# "Safe and Effective" Is It Enough?

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# Steps to Coverage Determination and Payment

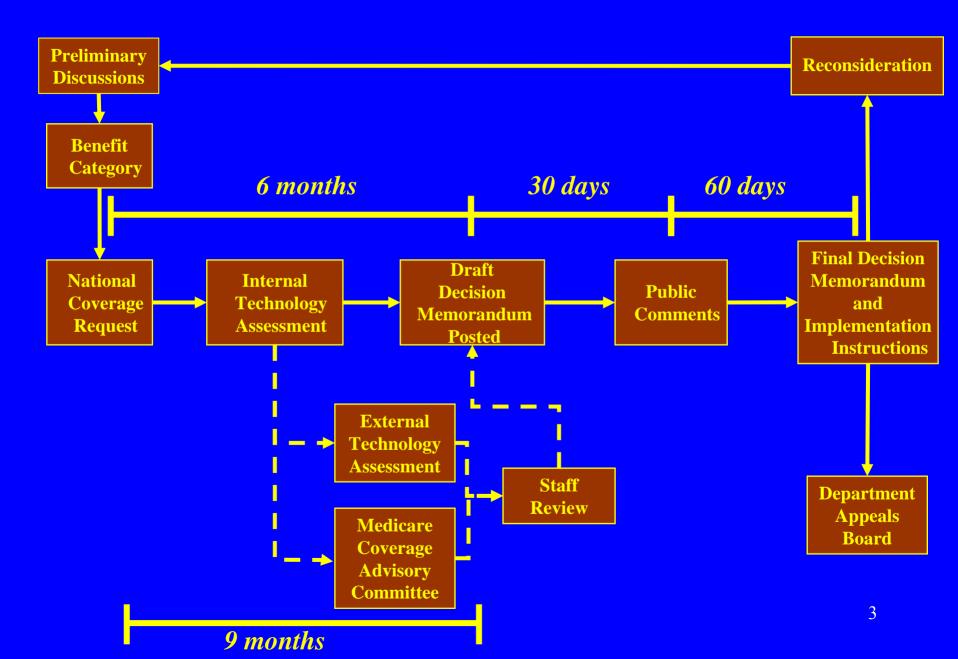
#### Outside of CMS:

- 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 populationDiffusion outside trial providers

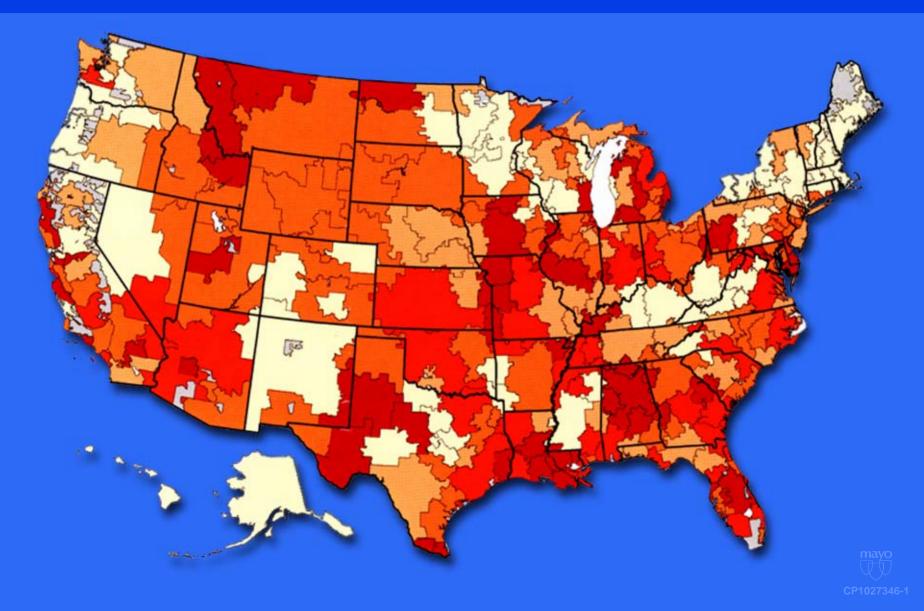
### National Decisions

- 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

	Amiodarone vs. Placebo		Subgroup	ICD Therapy vs. Placebo		
	No.	Hazard ratio (97.5% CI)		No.	Hazard ratio (97.5% CI)	
<b>⊢</b> ∔∙—-I	398	1.17 (0.72-1.90)	Female sex	382	0.96 (0.58-1.61)	<b>⊢</b> •−−1
H	1294	1.04 (0.83-1.30)	Male sex	1294	0.73 (0.57-0.93)	H•
H + + +	1119	1.00 (0.76-1.32)	Age <65 yr	1098	0.68 (0.50-0.93)	
H•	573	1.13 (0.83-1.52)	Age ≥65 yr	578	0.86 (0.62-1.18)	►• <u>+</u> +
H <b>a</b> -1	1292	1.06 (0.84-1.34)	White race	1283	0.78 (0.61-1.00)	<b>⊢</b> ● -
<b>⊢</b> •−1	400	1.08 (0.71-1.62)	Nonwhite race	393	0.75 (0.48-1.17)	⊢• <u>†</u> i
	1407	1.04 (0.84-1.29)	LVEF ≤30%	1390	0.73 (0.57-0.92)	<b>⊢</b> ●→
	285	1.24 (0.66-2.31)	LVEF >30%	285	1.08 (0.57-2.07)	· · · · · · · · · · · · · · · · · · ·
<b>H</b> •	999	1.06 (0.80-1.41)	QRS <120 msec	977	0.84 (0.62-1.14)	H++
H•	692	1.05 (0.78-1.41)	QRS ≥120 msec	699	0.67 (0.49–0.93)	<b>→</b> →
			6-Min walk test			
	517	1.61 (1.17-2.23)	<950 ft	526	1.14 (0.81-1.60)	<b>⊢</b> •−−
<b>⊢</b> •∔1	547	0.82 (0.56-1.20)	950-1275 ft	536	0.57 (0.38-0.88)	<b>⊢</b> •−−1
•	545	0.72 (0.46-1.12)	>1275 ft	526	0.45 (0.27-0.76)	<b>→</b> →
H.	1162	1.10 (0.85-1.42)	Beta-blocker	1157	0.68 (0.51-0.91)	⊢∎
<b>⊢</b> •	530	0.98 (0.69-1.38)	No beta-blocker	519	0.92 (0.65-1.30)	⊢• <u>†</u> →
	514	1.20 (0.87-1.65)	Diabetes	524	0.95 (0.68-1.33)	
	1178	1.00 (0.77–1.30)	No diabetes	1152	0.67 (0.50–0.90)	
0.25 0.5 1.0 2.0 4.0						0.25 0.5 1.0 2.0 4.0
Amiodarone Placebo						ICD Placebo

### COX2 Inhibitors

- Hormone Replacement Therapy
- Statins
- Proton pump inhibitors

### Is "Safe & Effective" Enough?



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**

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