Research Billing Audits: It's (almost) all in the planning?

Kelly Willenberg, DBA, RN, CHRC, CHC, CCRP
Kelly Willenberg & Associates

Wendy S. Portier, MSN, RN, CHC, CHRC, CCM
Kelly Willenberg & Associates

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Disclaimer

- No legal advice is provided.
- Please seek legal representation to have your questions clarified or discussed.
- The information, thoughts and opinions provided here are not legal advice: consult your institution's legal, compliance and other appropriate leaders and, at their discretion, your local Medicare Administrative Contractor (MAC), for any specific billing questions or issues

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Objectives

- Understand how to **plan and prepare** to perform a research billing audit including **document concordance** review processes
- **Review claims** against the coverage analysis and the billing rules including Medicare Advantage
- Identify useful **data to capture** during a research billing audit for analysis, calculating error rates, overpayments, and underpayments

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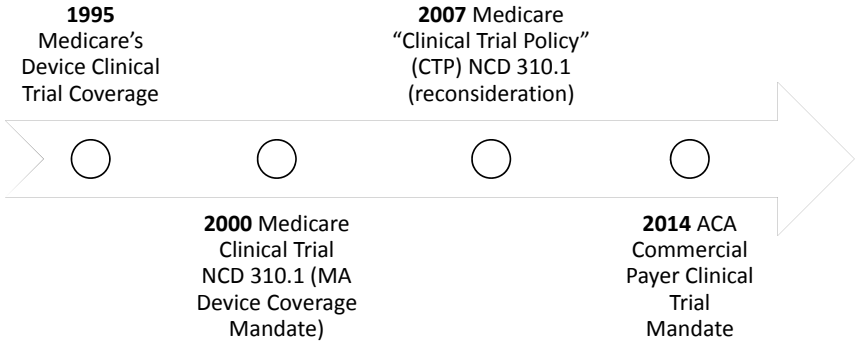
Clinical Trial Coverage & Billing Compliance Primary Rules*



State Laws – Clinical trial coverage laws or cooperative agreements
Medicaid – Coverage depends on state Medicaid programs
Medicare – Claims processing rules
False Claims Act - Protects federal taxpayers from overpayment for services provided
****Other laws, regulations, rules also are relevant but are largely captured by 310.1 and claims requirements***

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Foundation of Clinical Trial Coverage

- **Medicare – "Clinical Trial Policy"** National Coverage Determination 310.1
  - Medicare may cover the routine costs of qualifying clinical trials, if the routine costs are:
    - NOT paid for by the sponsor
    - NOT promised free in the **informed consent form**
    - Covered by Medicare
  - Routine costs:
    - Conventional care
    - Detection, prevention, & treatment of complications
    - Administration of investigational item
  - **All other Medicare rules apply!**

Industry Standard: Coverage determined through a Coverage Analysis (CA)!

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EXAMPLE: Coverage Analysis Billing Grid

Protocol related tests and procedures	Range of CPT/ HCPCS Codes	Pre-Procedure	Procedure	Post Procedure	1 Month	Unscheduled Repeat Angio/Revascularization	
Test and Services							
Physical Exam (E&M)	99201-99205; 99211-99215; 99218-99226; G0463	Q1		Q1	Q1	M	IDE Guidelines allow for the coverage of routine cost of conventional care. E&M visit at workup appears reasonable and necessary, prior to angioplasty procedure to establish patient's health/condition. The ACC/AHA guidelines recommend periodic follow-up after surgery for claudication. Follow-up consists of "periodic clinical evaluations" that should note any return or progression of symptoms of claudication Circulation. 2006;113(11):e463. If repeat Angio or revascularization is necessary, it is assumed it would be clinically indicated. Medical records must document medical necessity.
Duplex Ultrasound	93925-93926			S			DUS may be captured anytime 0-6 weeks post procedure. Per Exhibit B of the Executed CTA, sponsor to pay
Resting ABI	93922-93923	Q1		Q1	Q1	M	IDE Guidelines allow for the coverage of routine cost of conventional care. ABI at workup appears reasonable and necessary prior to angioplasty procedure for measurement of the severity of disease. The ACC/AHA guidelines recommend periodic follow-up after surgery for claudication. Follow-up consists of periodic clinical evaluations that should include measurement of the ankle-brachial pressure index (ABI). Circulation. 2006;113(11):e463. If repeat Angio or revascularization is necessary, it is assumed it would be clinically indicated. Medical records to document medical necessity.
Balloon Angioplasty	37220-37235; 75962, C1725, C1769, 75964, 36247, 35470, 35476; 36248,		Q1			M	Repeat angioplasty or bypass surgery can be used to treat in-stent restenosis and is recommend by the ACC per Circulation.2002; 105: 2586-2587 . MAC approval required for the study including the angioplasty. Prior authorization would be required for non-Medicare patients. Medical records must document medical necessity.

