

“Safe and Effective” Is It Enough?

Steve Phurrough MD, MPA
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid
Services

Steps to Coverage Determination and Payment

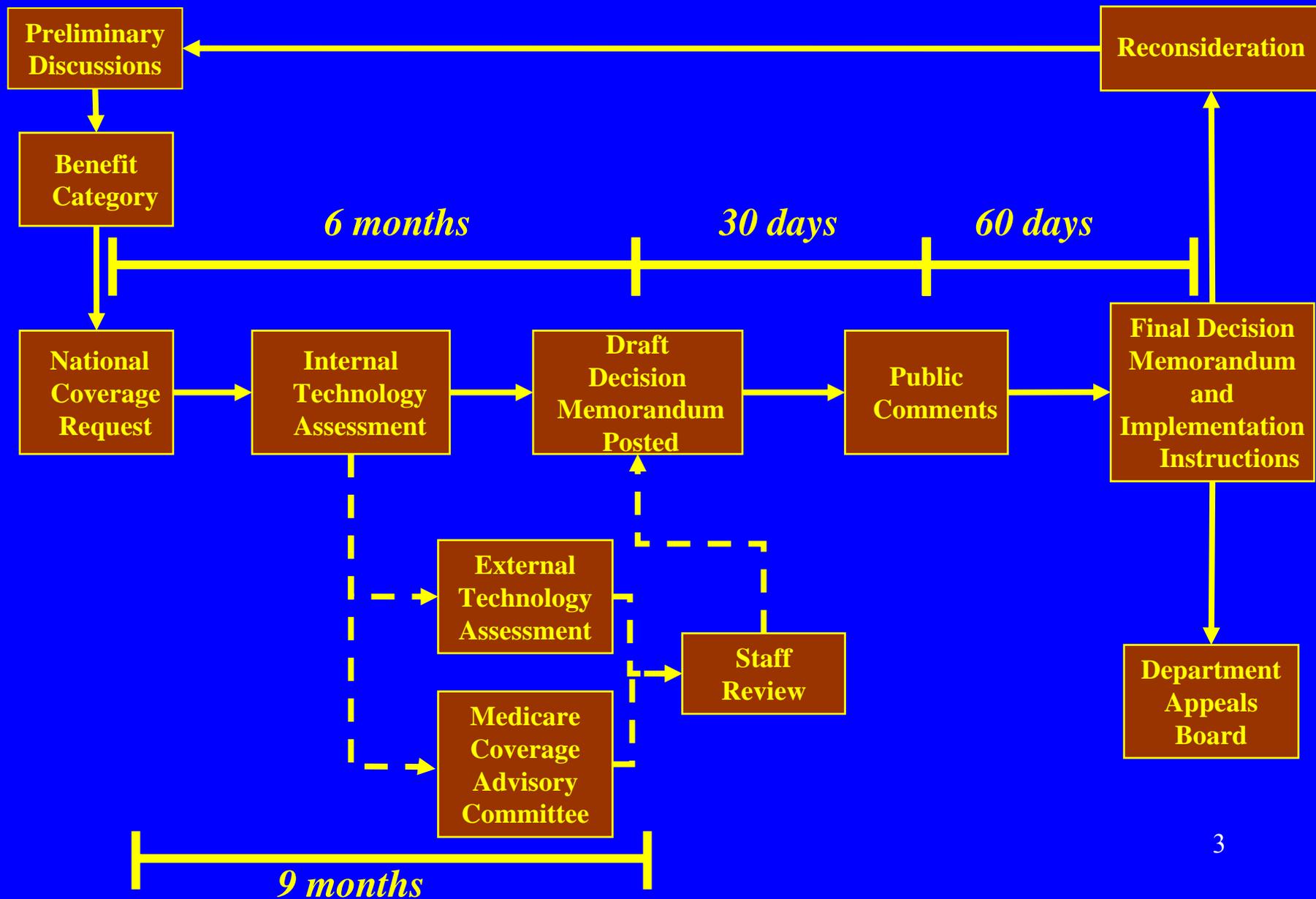
Outside of CMS:

- Congress determines benefit categories
- FDA approves drugs/devices for market

Within CMS:

- Coverage
- Coding
- Payment

MEDICARE NATIONAL COVERAGE PROCESS



Reasonable & Necessary

- Sufficient level of confidence that evidence is adequate to conclude that the item or service:
 - improves net health outcomes
 - generalizable to the Medicare population
 - generalizable to general provider community

Improved Net Health Outcomes

Assessed using standard principles of
evidence-based medicine (EBM)

