
# Primer on Medicare coverage policy

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# Presentation overview

- Overview of Medicare's coverage for:
  - Parts A and B services
  - Part C
  - Part D
- Implications for low-value care
- Organizations that develop and use comparative clinical effectiveness research
  - Patient-Centered Outcomes Research Institute
  - Institute for Economic and Clinical Review

# Statutory limits on Medicare coverage

- Service must also fall into a Medicare benefit category and not be excluded by the statute
- Section 1862(a)(1)(A) requires that service must be "reasonable and necessary for the diagnosis or treatment of illness or injury…"
- Statute does not define "reasonable and necessary"
- CMS attempted to define "reasonable and necessary" via rulemaking to include cost effectiveness or value in 1989 and 2000 and was unsuccessful
- CMS has operationalized the following definition: "Adequate evidence to conclude that the item or service improves clinically meaningful health outcomes for the Medicare population"

# Medicare coverage for Parts A and B services

- Policy not needed for many services in existing billing code or payment bundle
- Explicit legislative and executive coverage requirements for certain services
- National coverage determinations (NCDs)
- Local coverage determinations (LCDs)
- Policies in program manuals and memos
- Coding

# Explicit legislative and executive coverage requirements

- Off-label cancer drugs if published in selected third-party drug compendia
- Routine costs of qualifying clinical trials
- Routine costs of care for certain categories of Investigational Device Exemption studies
- Preventive services

# NCD process and outcomes

- Developed by CMS (Baltimore)
- Applied nationwide - do not vary regionally
- Decisions: national coverage, national noncoverage, or no decision (left to discretion of Medicare Administrative Contractors' (MACs') medical directors)

# Options in NCD process and outcomes

- MEDCAC: Advisory group of experts that provides CMS with independent guidance
- External technology assessment: Systematic analysis of the safety and clinical effectiveness of a service from an external entity
- Coverage with evidence development: Link coverage to collection of clinical evidence via study or registry
- FDA-CMS parallel process: Permits medical device manufacturer to request a concurrent review of clinical evidence by FDA and CMS

# LCD process

- Developed by MACs' medical directors
- Because applied in contractor jurisdiction, coverage policies can vary regionally
  - One exception: LCDs developed by Durable Medical Equipment Regional Contractors
- Decisions: local coverage, local noncoverage in region, or no coverage decision (claim by claim adjudication)
- Must be consistent with NCDs, statute, regulations

# Similarities between NCDs and LCDs

- Service eligible for coverage if FDA approved, in a statutory category, reasonable & necessary
- Consider available clinical evidence
- Are internally generated or based on external requests
- Publish proposed and final decisions on-line
- Provide opportunities for public input
- Include a reconsideration and challenge process

# Differences between NCDs and LCDs

- LCDs permit regional flexibility
- NCDs less flexible than LCDs because they are applied nationwide
- Some contend that LCDs are more responsive to community care standards than NCDs and allow initial diffusion of new technologies
- Some contend that there should be greater consistency in Medicare's coverage policies across regions

# Medicare coverage policies as they apply to Medicare Advantage plans

- Medicare Advantage (MA) plans are required to provide the same set of benefits that are available under Parts A and B
- MA plans are permitted to use tools not available in FFS Medicare, such as prior authorization
- MA plans have leeway in varying cost sharing for a particular service

# Medicare coverage for Part D drugs

- Part D sponsors create and manage formularies
- Part D statute and regulations place some constraints on which drugs plan sponsors cover and how they operate their formularies
- By contrast, formularies cannot be used for Part B drugs

# Low-value care

- Low-value services are paid for under Medicare's coverage and payment policies
- Recent MedPAC analysis quantifying use of low-value care
  - 31 measures developed by Harvard researchers
  - In 2014, 23% to 37% of beneficiaries received at least one low-value service, and total Medicare spending for low-value services was $2.4 billion to $6.5 billion
  - Results understate volume and spending on low-volume care

# Role of comparative clinical effectiveness research

- Highlight two organizations that develop and use comparative clinical effectiveness research
  - Patient-Centered Outcomes Research Institute (PCORI): sponsors comparative clinical effectiveness research
  - Institute for Clinical and Economic Review (ICER): uses comparative clinical effectiveness research to assess a service's value

# Patient-Centered Outcomes Research Institute (PCORI)

- PPACA established PCORI to identify, fund, and disseminate comparative clinical effectiveness research
- PCORI is funded by the Patient-Centered Outcomes Research Trust Fund from 2010-2019
- PCORI established national research priorities:
  - Assessment of prevention, diagnosis, and treatment options
  - Improving health care systems
  - Communication and dissemination research
  - Addressing disparities
  - Accelerating patient-centered outcomes research and methodological research

# PPACA limitations on PCORI and Medicare

- PCORI is statutorily prohibited from developing or using a dollars-per-quality adjusted life year (QALY) (or similar measure) as a threshold to determine the type of health care that is cost effective
- Medicare's use of effectiveness research:
  - Medicare can consider PCORI studies in coverage process but must use an iterative process that includes public comment
  - Medicare is statutorily prohibited from using an adjusted life year (or similar measure) to determine coverage, payment or incentive programs

# PCORI research

- As of July 2017, PCORI awarded $1.68 billion to 580 comparative clinical effectiveness, infrastructure, and methods projects
- In 2015, launched “pragmatic clinical trials”
- Some stakeholders contend that PCORI’s efforts may need to be more focused on comparative clinical effectiveness research

# Institute for Clinical and Economic Review (ICER)

- ICER is an independent nonprofit that receives funding from various nonprofit organizations and from the health care industry
- ICER's research reports are publicly available; analyses are used by payers and others
- ICER compares the clinical and cost-effectiveness of a treatment versus its alternatives

# ICER research

- Drug analyses use QALY and estimate a treatment's potential budget impact over a five-year period
- In public meetings, advisory board members vote on treatments' clinical effectiveness and value
- Some stakeholders raise concerns about ICER's methodology

# For Commissioner discussion

- Clarifications
- Using comparative clinical effectiveness information for coverage and payment policies and to address low-value services
- Commissioners can also consider this information's implications for developing quality measures based on the provision of low-value services