# Medicare Coverage for Medical Devices

## A look at "TCET"

August 24, 2023

# The Question

How does CMS decide what products are "**reasonable and necessary**?"

# Medicare Coverage of an Item or Service

## The Ground Rules

In Medicare Parts A and B:

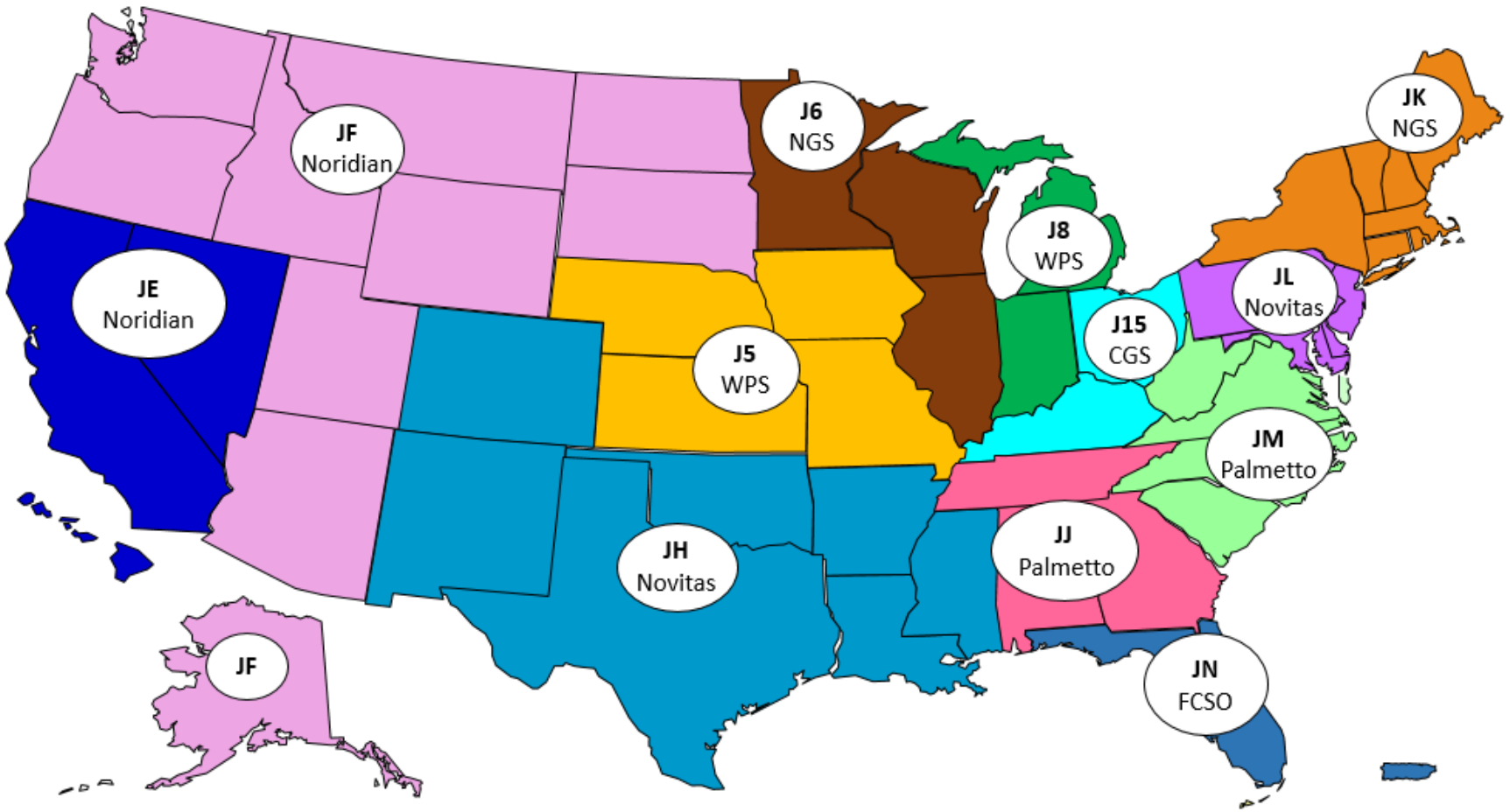
- Must fit into a Medicare benefit category (as defined in Section 1861 of the Social Security Act)
- NOT statutorily excluded from coverage under Parts A and B
- Must be "reasonable and necessary for the diagnosis or treatment of illness or injury"

