Medicare Coverage

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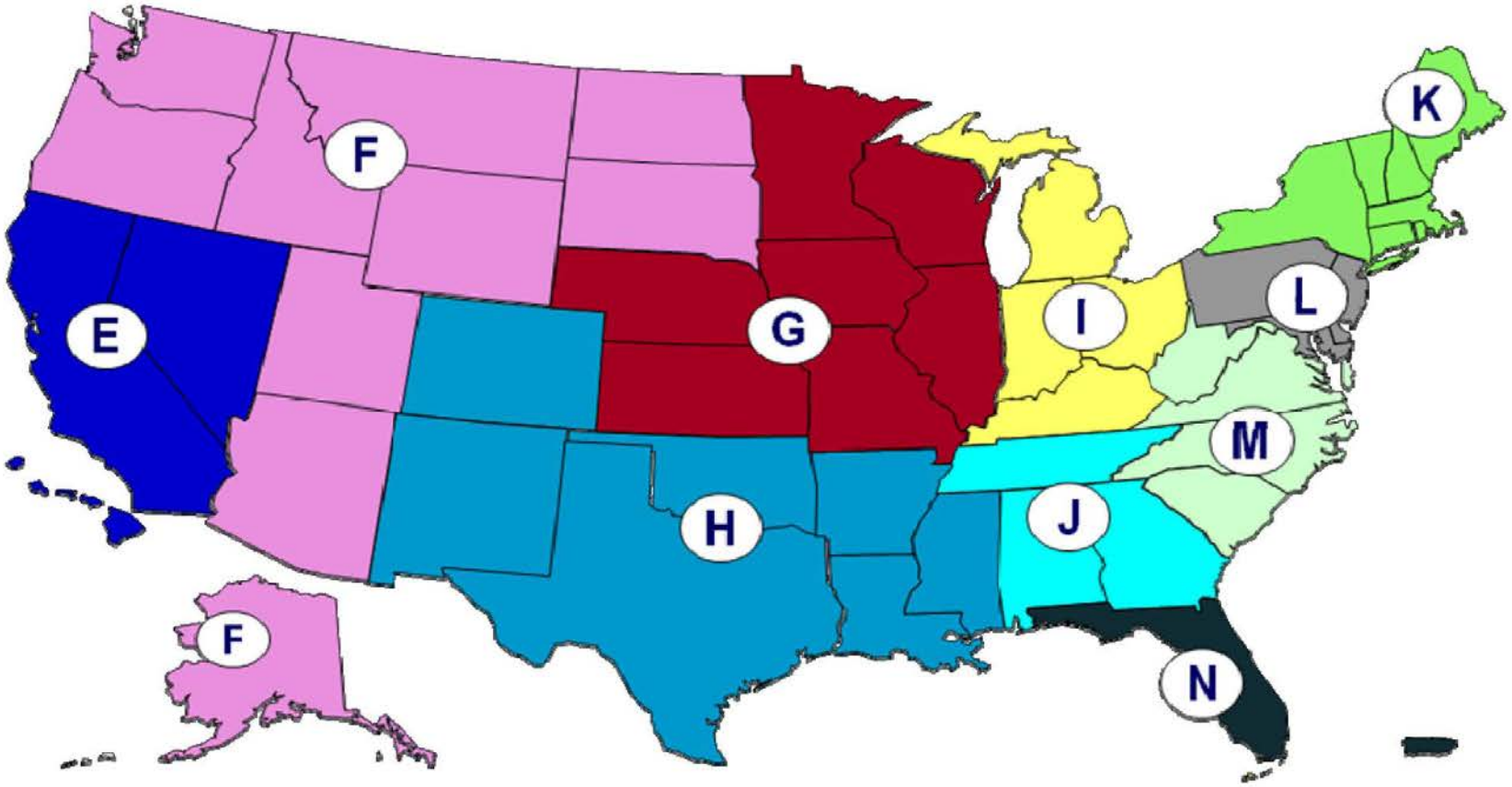
CMS

Overview

- A national program with local administration
  - Medicare Administrative Contractors (MACs)
  - Other contractor types (e.g. appeals)
- Coverage decisions
  - Claim by claim at the local level
  - Policy at the local level
  - Policy at the national level
    - National Coverage Determination (NCD)
    - Regulation

Consolidated A/B MAC Jurisdictions



Social Security Act 1862(a)(1)

Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—

(A) which, except for items and services described in a succeeding subparagraph or additional preventive services (as described in section 1395x(ddd)(1) of this title), are not 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 section 1142, which is not reasonable and necessary to carry out the purposes of that section,

***

What is the definition of R&N?

