It’s All About the Documentation When Coding

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Disclosure

The presenter owns Kelly Willenberg, LLC in relation to this educational activity.

Session Objectives

› Medical Necessity when you submit claims
› Coding for “qualifying” trials
› Common mistakes
Coding for Clinical Trials

- Up-coding
- Mis-coding
- Exception file in bill scrubber
- Denials

  - Possible return to provider statement on claims:
    - "Claim lacks information which is needed for adjudication"
    - "Missing/incomplete/invalid Investigational Device Exemption number for FDA-approved clinical trial services"
    - "Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable …"

Fragmented Information

Where Do Errors Start?

Physicians sometimes do not have adequate awareness of the billing continuum in clinical trials.

Starts with patient registration upon consent
- Are research visits identified separately from regular visits?
- How are charges segregated?
- How do you ensure that a routine cost has the necessary documentation for both professional and facility coding if not global?
21 CFR 312.60

An investigator is responsible for ensuring that an investigation is conducted with attention to the following components: the signed investigator statement, the investigational plan (protocol) and applicable regulations for protecting the rights, safety, and welfare of the subjects under the investigator’s care, and the control of the drug under his investigation.

The Approach

Coding Review

Coding Concepts

- Clinical Trial Number - NCT# from www.clinicaltrials.gov
- Revenue Codes – Devices, Supplies, and Drugs
  - 0624 - Investigational Device
  - 0278 - Medical/Surgical Supplies: Other implants
  - 0216 - Investigational Drugs
- Condition Codes
  - 30 - Qualified clinical trial
  - 53 - Initial placement of a medical device provided as part of a clinical trial or a free sample
- Diagnosis Codes
  - K01.10 - 2016 - Encounter for examination for normal comparison and control in clinical research program
- HCPCS Modifiers
  - Q2 - Investigational clinical service
  - Q1 - Routine clinical service
Each procedure or service must include a modifier

**Modifier Q0**
- 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

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**Q0**

- **Investigational clinical services** are defined as:
  - Those items and services that are being investigated as an objective within the study.
  - Investigational clinical services may include items or services that are approved, unapproved, or otherwise covered (or not covered) under Medicare.

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**Routine Clinical Services Are Defined As:**

**Q1**

- Those items and services that are covered for Medicare beneficiaries outside of the clinical research study, are used for the direct patient management within the study; and, do not meet the definition of investigational clinical services.
- Routine clinical services may include items or services required solely for the provision of the investigational clinical services (e.g., administration of a chemothapeutic agent);
- Clinically appropriate monitoring, whether or not required by the investigational clinical service (e.g., blood tests to measure tumor markers); and
- Items or services required for the prevention, diagnosis, or treatment of research related adverse events (e.g., blood levels of various parameters to measure kidney function).
Pertinent Research Modifiers

- Hospital Inpatient claims
  - Research modifiers not currently required
- Hospital Outpatient claims
  - Research modifiers required
- Physician claims
  - Research modifiers required

All: Use ICD-10 Z00.6 diagnosis code as secondary diagnosis
("Encounter for examination for normal comparison and control in clinical research program")

NCT# Reporting Applies To Items/Services If:

- The beneficiary is enrolled in a clinical trial; and the claim is for the investigational item/service; and/or
- The costs are related to the investigational item/service in a drug, device or CED trial; and/or
- The costs are related to the routine care for the condition in the clinical trial.

NCT# REPORTING ON CLAIM

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<thead>
<tr>
<th>Claim Type</th>
<th>Code Claim Form</th>
<th>Electronic Claim</th>
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### Device Claims

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<th>Claim Type</th>
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<td>Technical UV/OE (CMS1500)</td>
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### Drug Claims

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### 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
- **Z00.6**: Encounter for examination for normal comparison and control in clinical research program
- **Mandatory**: 8-digit clinical trial number
The billing provider must include the following information in the individual patient’s medical record:

- Trial name
- Sponsor, and
- Sponsor-assigned protocol number

AMA defines “Medical Necessity” as:

“Health care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing, or treating an illness, injury, disease or its symptoms in a manner that is in accordance with medical practice, clinical appropriate in terms of type, frequency, site, and duration, and not primarily for the convenience of the patient, physician, or other health care provider.

(AMA House of Delegates, 12/9/98)
Medical Necessity

Health care services or supplies needed to prevent, diagnose or treat an illness, injury, condition, disease or its symptoms and that meet accepted standards of medicine.

