



Medicare Coverage & Evidence Development

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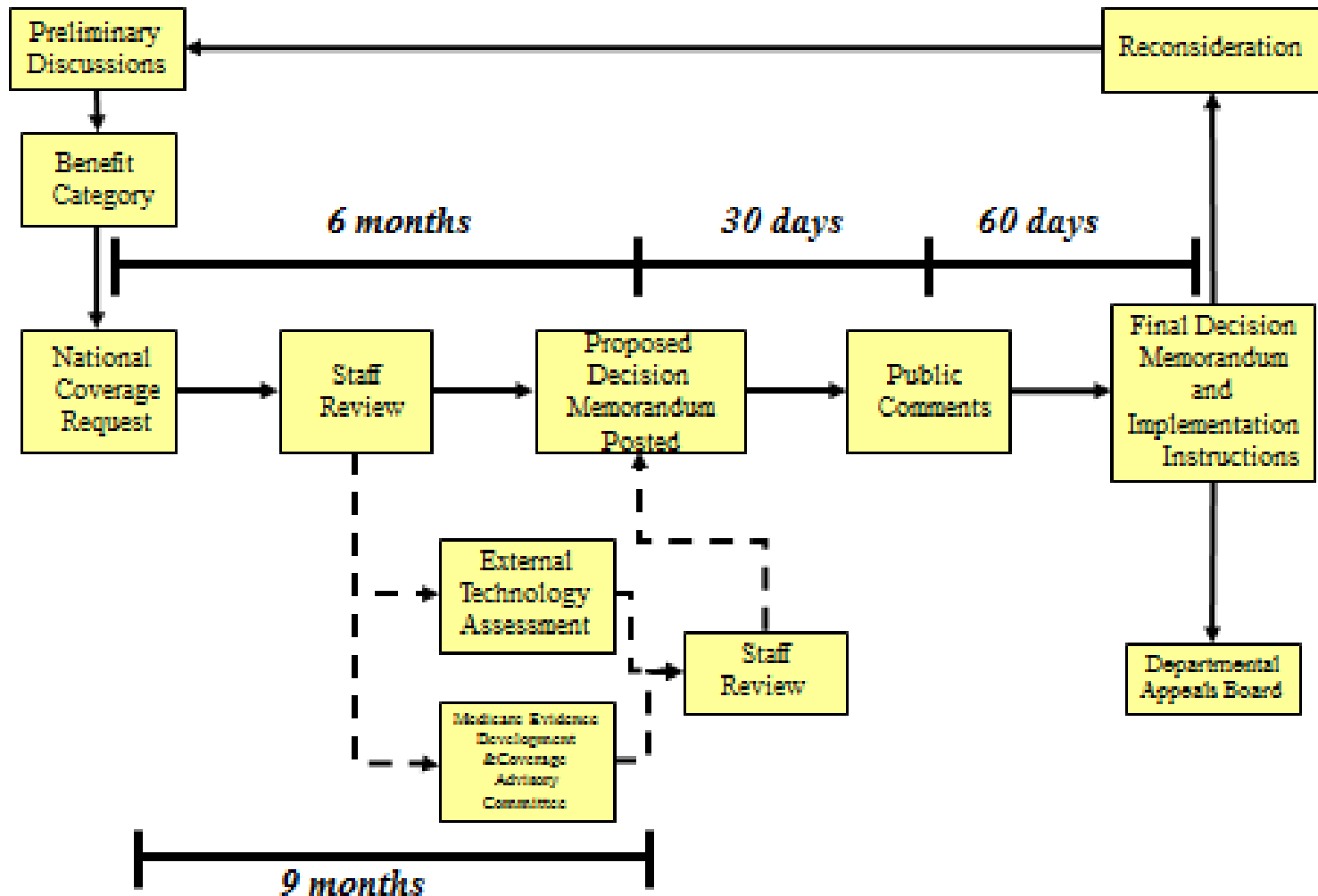
Medicare Construct

- 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 outcomes

MEDICARE NATIONAL COVERAGE PROCESS

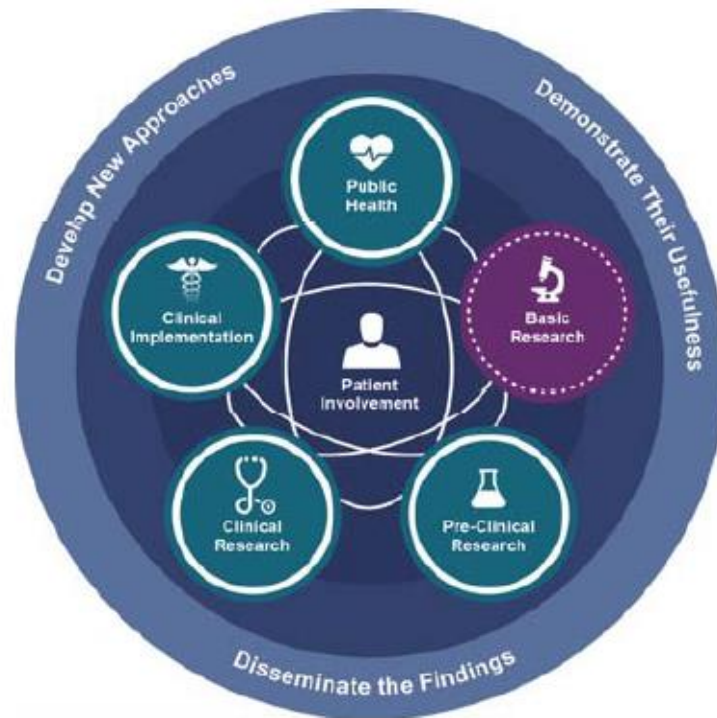


Coverage with Evidence Development (CED)

- 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

NIH Translational Science Spectrum

The translational science spectrum represents each stage of research along the path from the biological basis of health and disease to interventions that improve the health of individuals and the public



THANK YOU.
