
Evidence-based Medicare coverage: Coverage with Evidence Development (CED)

David Matchar, MD

Professor and Director,

Duke-GMS Medical School, Singapore

Duke Center for Clinical Health Policy
Research, Durham, NC



Reasonable and necessary?

- ^{NA} No specific coverage list in the original Social Security Amendments
- ^{NA} Congress delegated the coverage decision to HEW (now HHS)
 - “May not reimburse for items and services which are not reasonable and necessary...”



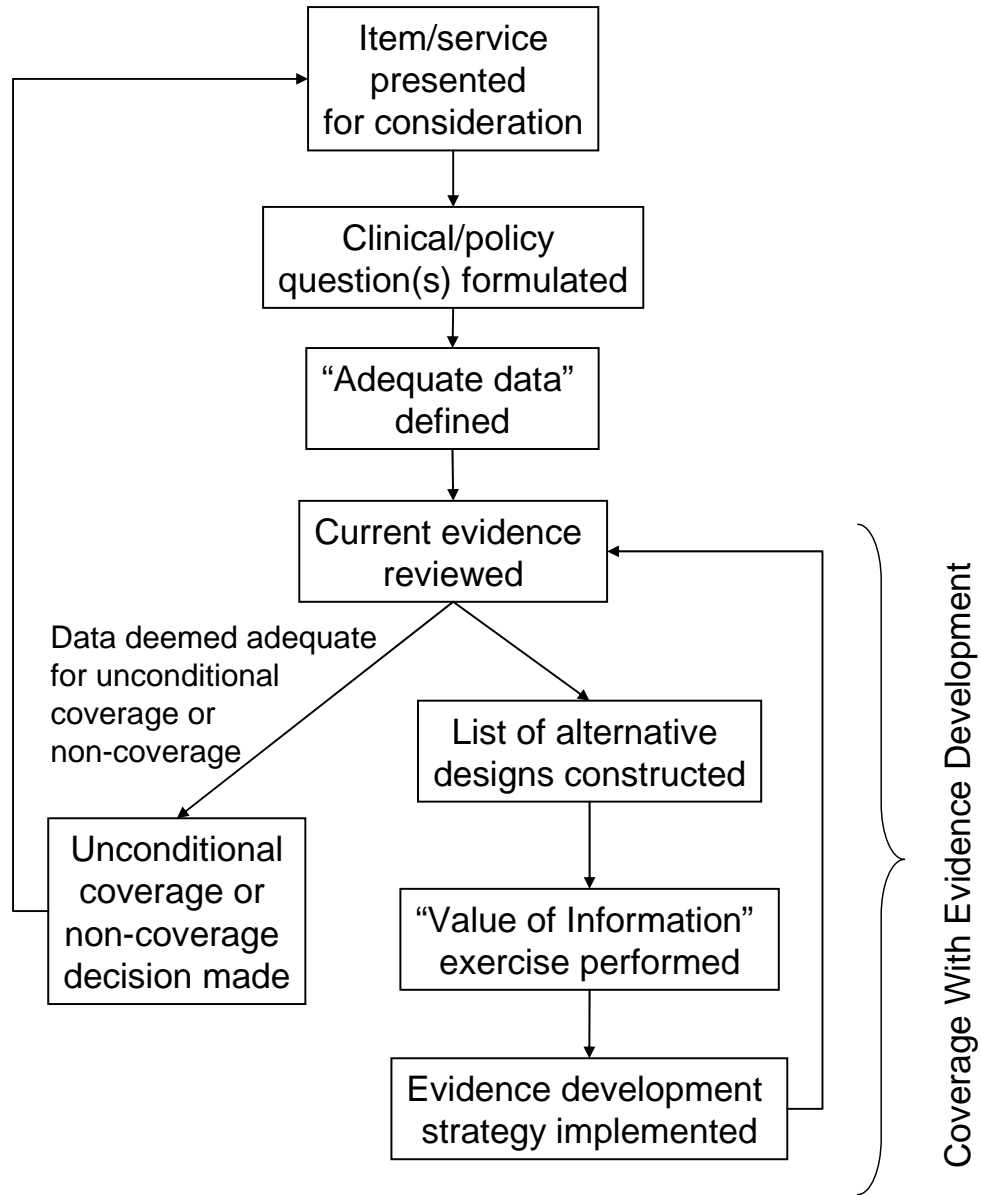
Current status: case law for criteria

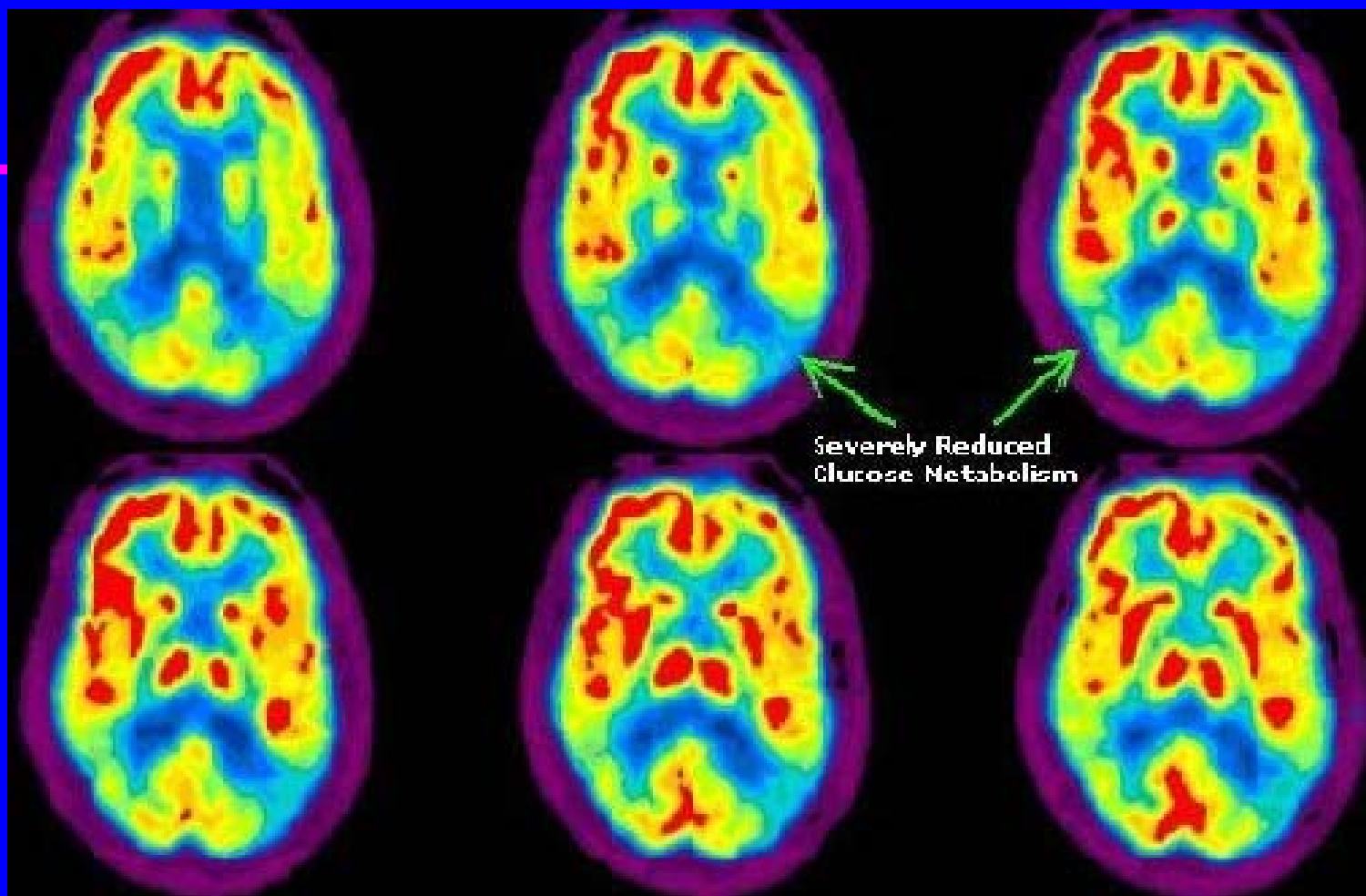
- ^{NA} An open process, meticulous documentation, easy access via the CMS web site and public meetings of the MCAC
- ^{NA} The accumulated decisions constitute a body of case law



