Coverage Overview and Best Practices

Prepared for AdvaMed

Avalere Health | An Inovalon Company
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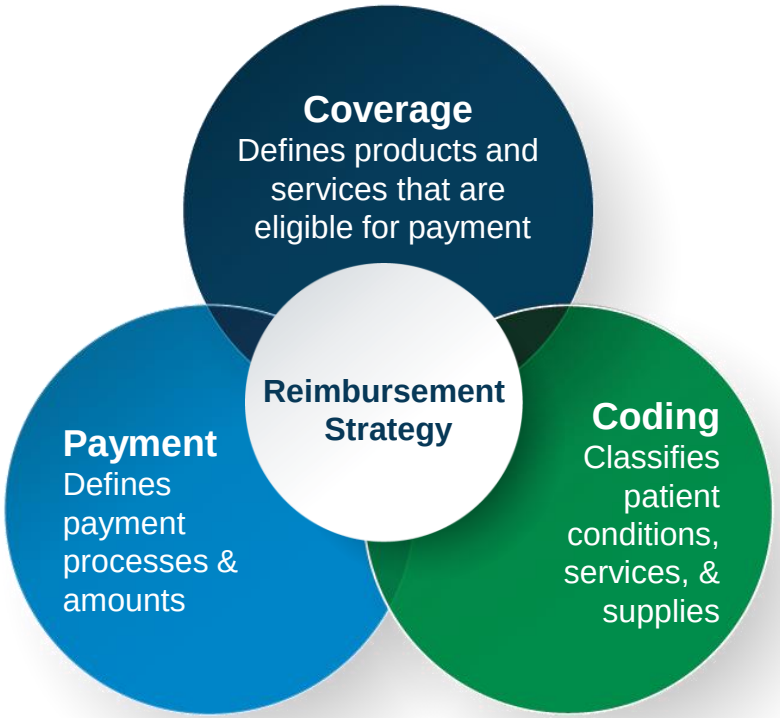
The Reimbursement Process Is Key to Product Success

- Reimbursement is the general term used to describe coverage, coding, and payment processes for medical services, devices, drugs, and supplies
- Gaining reimbursement for a product is vital once the new product is approved by the FDA*
- Adequate reimbursement helps ensure patient access to technologies
- Lack of coverage or inadequate payment may hinder adoption or lead to discontinued use of a medical device, drug, or service
- Different payment systems can create varying incentives and disincentives for providers to utilize certain devices, drugs, and procedures



Each aspect is a separate function, but all are required to establish reimbursement.

FDA: Food and Drug Administration
*Reimbursement for lab diagnostics does not always require FDA approval

A Successful Reimbursement Strategy Incorporates Multiple Elements

- Achieving optimal reimbursement is a long process that must begin well in advance of product launch
- Taking proactive steps prior, during, and post launch will help remove or mitigate the potential effect of coverage, coding, and payment barriers

Stakeholder Engagement

- Key opinion leaders (KOLs)
- Medical specialty societies
- Patient groups/coalitions
- Payers

Value Proposition

- Clinical and economic data and supporting arguments
- Focus on evidence-based medicine
- Guideline/quality measure strategy

Investment & Support

- Appropriate investment to implement short and long-term strategies
- Organizational support
- Development of key materials
- Continued monitoring

Value messages should be tailored to address key issues for each stakeholder group

FDA Approval Does Not Guarantee CMS Coverage & Payment

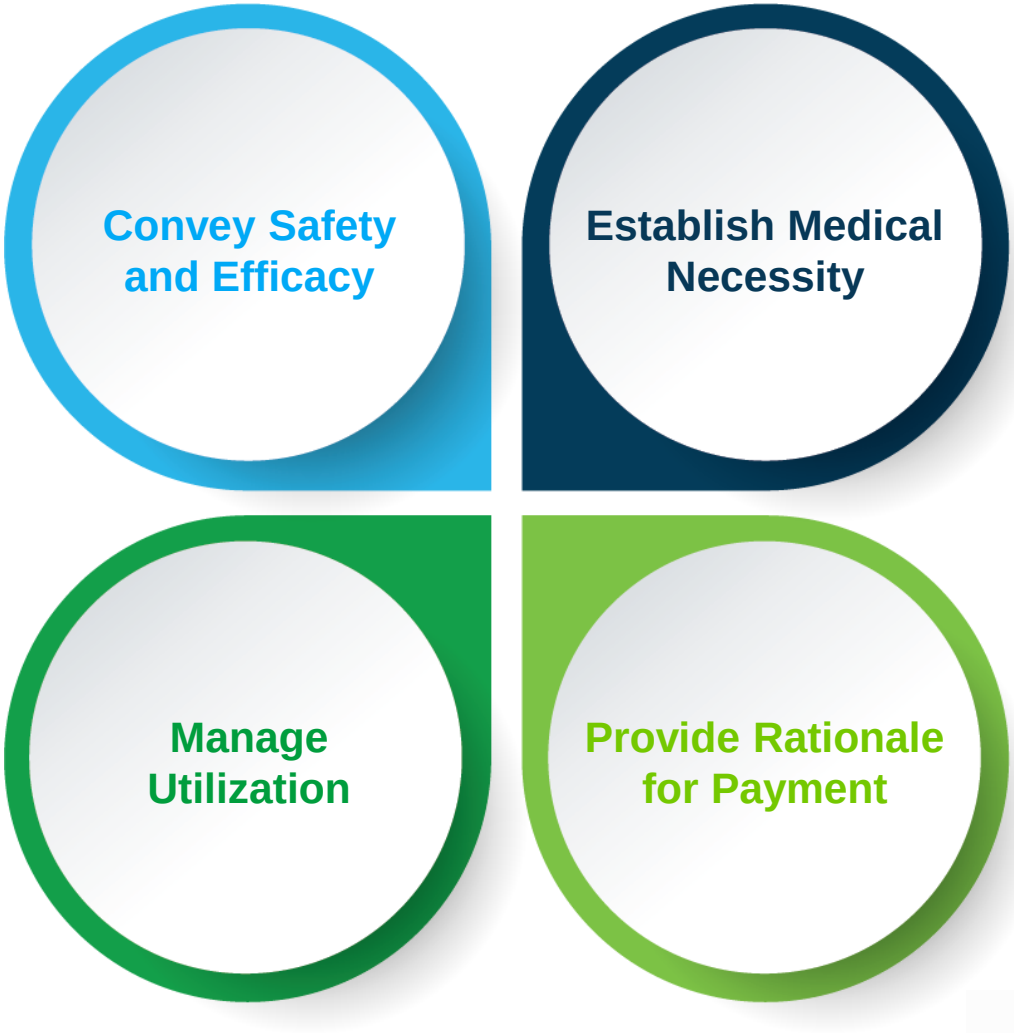
FDA "Safe and Effective"	CMS "Reasonable and Necessary"

• FDA approval/clearance does not guarantee CMS coverage of new products
  ○ CMS must also view the therapy as reasonable and necessary; however, the definition of reasonable and necessary can be ambiguous
  ○ Manufacturers may need to engage CMS at the national level or local level through MACs and provide educational materials regarding a new device and its use
	• CMS generally covers FDA-approved indications of a therapy, if deemed reasonable and necessary for the Medicare population

Timing of FDA approval combined with the manufacturer's business goals will drive timelines and interactions with CMS

CMS: Centers for Medicare and Medicaid Services
MAC: Medicare Administrative Contractor

Coverage Policies Serve a Variety of Purposes



Understanding the Parameters of a Coverage Policy Is Paramount to Product Strategy & Success

Non-Covered

- Payer has an explicit negative coverage policy for a device

Not Specified

- Payer has neither a positive or negative coverage policy for a device
- Lack of a specific coverage policy does not imply non-coverage

Covered

- Payer has an explicit positive coverage policy for a service
- Even positive coverage policies may limit coverage based on specific criteria or conditions

