



Coverage with Evidence Development

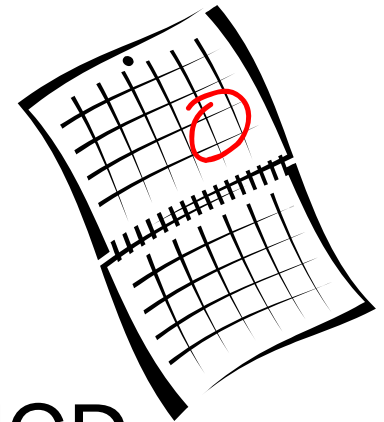
Medicare's Experience with the National
Oncologic PET Registry

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Abbreviations

- CMS: Centers for Medicare & Medicaid Services
- NOPR: National Oncologic PET Registry
- NCD: National Coverage Determination
- CED: Coverage with Evidence Development
- CSP: Coverage with Study Participation
- CAD: Coverage with Appropriateness Determination

Timeline



- January 2005: FDG PET “for 6” NCD
- May 2006: NOPR begins registration
- Various NCI sponsored trials enroll
- Publications
 - Methods: November 2007
 - Results: May - December 2008
- April 2008: CMS opens reconsideration
- April 2009: PET “for Solid Tumors” NCD

Evidence Reviewed

- NOPR data
- Internal and external TAs
- Published medical literature
- Guidelines
- Expert opinion
- Public Comment

NCD: PET for Solid Tumors

Final Outcome

- Covered w/o CED
 - Initial management of most solid tumors and myeloma
 - Subsequent cervical, ovarian CA
- Covered only with continued CED
 - Subsequent most solid tumors
- Noncovered
 - Initial management of prostate CA

Issues that arose:

- NOPR financing: administrative costs
- Human subject research protections
 - What part of NOPR is research?
 - Who is an investigator?
- Incenting the oncologists to submit data
- Evolving understanding of CMS' CED authority
 - AHRQ
 - CAD v CSP

Lessons

- CED does not always lead to “Yes”
- CED is not exclusive to a single study
- CED implementation is limited by Medicare payment rules
- CED is exclusive to enrolled subjects

Resources

- <http://www.cancerpetregistry.org/>
- <http://www.cms.hhs.gov/center/coverage.asp>
- <http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=218>

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