- Congress has not defined it in statute.
- Attempted unsuccessfully to define via rulemaking in 1989 and 2000.
- We explored attempting rulemaking again, but there has been no traction.
- For practical uses, CMS has operationalized the following definition:

  Adequate evidence to conclude that the item or service improves clinically meaningful health outcomes for the Medicare population

What is a Covered Service?

Generally, an item or service:

- which, if subject to FDA review, has been approved or cleared for at least one indication;
- which falls within a part A or B Medicare Benefit Category (generally found in § 1861 of the Act);
- which is not statutorily excluded based on § 1862(a)(2)-(15) of the Act;
- which is **reasonable and necessary** based on § 1862(a)(1)

NCD Scope

- Binding on Part A and Part B (FFS Medicare)
  - Generally not done on oral medications
- Part C plans must at minimum provide NCD covered services
- Do not directly affect Part D plans.

The Preferred Road to Therapeutic Coverage

- ✓ Provide adequate evidence that
- ✓ A treatment strategy using the new therapeutic technology compared to alternatives
- ✓ Leads to improved clinically meaningful health outcomes
- ✓ In Medicare beneficiaries

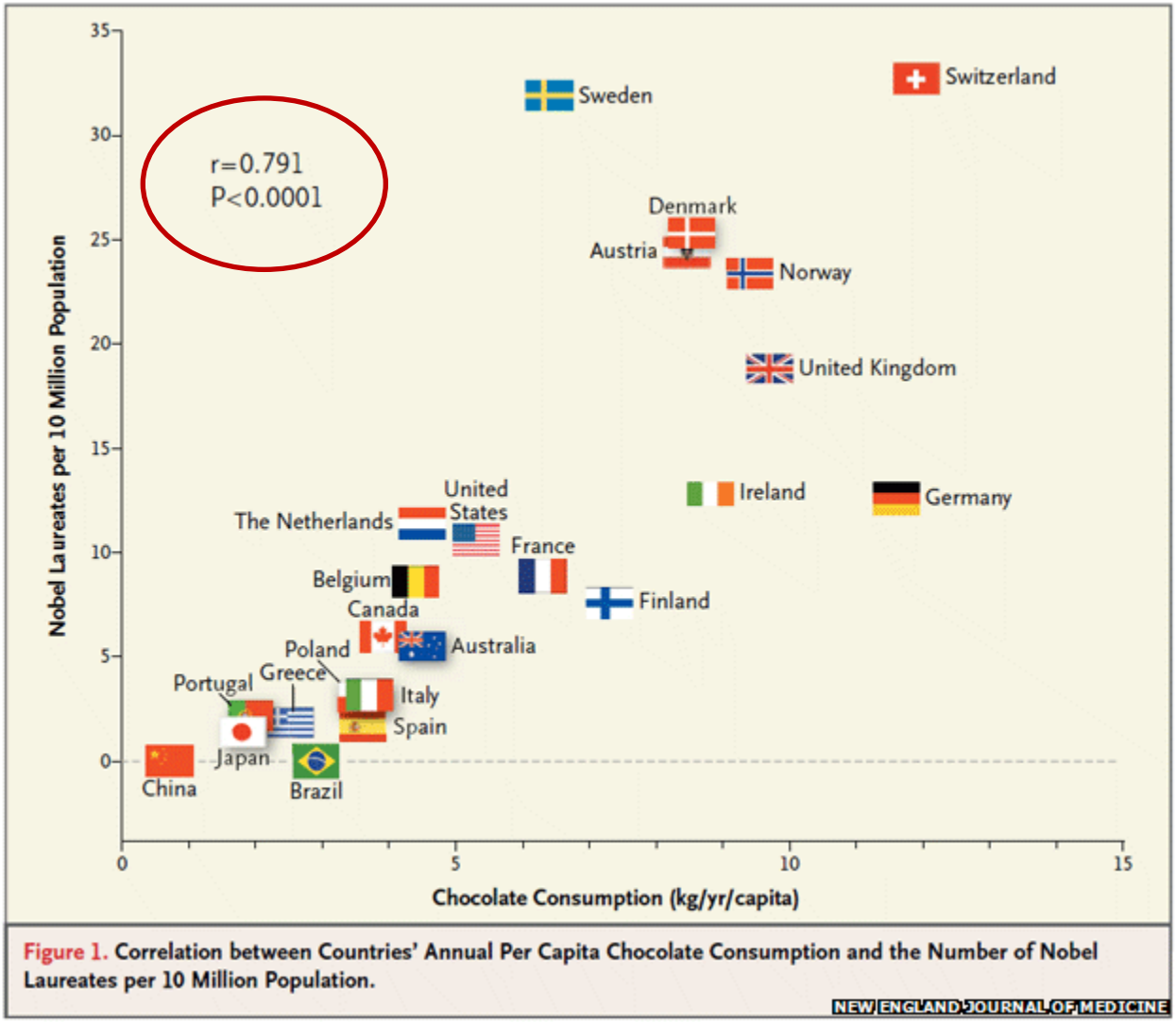


Figure 1. **Correlation between Countries' Annual Per Capita Chocolate Consumption and the Number of Nobel Laureates per 10 Million Population.**

NEW ENGLAND JOURNAL OF MEDICINE

A significant p value ≠ proof of causality.