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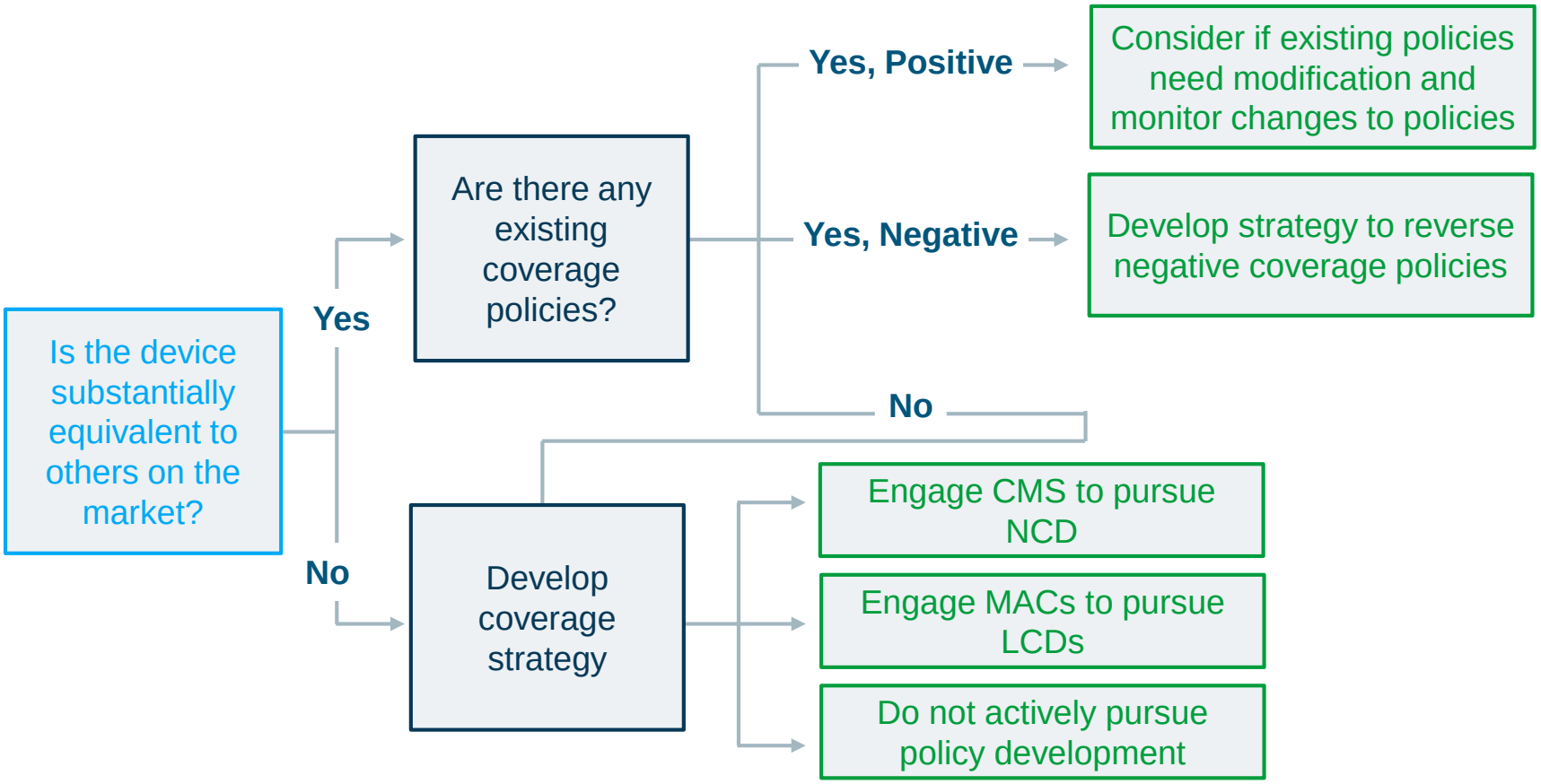
Key Questions to Ask When Developing Coverage Strategy



Specific coverage strategies should be shaped by strength/availability of clinical data and evidence as well as alignment with CMS priorities

PMA: Premarket Approval
NCD: National Coverage Determination
LCD: Local Coverage Determination

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Medicare Coverage Landscape

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 Reasonable and Necessary Qualification, Products or Services Must:

- Improve health outcomes
- Be safe and effective
- Not be deemed experimental or investigational

In Addition, Products or Services Must:

- Be approved by the FDA (with a few exceptions)
- Fall into a statutorily-defined benefit category

Cost or cost-effectiveness is not an explicit factor in determining coverage for products or services, though it may be considered in payment policies and the decision to initiate formal coverage reviews

SSA: Social Security Act

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Medicare Coverage Determinations May Occur at the Local or National Level

National Coverage Determination (NCD)

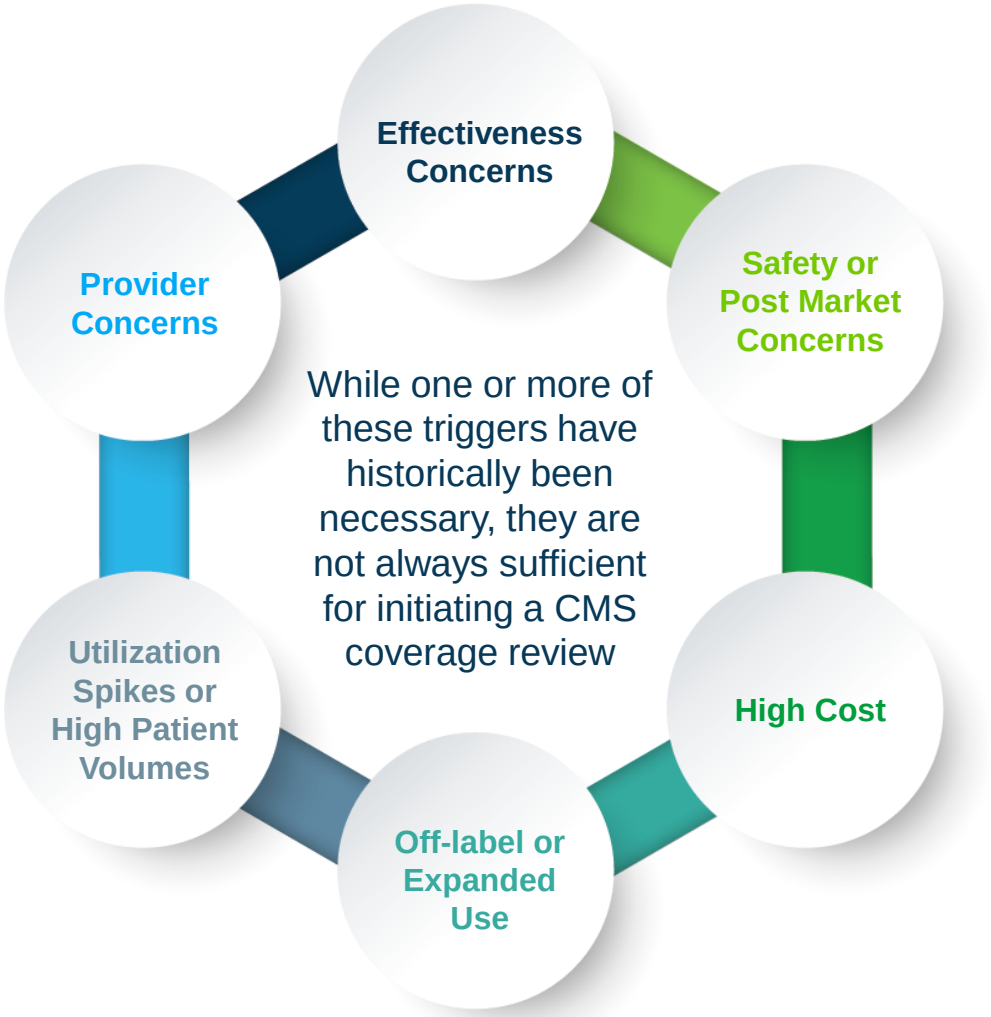
- Developed by CMS Central Office/Coverage and Analysis Group
- Typically for new products lacking in a robust evidence-base, high-volume, and/or expensive procedures
- Follows statutorily set timelines with a lengthy public process
- Sets one national policy; binding on all contractors

