

Lessons from CMS:

Coverage with Evidence Development (CED)

Oncology “Demo” 2006

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As goes Medicare . . .

- Coverage = Medicare will or will not pay
 - If Coverage required data elements, then easier to obtain data
- Payment = how much Medicare will pay
 - If Payment was increased when additional useful data submitted, then easier to obtain data
- These two ideas underpin CED and the Oncology Demo 2006

CED

- Advanced/emerging coverage standard in which additional 'data' gathered in the course of routine care
- Two flavors:
 - Registry based
 - To get coverage of intervention, additional information about patient/disease required
 - Clinical trial based
 - To get coverage, patient must be enrolled in clinical trial of intervention

Sec. 1862. [42 U.S.C. 1395y] (a) 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—

(1)(A) which, except for items and services described in a succeeding subparagraph, **are not reasonable and necessary** for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,

(B) in the case of items and services described in section [1861\(s\)\(10\)](#), which are not reasonable and necessary for the prevention of illness,

(C) in the case of hospice care, which are not reasonable and necessary for the palliation or management of terminal illness,

(D) in the case of clinical care items and services provided with the concurrence of the Secretary and with respect to research and experimentation conducted by, or under contract with, the Medicare Payment Advisory Commission or the Secretary, which are not reasonable and necessary to carry out the purposes of section [1886\(e\)\(6\)](#),

(E) **in the case of research conducted pursuant** to section [1142](#), which is not reasonable and necessary to carry out the purposes of that

CED examples

- Registries –
 - Required for use of implantable cardiac defibrillators (ICD's) for primary prevention
 - Baseline variables regarding cardiac risk (e.g. heart function measures) required
 - National Oncologic Pet Registry
 - To get a PET scan, ordering physician had to input information about patient's clinical status, and expectations/potential responses in light of PET scan results
- Clinical trials –
 - Numerous, including randomized trials of cancer drugs for off-label non-compensated listed indications

CED implementation

- Required 'other actor'
- Registries, registry housed outside CMS
 - ICD registry woven into National Cardiac Disease Registry
 - PET registry created
(<http://www.cancerpetregistry.org/>)
- Clinical trials – designed and run elsewhere (e.g. NHLBI, NCI)

CED findings

- ICD registry: complication rates vary between implanting physicians
- PET registry: about 1/3 of clinical decisions 'altered' by PET
 - Based on analysis of 23,000 scans
 - 'Post-pet' plan changed to 'watching' in 37%, treatment in 48%
 - Biopsy avoided in 70%
 - Goals of therapy changed 5%

Challenges/lessons

- For registries –
 - Needing 3rd party for registry large impediment
 - Human subjects issues not straightforward
 - No ability for CMS to fund analyses or follow-on data collection
- For clinical trials –
 - Push back from manufacturers
 - Co-payment issues messing up blinding (CMS unable to homogenize copayment between interventions of different costs or placebo)

Criticism came from unexpected corners

- Too large a sample
- Not the right question

Panel pans clinical trials justifying PET coverage

Poor review of efficacy studies for applications monitored by PET registry disappoints proponents

Oncology demo 2006

- Goal was to gather more information about patients and treatment patterns in 'routine care'
- Mechanism: added new billing codes that could be included on claim form
- Additional payment (\$23) for submitting codes, independent of content

Demo 2006

- Codes could be submitted with E&M visit (regular doctor visit) by medical oncologists
 - Bypassed HIT requirements
- 3 codes:
 - Disease status, Visit Focus, Guideline adherence
- Limited number of cancers
- Payment is \$23

Justification

- Disease status
 - Captured details like stage of patient, whether cancer had recurred
 - Significant and critical augmentation over diagnosis codes that are used on billing
 - Guideline adherence asked about
 - Guidelines capture the current standards, and are a shortcut to
 - Kept up to date
 - ‘Shortcut’ around laborious slow measure by measure development
- Focus of the visit – necessary for quality measurement and determining what guideline being followed

Colon cancer disease status codes

Colon cancer (153.0-153.9)	
	ONCOLOGY; DISEASE STATUS; COLON CANCER, LIMITED TO INVASIVE CANCER, ADENOCARCINOMA TYPE; EXTENT OF DISEASE INITIALLY ESTABLISHED AS T1-3, N0, M0 WITH NO EVIDENCE OF DISEASE RECURRENCE, OR METASTASES
	ONCOLOGY; DISEASE STATUS; COLON CANCER, LIMITED TO INVASIVE CANCER, ADENOCARCINOMA TYPE; EXTENT OF DISEASE INITIALLY ESTABLISHED AS T4, N0, M0 WITH NO EVIDENCE OF DISEASE RECURRENCE, OR METASTASES
G9086	ONCOLOGY; DISEASE STATUS; COLON CANCER, LIMITED TO INVASIVE CANCER, ADENOCARCINOMA TYPE; EXTENT OF DISEASE INITIALLY ESTABLISHED AS T1-4, N1-2, M0 WITH NO EVIDENCE OF DISEASE RECURRENCE, OR METASTASES
G9087	ONCOLOGY; DISEASE STATUS; COLON CANCER, LIMITED TO INVASIVE CANCER, ADENOCARCINOMA TYPE; M1 AT DIAGNOSIS, METASTATIC, LOCAL RECURRENT, OR PROGRESSIVE, RADIOLOGIC, OR BIOCHEMICAL EVIDENCE OF DISEASE
G9088	ONCOLOGY; DISEASE STATUS; COLON CANCER, LIMITED TO INVASIVE CANCER, ADENOCARCINOMA TYPE; M1 AT DIAGNOSIS, METASTATIC, LOCAL RECURRENT, OR PROGRESSIVE, RADIOLOGIC, OR BIOCHEMICAL EVIDENCE OF DISEASE
G9089	ONCOLOGY; DISEASE STATUS; COLON CANCER, LIMITED TO INVASIVE CANCER, ADENOCARCINOMA TYPE; EXTENT OF DISEASE UNKNOWN, NOT YET DETERMINED, UNDER EVALUATION, PRE-SURGICAL

