Coverage Analysis and Research Billing
Beyond SOC vs. Study Paid

March 14, 2014
Overview

Laws and regulations for billing for patients in clinical trials

CMS’s National Coverage Decision, Affordable Care Act, STARK/anti-kickback, False Claims Act

Pre-study requirements

MCA, Billing plan, contracts (STARK), IDE pre-approval

STAGES

The Secret Life of a claim
Effective for items and services furnished on or after July 9, 2001, Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.
Medicare Coverage Continued

Coverage Includes:

Includes all items and services that are otherwise generally available to Medicare beneficiaries

- Benefit category exists
- Not statutorily excluded
- Items and services that are typically provided absent a clinical trial (e.g. conventional care)

- Items or services **required solely for the provision of the investigational item or service** (e.g. administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications.

- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service- in particular for the diagnosis or treatment of complications.
Medicare Coverage Continued

Coverage Excludes

- The investigational item or service, unless otherwise covered outside of the clinical trial
- Items and services provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually only requiring only a single scan)
- Items and services customarily provided by research sponsors free of charge for any enrollee in the trial.
Patient Protection and Affordable Care Act

“This is a big !@#$%^& deal.”

May 23, 2010 - Vice President Joe Biden, caught on open mic congratulating President Obama on the passage of the PPACA.
PPACA Section 10103 (Section 2709)

Coverage for Individuals Participating in Approved Clinical Trials

- Effective 2014
- Group and Individual Health Plans cannot deny or limit coverage of routine patient costs for items and services furnished in connection with approved trial.
  - Except: Plans Governed under ERISA (i.e., Self–insured plans)
  - Except: “Grandfathered” Plans (where the person was enrolled on/before March 23, 2010)
- Criteria remarkably similar to Medicare
  - “Routine costs”- items typically covered absent a clinical trial
  - “Approved trials”- trials under IND, Federally funded
- Unlike Medicare, limited to trials of “Cancer or other life-threatening disease or condition.”
- Cannot discriminate on basis of individual’s participation in trial

*Patients should continue to check with their insurance plans before enrolling*
Other laws governing research

**STARK/Anti-kickback**-

Section 1877 of the Social Security Act (the Act) (42 U.S.C. 1395nn), also known as the physician self-referral law and commonly referred to as the “Stark Law”:

Prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership, investment, or compensation), unless an exception applies.

Prohibits the entity from presenting or causing to be presented claims to Medicare (or billing another individual, entity, or third party payer) for those referred services.

Establishes a number of specific exceptions and grants the Secretary the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.
Other laws governing research billing

False Claims Act

The False Claims Act imposes liability on any person who submits a claim to the federal government that he or she knows (or should know) is false.

. . . is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person . . . .

31 U.S.C. § 3729. While the False Claims Act imposes liability only when the claimant acts “knowingly,” it does not require that the person submitting the claim have actual knowledge that the claim is false. A person who acts in reckless disregard or in deliberate ignorance of the truth or falsity of the information, also can be found liable under the Act. 31 U.S.C. 3729(b).
Pop Quiz!

1. Medicare covers the _________ costs of ________ clinical trials.
   
   *Medicare covers the *routine* costs of *qualifying* clinical trials.*

2. Patients should always expect to pay ________________.
   
   *Patients should always expect to pay *their copays, deductibles and coinsurance.*
Coverage Analysis

Items needed for a comprehensive coverage analysis

**Full Protocol**- The study table rarely tells the entire story

**ICF**- The cost section often makes promises that do not match reality

**Sponsor’s preliminary budget**- sometimes it looks remarkably similar to the study table

**Preliminary CTA**

**FDA Approval letter designating IDE category**

**Anything else you get from the sponsor**- Instructions for use, device descriptions, coding guides, templates for invoicing- never too much information
Coverage Analysis

☐ This study requires Medicare Coverage Analysis (This project includes patient charge items and services performed on an Intermountain campus during the course of the research study and therefore involves the potential for billing to the patient or a third party payer, including Medicare)

☐ This study does NOT require Medicare Coverage Analysis. Please check all of the boxes that apply below:

☐ The study is supported by a grant that funds ALL of the patient care activity required for the protocol and all patient care costs will be billed to the study. No services related to the study will be billed to the patient or his/her insurance.

☐ The study is supported by a sponsor that funds ALL of the patient care activity required for the protocol and all patient care costs will be billed to the study. No services related to the study will be billed to the patient or his/her insurance.

☐ The study does NOT involve any activities or patient charge items. (i.e. Retrospective chart review, survey, or observational study).

☐ Other; Please explain:
Coverage Analysis cont.

Medicare NCD or Clinical Trials Policy

Medicare’s National Coverage Decision on Routine Costs of Qualifying Clinical Trials was the tool primarily used as the basis for conducting the Medicare coverage analysis. In order to utilize the NCD in the coverage analysis, the trial must first meet the criteria for classification as a “deemed” qualifying clinical trial as outlined in the NCD and validated in the following steps:

Step 1

a. The study is automatically deemed to qualify for coverage consideration according to the NCD deeming criteria.

☐ Yes (mark appropriate box and go to step 2)  ☐ No (Go to step b)

☐ Trial is funded by NIH, CDC, AHRQ, CMS, DOD or VA
☐ Trial is supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD or VA
☐ Trial is conducted under an investigational new drug application (IND) reviewed by the FDA
☐ Study is a drug trial that is exempt from having and IND under 21 CFR 312.3(b)(1)
☐ The study is required through the Coverage with Evidence NCD process

b. The study meets ALL of the following qualifying criteria required by the NCD for consideration for coverage of routine care costs.