Generalizability

- Medicare population
- Diffusion outside trial providers

National Decisions

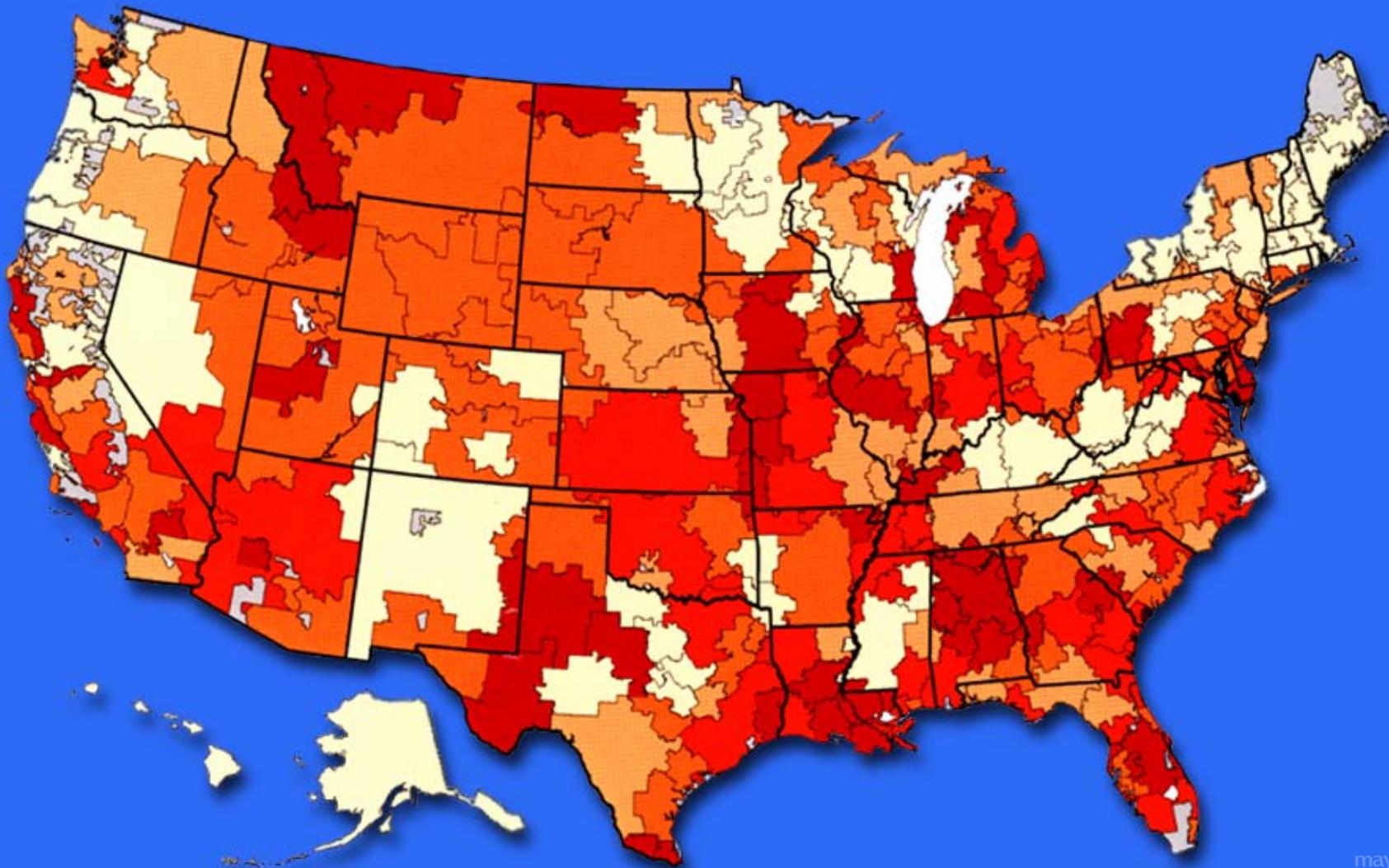
- National Coverage
- National Noncoverage
- National Coverage with restrictions
 - Specific populations
 - Specific providers/facilities
 - Evidence development

What is 'enough' evidence?

Do physicians and patients have enough information upon which to base healthcare decisions?