Residual uncertainty

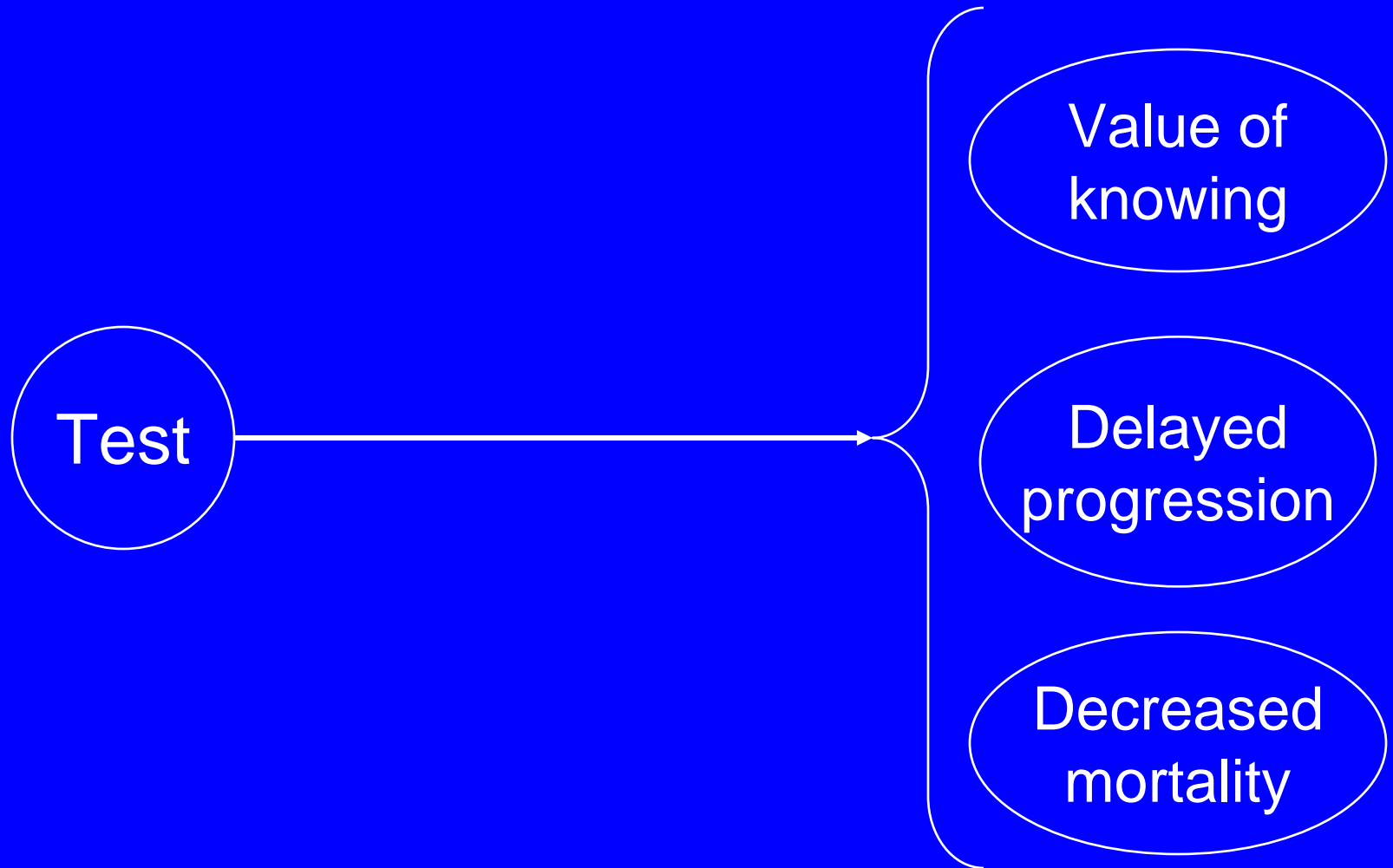
- N_A Long-term effects
- N_A Outcomes of importance to beneficiaries
- N_A Effects in specific subgroups (e.g. the elderly)
- N_A Off-label uses of a drug
- N_A New applications for marketed services/devices
- N_A Real-world impact



