Program for FDA-CMS Parallel Review: What You Need to Know

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FDA Statutory Authority

Federal Food Drug & Cosmetic Act

21 USC 321: Definitions; generally
Text contains those laws in effect on March 28, 2018

§321. Definitions; generally

(p) The term "new drug" means-
(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to June 25, 1938, it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or
(2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

Federal Food Drug & Cosmetic Act

21 USC 360c: Classification of devices intended for human use
Text contains those laws in effect on March 28, 2018

§360c. Classification of devices intended for human use

(a) Classes of devices

(1) There are established the following classes of devices intended for human use:

(A) CLASS I, GENERAL CONTROLS.-

(i) A device for which the controls authorized by or under section 351, 352, 360, 360f, 360h, 360i, or 360j of this title or any combination of such sections are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

…

(B) CLASS II, SPECIAL CONTROLS.-A device which cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance, including

…

(C) CLASS III, PREMARKET APPROVAL.-A device which because-

(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and

…

Medicare Statutory Authority

Social Security Act

42 USC 1395y: Exclusions from coverage and medicare as secondary payer
Text contains those laws in effect on March 28, 2018

§1395y. Exclusions from coverage and medicare as secondary payer

(a) Items or services specifically excluded

Notwithstanding any other provision of this subchapter, no payment may be made under part A or part B for any expenses incurred for items or services-

(1)(A) which, except for items and services described in a succeeding subparagraph or additional preventive services (as described in section 1395x(ddd)(1) of this title), are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,

(B) in the case of items and services described in section 1395x(s)(10) of this title, which are not reasonable and necessary for the prevention of illness,

(C) in the case of hospice care, which are not reasonable and necessary for the palliation or management of terminal illness,

(D) in the case of clinical care items and services provided with the concurrence of the Secretary and with respect to research and experimentation conducted by, or under contract with, the Medicare Payment Advisory Commission or the Secretary, which are not reasonable and necessary to carry out the purposes of section 1395ww(e)(6) of this title,[1]

(E) in the case of research conducted pursuant to section 1320b–12 of this title, which is not reasonable and necessary to carry out the purposes of that section,

Purpose of Parallel Review

What Are We Encouraging?

CDRH Review Team

Manufacturer

Payer

Create awareness

~~Provide~~ a process to enable manufacturers to include and engage payers during meetings with CDRH using the Pre-Submission program.

Parallel Review Requirements

History of Parallel Review

Purpose: Reduce the time between FDA marketing approval and a coverage decision/patient access

Announced: 75 Fed. Reg. 57045 (Sept. 17, 2010)

Described: 76 Fed. Reg. 62808 (Oct. 11, 2011)

Extended: 78 Fed. Reg. 76628 (Dec. 18, 2013)

Extended: 81 Fed. Reg. 73113 (Oct. 24, 2016)

Parallel Review 101

- Manufacturer meets jointly with FDA and CMS using FDA's Pre-Submission program and incorporate feedback from both agencies in pivotal clinical trial
- Medical device requires an original or supplemental PMA or the granting of a de novo request
- Device isn't excluded by statute from Part A and/or Part B Medicare coverage
- Device addresses the needs of the Medicare population
- It's not your only option for getting CMS & FDA feedback

Parallel Review Lessons Learned

- Earlier interaction is more beneficial - good to have all parties present when planning the trial
- Agencies have different evidentiary requirements and may not always agree
- Agencies don't change evidentiary requirements by coordinating efforts

Private Payers

- Medicare/NCD is not appropriate for many devices
- Answer: Add Private Payers

Private Payer Opportunities

Purpose: Assist sponsors in receiving private payer input on clinical data needed to support coverage decisions

Announcement: 81 Fed. Reg. 9203 (Feb. 24, 2016)

More Information: Payer Communication Task Force, https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/ucm456149.htm

Don’t Forget

- Military—*e.g.*, VA, TRICARE
- Integrated Medical Systems—*e.g.*, Kaiser Permanente & Geisinger

