Updates in Clinical Trial Billing and Reimbursements
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Agenda for the Day

• Nurse Coordinator and CRA role in Billing
• Recent Cases
• What happens when the unexpected occurs
• Billing lessons
• Thoughts and Discussion

In 2011

• Identified 19.8 billion in savings resulting from legislative, regulatory and administrative actions
• Excluded 2662 individuals and entities from participation in federal health care programs
• Prompted 732 criminal actions against individuals that were indentified to have engaged in crimes
YOU Help With
- Communication of study intelligence
- Clarity of study documents
- Collaboration of study logistics
- Coordination of study information

FRAGMENTED BILLING INFORMATION

What Can Impact The Process?
- Budget
- Contract
- Coverage Analysis
- Informed Consent
- Who you are billing
- Reimbursement
Protocol, Budget, Contract, Coverage Analysis and Consent

• Research team must remember that the coverage analysis drives all documents and what occurs when patient is consented
• Recent case showed there was an “intent” for another “payer” to cover the costs
• Coordinators usually are the “force”
The PI and Coordinator Perspective

The short version approach to “routine” costs:

1. Detection or prevention of complications (adverse events)
2. Conventional care
3. Administration of investigational item

NCD 310.1

- Medicare covers the routine costs of qualifying clinical trials, 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
“ROUTINE COSTS” UNDER THE CTP

• “Items or 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; and
• “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.”

COSTS THAT CANNOT BE BILLED

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

YOUR Protocol Related Requirements

• Reading and understand the protocol requirements
• Helping PI’s to understand their responsibilities
• Working with Sponsor
Pre Study - Are you ready?

- Must have full IRB approval including recruitment materials prior to accruing and know what is in consent
- Contract must be signed with final signatures and convergence of study documents prior to registering a patient
- Must have NCT# in order to bill clinical trials
- Is the Research Account set up and is the patient flag ready to be turned on?

Interview and Documentation in Consent Process

- Tell the subject what will occur if they are on a Medicare Advantage Plan and they enroll in a drug study
- Make sure you present what is being provided for free or at no cost and that the patient understands it
- Ensure that you tell them that they have responsibilities to pay their co-payments and deductibles
- Tell them that the clinical trial will go onto the claim if they have a government payer

Remember....

- The consent is a "live" document
- When the patient (and their family members) do not understand who is responsible for costs, problems may arise later when there are accounts that the patient is responsible for financially
- In litigation, it is very likely that the judge or jury will lean toward the patient and what they understood
With Medicare Advantage Patients

- Identify the plan
- Explanation to patient
- Routine Visit Occurrences
- Co-payments Not Collected
- Bill reverts to regular M/C
- Gap not reimbursed sent to MAP

Medicare Advantage

- Original Medicare pays for the costs of routine services provided to a Medicare Advantage enrollee who participates in a qualified clinical trial.
- MA plans pay the patient the difference between:
  - Original Medicare cost-sharing incurred, and
  - Services the MA plan's in-network cost-sharing for the same categories of items or services

To Be Eligible

- Beneficiaries (or providers acting on their behalf) must notify the MA plan that the patient has received qualified clinical trial services
- And provide documentation of the cost-sharing incurred
Other Payors

- Commercial third-party payors do not necessarily accept the same guidelines as Medicare with respect to clinical trial services, sometimes classifying all services as "investigational" or "experimental."
- Obtain insurance payor guidelines in writing to ensure they correctly bill services associated with a clinical trial.
- Most states have enacted laws regarding clinical trials: http://www.cancer.gov/clinicaltrials/learningabout/payingfor/laws

Billing Lessons

Study Coordinator Responsibilities in Screening

- Procedures that are to be performed as part of the practice of medicine and that would be done whether or not trial entry was contemplated, such as for diagnosis or treatment of a disease or medical condition, may be performed and the results subsequently used for determining trial eligibility without first obtaining consent.
- Informed consent must be obtained prior to initiation of any clinical screening procedures that is performed solely for the purpose of determining eligibility for research.
Key in Screening

- Medical documentation for conventional care for the overall management of the patient
- Help your PI to understand that documentation only "screening for study XYZ" or "admission for evaluation of study XYZ" negates therapeutic intent

Example of Improper Documentation

- Screening Visit noted when all routine care being performed
- Screening note states that patient was admitted for evaluation and screening for "X Study"
- Negates therapeutic intent as to why patient was admitted under medical necessity
- Entire bill is not routine cost but coverage analysis and consent says it is

Billing Compliance and Adverse Events

- What does the consent say?
- Does the contract state the same?
- Track the adverse events – even the ones that occur outside of your facility
- Adverse Event (AE) vs. Complications – Know the difference
Complications