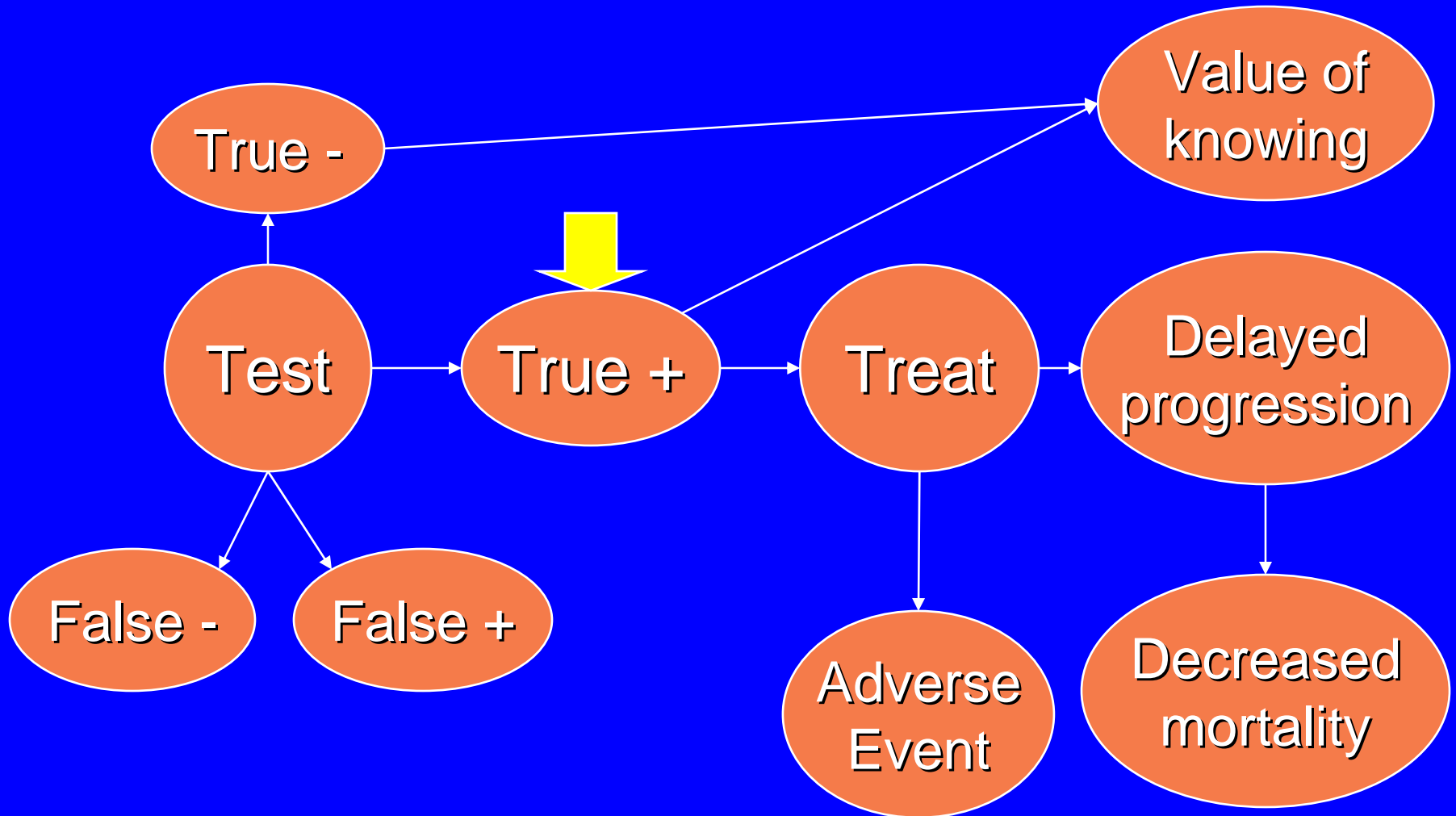


www.petnetpharmaceutical.com/

Illustration: PET in cognitive impairment



Indirect inference: causal pathway



PET and AD diagnosis: mild dementia

	True + (%)	False + (%)	False – (%)	True – (%)	Correct (%)
No PET/ Rx	56	44	0	0	56
PET/ Rx+	49	6	7	38	87
No PET/ no Rx	0	0	56	44	44