Local Coverage Determination (LCD)

- Issued by MACs in the absence of an NCD
- Historically, more transparent than the NCD process
- Generally follows set timelines; can be swifter review than NCD process
- Allows for local variation in coverage

Although national coverage review can have a substantial impact, most coverage decisions are made at the local level

Several Key Triggers May Lead to Coverage Review at Either National or Local Levels



Provider Considerations

Contention between provider communities, specific provider qualifications, or training requirements may trigger a review

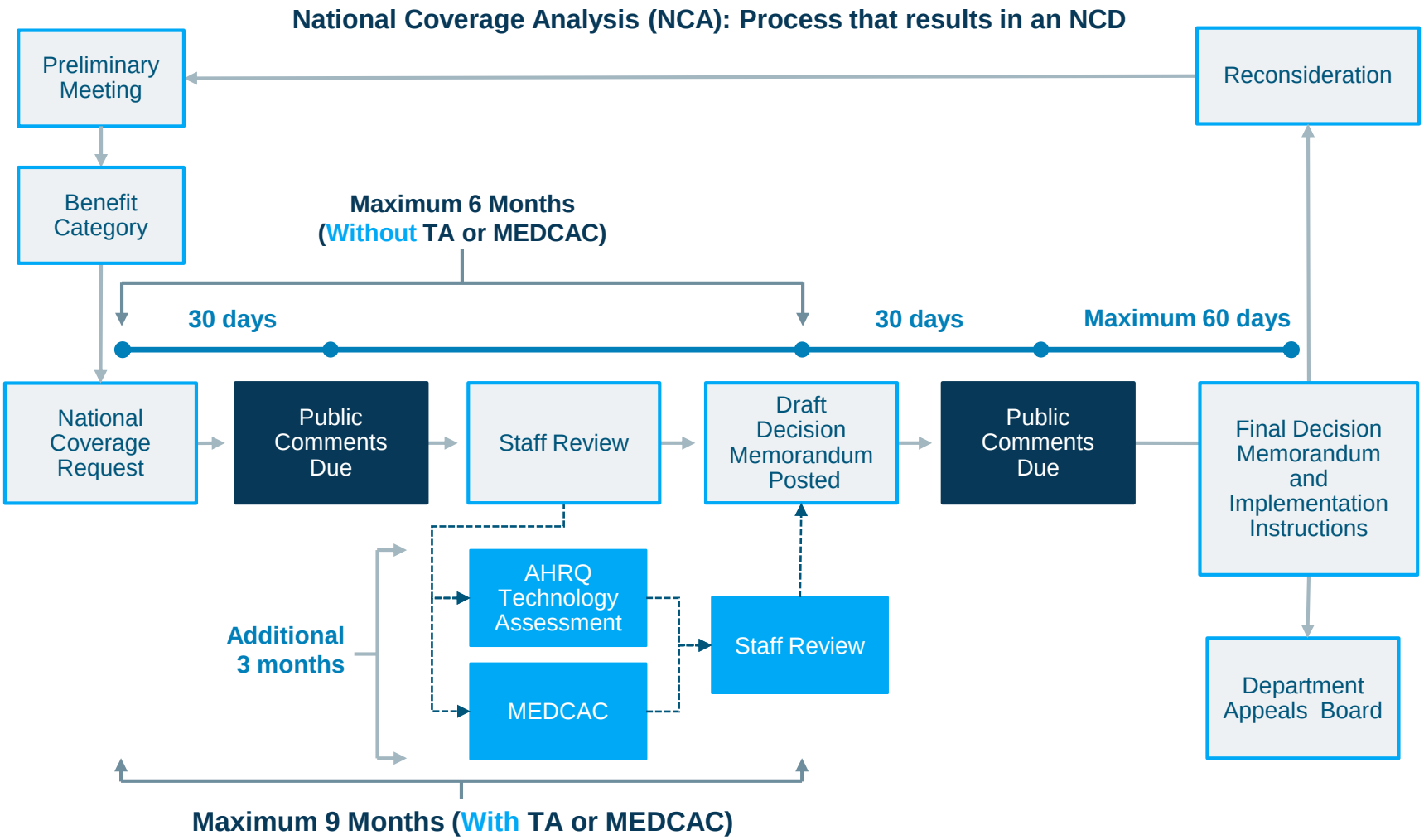
Effectiveness Concerns

Primary reason for a coverage review, likely due to unclear or controversial evidence or uncertainty about the relative clinical value of a new technology compared to the standard of care

Safety Concerns

May initiate coverage review due to lack of data on safety in Medicare populations or reports of adverse events or other serious safety issues

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



AHRQ: Agency for Healthcare Research and Quality; MEDCAC: Medicare Evidence Development & Coverage Advisory Committee; TA: Technology Assessment

Medicare's NCD Process Can Result in a Variety of Outcomes

National Coverage Decision	Coverage with Evidence Development	Coverage Left to MAC Discretion	National Non-Coverage Decision
Coverage is generally consistent with FDA label/intended use	CMS finds the technology compelling but would like to see further evidence generation	CMS makes no formal coverage decision; local Medicare Administrative Contractors can issues local guidance	CMS finds a technology or service "not reasonable or necessary" and restricts beneficiary access through a non-coverage decision

Coverage with Evidence Development (CED) Tracks

CED Generally Falls into Two Categories

Clinical Trial or Study Participation

- Allows for coverage of a technology or service when the used within the confines of a clinical study
- Study participation can limit beneficiary access to a novel technology
- Participation in a clinical study as a condition for coverage can be costly and can slow adoption of a new technology

Registry Requirement

- Allows for coverage when a beneficiary who receives a certain technology or service is documented in an approved registry
- CMS and FDA have used CED registry data to expand coverage and support further indications
- CED registries can be expensive and cumbersome for the providers submitting beneficiary data to them
- Registries are “unfunded mandates” from CMS; the Agency can require one as a condition of coverage but does not support a registry financially

CMS can require both study participation and a registry as a condition for coverage; the two are not mutually exclusive

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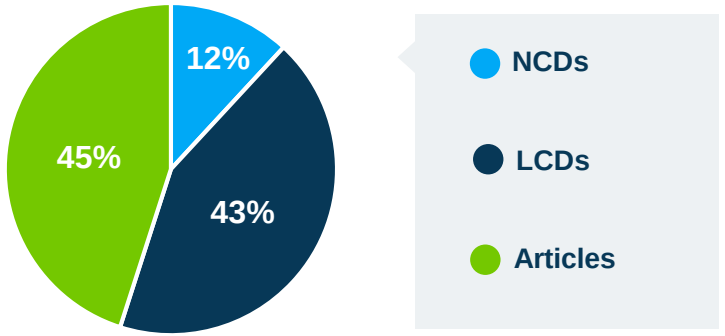
Majority of Medicare Coverage Decisions Occur at the Local Level

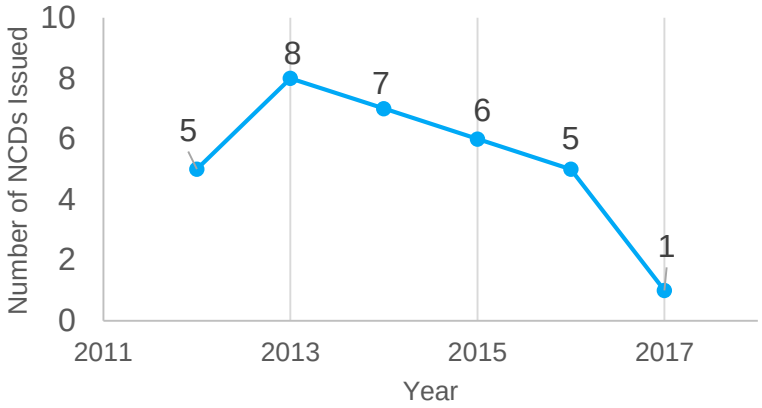
NCD: Coverage policies issued by the Coverage and Analysis Group within CMS National that are binding for all local Medicare contractors

