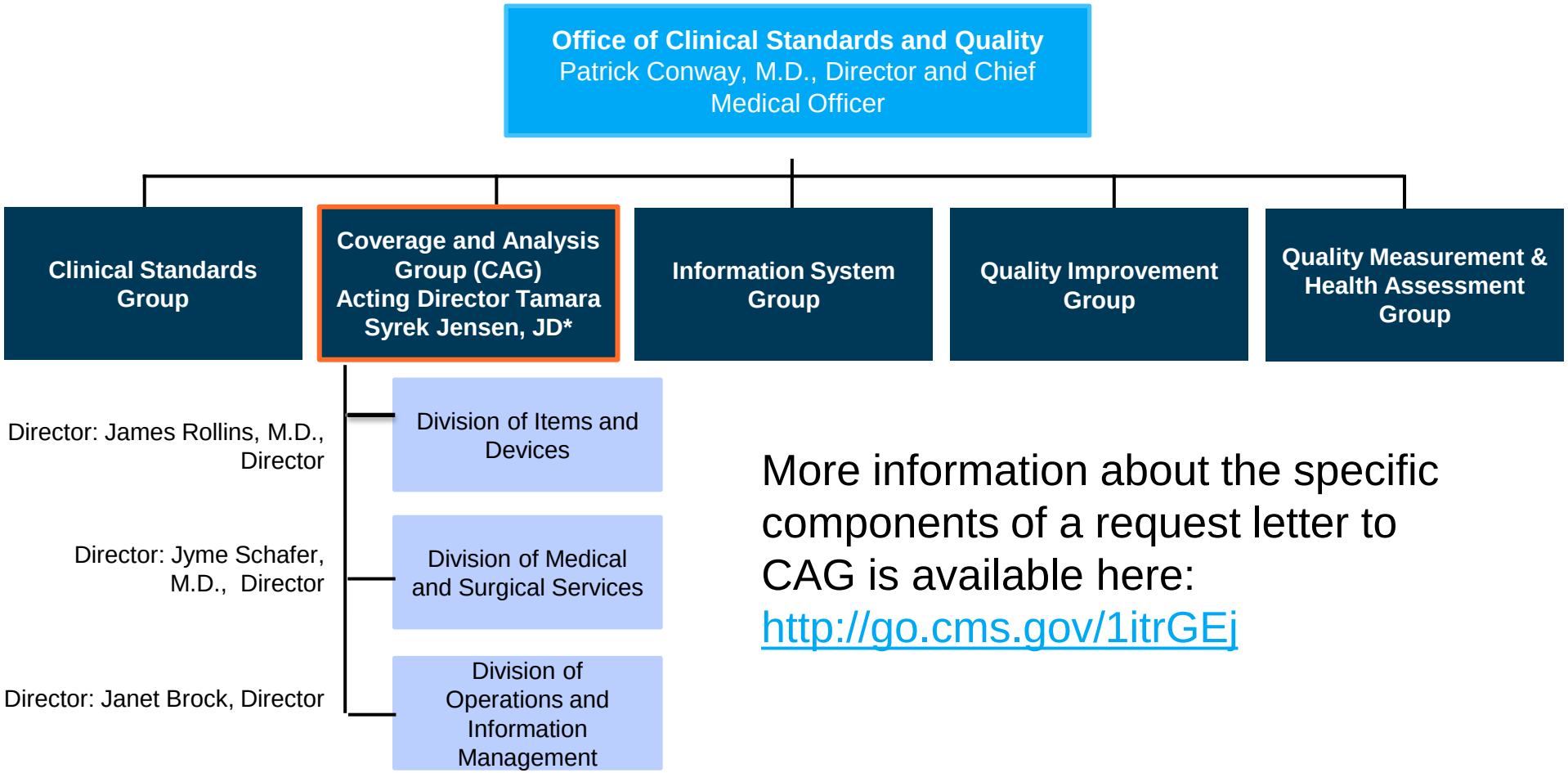
Medicare is a big payer for the technology and there is a robust evidence base

Given the high stakes associated with pursuing an NCD which is time and cost intensive with its multi-faceted strategy, the life sciences industry has historically supported local coverage practices

1 Who Do You Direct Communications to at CMS to Schedule a Meeting or Send a Written Request?

"We encourage, but do not require, potential requesters to communicate, via conference call or meeting, with our staff in the Coverage and Analysis Group (CAG)…before submission of a formal [NCD] request."