# The "Reasonable and Necessary" Process

## CMS Coverage Pathways

- National Coverage Determination – "a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title" (Section 1862(l)(6)(A)) of Social Security Act)
- Local Coverage Determination – Medicare Administrative Contractors (MACs) develop coverage determinations that apply only to their geographic jurisdictions.
- Claim-by-Claim Adjudication – At discretion of MACs

# A/B MAC Jurisdiction




Source: CMS Map

# Estimated Process Times

## CMS Coverage Determinations can take months

Estimated time for CMS processes:

- National Coverage Determination: 9-12 months
- Local Coverage Determination: 9-12 months

Data from CMS

# The "MCIT" rule

## CMS establishes a new coverage pathway

In January 2021, CMS finalized a regulation creating the **Medicare Coverage for Innovative Technologies (MCIT)** pathway.

- Applied only to medical devices designated as breakthrough by the FDA
- Granted four years of automatic Medicare coverage for breakthrough devices, effective the date of FDA approval for marketing.
- Effective March 15, 2021

Anticipated uptake:

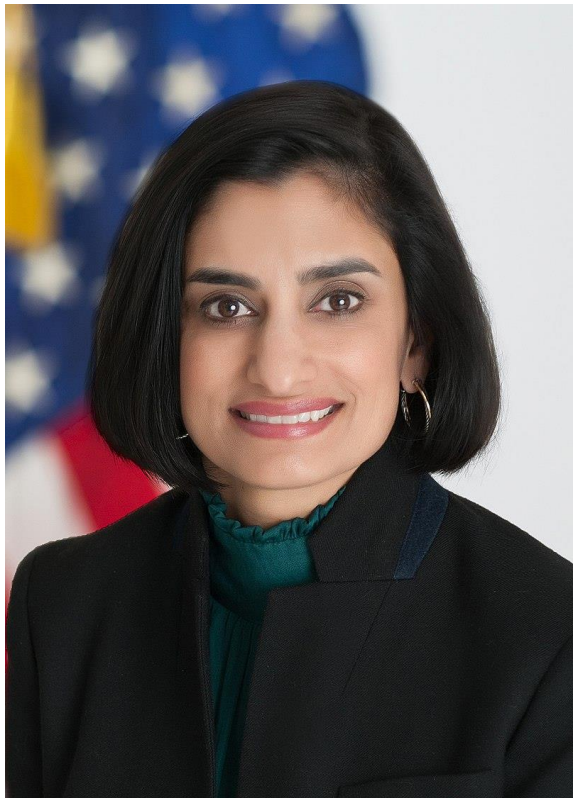
- Year 1 – 2 manufacturers
- Year 2 – 3 manufacturers
- Year 3 – 4 manufacturers

# Rationale for MCIT

## Concern with delays

"Under current rules, FDA approval of a device is followed by an often lengthy and costly process for Medicare coverage. The lag time between the two has been called **the "valley of death"** for innovative products, with innovators spending time and resources on FDA approval, only to be forced to spend additional time and money on the Medicare coverage process." – CMS Press Release

"For new technologies, CMS coverage approval has been a chicken and egg issue. Innovators had to prove their technologies were appropriate for seniors, but that was almost impossible since the technology was not yet covered by Medicare and thus not widely used enough to demonstrate their suitability for Medicare beneficiaries. These efforts will ensure seniors get access to the latest technologies while lowering costs for innovators. Arcane bureaucratic requirements have no business preventing seniors' access to a technology that might save their lives." – CMS Administrator Seema Verma (pictured)