• NCD 310.1 states that the detection, prevention and treatment of complications are billable in "qualifying" trials
• Know if your trial is "qualifying"
• Know what the consent and contract state
• Know the complications of the study drug and the investigational device

Research Modifiers

• NCT #
• Hospital Inpatient claims
  ▪ Research modifiers not currently required
• Hospital Outpatient claims
  ▪ Research modifiers required
• Physician claims
  ▪ Research modifiers required
• All: use V70.7 diagnosis code as secondary diagnosis and must be combined with the Condition Code 30 on outpatient and physician claims
  ▪ ("examination of participant in clinical trial")

EFFECTIVE JANUARY 1, 2014

• It will be mandatory to report a clinical trial number on claims for items and services provided in clinical trials that are qualified for coverage as specified in the "Medicare National Coverage Determination (NCD) Manual," Section 310.1.
Clinicaltrials.gov

- The NCT # rule has effectively turned the NCD 310.1 into a rule where coverage requires the NCT # on the claim.
- Studies without an NCT # need to be properly classified as it does not make it so Medicare will not cover without it but you have to follow the NCD in order to bill.

NCT # Use MLM 8401 Registry Number

- Effective January 1, 2014 CMS will no longer consider the inclusion of the clinical trial number to be "voluntary," instead, healthcare providers will be required to report the 8-digit trial number on all claims during the time period the beneficiary participates in the trial. MLN Matters MLM8401, dated August 9, 2013, includes claim submission details and dates.
- Medicare Part B clinical trial/registry/study claims with dates of service on and after January 1, 2014, not containing an 8-digit clinical trial number will be returned as unprocessable to the provider for inclusion of the trial number.
- CMS will use this number to identify all items and services provided to beneficiaries during their participation in a clinical trial.

MLM SE1344 Update

- Beginning January 1, 2014 and continuing no later than December 31, 2014, physicians, providers and suppliers who do not have the capability of submitting the actual clinical trial number may instead report an 8-digit generic number of 99999999 using the same submission instructions previously published.
- CMS reiterates that trial-related claims will be returned if they do not contain either the actual clinical trial identifier number or the 8-digit generic number 99999999 – the field cannot be left blank.
- CMS stresses that if providers can report the actual clinical trial number, that is the number that should be included on the claim; the generic number is only to be reported by those healthcare providers who do not have the ability to report the actual number.
Investigational Services

Modifier QØ
- Investigational clinical service provided in a clinical research study that is in an approved clinical research study

Modifier Q1
- Routine clinical service provided in a clinical research study that is in an approved clinical research study

V70.7
- Examination of participant in clinical trial

Mandatory
- 8-digit clinical trial number

Early Enrollment

Since a study is not currently required to register on ClinicalTrials.gov until 21 days after the first subject is enrolled, how is billing impacted for early subjects enrolled before the sponsor has completed the registration?

What Do You Do When The Following Occur?

- Serious Adverse Events
- Admissions to Other Hospitals
- Non Compliance in Billing
Definitions

- **Adverse Event (AE):** Any untoward medical occurrence including, any abnormal sign, symptom, or disease, associated with the subjects participation in research, (e.g., an abnormal physical exam or laboratory finding.)
- **Non-Adverse Event (Non-AE):** Non-medical events that may involve social or economic harm rather than physical/psychological harm, (e.g., breach of privacy that leads to stigma or loss of insurance coverage, false HIV-testing)
- **Injury:** Medicare Secondary Payer Rules

Admissions to Other Hospitals

- Identify admits early
- Tell patient and family members to call if they are seen at other facilities
- Know what is in the consent regarding SAE’s and complications
- Remember, a government payer patient requires identification of study related items and services when billed
- Usually up to the study coordinator to assist

Non Compliance in Billing

- Allowing billing to go when you know it’s incorrect
- Ordering items incorrect
- Requesting items be segregated when not needed
- Waiving copayments
- Writing off patient balances
- No codes when appropriate
- Not syncing up the professional and facility side billing
- Leaving money on the table – not billing anyone
Denials on Clinical Trial Patients By Payers

- Denials can and will occur
- What is the denial process?
- Talk with patient and answer their questions
- Do not request Sponsor to cover cost or have invoiceable costs in budget and contract that only benefit a few

Billing Compliance Purpose

- Information must be coordinated in order to manage research billing compliance
- Processes must be established to identify patients in billing systems for every study
- Functionality in billing loop for research patients must be identified
- Comprehension of medical documentation and impact on coding clinical trial patients
Risks Associated With Billing Non-Compliance

- Billing for services that are already paid by the sponsor (double billing)
- Billing for services promised free in the informed consent
- Billing for services that are for research-purposes only
- Billing for services that are part of a non-qualifying clinical trial
- Billing Medicare Advantage for drug clinical trials
- Billing for Device Studies to Government Payers without Medicare Contractor approval
- Billing without NCT# on the claim

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