- Plans may use national guidelines such as InterQual© or MCG or internally developed regional guidelines to determine medical necessity
- Guidelines must be reviewed annually

Medical Necessity

- All payors considering the use of evidence-based medicine to determine medical necessity
- Another definition:
  - The conscientious, explicit and judicious use of current best evidence in making decisions about the care of an individual patient.
- Clinical trial data and analysis contributes to the understanding of disease processes and responses to treatments.

Medicare’s Definition

To be reasonable and necessary, a service must be safe and effective, not experimental or investigational; appropriate, including frequency and duration, and in accordance with accepted standards of practice; must meet but not exceed the patient’s need; and be at least beneficial as other existing and available alternatives.

(Program Integrity Manual Sec. 13.5.1)
Certificates of Insurance Coverage

- **Medical Necessity** - Health care services or supplies needed to prevent, diagnose or treat an illness, injury, condition, disease or its symptoms and that meet accepted standards of medicine.

Example

- The individual’s medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from health care professional’s office, hospital, nursing home, home health agencies, therapies, and test reports.
  - Additional documentation requirements include:
    - Trial name, trial sponsor, ClinicalTrials.gov identifier number and sponsor-assigned protocol number
    - The specific routine items and services provided to the individual (Time and Event or approved study budget)
    - Copy of the signed and dated study-specific Informed Consent Form
    - The specific FDA-approved prescription pharmaceutical(s) or biologic(s) being used in combination with a clinical trial that are and are not supplied by the clinical trial sponsor

Commercial Payer Requirements

Example

- The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the service.
Pre-Authorization

A decision by health plans that requested health care services are medically necessary
- Sometimes called prior authorization, prior approval or precertification
- Review includes benefit coverage, medical necessity, Experimental / Investigational, appropriate place and level of care
- A request for services sent to payer utilization management department prior to services rendered
- Health plans require preauthorization for certain services before they are received, except in an emergency
- Service request reviewed and decision rendered usually within 14 days for non emergent requests; can request expedited reviews

Genetic & Molecular Diagnostic Testing Medical Management Policy

Example: XXXXX considers genetic testing medically necessary to establish a molecular diagnosis of an inheritable disease when all of the following are met:
- The member displays clinical features, or is at direct risk of inheriting the mutation in question (pre-symptomatic); and
- The result of the test will directly impact the treatment being delivered to the member; and
- After history, physical examination, pedigree analysis, genetic counseling, and completion of conventional diagnostic studies, a definitive diagnosis remains uncertain, and one of the following diagnoses is suspected (this list is not all-inclusive): XXXXX

- Requires Prior authorization

Example - Payer Clinical Trial Coverage Policy

"Consistent with Centers for Medicare & Medicaid Services (CMS) policy and Patient Protection and Affordable Care Act (PPACA) requirements, XXXXX covers medically necessary routine patient care costs in clinical trials (in the same way that it reimburses routine care for members not in clinical trials) according to the limitations outlined below. All of the following limitations apply to such coverage:
- All applicable plan limitations for coverage of out-of-network care will apply to routine patient care costs in clinical trials; and
- All utilization management rules and coverage policies that apply to routine care for members not in clinical trials will also apply to routine patient care for members in clinical trials; and
- Members must meet all applicable plan requirements for precertification, registration, and referrals; and
- To qualify, a clinical trial must have a written protocol that describes a scientifically sound study and have been approved by all relevant Institutional review boards (IRBs) before participants are enrolled. Providers will not routinely be required to submit documentation about the trial to XXXXX, but XXXXX can, at any time, request such documentation to confirm that the clinical trial meets current standards for scientific merit and has the relevant IRB approvals."
Common Mistakes from Billing Audits and Reviews

- Study protocol
- IRB-approved Informed Consent Form
- Final Contract and Budget
- FDA Status of Investigational Item (IND or IDE)
- Coverage Analysis

Validating Medical Necessity Documentation for Coding

- For each study selected:
  - Study protocol
  - IRB-approved Informed Consent Form
  - Final Contract and Budget
  - FDA Status of Investigational Item (IND or IDE)
  - Coverage Analysis

- Verify that the patient received the services per the clinical trial and SOE
- Use Coverage Analysis as your translation tool into the billing and coding
  - Verify that the charges for each item or service associated with conventional care were actually documented as medically necessary
  - Anything not documented correctly cannot be coded so it will not be reimbursed

Review the Coverage Analysis Against the Schedule of Events
Coverage Analysis

- **Coverage Analysis Must**
  - Be done correctly with a clinical assessment in mind
  - Record the intent to bill from the start
  - Document the QCT analysis
  - Cite sources
  - CPT codes (best practice)

- **Validate with Credible Sources**
  - National Guideline Clearinghouse – AHRQ / NIH
  - National Comprehensive Cancer Network
  - American College of Cardiology (and others)
  - JAMA, NEJM, etc.
  - Attestation of PI but only in rare instances if no guidelines can be found

What Else Is Important?