# Expanding "Reasonable and Necessary"

## Incorporating policies of the commercial market

- The same rule modified the regulatory language defining "reasonable and necessary"
- Largely moved existing, sub-regulatory standards into formal regulation
- New: CMS permitted to incorporate commercial market coverage policies into the determination of whether or not to cover a product or service:

"For national and local coverage determinations, which have insufficient evidence to meet paragraphs (b)(3)(i) through (v) of this section, CMS will consider coverage to the extent the items or services are covered by a majority of commercial insurers. As part of CMS' consideration, CMS will include in the national or local coverage determination its reasoning for its decision if coverage is different than the majority of commercial insurers."

# Biden Administration Pauses MCIT

## Intervention prevents rule from taking effect

- March 2021 – CMS delays effective date by 60 days
- Outlines concerns:
  - Operational issues – establishing coding and payment for covered devices, and benefit category determinations
  - Overlapping rules – CMS had a pending rule related to Benefit Category Determinations pending for DME (since rescinded)
  - Breakthrough Device Volume – Higher numbers of breakthrough devices than cited in final rule.
    - End of 2018 (as used in MCIT rule) – 97
    - End of 2021 – Over 400
  - Medicare Patient Benefit/Protection and Other Issues – "evidence basis for Medicare coverage of these technologies"

# …and Repeals It

"Safe and Effective" vs. "Reasonable and Necessary"

November 2021 – CMS formally repeals MCIT rule

**Concern about evidence**

"we believe that the finalized MCIT/R&N rule is not in the best interest of Medicare beneficiaries because **the rule may provide coverage without adequate evidence that the Breakthrough Device would be a reasonable and necessary treatment for the Medicare patients that have** the particular disease or condition that the device is intended to treat or diagnose."

**Replacement on the way**

"CMS acknowledges that more can be done to address the current uncertainty surrounding Medicare coverage of new medical technologies and while we are unable to provide a specific timeframe for doing so, we are working expeditiously to develop an alternative expedited coverage pathway with adequate patient safeguards to ensure devices are safe for Medicare patients and an evidence base that is generalizable to Medicare beneficiaries is further generated."

# Introducing TCET

## New CMS Process to Expedite Coverage

- June 2023 – CMS releases a notice (not rule) establishing "Transitional Coverage for Emerging Technologies" (TCET)
- Relies on "Coverage with Evidence Development" to help CMS develop larger evidence base.

# What is Coverage with Evidence Development?

...because its not coverage

- Designation CMS can provide through an NCD
- CMS is NOT designating a product as "reasonable and necessary"
- CMS is providing Medicare coverage for a product or service for the purpose of advancing research

Recent example:

- Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD)

# How TCET Works

Work prior to FDA approval

- **"Nomination" for TCET pathway** – Device manufacturers can self-nominate to participate in the TCET pathway. This nomination would need to come 12 months prior to anticipated FDA decisions on coverage.
- **CMS decision on TCET pathway** – CMS would review the nomination submitted by the manufacturer, and make a provisional decision within 30 business days. Decisions on whether or not a device falls into an available Medicare benefit category may take additional time; as noted earlier, if the device fails to fall into a Medicare benefit category, its eligibility for TCET would be lost.
- **Evidence development** – After provisional acceptance to TCET, CMS would hold an "Evidence Preview" meeting with the manufacturer. Following that meeting, CMS and AHRQ would work with the manufacturers to develop an Evidence Development Plan in advance of the formal NCD being issued.