T1-4, N1-2, M0
(i.e. Stage III)

M1, Metastatic, Locally recurrent, Progressive

New Measure: Guideline Adherence

- Guidelines designated: NCCN, ASCO
- Possible responses:
 - Yes, treatment adherent to guidelines
 - No, patient on IRB approved clinical trial
 - No, treating physician disagrees with guideline recommendations
 - No, patient prefers alternative/no treatment
 - No, patient comorbidity/PS precludes guideline Rx
 - There are no guidelines relevant to patient's condition
 - No, another reason

An embedded quality measure

- Stage III colon cancer patient offered adjuvant chemo
- Demo ascertainment
 - Denominator:
 - ICD-9 code for colon cancer;
 - Disease status code (T1-3, N1-2, M0)
 - Focus of the visit: supervising rx
 - Numerator:
 - Yes, following guidelines
 - Patient refused guideline based therapy
 - Validity: J codes for specific chemotherapies

Demo evaluation

- Field reports, site visits, surveys, claims data analyses
- Participation 66% of visits (90% in 05 demo)
- Key finding: Substantial implementation impediments
 - Doctors offices created 'cheat sheets' that lost information
 - Meaning of guideline adherence not clear
 - Disease status/stage codes validated only somewhat

Loss of information

- Many practices developed their own tools, “cheat sheets”
- The level of detail, focus and precision in these ‘cheat sheets’ varied from practice to practice
- Sometimes important gaps created

Information gap

“Keep in mind even if the [G-code] descriptions were laid out in detail somewhere in the CMS paperwork, many of us never saw the original detailed descriptions and instead only saw a summary sheet that could be attached to the patient encounter form.”

Table 10. Description of G9071 from case study physician practices vs. CMS instructions

Description of G071 (breast cancer)	Source
Oncology; disease status; invasive female breast cancer (does not include ductal carcinoma in situ); adenocarcinoma as predominant cell type; Stage I or Stage IIA-IIB; or T3, N1, M0; and estrogen-receptor (ER) and/or progesterone-receptor (PR) positive; with no evidence of disease progression, recurrence, or metastases	CMS guidelines ¹⁸
“Stage 1-2B, ER/PR POS or T3, N1, M0, Stable”	Case study physician practice
“Onc Dx breast Stg 1 or Stg IIA-IIB HR no progression”	Case study physician practice
“Onc Dx brst Stg 1-2B no dx pr”	Case study physician practice

Uncertainty regarding guidelines

Interviews with physicians revealed differing nomenclature used within the context of “clinical guidelines”. None of the physicians interviewed described clinical practice guidelines as defined by Field and Lohr, “systematically developed statements to assist practitioners and patient decisions about appropriate health care for specific circumstances”.²⁰ Some physicians were very specific in their definitions, particularly those who participated in clinical research or clinical trials. When probed, all of them recognized the difference between general guidelines and clinical protocol. However, the following terms were frequently used interchangeably by many of the physicians interviewed to describe clinical guidelines:

- Standard of care
- Best practices
- Evidence-based medicine
- Evidence-based guidelines
- Clinical pathways
- Clinical guidelines (e.g., www.UpToDate.com or www.adjuvantonline.com)
- Quality patient care

Information gap

Within the context of adherence to clinical guidelines, the meaning of this varied significantly among the physicians interviewed. Some physicians indicated checking “adheres to guidelines” even though they “went beyond” the clinical guidelines due to more current evidence. They explained that this was the appropriate selection since treatment that went “over and above” the guidelines would likely be adopted in the next updated clinical guidelines.

Other physicians reported checking “adherence to guidelines” (G9056) since they always practiced a “high standard of care, consistent with evidence-based medicine”. However, physicians reported that they often did *not* review the applicable ASCO or NCCN guidelines to ensure that their treatment decision was within the clinical guidelines. Some physicians said:

Lessons learned

- Must be very careful of assumptions made when we ask “front line” physicians to submit data that is analyzable
- Should probably assume that the overarching purpose will not be easy to convey, and thus cannot rely on doctors having appropriate heuristics
- Very difficult to instruct/promulgate guidance of sufficient detail
 - Many built-in filters between CMS info and what docs see
 - (specialty societies, friends, office managers)
 - “I just read the newspaper to find the summary of the editorial that accompanied the article”

How to move forward

- For rapid learning we will need more data at the clinical encounter
- Have to appreciate that the bandwidth in clinical medicine is pretty occupied
 - Busy doctors, already multi-tasking
- Will be very hard to get buy-in that downstream learning valuable. Today's care is about today's patient, and today's bill
- Doctors who do a lot of clinical trial work may be the easiest to move