Many fewer false positives and
a few more false negatives

Integrative Model

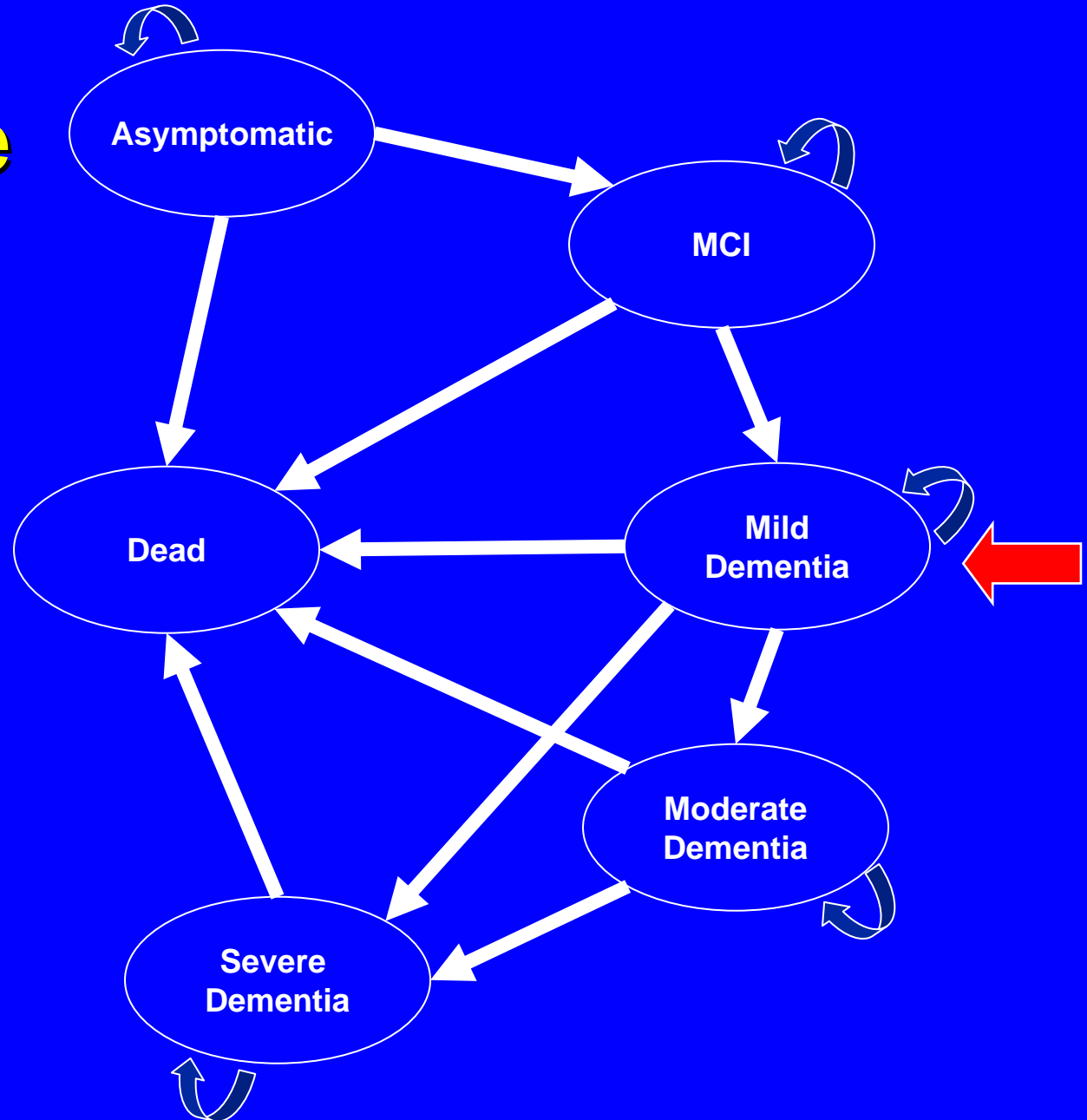
Data inputs

Epidemiological studies

Test performance studies

Drug trials

QOL/preference studies



Results: integrative model

	QALY	LE	SDFLE
No PET/ Rx	4.10	7.89	4.02
PET/Rx+	4.09	7.88	4.00
No PET/ no Rx	4.02	7.82	3.86

Primary conclusion

^{NA} NI could improve the overall accuracy compared to clinical exam

However,

^{NA} Treatment based on an exam leads to better health outcomes than treatment based on NI results.

How can this make sense?

- ^{NA} Recall, net accuracy with NI is better because there are many fewer false positives and a few more false negatives
- ^{NA} However, false positives \neq false negatives
 - Incorrectly treating (false positive) is not as bad as incorrectly not treating (false negative)
 - » Incorrectly treating: Rx is relatively benign and may be beneficial even if patient doesn't have AD
 - » Incorrectly not treating: patient loses benefit of Rx

When testing is preferred

1. If a new treatment becomes available that is not only more effective than current therapies but is also associated with a risk of severe adverse effects.

**Increases the benefit
of avoiding false positives**

When testing is preferred

2.If the results have demonstrable benefits beyond informing choice of therapies - the “value of knowing.”