# How TCET Works

National Coverage Determination brings in NCD

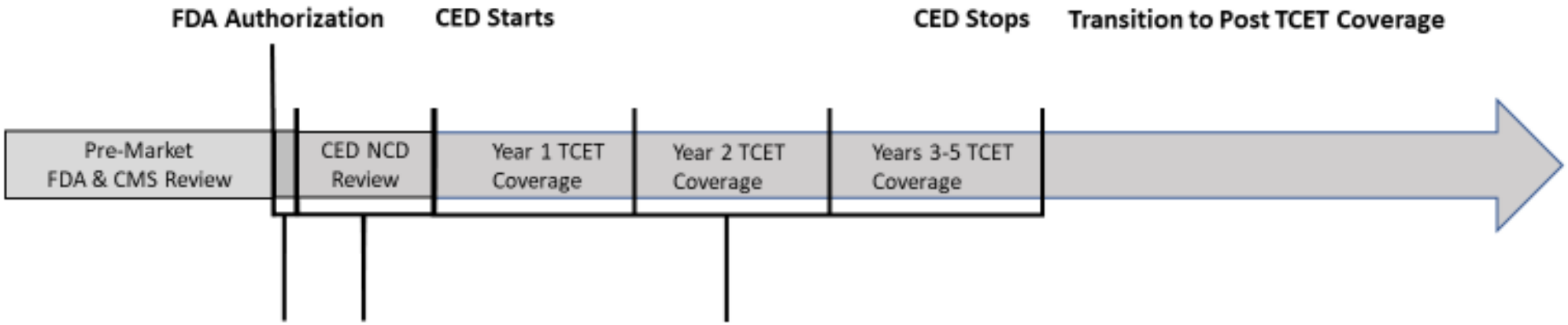
- **Use of Coverage with Evidence Development** – Once the device receives FDA approval, CMS will automatically announced the initiation of the NCD process. CMS intends to finalize the NCD within six months of FDA approval.
- **Applicability to similar devices** – CMS indicates it will endeavor to establish coverage policies applicable to broad groups of similar devices expected to come to market, potentially eliminating the need for NCDs on individual products.
- **CEDs time-limited** – CED coverage would not be indefinite; CMS will provide CED as long as is necessary to generate necessary supportive evidence, but not in perpetuity. The length of the CED will be dependent on the evidence development plan CMS establishes with the manufacturer.

# How TCET Works

## CMS Makes a Final Decision

- **NCD Reconsideration** – At the end of the initial evidence collection time, CMS would initiate a reconsideration of the initial NCD to determine of the product has sufficient evidence to merit Medicare coverage. CMS would offer one of four recommendations: 1) a positive coverage NCD, with no further evidence development requirements; 2) continued CED; 3) non-coverage; 4) permitting MACs to use their own discretion.

# TCET Proposed Pathway/ Timeline




- Nomination
- CMS review and feedback
- CMS benefit category review
- Evidence Preview
- Stakeholder Meeting
- Approve EDP
- Open NCA
- Propose NCD
- Public comment
- Finalize NCD
- Intermittent EDP progress updates
- Evidence development stops and results are published
- CMS (re)reviews evidence
- NCD Reconsideration (possible outcomes include: an NCD without evidence development requirements; an NCD with CED; a non-coverage NCD; or MAC discretion)

Legend: TCET – Transitional Coverage for Emerging Technologies; FDA – Food and Drug Administration; CED – Coverage with Evidence Development; CMS – Centers for Medicare and Medicaid Services; NCD – National Coverage Determination; EDP – Evidence Development Plan; NCA – National Coverage Analysis; MAC – Medicare Administrative Contractor.

# TCET Characteristics

## Differences from MCIT

- NO automatic coverage for FDA approved breakthrough devices
- NO changes to federal regulations

# Other CMS News

## Beyond TCET

CMS also released two guidance documents:

- NCD process - CMS released draft guidance articulating in greater detail how CMS considers evidence presented in an NCD
- Coverage with Evidence Development – CMS released draft guidance stating the principles for Coverage with Evidence Development, and standards for clinical studies CMS would support through cED

# Thank You!

Dan Farmer
Principal
BGR Group
Health and Life Sciences Practice
dfarmer@bgrdc.com