42 CFR 410.32

(a) *Ordering diagnostic tests.* All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary (see § 411.15(k)(1) of this chapter).

The Preferred Road to Diagnostic Coverage

- ✓ Provide adequate evidence that
- ✓ The incremental information obtained by new diagnostic technology compared to alternatives
- ✓ Changes physician recommendations
- ✓ Resulting in changes in therapy
- ✓ That improve clinically meaningful health outcomes
- ✓ In Medicare beneficiaries

PATIENT

Usual Workup

Workup + New Test

Usual Therapy

Different Therapy

Better Outcome

Usual Outcome

Worse Outcome

Some Diagnostic Questions

- What data does it generate?
- What clinical information do the data provide?
- (How) Have we gotten this information before (from other sources) ?
- What (different) decisions are made based on this information?
- What are the advantages/disadvantages of basing decisions on this new test?

Other Potential Advantages

Compared to Current Practice

- Less invasive
- Clinically significant faster turnaround
- Reduced patient exposure to radionuclide(s), allergens/sensitizers, toxins etc
- Clinically significant broader availability (e.g. community based testing versus sending to national reference lab)

Health Outcomes of Interest

More Impressive

- Longer life and improved function/participation
- Longer life with arrested decline
- Significant symptom improvement allowing better function/participation
- Reduced need for burdensome tests and treatments