LCD: Coverage policies issued by local Medicare Contractors that govern a specific part geographic region, includes draft LCDs

Articles: Policy updates, coding, and claims processing guidance issued by local Medicare Contractors

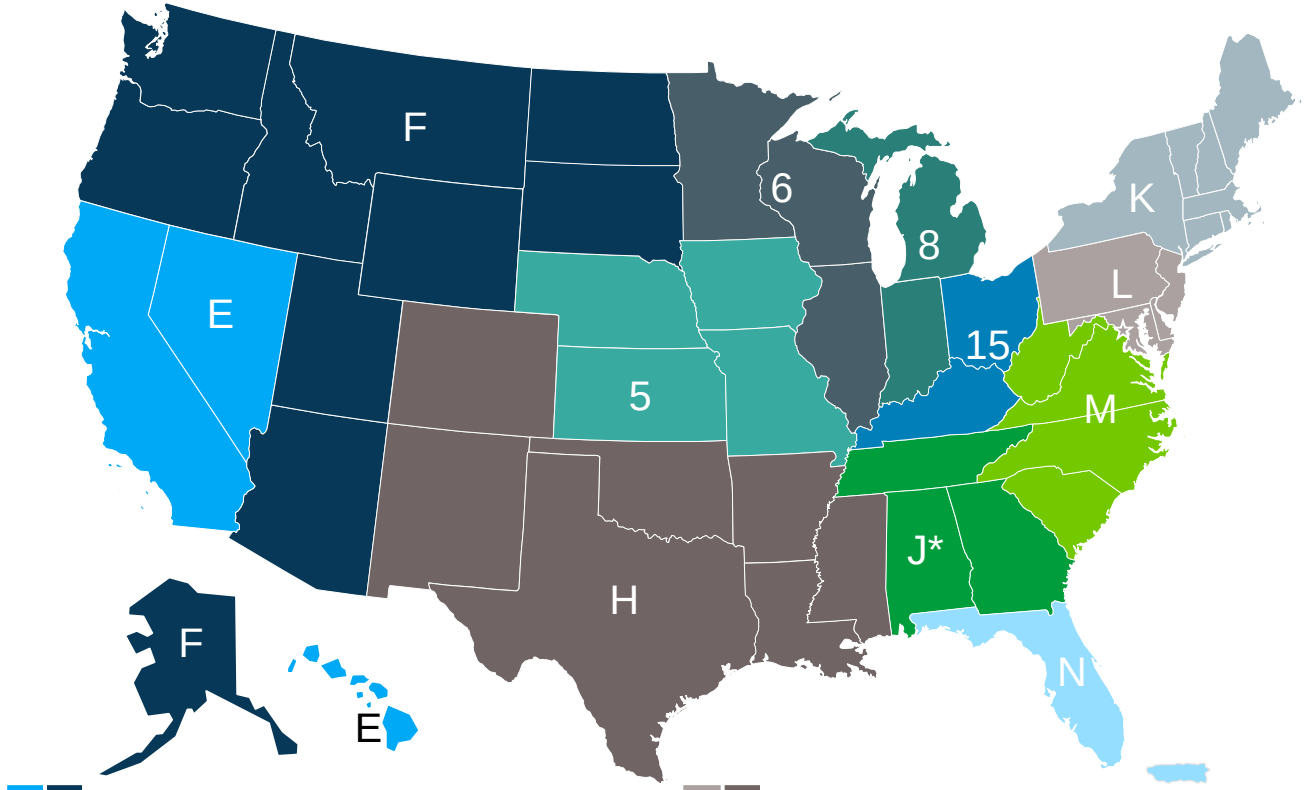
Active Coverage Items, November 2017





Box 1: Medicare Coverage Database, Q4 2017. https://www.cms.gov/medicare-coverage-database
Box 2: Analysis of CMS National Coverage Database 2012-2017 performed 11/17/2017

Local Medicare Policy Is Developed & Implemented by MACs in Distinct, Designated Regions



E F Noridian Administrative Services, LLC (NAS)	L H Novitas Solutions, Inc. (Novitas)
M J Palmetto GBA, LLC	15 CIGNA Government Services (CGS)
5 8 Wisconsin Physicians Service (WPS)	N First Coast Service Options, Inc. (FCSO)
K 6 National Government Services (NGS)	

Source: https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Downloads/AB-MAC-Jurisdiction-Map-Oct-2017.pdf Note: This map represents the MAC contracts as of October 2017
*CMS awarded jurisdiction J's contract to Palmetto GBA, LLC, with transition occurring early 2018

MACs Communicate Coverage Via Two Pathways

1

LCDs

- LCDs are formal coverage policies that CMS requires to go through a public comment and review period
- LCDs apply on a regional basis, but MACs may often have similar policies for similar technologies

2

Articles

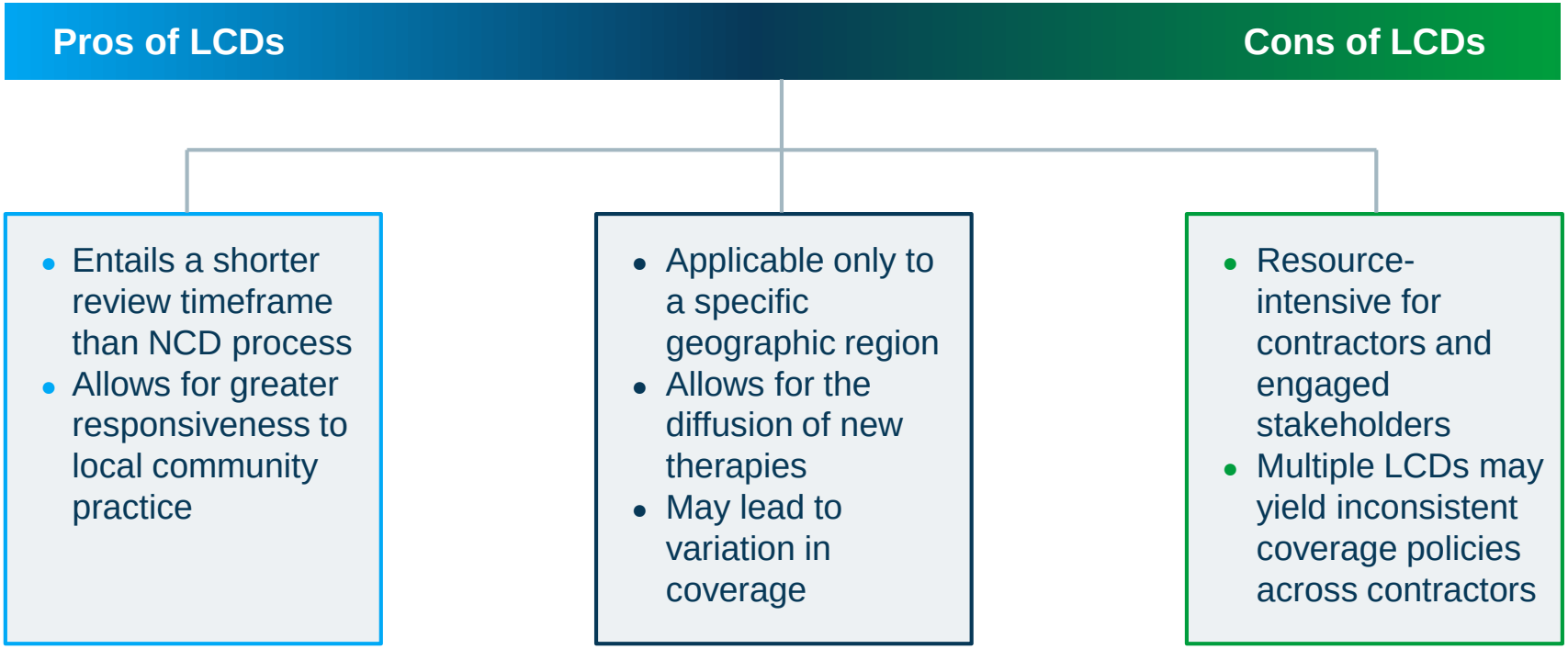
- MACs issue articles periodically that include policy updates, coding, and claims processing guidance
- The majority of updates to local policy are communicated via articles
- Articles carry the same weight as a formal LCD but can be issued without a formal public comment and review period