50 – 75 % of all healthcare
provided in physicians' offices
has no evidentiary support

Percutaneous Coronary Interventions

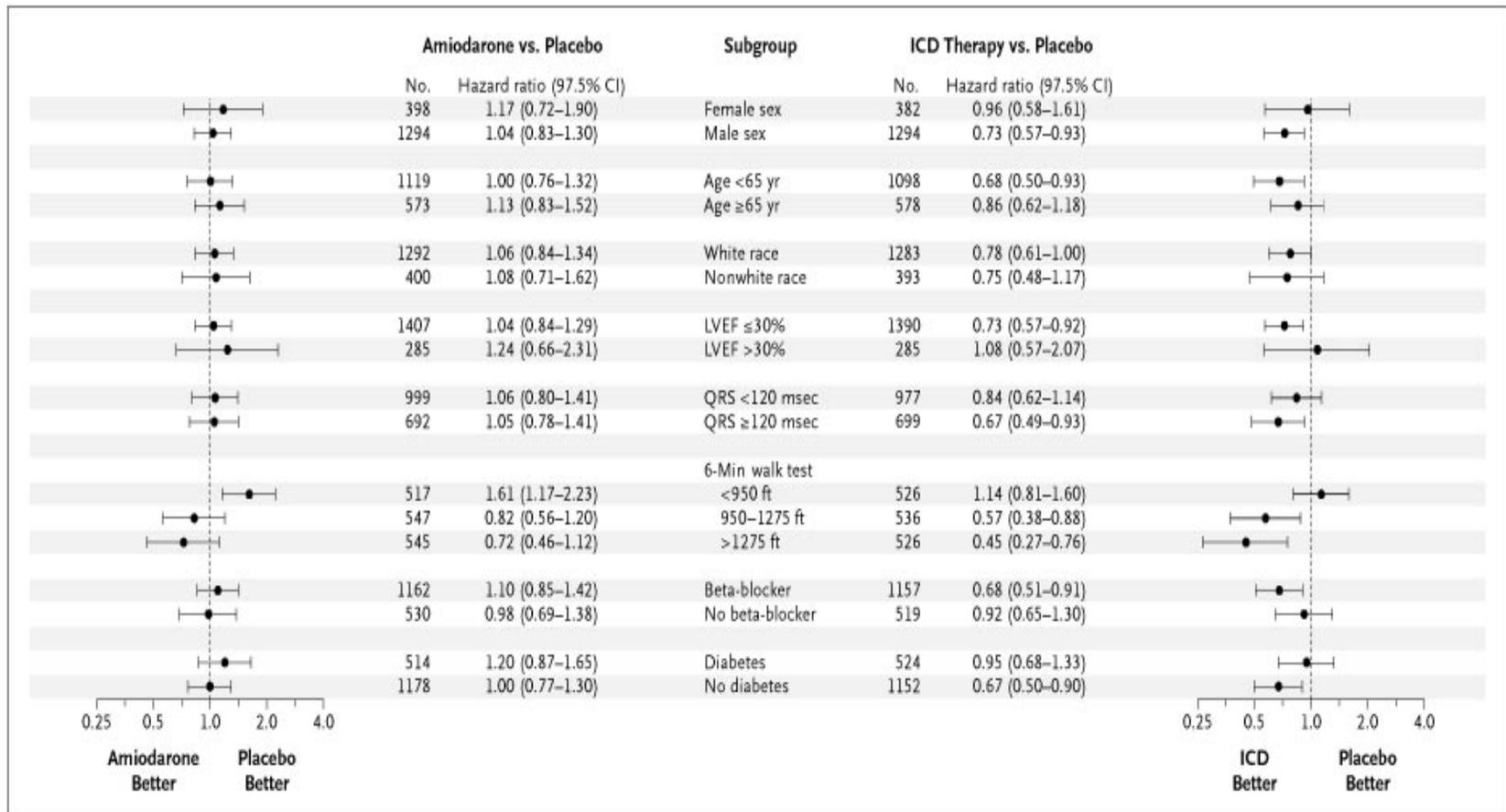


Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT)

- Absolute reduction in mortality = 6.8%
 - ICD therapy = 22.0%
 - Placebo = 28.8%

Median follow-up = 45.5 months

SCD-HeFT



- COX2 Inhibitors
- Hormone Replacement Therapy
- Statins
- Proton pump inhibitors

Is “Safe & Effective” Enough?

NO!

Does
“Safe & Effective”
equate to
“Reasonable & Necessary”

Most of the time

When does S&E \neq R&N?

- Patient population
- Trial design
- Additional data
- Ongoing safety issues
- Narrow benefit

Data Collection

- Post market study with FDA
- Post coverage claims analysis
- QIOs
- Coverage with evidence development (CED)

CED

- Trials
 - PET for Alzheimer's Disease
 - Colorectal Cancer Drugs
- Registry
 - ICD
 - PET for Cancer

Contact Information

Steve Phurrough

SPhurrough@cms.hhs.gov

410-786-2281