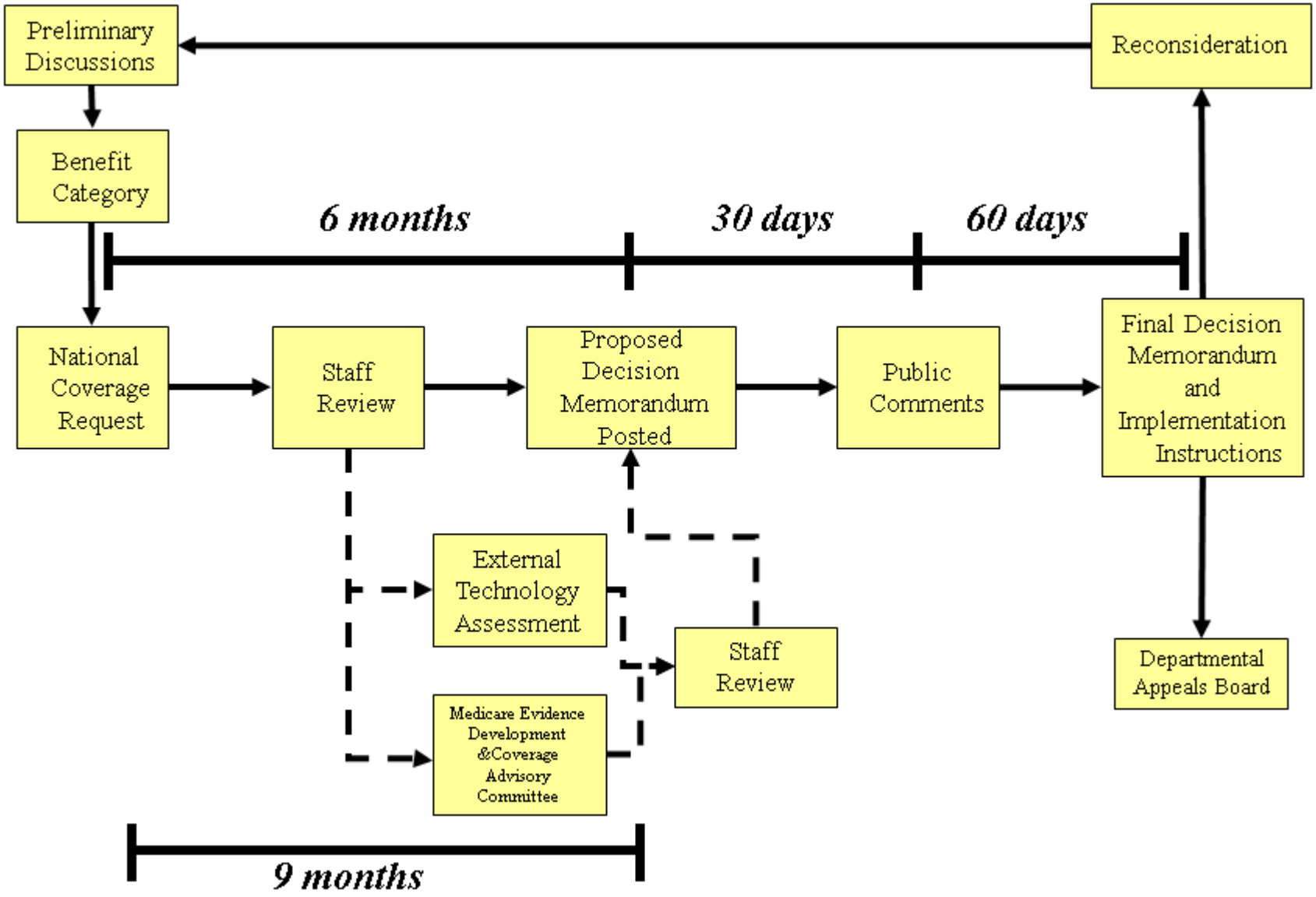
Less Impressive

- Longer life with declining function/participation
- Improved disease-specific survival without improved overall survival
- Surrogate test result better
- Image looks better
- Doctor feels confident

Medicare has stated publicly that as a matter of policy that it does not generally consider cost in making national coverage determinations.

National Coverage Determinations

MEDICARE NATIONAL COVERAGE PROCESS



What prompts NCDs?

- External request
  - Current national non-coverage policy
  - Substantial LCD variation
- Internally generated
  - Extensive literature or important new study
  - Technological advance with potential major clinical or economic impact
  - Major concerns about inappropriate use

NCD Outcomes

- National Coverage
  - Conditions
- National Noncoverage
- National Coverage with Data Submission
  - Appropriateness
  - Evidence Development
- No National Coverage Determination
  - left to local contractor discretion

Local Medicare Coverage

LCD Definitions in SSA

1862(l)(6)(B) Local coverage determination.—The term “local coverage determination” has the meaning given that in section 1869(f)(2)(B).

1869(f)(2)(B) Definition of local coverage determination.—For purposes of this section, the term “local coverage determination” means a determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary–or carrier–wide basis under such parts, in accordance with section 1862(a)(1)(A).

1862(a)(1) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—

(A) which, except for items and services described in a succeeding subparagraph or additional preventive services (as described in section 1395x(ddd)(1) of this title), are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,

Local vs. National Coverage

- Many coverage decisions are LCDs
- LCDs can be overturned by ALJs
- Allow initial diffusion of innovations
  - learning curve with new tech
  - revenue for small companies
- Responsive to community care standards
- Allow regional flexibility / variation in policy

POLICY, REGULATION & ETHICS

PERSPECTIVE

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Medicare coverage: engaging on evidence