As a general rule, in the absence of a policy, claims are processed and paid for

Source: http://www.cms.hhs.gov/manuals/downloads/pim83c13.pdf

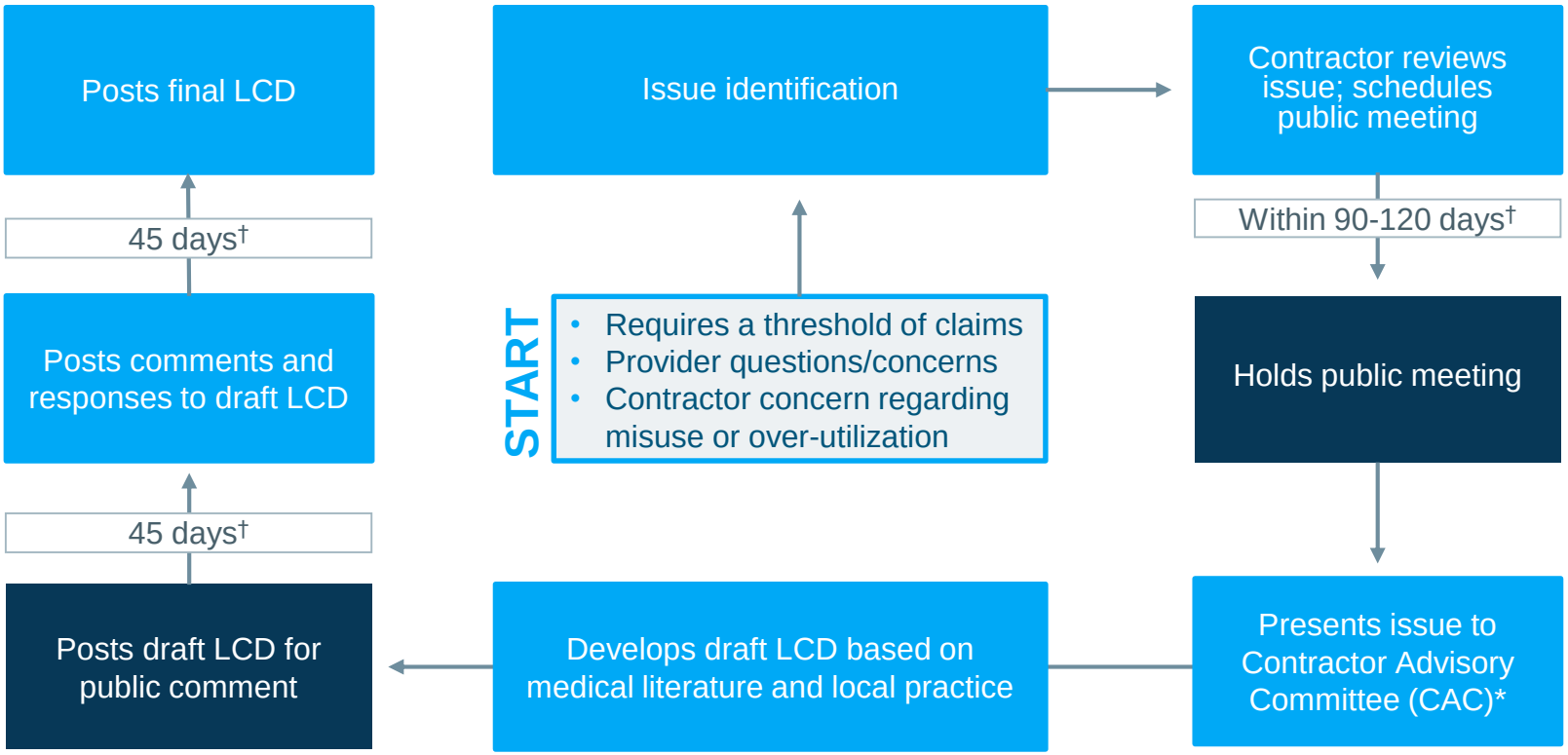
CMD: Contractor Medical Director

Traditionally, Local Medicare Coverage Strategy Has Been More Advantageous to Industry Than NCD Process



The LCD process allows for greater opportunities to develop coverage policies for emerging products and services

Contractors Follow a Formal LCD Process to Implement Coverage Decisions



The formal LCD process allows for public input, including from manufacturers

†Timeline not statutorily mandated; contractors aim to meet these timelines
Source: Medicare Program Integrity Manual, Chapter 13 – Local Coverage Determinations.
https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf

Each MAC Has at Least One CMD, Who Drives Policy Decisions

Contractors must employ a minimum of two Contractor Medical Directors (CMD) per jurisdiction, with an alternate when the CMD is unavailable for extended periods of time

- Must be a clinician currently licensed to practice medicine in the U.S.
- Physicians with patient care experience and those actively involved in the practice of medicine are preferred

1. **CMDs** may not hold a medical director position in the MAC's parent company
2. **CMDs** are meant to be leaders in the provider community, interacting with professional societies and educating clinicians on LCDs
3. **CMDs** provide clinical expertise in developing LCDs and internal medical review (MR) guidelines and help determine when LCDs are needed or must be revised
4. **The CMD** is also the acting co-chair of the local CAC

Medicare Program Integrity Manual. Medicare Improper Payments: Measuring, Correcting, and Preventing Overpayments and Underpayments. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c01.pdf

CACs Are Critical in Influencing Local Coverage Policies

1. Each state has a local CAC that informs the MAC Medical Director regarding coverage determinations

2. The purpose of the CAC is to provide:
   - A formal mechanism for providers within a State to participate in the development of an LCD
   - A mechanism to discuss and improve administrative policies
   - A forum for information exchange between carriers and physicians

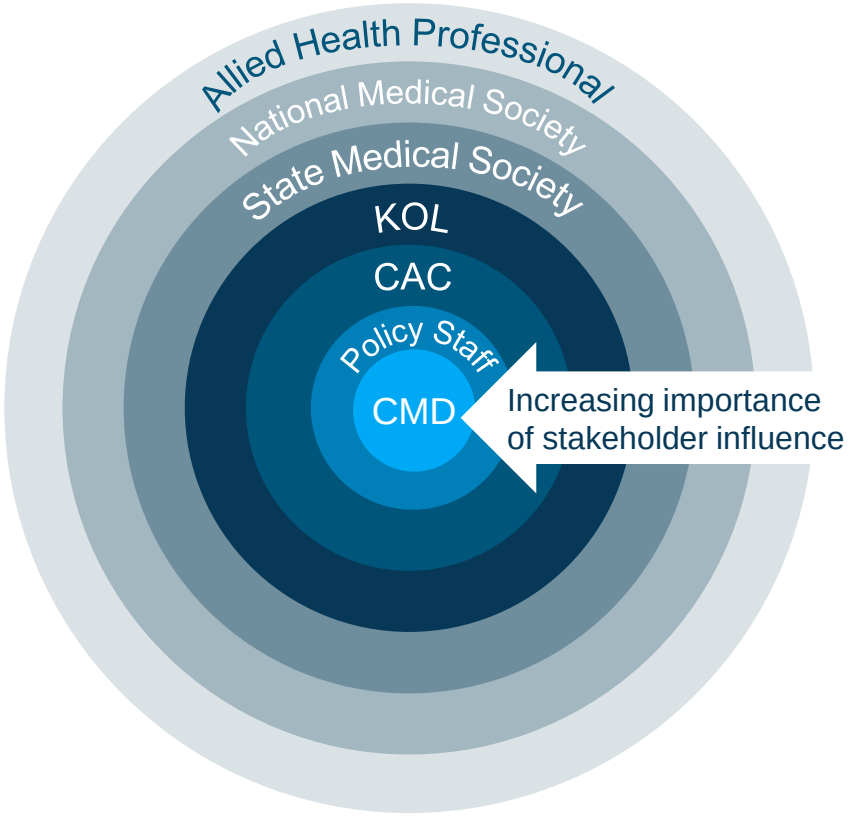
3. CAC members disseminate proposed LCDs and discuss inconsistent or conflicting MR policies
   - Comprised of physicians from key specialties and committee to the State, not regionally-based CACs