- Verify items charged correctly when both facility charges and professional charges are involved
- Verify what the patient was told when they signed their informed consent
- Be aware of variable billing issues in screening such as “outside of window” or “repeated tests just for eligibility

Documentation Check

- Consent language
- Consent example:
  - The costs of doctors’ fees for clinical evaluations, procedures, and tests required to be done for research purposes will be paid by the Sponsor. The administration of the supplied study drug will be billed to your insurance as usual care.
Medical Record Check

- Must have medical necessity for proper coding if billing is to occur per coverage analysis
- Consent told the patient the infusion of the study drug would be billed to insurance
- Physician note in medical documentation states the following: “Patient in clinic to have research infusion per protocol. Patient is on study XYZ, day 45 and received study drug per IV infusion over 3 hours.”

Consistency Check and Coding

- Deemed and qualifying study
- Infusion of the study drug is considered a routine cost
- Physician needs to document that the infusion is conventional care
- Infusion—administration of intravenous fluids and/or drugs over a period of time for diagnostic or therapeutic purposes

Case Study

CT Scans
Orders and Medical Necessity

- Brief Clinical History pertinent for chronic pulmonary nodule
- Chest CT Scan Order
  - RESEARCH – STUDY 123XYZ

Study 123XYZ Routine Care or Research?

Routine Care for Diverticulitis?

- Brief Clinical History Diffuse abdominal pain for 5 days with questionable for Diverticulitis with abscess
- Abdomen CT Scan Order
  - DIVERTICULITIS

Medical Necessity from Documentation?

- Progress Note from Office Visit: Pt is a 65 year old female here today for research study visit.
- Assessment: She is doing well and responding well to the study product. Review of study diary and patient questionnaires.
- Plan: Continue with study related visits per protocol.

Other Issues

- Not a covered benefit
- Lack of pre-authorization
- Government codes on commercial payer claims
- Lack of NCTE when there is a Z00.6 and a condition code 3D
- Ordered test with certain ICD-9 / ICD-10 codes and there is an LCD that prohibits payment
- Z00.6 not in secondary position so it is removed from the claim by coders
- Documentation by physicians inadequate

Denials

Causes
The Clinical Trial Billing Compliance Cycle

**Patient On Study Review**

- "Back End" Cycle
- "Middle" Cycle
- "Front End" Cycle

- Review protocol for feasibility
- Do a Qualifying Clinical Trial status
- Perform Coverage Analysis with validation
- Review draft budget, contract and consent
- National Guidelines for disease
- NCD's and LCD's review
- Review draft budget against CA
- Provide consent language based on CA
- Ensure Coverage Analysis guides other documents especially the consent language in the expected costs section
- Budget negotiation detailed to coverage analysis level
- Contract language matches financial piece and consent
- Consistency checklist confirming all pieces match in language prior final IRB approval
- Document review ends with final IRB approval and study start up

- Patient signs consent understanding financial implications
- Patient Flagged in billing systems
- Identification of Study Specific Visit
- Charge review against Coverage Analysis and medical documentation
- Coding rules applied
- NCT# applied
- Medicare Advantage review for drug clinical trials

**Contract Negotiation & Execution**

- Protocol Entry
- Review draft consent
- Consent Form Finalization
- Budget Negotiation
- Consistency Check
- Start Up
- Patient Signs Consent
- Pt Flagged
- Pt Identified Each Visit
- Charge Review & Split

- Review draft budget
- Review contract
- Coding with Claim Released

- Collaborate with nursing, clinical, and HIM staff to verify, validate, and code based on medical documentation
- Make certain to avoid reimbursement penalties by maintaining detailed medical records, ensuring accurate modifier and diagnosis code assignment and tracking of all medical care provided to the trial patient