Tamara Syrek Jensen & Louis B Jacques*

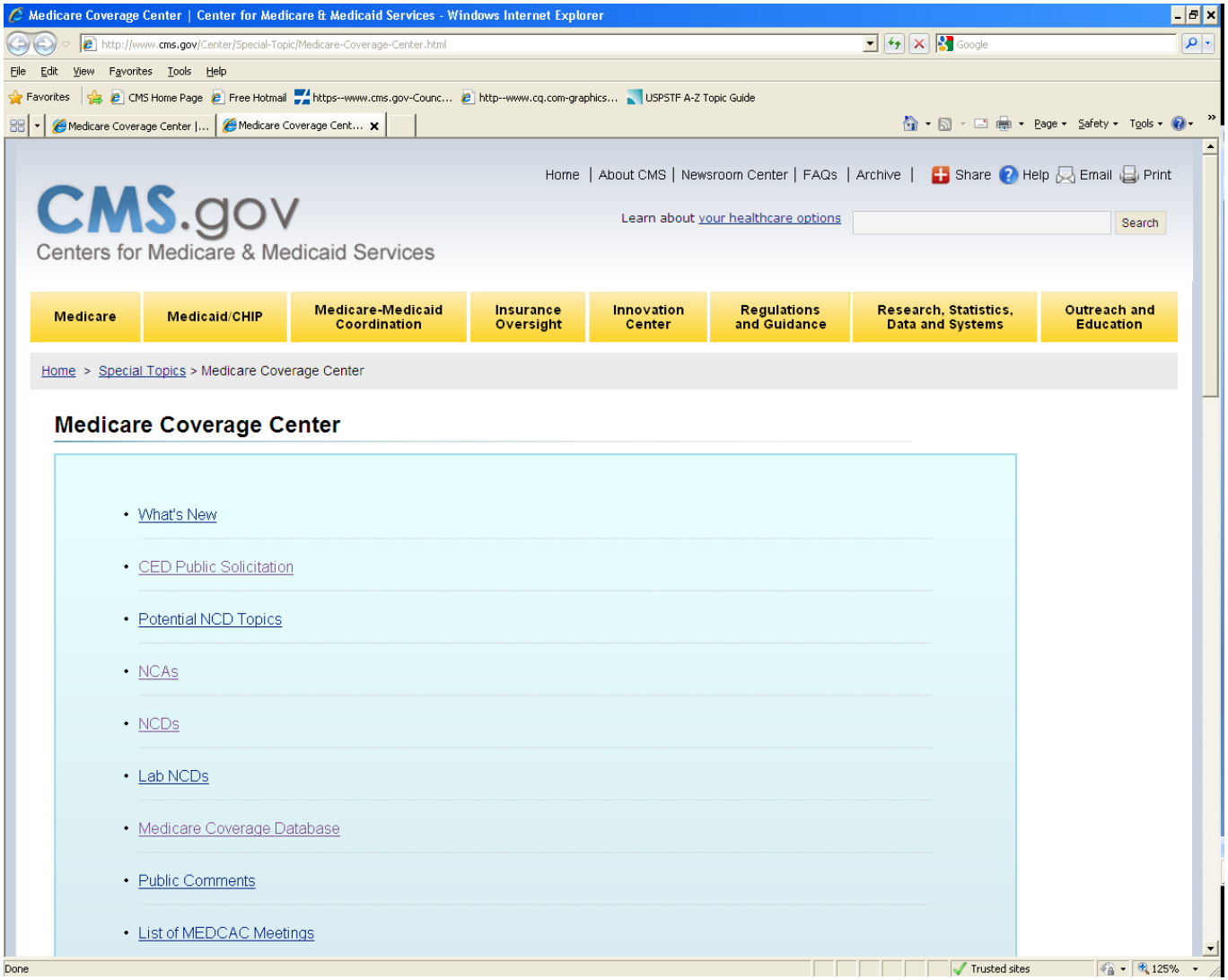
Experience tells us that many developers of innovative technologies fail to anticipate the evidentiary needs of insurers, particularly of Medicare. Some assume that Medicare payment begins *pro forma* upon approval or clearance by the US FDA with little regard to the distinct role of the Centers for Medicare & Medicaid Services (CMS). We offer our own suggestions, hoping they will lead to mutually satisfying discussions as we consider coverage of regenerative medicine technology. Medicare is governed by Title XVIII of the Social Security Act, which among other provisions describes the scope of the insurance benefit, methods of payment for items and services that may be covered and the process timelines for national coverage determinations. CMS implements these provisions with regulations, instructions in manuals and other guidance that are available to the public. We will focus our comments on the 'reasonable and necessary' requirement for coverage under Part A and Part B of items and services in Section 1862(a)(1)(A) of the Social Security Act.

The scope of the Medicare insurance benefits under Part A and Part B is established by Congress. One should not assume that every beneficial technology falls within these benefits and is thus a potential candidate for coverage. Some items and services such as eyeglasses, hearing aids and cosmetic surgery are generally excluded by the statute. Oth-

> "We believe that proactive engagement with Centers for Medicare & Medicaid Services may help stakeholders to address these issues while these technologies are under development."

tion. This paradigm speaks to the methodologic design of the supporting clinical studies, the impact of the studied technology on patients and the generalizability of those findings to Medicare. While some may aim to fulfill this expectation in its most minimal iteration, we find little reason to recommend this strategy. Historically, our review is more

Jensen, TS, Jacques LB. Medicare coverage: engaging on evidence. Regen Medicine, Vol. 6, No. 6s, Nov 2011: 99-101.



http://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center.html?redirect=/center/coverage.asp

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