4. CAC meetings are the primary forum for discussion of proposed LCDs, developed by MAC medical directors

CACs are a key component in informing the development of local Medicare policies

Medicare Program Integrity Manual. Local Coverage Determinations.
https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf

Specialty Societies and KOLs Play a Key Role in LCD Development



1 | CMDs and CACs will often consult professional societies or KOLs to provide input on evidence for LCD development

- After draft LCDs are released, professional societies and KOLs also have opportunity to provide comments

2 | Engagement with the physician societies and KOLs could help garner coverage support

Companies may consider conducting a comprehensive stakeholder mapping to ensure that all of the necessary physician societies and KOLs are included in coverage support initiatives

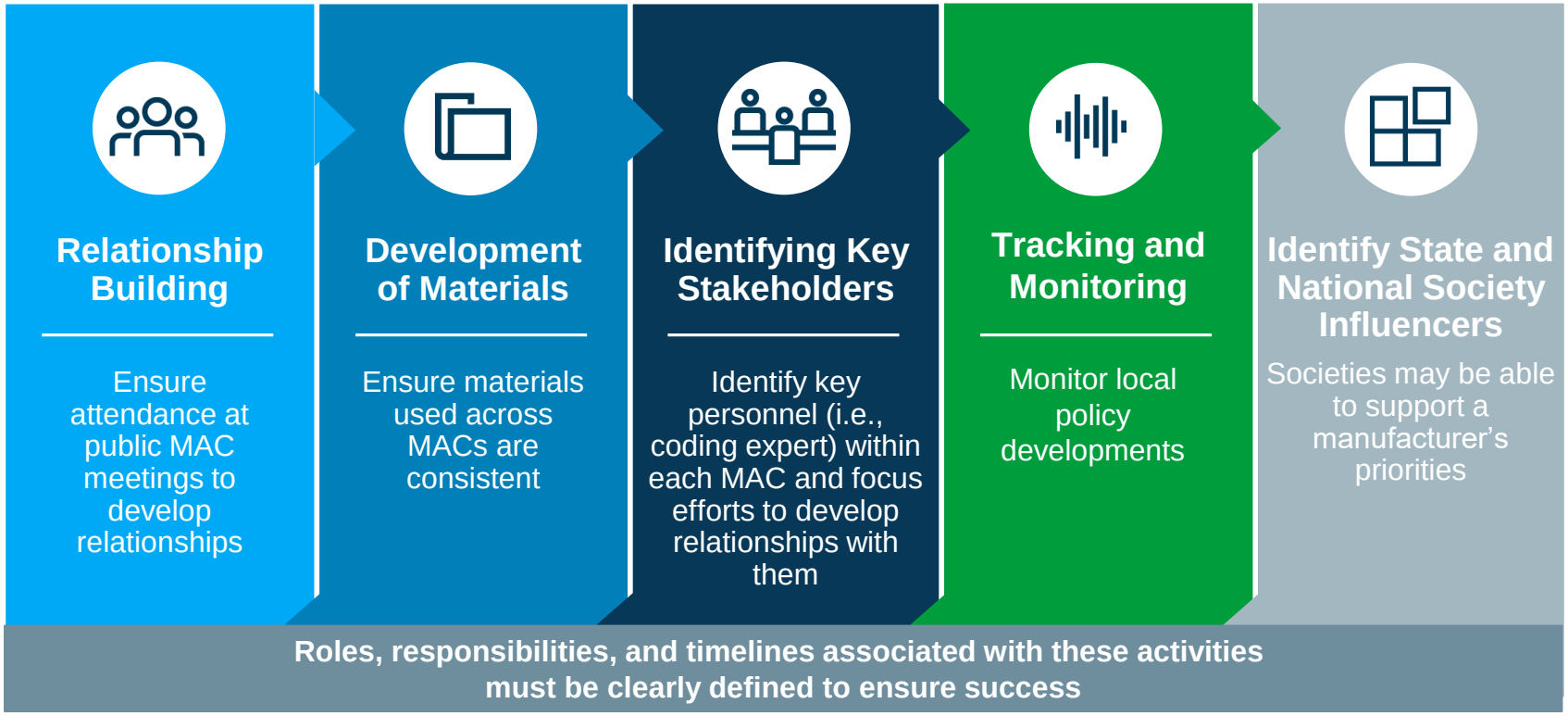
KOL: Key Opinion Leader; LCD: Local Coverage Determination; CMD: Contractor Medical Director; CAC: Coverage Advisory Committee

Understanding MACs is Key for Successful Engagement

What to Know

- ☑ Current MAC policy landscape (i.e., prevalence of restrictive coverage policies)
- ☑ Provider concerns (e.g., claims denials, billing and coding questions)
- ☑ MAC dynamics and priorities
- ☑ MAC key stakeholders (e.g., CAC members, CMDs, state level KOLs, state specialty society representatives)

Manufacturers Need to Coordinate a Number of Factors When Implementing a MAC Engagement Strategy



Each MAC is likely to have different processes, key personnel, and approaches. Manufacturers should develop strategies tailored to each MAC, while ensuring consistency across MACs

Creating a Local Coverage Strategy

Coverage strategies should be dynamic in response to changes in device design and trial results

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Coverage and the Interplay Between CMS & FDA

Medicare Reimbursement Considerations of IDEs

Medicare pays for Category B devices in clinical trials under the joint CMS/FDA IDE policy

Category A – Experimental	Category B – Investigational
• FDA deems an IDE as Category A when it is unsure if device is safe and effective, "absolute risk" of device has not been established • Medicare **will not reimburse the device**, but may only cover routine care items and services related to the IDE study	• FDA deems an IDE as Category B when it is comparable or substantially equivalent to a previously approved device, or not SR • Medicare **may reimburse both the device and routine care items and services** related to the IDE study

After a device receives IDE approval from the FDA, a manufacturer must request coverage for their Category B device or Category A or B IDE study items and services from CMS within approximately 30 days

IDE: Investigational Device Exemption
SR: Significant risk
Source: Medicare Coverage Related to IDE Studies, http://www.cms.gov/Medicare/Coverage/IDE/

Parallel Review Allows for Simultaneous FDA/CMS Review for Premarket Approval & Coverage Determination

Parallel Review Overview

- Established by FDA/CMS to decrease time between FDA's approval of a premarket application and CMS NCD
- Fully implemented in 2016 after being established as a pilot program in 2011
- Process divided into two stages:
  1. FDA and CMS meet with manufacturer to provide feedback on the proposed clinical trial
  2. FDA and CMS review clinical trial results submitted in the PMA independently

Parallel Review Criteria

- Sponsor has approved IDE or has sufficient interaction with FDA through pre-IDE process
- New technology requires an original/supplemental application for PMA or petition for de novo review
- Technology falls within scope of Part A or Part B Medicare benefit category and is not subject to an NCD

Source: Food and Drug Administration Center for Devices and Radiological Health Innovation (link)

FDA/CMS= Food and Drug Administration/Centers for Medicare and Medicaid Services; NCD: national coverage determination PMA: Premarket approval IDE: investigational device exemption

Coverage Considerations

Manufacturers must start to develop coverage strategy early enough to ensure evidence is relevant to payers

- Are similar devices covered under Medicare and private payers? Are there any non-coverage decisions?
- Will the device qualify for coverage under Medicare as an IDE during clinical trials?
- What is the study population and how does that compare to Medicare and private insurer populations?
- Will the evidence generated from FDA clinical trials be sufficient to meet the needs of payers?
- What is the evidence generation plan to support payer coverage?
- What is the company's engagement plan for CMS, MACs, and other payers?
- What is the optimal coverage outcome what steps are needed to achieve that?

