Institute of Medicine
Appropriate Use of Advanced Technologies for Radiation Therapy and Surgery in Oncology

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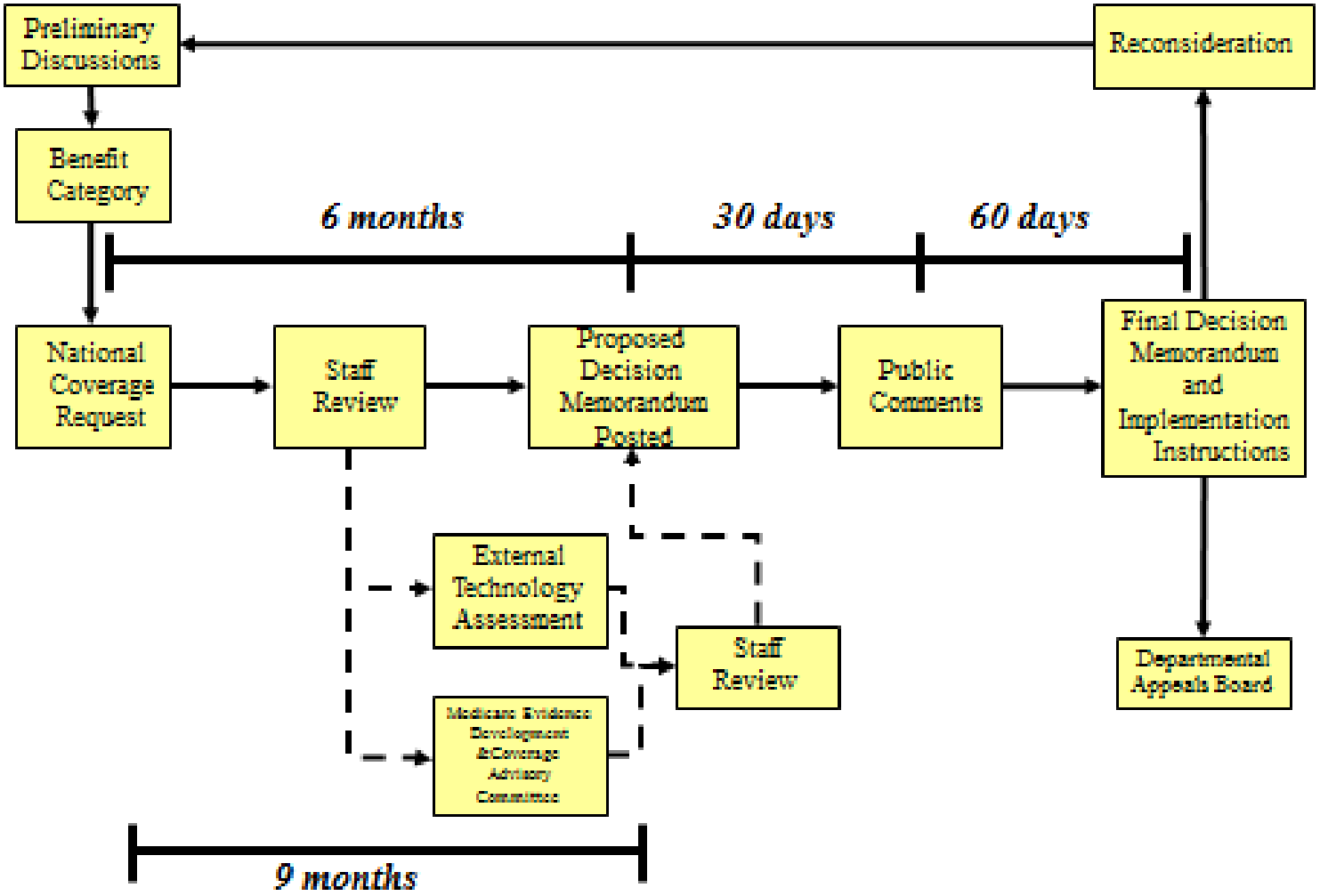
July 20, 2015

Medicare - 50th - medicaid

MEDICARE NATIONAL COVERAGE PROCESS



Medicare Coverage Construct

§ 1862(a)(1) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—

(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

(E) in the case of research conducted pursuant to § 1142, which is not reasonable and necessary

Evidence-Based Coverage

CMS has operationalized the following definition:

- Adequate evidence to conclude that the item or service improves clinically meaningful health outcomes for the Medicare population

First Used in a National Coverage Determination (2000)

- The recommended approach for evaluating diagnostic tests is review of high quality studies that provide direct evidence that test results improve health outcomes.