Improves ability to
adjust and to plan

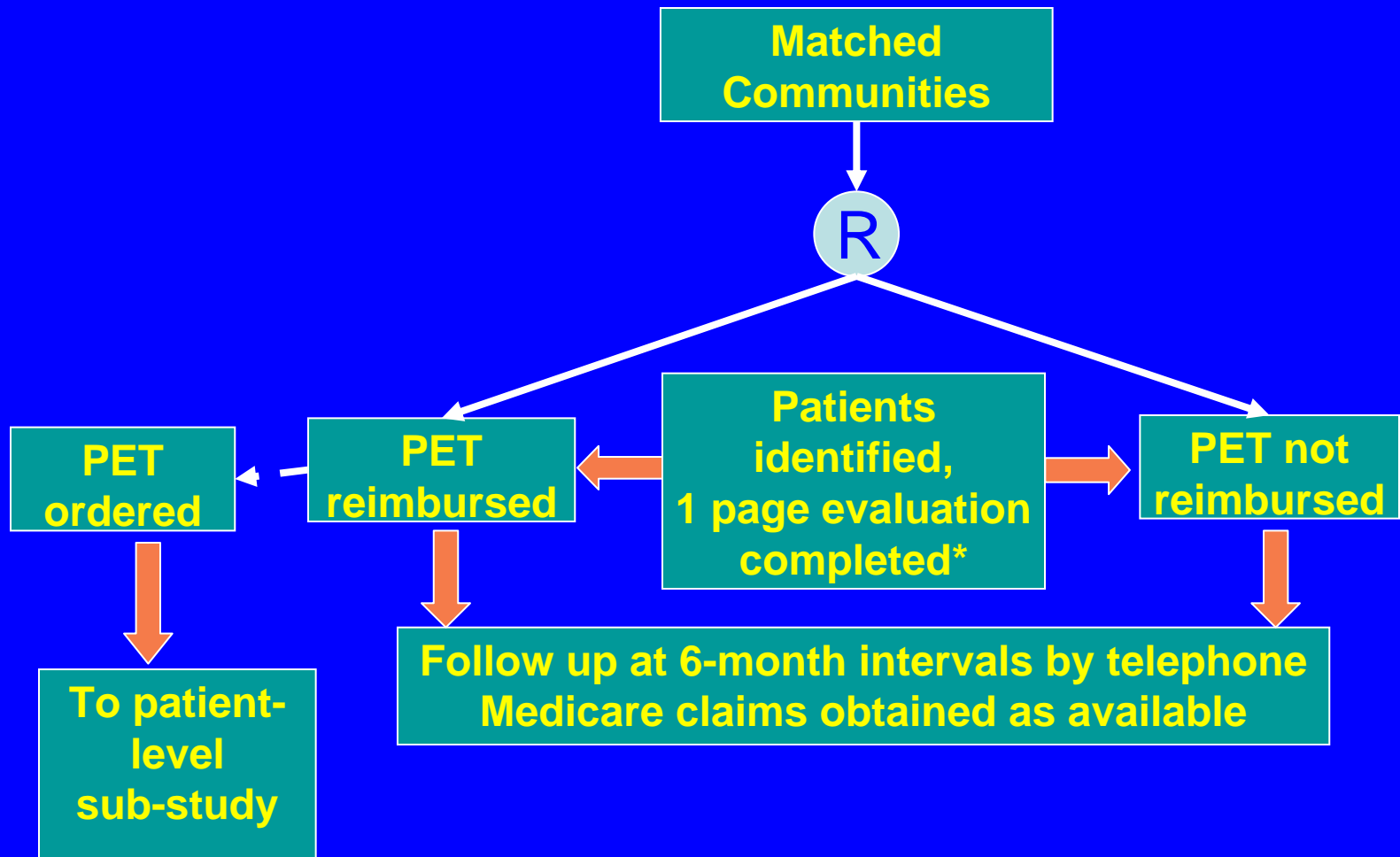
When testing is preferred

3. If testing could be demonstrated to be a better reference standard than clinical examination.

Predicting response to therapy: compared to a standard examination, testing better distinguishes patients who respond to therapy or who will have adverse effects