-CMS, Revised Process for Issuing NCDs, Aug. 2013



More information about the specific components of a request letter to CAG is available here: http://go.cms.gov/1itrGEj

*Note: Tamara Syrek Jensen is the acting CAG Director until a formal replacement is selected.

2 Meeting with CMS Prior to Launch is a Strategic Decision for Product Sponsors and Other Stakeholders

Key opportunities to meet with CMS prior to launch may include:

Evidence Base	• Identify the strength of the current evidence base to gain an understanding for what gaps exist and may influence coverage • Gain insight into how CMS perceives the specific " therapeutic need" for beneficiaries based on the existing epidemiology and demographics
Trial Design	• Obtain guidance on trial design to elucidate any concerns that may currently exist in a specific protocol • Gain informal agreement that the existing or proposed design meets the evidentiary needs
Policy Clarification	• Enhance understanding of the current policy on a specific class of products and why coverage has been difficult or denied • Seek to understand what quality of life parameters may also influence coverage for this therapeutic area

2 A Successful Meeting with CMS Prior to Launch May Yield Valuable Insight

Create awareness

- Provides a lens into how receptive Medicare is to evaluating or re-evaluating coverage for a specific product or class of products
- Gauges Medicare's initial reactions to the strength of the evidence supporting the use of the product or class of products

Gain Insight

- Reveals what level of impact quality of life measures have on the evidence base though these measures may be more subjective
- Identifies expectations of collaborative support (if appropriate) by other industry members or stakeholders

Inform actions

- Elucidates potential areas of concern for CMS including additional types of evidence that may be needed to influence coverage
- Guides preparation of a potential coverage request that will resonate best with CMS

Building a relationship of mutual collaboration will only enhance communication and trust for when an explicit request is made

2 However, It Is Important to Consider the Following Before Engaging CMS

Risks of Pre-Launch Engagement

- If CMS makes recommendations prior to a formal coverage request on such things like trial design or beneficiary type, CMS will hold the requestor accountable for factors previously discussed
- A meeting also puts the therapy on CMS' radar for future coverage activity (that could be restrictive) particularly if there are concerns expressed about the quality of evidence being collected

Risks of Post-Launch Engagement Via a Formal NCD Request

- Not all services and products need a national coverage determination
  - If results are unfavorable, the coverage decision is binding and may affect private payers as well since they frequently reference NCDs
  - The decision also pertains to the entire country
- Once a formal request is received, all correspondence and data become public record
  - » Manufacturers, professional societies, and other public stakeholders will be able to inform CMS' decision-making

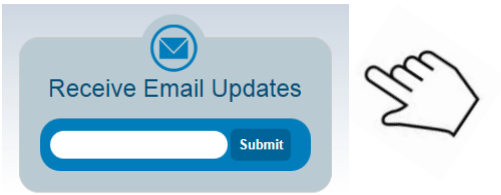
2 Preemptive Due Diligence is Necessary as Engagement With CMS is Not Always Advisable or Required

Factors to Help Determine Whether to Engage CMS	Example Areas of Due Diligence
Assess existing local and national Medicare coverage	Are there existing policies that dictate coverage for your item and service? Is it more restrictive than desired? Who is the decision-maker you would need to engage with (e.g., CAG vs. local MAC)?
Determine coding and payment	Does your item or service have an adequate code and payment rate in place?
Evaluate the competitive landscape	How will other players affect the coverage situation (physician societies, manufacturers, hospitals)?
Understand the evidence base	Does your evidence base and that in the public domain align with Medicare's evidence requirements? Are there any potential gaps?
Explore professional societies	How do professional societies align or do not align with your position given their influence with the Agency?
Assess risk/benefit of engaging at national or local level	What are the pros and cons of engaging at the national level and the local level? Are you prepared for either outcome, positive or negative? If so, what are the next steps?
Formulate a clear ask if it is determined CMS must be engaged	Why are you asking for CMS' time? What do you aim to accomplish?