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Case Studies: Cologuard and TAVR

Cologuard: Technology Overview

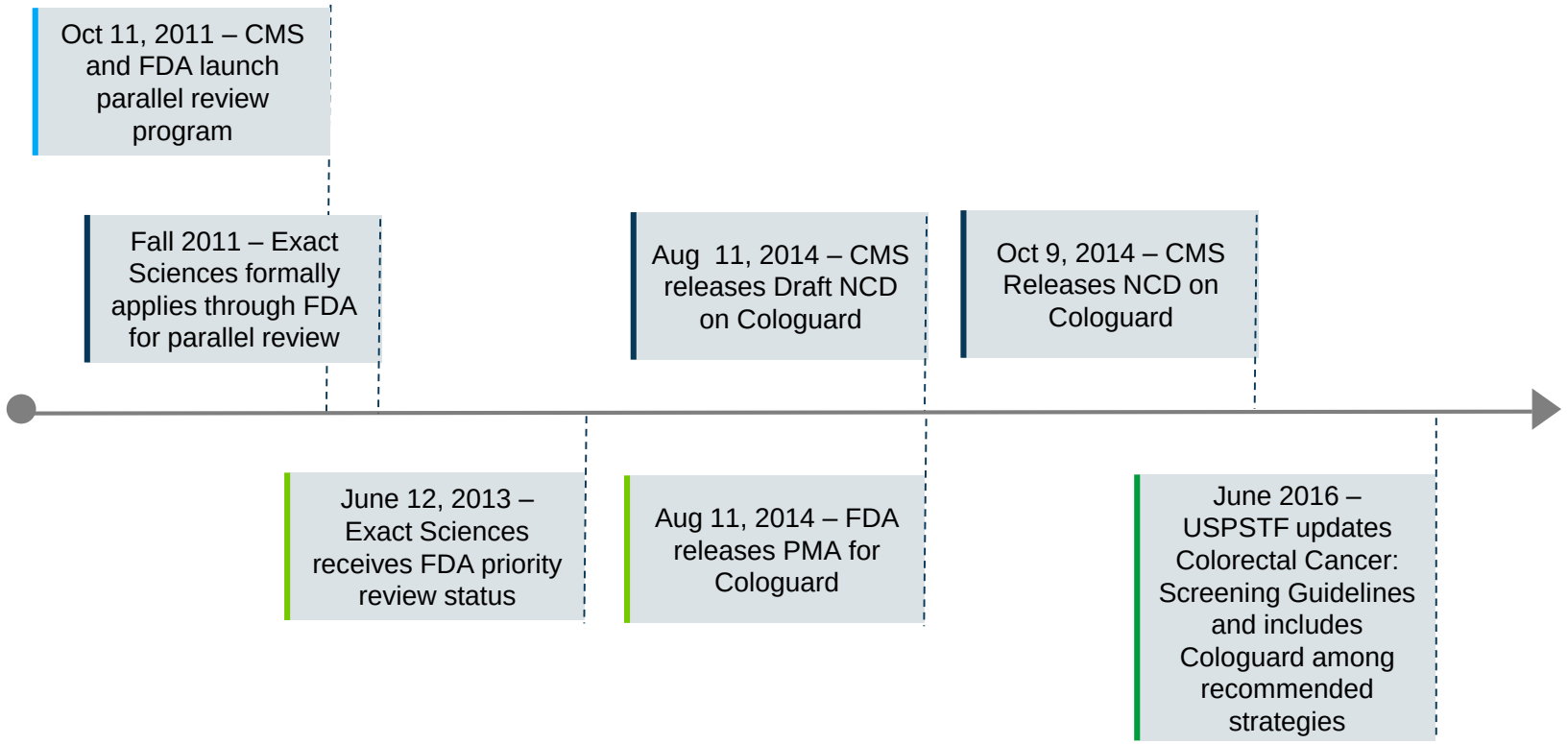
Cologuard is a qualitative non-invasive screening test indicated for the detection of colorectal cancer or advanced adenoma

Exact Sciences received Premarket Approval from the FDA for Cologuard on August 11, 2014. Cologuard is indicated to screen adults of either sex, 50 years or older, who are at typical average-risk for colorectal cancer

Cologuard was the first noninvasive screening test for colorectal cancer that analyzes both stool DNA and blood biomarkers