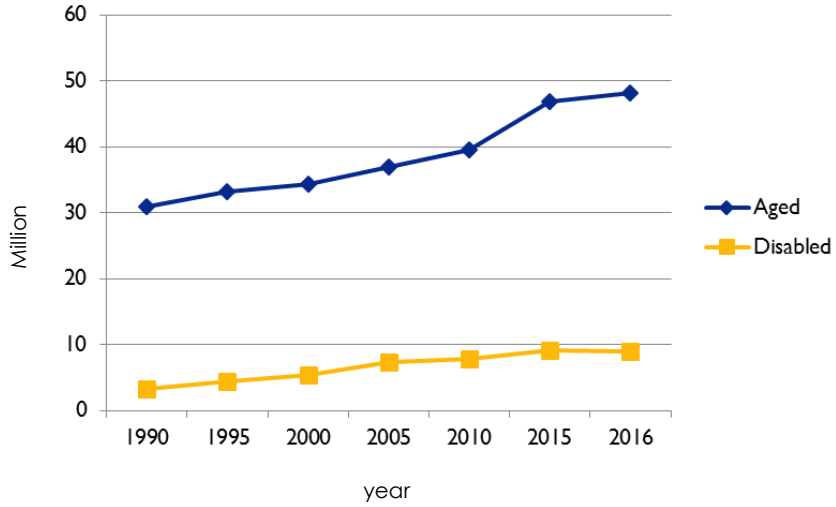
Thank You

MEDICARE COVERAGE & EVIDENCE DEVELOPMENT

LINDA GOUSIS, JD
COVERAGE AND ANALYSIS GROUP

Medicare Construct

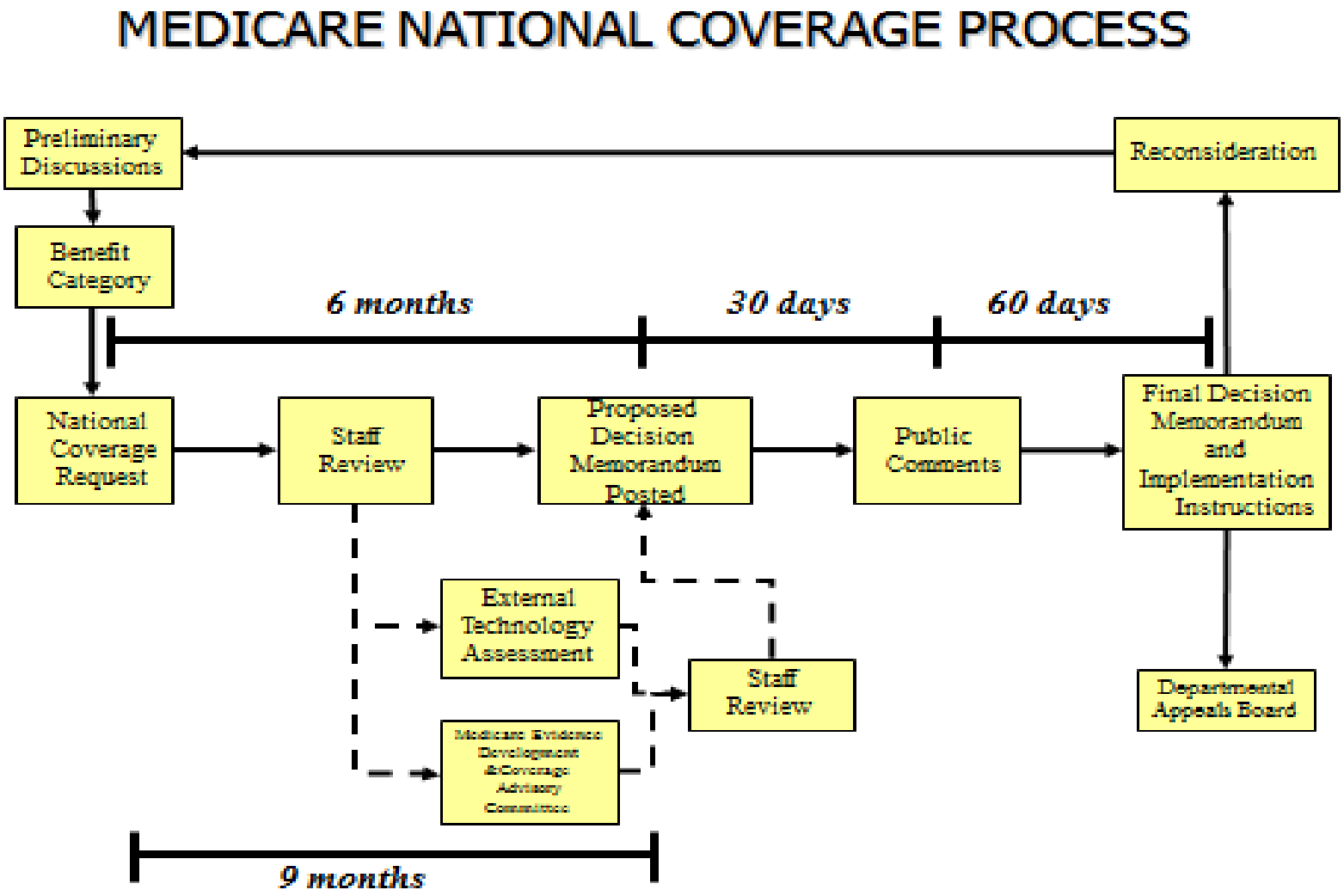
- Established by the Social Security Act of 1965, Title XVIII
  - §1862(a)(1)(A) reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member
  - (E) in the case of research conducted pursuant to §1142, which is not reasonable and necessary
- Defined benefit program
  - Beneficiaries
    - Age ≥ 65 years
    - Disabled individuals
    - End stage renal disease
  - Providers
  - Settings



Evidence-based Medicare Coverage

- Coverage determinations address whether the evidence is sufficient to conclude that the item (drug or device) or service improves clinically meaningful health outcomes for the Medicare population
- Considers the quality, strength and totality of evidence
- Focuses on important patient centered health outcomes

Medicare Program: Revised Process for Making National Coverage Determinations
78 Fed. Reg. 48164 (Aug. 7, 2013)