☐ The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category.
☐ The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.
☐ Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers.
☐ The principal purpose of the trial is to test whether the intervention potentially improves the participant’s health outcomes.
☐ The trial does not unjustifiably duplicate existing studies.
☐ The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully.
☐ The trial is in compliance with Federal regulations relating to the protection of human subjects; and
☐ All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

☐ Yes (go to step 2)  ☐ No (STOP)
Medicare Coverage Analysis cont.

Step 2: The study involves an evaluation of an item or service or the underlying procedure to implant the device falls within a Medicare benefit category and is not statutorily excluded from Medicare coverage.

Step 3: The research study title and ClinicalTrials.gov registry number for this study is posted on the CMS website and in the Federal Register. *(MUST be on the claim or it will be denied by Medicare!)*

Step 4: Sponsored covered items and services: Review the study budget. Identify items and services paid by the sponsor. These items and services may not be billed to other third party payers (including Medicare) and thus, would not need to be analyzed to meet the definition of routine care costs. NOTE: If the PI feels that an item or service is only being done for research purposes and indicates he/she would not order the service as part of his/her routine practice, there is no need to research Medicare rules. However, if the PI states it is routine, Medicare coverage limitations must still be researched. (Go to step 5)

Step 5: Does a specifically applicable National Coverage Decision (NCD) exist?

Step 6: Is the specific NCD a non-coverage decision?

Step 7: Other National or Local Coverage Determinations. Does an applicable NCD or LCD exist?
Billing Plans

SOC “routine” vs. Study paid

Pl’s attestation- good starting point

National guidelines- NCCA, AHA. . . some specialties have better

Pl’s historical data- you mean you really do 3 EKGs a week for patients with this same diagnosis outside of a trial?

Is the sponsor offering to pay for it? Do we really want them to?

Other billing plan purposes

Helps to build the budget

Names “external billers”- Who is doing the x-ray reads, the eye exams, the neuro exams and do we need/have an ISSA?

Shows “due diligence” if audited.
Investigational Device Exemptions

DEVICE "G" NUMBER: G120263/S004

Part A requirements:
1. The name of the device (both trade, common or usual and classification name) and a narrative
   description of the device. Include a statement as to the devices similarities and differences from
   the other products if not explicitly and clearly indicated in submitted documents.
   Attachment #1
2. A copy of FDA approval letters.
   Attachment #2 FDA approval letters
3. A copy of the approval letter from the Provider's Institutional review board (IRB). A copy of the
   approval letter for any time extension or other updated must also be submitted after the initial
   approval.
   Attachment #3 Stamped, dated IRB approval letter
4. A description of the action(s) taken to conform to any applicable FDA and/or IRB special
   controls and/or other requirements.
   Attachment #4 Study protocol
5. A copy of the study protocol, including patient inclusion criteria.
6. A sample of the patient consent form. Form must clearly disclose the receipt of any payment(s)
   from the sponsor to facility and/or Principle Investigator (PI).
   Attachment #5 Stamped, dated IRB approved Informed consent form
7. A copy or description of the Provider's protocol for obtaining informed patient consent.
   Attachment #6 SOP for department's consenting process

Part B requirements:
8. Copies of all agreements between the sponsor and the provider, especially but not limited to, financial agreements, any and all payments for each aspect of the study.
   Attachment #7 Fully executed Clinical Trial Agreement
9. The Principle Investigator's budget for the study, showing allocation of all funds from all
   sources. The budget should specify both the costs of the services (including evaluations), tests
   and procedures that will be performed throughout the course of the study and which will be
   billed to Medicare. Submit the PIs determination of which tests and procedures are necessary
   to the "research" and which tests and procedures are "standard of care" for the treatment of
   the underlying disease in the absence of the study intervention.
   Attachment #8 Fully executed study budget
   Attachment #9a fully executed Billing Plan
10. A description of the facility's processes/procedures for ensuring that Medicare is not billed for
    any non-routine care costs and sponsor or other reimbursed costs.
    Attachment #9 Intermountain's Research Billing Procedure
Pop Quiz!

Medicare Coverage Analysis and billing plans are done:

A. To ensure the routine costs are billable (i.e. qualified clinical trial.)

B. To show due diligence in case of an audit.

C. Because Shanna doesn’t look good in orange.

D. All of the above
Bill hold and charge allocation

STAGES-

Holds facility claims

Allows us to view charges prior to billing

Emails employed and non-employed physician’s offices to alert them of research charges

Cerner-

Proactive approach

New features and capabilities- more to come!
The Secret Life of a Claim

Research paid

Facility-Allocated to study- manager approves- charges move to institutional account-discount applied- manager approves monthly account for payment

Medical Group- Encounter sent to designee- charges entered on “case”- manager approves monthly account for payment
Pop Quiz!

Forgetting to put charges in STAGES or allocating them incorrectly:

A. Creates a ton of extra work for many people.
B. Causes refunds to Medicare which may trigger an audit.
C. Is unfair to patients who receive bills they shouldn’t.
D. Causes Shanna to bang her head on her desk which is disruptive to others in the Office of Research.
E. All of the above.
Questions
Thank You

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