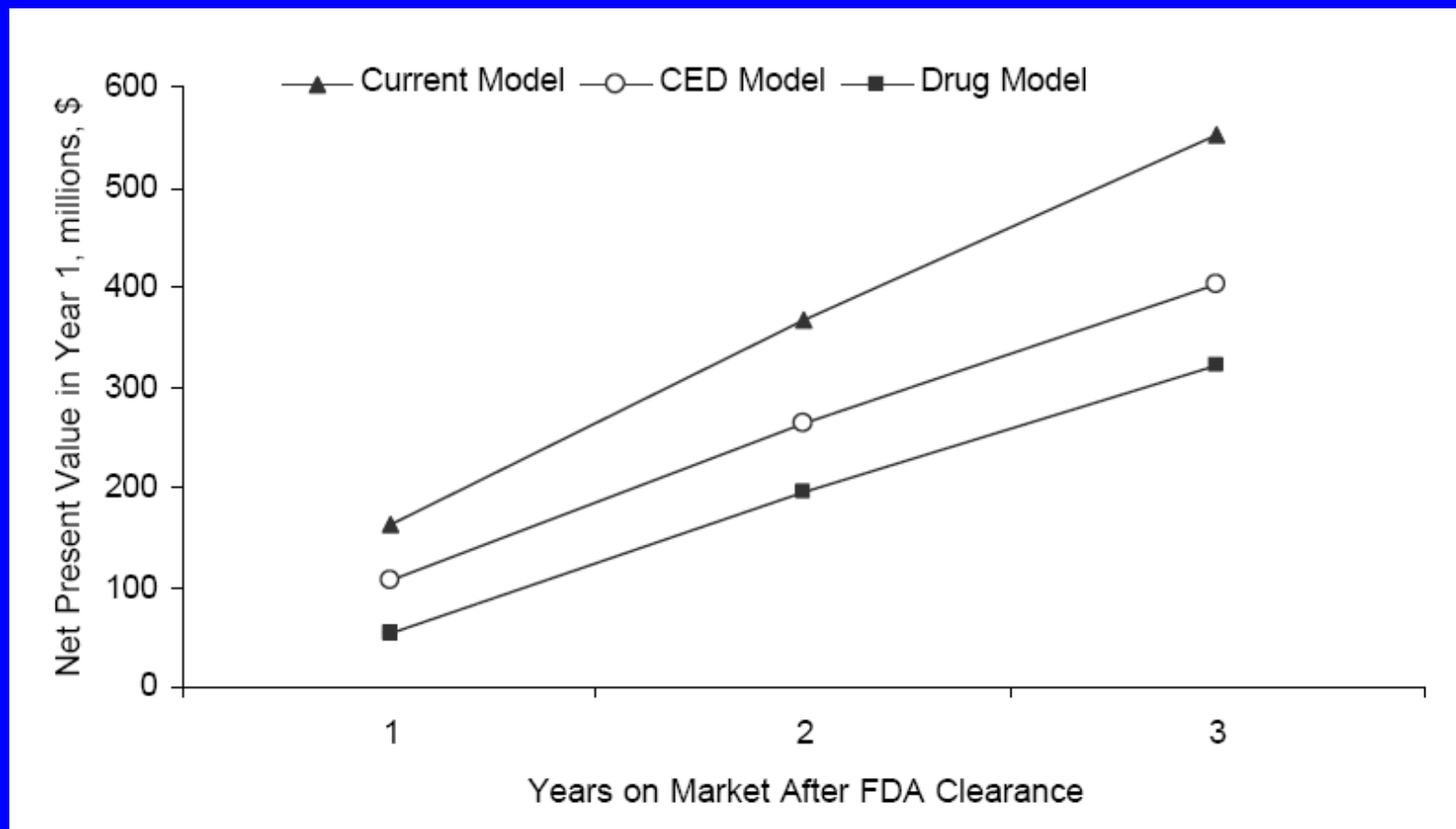
CED and PET/AD

- ^{NA} Based on analysis, CMS made a national non-coverage decision
- ^{NA} Pressure led to conditional coverage
- ^{NA} Meeting convened with CMS, NIA, FDA, ADA, and other stakeholders
- ^{NA} Commissioned design of a PCT



* Medicare claims at the community-level for individuals with relevant ICD codes will be examined

CED Impact on Firm Investment



Current Model - represents current regulatory— level of evidence necessary for approval of class III med devices is far less than that required for pharmaceutical products

CED - make coverage contingent on participation in a clinical trial or national registry

Drug Model - approval process for class III medical devices is the same as that currently employed for pharmaceutical products

Source: Reed et al

Conflicting goals