Medicare Coverage and Genetic Testing

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CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Steps to Medicare Reimbursement

- Regulatory approval (if applicable)
- Benefit determination
- Coverage
- Coding
- Payment

Regulatory approval

- Required for Medicare coverage if technology is under FDA purview
  - For at least one indication
  - CMS can cover off-label uses
- Any new FDA guidance on genetic testing could affect CMS payment
- “Home brew” tests may be coverable without FDA approval

Benefit Categories

- Defined in Title 18 of SSA
- E.g. inpt, outpt, ambulance, DME, etc
  - Rx drugs added Dec. 03
- Diagnostic services are a benefit category
- Screening / prevention are not

Benefit Categories (con't)

- Screening vs diagnosis
  - Depends on signs or symptoms
  - Strong family history would not qualify test as diagnostic
    - Genetic tests in high risk pts (eg family hx of breast / ovarian cancer) would be screening
    - Diabetes test for high risk pts added by law
    - Rulemaking may be an option
- Tests that identify treatment-responsive subpopulations (e.g. pharmacogenomics) are diagnostic

CMS's Statutory Authority for Coverage

- Section 1862(a)(1)(A) of the Social Security Act
- coverage and payment limited to items and services
  - found "reasonable and necessary"
  - for treatment of illness or injury…
- Applied at local and national level
- Costs, CEA, CBA not considered*

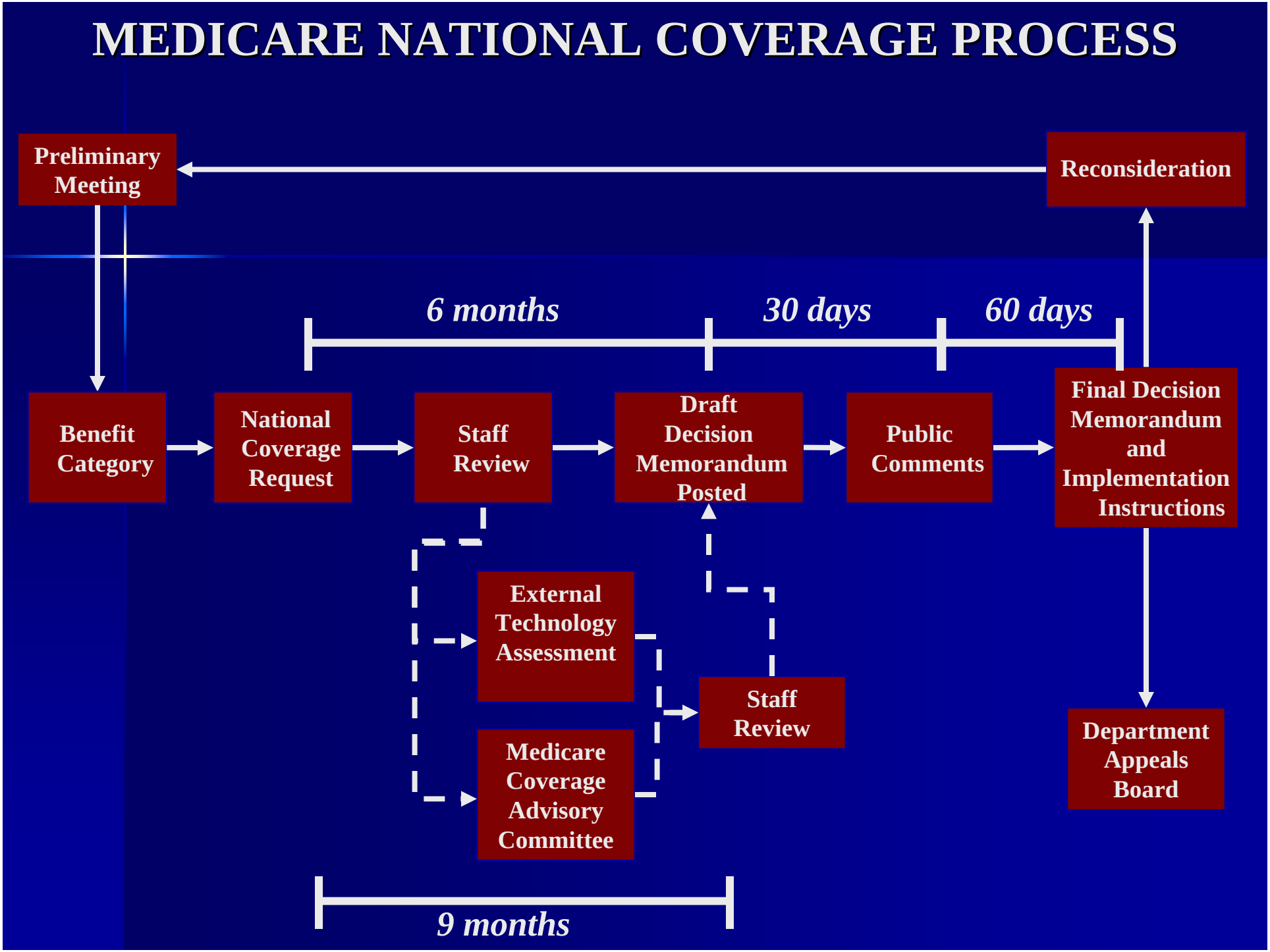
Coverage of Genetic Tests

- One NCD on cytogenetic testing
- All coverage based on LCDs
- Total claims for 2002 were 270,000. Costs about $13 million
- Most NCDs address $50-100 million +
- Likely more NCDs with advances in genetic testing, pharmacogenomics, personalized medicine

Coverage: LCDs

- Developed by Medicare contractors
- Formal process for development
- Medical directors, CACs, draft policies, final and reconsiderations
  - Contractors interact but policy is local
- Apply R&N, more weight on expert input
- Non-binding on ALJs for claim appeals
- LCDs can be appealed to ALJs and DAB
- Variations in LCDs may lead to NCD

MEDICARE NATIONAL COVERAGE PROCESS



Reasonable and Necessary

- Adequate evidence to conclude that item or service improves net health outcomes
  - emphasis of outcomes experienced by patients
    - function, QoL, morbidity, mortality
  - generalizable to the Medicare population
  - as good or better than current covered alternatives
- CMS use standard EBM framework

Sources of evidence

- Published literature
- Systematic reviews
- Clinical guidelines
- Expert input
- Views of other stakeholders
- Evidence weights influenced by source and methods used
- EBM approach places emphasis on sources with least potential for bias

Diagnostic framework

- Developed by MCAC; applied by CMS
- Test performance (sensitivity / specificity)
- Impact on patient management and outcomes
  - Is there beneficial intervention available?
- Does information itself provide benefit?
  - Certainty itself not assumed to be “beneficial”
  - Value / impact likely to vary by test
  - Ideally benefits would be empirically shown