Stakeholders benefit most from the coverage process when a targeted approach is applied. It is not advantageous to engage CMS for a broad therapeutic area or list of therapies.

Where Can you Monitor NCD Activity?

- Sign up for the CMS Coverage listserv to receive notification regarding updates to the CMS Coverage pages on the bottom right of any page on CMS.gov



- All open NCDs can be viewed here: http://go.cms.gov/1mADpF5
  - Click on each NCD and then click on the tracking sheet to see the dates for public comment
  - All public comments can be accessed through each NCD's tracking sheet
- There is no list of future NCDs to help anticipate upcoming NCDs
  - There is a "Potential NCD List," but it has not been updated since November 2012 and thus not a good indication of future NCDs
- AHRQ technology assessments that are in-progress are also a signal that CMS may be interested in opening an NCD on the topic *but* it does not guarantee NCD activity: http://1.usa.gov/1kMexdy

How Can the Public Engage Once an NCD is Opened?

- By submitting evidence-based public comment letters (1) when the NCD is initially opened and/or (2) when the proposed NCD is posted
- If an AHRQ TA is conducted or a MEDCAC is convened, patients can provide written comments for the former and both written and public testimony at the latter
  - AHRQ TAs commissioned by Medicare are available here: http:// 1.usa.gov/Rz6l58
  - Upcoming MEDCAC meetings are available here: http://go.cms.gov/1lPKb6M
- If a MEDCAC is convened, there is at least one patient advocate that sits on the panel. The roster for a MEDCAC is announced in advance of each meeting
  - The pool of MEDCAC members that can be called on for a MEDCAC meeting (15 are called) is available here: http://go.cms.gov/1ri5hTD
  - There are also opportunities for scheduled 5-10 minute presentations and ad hoc public comments at each MEDCAC meeting

Evidence-Based Comment Letters Carry More Weight in Medicare Coverage Decisions

"Public comments providing information on unpublished evidence, such as the results obtained by individual practitioners or patients, are less rigorous and therefore less useful for making a coverage determination."

-CMS, Revised Process for Issuing NCDs, Aug. 2013

- CMS prefers evidence-based comment letters that cite published clinical evidence regarding the clinical benefit of a medical intervention
- Form comment letters that do not cite any new published evidence and/or is purely anecdotal are less useful to CMS
- A robust comment letter addresses three key points with supporting published evidence where appropriate:
  1. **Medical Need for Coverage:** Addresses the need for expanded coverage in the Medicare population
  2. **Clinical Benefit for the Over 65 Population:** Cites relevant clinical evidence on meaningful endpoints (quality of life and clinical health outcomes)
  3. **Desired Coverage Outcome**: Clearly states the desired coverage outcome

Key Takeaways About Medicare's Coverage Process

1	Both CMS National and local Medicare Contractors issue coverage decisions for Part A and B services
2	Most coverage decisions are made at the local level
3	The absence of a coverage decision does not equate to non-coverage
4	Coverage decisions are made at the class, not product level
5	The national and local coverage processes are lengthy and public pathways that can be initiated by Medicare or any stakeholder
6	Medicare relies on the FDA label, published evidence, health technology assessments, and clinical guidelines to inform its coverage decisions
7	Medicare's coverage decisions for surgical procedures for high-risk patients often condition coverage on specific patient selection and facility and operator criteria

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Question and Answer

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