Medicare Evidence Development & Coverage Advisory Committee (MEDCAC)

- Reviews and evaluates evidence and examines benefits, harms, and appropriateness of items and services.
- Recent meetings have discussed health outcomes for chronic heart failure and obesity/bariatric surgery.

https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/MEDCAC.html

Medicare Beneficiaries in Clinical Studies

- Initial studies on new technologies may not include many older adults ≥ 65 years of age for several reasons including:
  - Heterogeneity – may have multiple comorbidities and/or be taking multiple medications
  - Non-adherence - may have difficulty following protocols and/or making all study follow-up visits
  - Other considerations – measurement issues, cognitive function

Study Endpoints and Eligibility Criteria

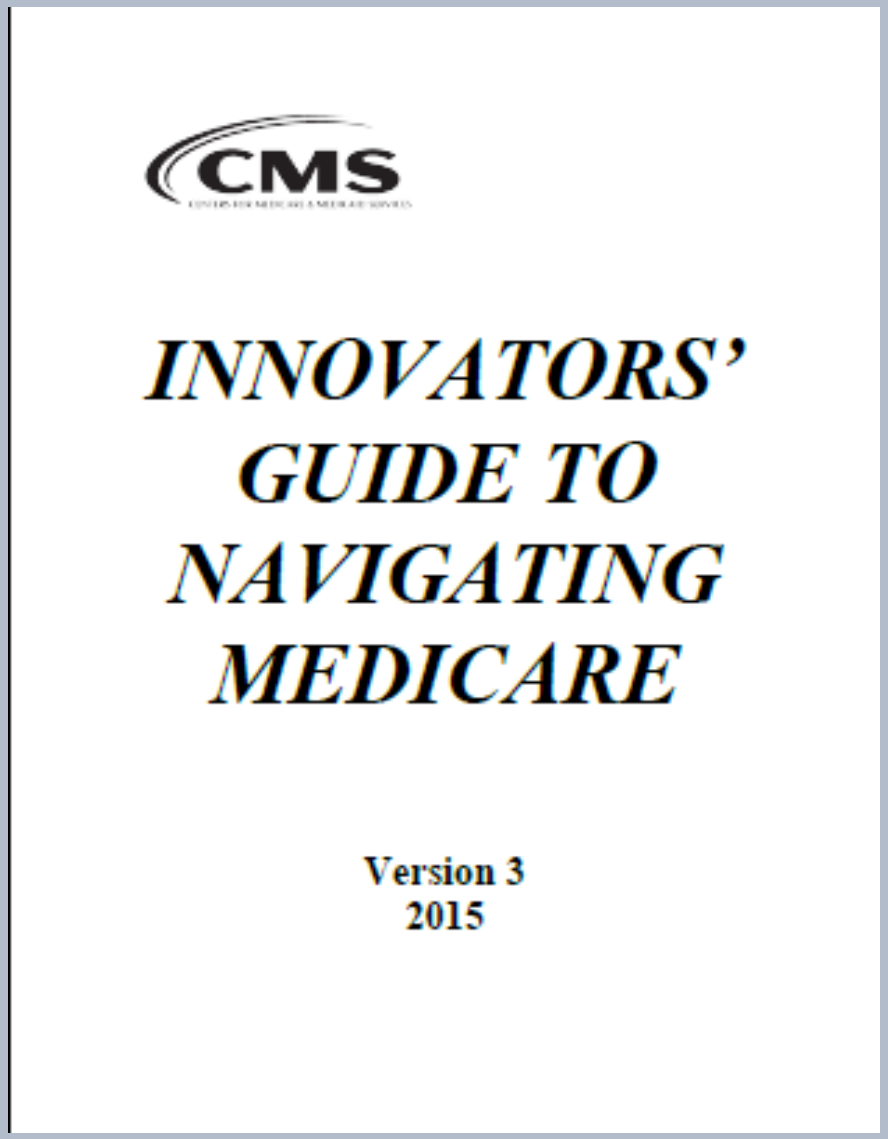
- Important to determine the strength and generalizability of published evidence to the Medicare population
- May assist in establishing parameters of coverage with evidence development (CED)

Coverage with Evidence Development (CED)

- Coverage in the context of approved clinical studies or with the collection of additional clinical data
- Allows for positive coverage when evidence is insufficient for a more favorable decision.
  - Evidence gaps may be due to low number of beneficiaries in clinical studies, lack of meaningful health outcomes, limited generalizability, inconsistency of study findings.
- May involve randomized controlled trials, observational studies and/or registries
  - Specific interventions,
  - benefits and harms,
  - health outcomes

Other Clinical Studies under Medicare

1. Investigational Device Exemptions (IDE) Studies
   - Regulation at 42 CFR 405.201
   - New centralized process in 2015
2. Clinical Trial Policy
   - Routine costs in clinical trials funded by certain federal agencies
   - National Coverage Determination (NCD) Pub 100-3, Section 310.1



www.cms.gov/Medicare/Coverage/CouncilonTechInnov/Downloads/Innovators-Guide-Master-7-23-15.pdf

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