CMS ICD "Pay for Data" Model

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FDA and CMS Roles

- FDA is a public health / regulatory agency
  - ensures products safe, do what they claim
  - assumes marketplace sorts out questions of clinical value and comparative effectiveness
  - efficacy standard varies by risk
- CMS is regulator and purchaser
  - Does technology improve health outcomes?
  - Better than what already exists
  - Can cover off-label indications

Steps to Coverage Determination and Payment

Outside of CMS:

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

Within CMS:

- Coverage
- Coding
- Payment

CMS's Statutory Authority for Coverage

- Section 1862(a)(1)(A) of the Social Security Act
- Coverage and payment limited to items and services
  - found "reasonable and necessary"
  - for treatment of illness or injury...

What standards are used in an NCD?

- Evidence of improved health outcomes
- Appropriate for Medicare population
- Could be replicated in provider community

National Decisions

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

Coverage with Evidence Development

- Used for promising innovations with insufficient evidence for Medicare population
- July 12, 2006 CMS released a guidance document concerns the circumstances under which CMS would issue a national coverage determination (NCD) requiring, as a condition of coverage, collection of additional patient data to supplement standard claims data.
- Further implementation thru clinical trials NCD and device-specific NCDs

Medicare ICD expanded coverage

- Effective 1/05
- Based on the results of SCD-HeFT trial
- Linked to submission of data to national ICD database
- Can answer residual questions regarding safety & effectiveness in certain groups of patients & providers
- Initial hypotheses developed

ICD Implant Data Form

- One page printed form
- Data elements include:
  - Demographics
  - Patient history & clinical characteristics
  - Medications
  - Provider information
  - Clinical indications
  - Complications

Medicare Coverage Determination for ICDs

Detailed descriptions of the clinical indications covered and restrictions are available at:

http://www.cms.hhs.gov/center/coverage.asp

ICD Data Reporting

- When would CMS require data submission?
  - Clinical trials results are promising but not definitive
  - Additional data may allow CMS to broaden policy
- What will CMS do with the data?
  - Data will be used to determine that services provided are reasonable and necessary
  - Address hypotheses related to patient characteristics, clinical indications, provider competency, complication variation across implanters, hospitals and device manufacturers

ICD Data Reporting

- Which patients must be reported?
  - Device implants for primary prevention clinical indications (e.g. no history of cardiac arrest or arrhythmia)
- How do providers fulfill the requirement?
  - By participating in IDE Category B clinical trials, other trials identified by CMS or by reporting data to an approved registry
  - This requires participation by the hospital AND physician to ensure all required data is obtained

Physician Quality Reporting Initiative (PQRI)

- Foundation is evidence-based measures developed by professionals
- Reporting data for quality measurement rewarded with financial incentive
- Measurement enables improvements in care
- Reporting is the first step toward pay for performance

PQRI and Registries

- NCDR was qualified registry for 2008 reporting
- A number of others also qualified
- 2009 process underway

Lessons for AF ablation

- NCD could be used to require data collection
  - Clinical indications, demographics, other treatments tried
  - Difficulties in obtaining data on medical and surgical treatment and patient follow-up
- PQRI also an incentive for data collection
  - Quality measures require broad consensus, may focus on broad safety issues