Cologuard: Coverage Timeline

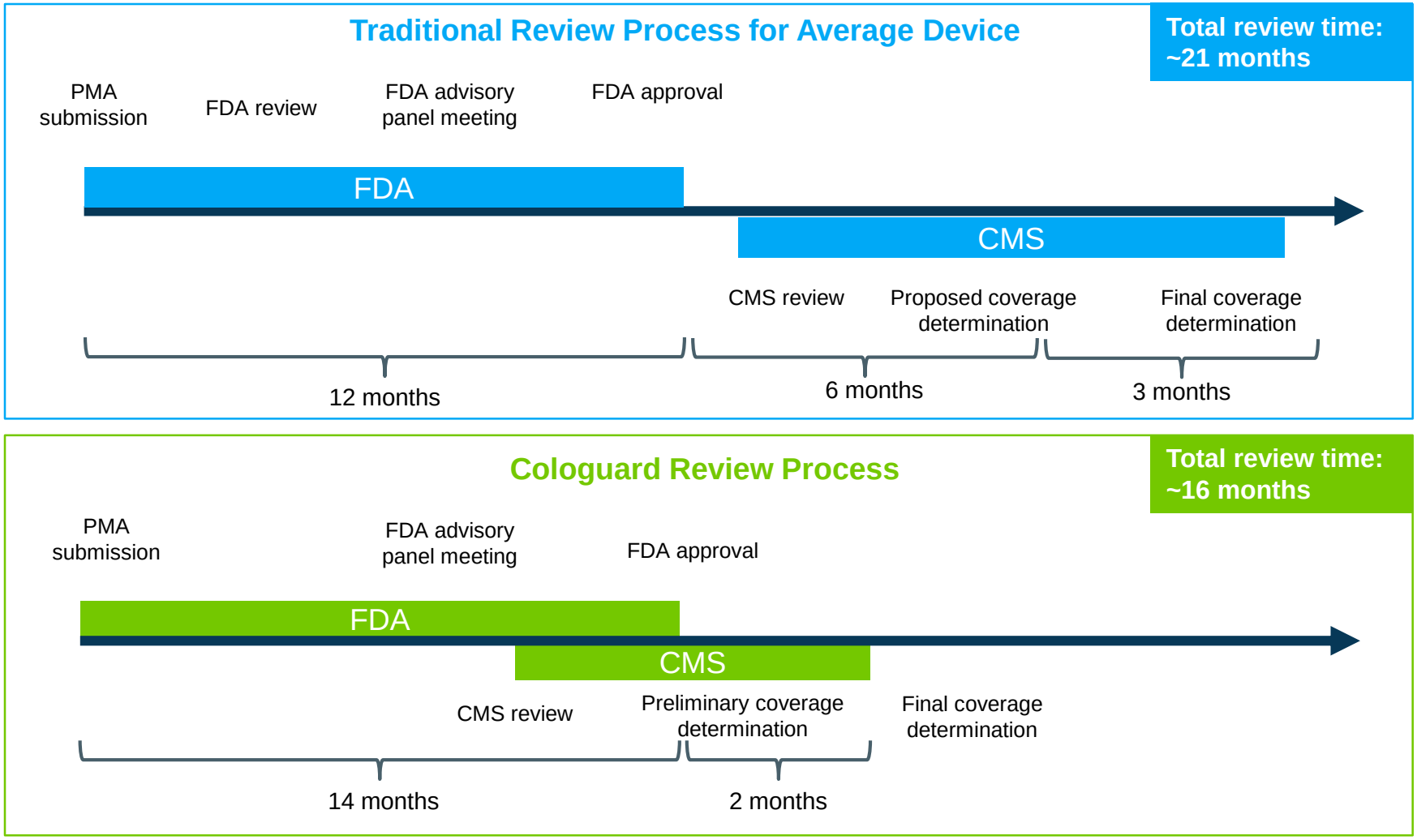
COLOGUARD COVERAGE TIMELINE



Exact Sciences engaged with CMS as early as 2009 and was asked to be the first case to participate in the then-unestablished parallel review process

PMA: Premarket Approval
USPSTF: US Preventive Services Task Force

Cologuard: Expedited Coverage Under Parallel Review



Source: Exact Sciences' experience with the FDA and CMS parallel review program (Ridge et al.)

Cologuard: Key Coverage Learnings

Strategy and Perceptions

- This unfolded under a circumstance where there was a large public health problem with limited testing options, so there was a willingness to collaborate from multiple stakeholders
- Exact Sciences took ownership of and drove the parallel review coverage process
- Exact Sciences learned about the then-unestablished parallel review process through early meetings with CMS
- Exact Sciences leveraged the large data set from Cologuard's Deep-C pivotal clinical study in their conversations with CMS

Stakeholder Engagement

- **CMS**: Exact Sciences engaged CMS in the coverage process as early as 2009 and consistently met with them in person throughout the coverage process
  - In addition to clinical information, Exact Sciences shared information about their business plan and the workflow associated with the device with CMS
- **KOLs**: Prominent KOLs participated as scientific advisors and Board members to Exact Sciences prior to the launch of Cologuard

Impact

- Exact Sciences was successful in the parallel review process in part because of the unmet clinical need. They had a well thought out business plan and had considered how the technology would be used in clinical practice to help patients

STS: Society of Thoracic Surgeons; ACC: American College of Cardiology; SCAI: Society for Cardiovascular Angiography and Interventions

TAVR: Technology Overview

TAVR is a minimally invasive surgical procedure that replaces a damaged heart valve with a fully collapsible replacement valve through a catheter

Edwards Lifesciences gained premarket approval from the FDA on October 19, 2012 for their SAPIEN device. The SAPIEN is approved for patients with symptomatic aortic stenosis who are considered an intermediate or high risk patient for standard valve replacement surgery

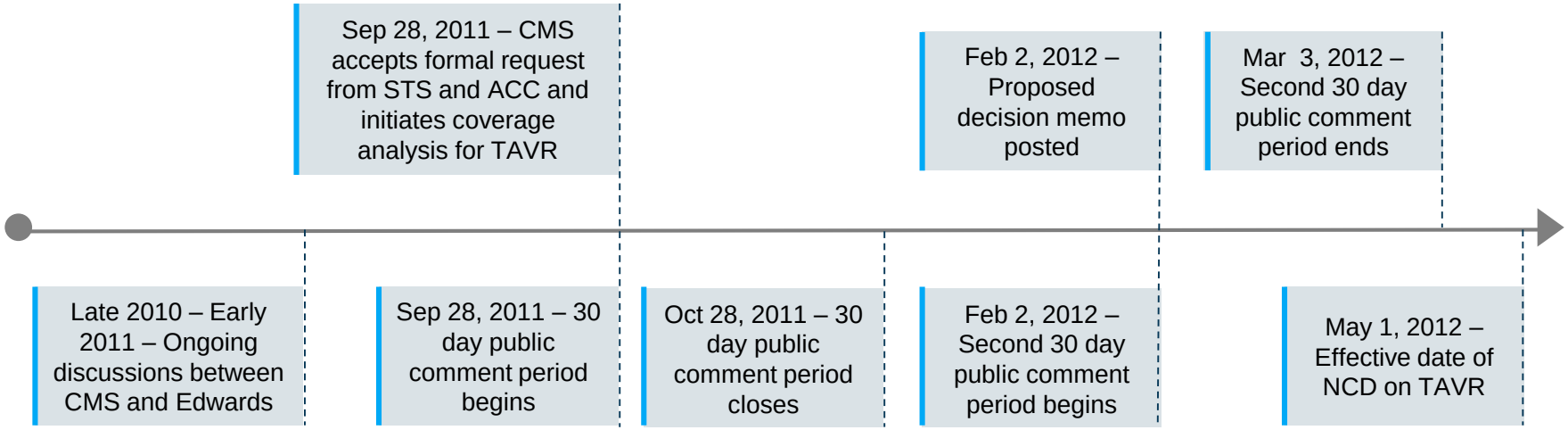
The TAVR procedure was revolutionary in that it permitted valve replacement to occur without a sternotomy

TAVR: Transcatheter aortic valve replacement

TAVR: Coverage Timeline

- CMS covers TAVR under CED under two conditions:
  - For the treatment of symptomatic aortic valve stenosis under CED with the following conditions:
    - There is FDA approval of the indication and corresponding system;
    - Two cardiac surgeons evaluate the patient;
    - The patient is under the care of a heart team; and
    - The hospital and heart team meet volume requirements and participate in a prospective, national, audited registry.
  - For indications that are not approved by the FDA, when patients are enrolled in qualifying clinical studies.

TAVR COVERAGE TIMELINE



STS: Society of Thoracic Surgeons; ACC: American College of Cardiology; CMS Decision Memo for Transcatheter Aortic Valve Replacement (TAVR) (CAG-00430N):https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=257

TAVR: Key Coverage Learnings

Strategy and Perceptions

- Before FDA approval of SAPIEN, Edwards was wary of the restrictive nature of NCDs and their impact on coverage; however the transformative nature of this technology drove this pathway. Without the NCD, patient access to this technology would have been limited

Stakeholder Engagement

- **Specialty Societies**: STS and ACC drove the coverage process and made the official request to CMS for an NCD. The societies were not aligned on every aspect of TAVR coverage
- **CMS**: Edwards engaged the CMS coverage as early as the Fall of 2010 and consistently met with them in person throughout the coverage process. Edwards did not initiate the coverage process with the clear intent to get an NCD
- **Patient Advocacy**: Patients lent their voice to the process through outreach to their Members of Congress

Impact

- Registry requirements are burdensome to hospitals, but participation is necessary to receive Medicare payment for TAVR. The well-designed registry provided additional clinical data for TAVR, which allowed for the advancement of the technology

STS: Society of Thoracic Surgeons; ACC: American College of Cardiology

Coverage Considerations: Exact Sciences and Edwards

Key lessons from the case studies include:

- Advance planning, including reimbursement landscape assessments, shaped the companies' coverage strategy and was a key element of success
- Application to the larger public health need of Medicare beneficiaries and business strategy were integral parts of the companies' strategies
- Engaging with coverage experts was vital to the companies' coverage strategies and outcomes
- Recognizing the multitude of coverage possibilities, both Exact Sciences and Edwards were fully prepared for success under different pathways and worked to shape the most appropriate outcome
- Securing the support and engagement of specialty societies was integral to the coverage process
- Meeting with CMS early and frequently was essential to ensuring dialogue between the parties