Medicare Coverage Questions

1. What is the health benefit (outcome)?
   - Eg., longer life with improved function, less need for burdensome tests, significant symptom improvement

2. Are there conditions needed to ensure positive outcome?
   - E.g., Patient population, Practitioner specialty, Provider criteria (volume)

3. Implementation

The Ongoing (Original) Dilemma

- Intense public interest in coverage of certain (usually new) technologies
- Published evidence base was
  - Suggestive but insufficient to reach a positive R&N decision
  - Too immature for confident decision
- In general, clinical trials under-enroll subjects representative of the beneficiary population

Evidence Development

1. Investigational Device Exemptions (IDE)
    - Regulation at 42 CFR 405.201
    - New centralized process

2. Clinical Trial Policy
    - Routine costs in clinical trials
    - Investigative item or service
    - NCD Manual, Pub 100-3, Section 310.1

3. Coverage with Evidence Development
    - Individual NCD policy

Collaboration

- FDA
  - Parallel Review
  - Investigational Device Exemptions (IDE)
- NIH
  - Clinical Trials (e.g. National Lung Screening Trial)
- AHRQ
  - Technology Assessment
  - Coverage with Evidence Development

Statutory Background:

- In order for Medicare to pay for any item or service, it must have a benefit category in the Medicare statute:
  - 1861(s)(1) of the Social Security Act (the Act): "Physicians' services"
  - 1861(s)(2)(a) of the Act: "Services and supplies (including drugs and biologicals which are not usually self-administered by the patient) furnished as an incident to a physician's professional service are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills …"
  - 1861(s)(2)(B) of the Act "hospital services (including drugs and biologicals which are not usually self-administered by the patient) incident to physicians' services rendered to outpatients…"
  - 1861(s)(4) of the Act "X-ray, radium, and radioactive isotope therapy, including materials and services of technicians

Payment Mechanisms: Physician Fee Schedule

- Physician Fee Schedule used for:
  - o Physicians' and practitioner services: The services of the physician him/herself (such as surgical services)
  - o "Incident to" services that are not paid separately (such as the services of the physician's staff, medical equipment and medical supplies). Payment to physician includes payment for "incident to" services. Drug and biologicals "not usually self-administered" are separately paid
  - o Radiation therapy services when provided in a freestanding setting (not a hospital outpatient department)

Payment Mechanisms: Physician Fee Schedule

- Physician Fee Schedule:
  - Sum of physician work, practice expense and malpractice summed, geographically adjusted and multiplied by a $ conversion factor
- Data Sources:
  - Work = Estimates of the time and intensity of physician work effort from the Relative Value Update Committee as modified by CMS or other independent sources
  - Practice Expenses = Estimates of direct cost inputs combined with practice expense surveys
  - Malpractice = Malpractice premium data by specialty and risk factors for individual services

Payment Mechanisms: Hospital Outpatient Services

- Hospital Outpatient Prospective Payment System Used For:
  - Institutional services provided by the hospital
  - "Incident to" therapeutic services provided to hospital outpatients not paid separately (such as drugs and biologicals)
  - Radiation therapy services when provided in a hospital outpatient department
- Data Sources:
  - Hospital charges on claims in combination with hospital costs reported on cost reports are grouped to determine geometric mean cost
  - Special pass-through payment for new technology not yet incorporated into data reported by hospitals
  - New Technology group for new technologies that cannot be classified into an existing group

Payment Mechanisms: Drugs and Biologicals

- Drugs and Biologicals: Only covered under Medicare Part B when "not usually self-administered." If usually self-administered, covered under Part D as a prescription drug
- Defined to include those in the United States Pharmacopoeia, the National Formulary, or the United States Homeopathic Pharmacopoeia, or as are approved by the pharmacy and drug therapeutics committee of the hospital
- Data Source:
  - Most drugs and biologicals: Average Sales Prices + 6 percent
  - Radiopharmaceuticals: Invoice or 95 percent of average wholesale price depending upon how paid in 2003