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Clinical Trial Billing Compliance - Synchronous Work Flow is Key

- Vetting & Feasibility Analysis
- Coverage Analysis & Billing Plan
- Budgeting, Pricing & Contracting
- IRB Approval
- Enrollment & Informed Consent
- Identification, Registration, Scheduling & Tracking
- Authorization & Documentation for Medical Necessity
- Charge Capture
- Charge Segregation
- Claims Submission
- Denials Management
- Amendments

Compliant Billing

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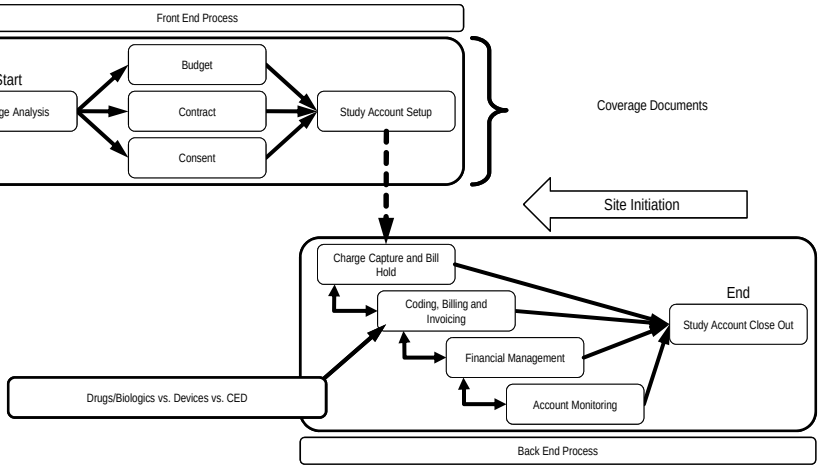
Clinical Trial Revenue Continuum



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What Does It Take to Get Clinical Trial Billing Compliance Right?

- A broad understanding of many fragmented, disconnected processes and systems
- An appreciate of many events that take place before and after billing
- Correctly debiting a study account and billing a third party (insurance, patient, etc.)
- Four main reasons for incorrect billing:
  1. Technological error
  2. Human error
  3. Training
  4. Awareness

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Areas to watch in research billing and finance

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- Inadequate financial accounting
- **Research subjects not identified**
- **Document non-concordance**: Protocol, Coverage Analysis, Budget, Contract, ICF
- **Charge capture**/billing for research related services and routine costs, study drugs and devices
- No monitoring of billing inquiries
- Poor budget process, lack of proper accounting and invoicing to Sponsors
- Claims lack proper **research coding**: dx, modifiers, CCs, and NCT # on claim
- **Charge segregation** occurring between research and payer or Medicare and Medicare Advantage
- Communication on **denials management** not thorough or lack of attention to detail

September 30, 2013

Emory Settles FCA Case, Cites Challenges of Billing for Trials

Simmering tensions over the sharing of revenues from clinical trials set in motion a series of events that ultimately led to Emory University's recent $1.5 million False Claims Act settlement. That's the picture painted by an unsealed whistleblower complaint filed in December 2009 by a former Emory employee.

Accused of improperly billing Medicare, Medicaid and TRICARE for services that should have been reimbursed by the sponsors of cancer and other studies, Emory acknowledged only that "billing errors occurred."

Whistleblower Elizabeth Elliott worked for Emory for a relatively short time; she was a clinical research finance manager at Emory's Office of Clinical Research

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Research billing audit goals

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Although there are many nuances, and scope depends upon specific institutional goals, in a nutshell:

- Identify system or human **error in research billing**
- Make **repayments** if overpayments are found, following required timelines
- Identify **underpayments** and invoice/bill as possible
- **Correct** process errors or gaps
- **Educate** users as applicable
- Conduct **follow-up review** to assure sufficient remediation
- Document **quality assurance** diligence

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Clinical Trial Billing & Coverage Risks

- Billing for services paid for by the **sponsor**
- Billing for services promised **free in the informed consent form**
- **Identifying subjects** enrolled in the study and reviewing claims
- Keeping up with **amendments**
- **Denial of coverage** and lost revenue

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Auditing Approaches and Processes Including Claims and Denials Review

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Before Audit can be Planned, Identify Standards

- Audits are designed to track and evaluate **existing processes** and their results
- In order to identify **audit scope**, need to have evaluated the potential failure of existing process(es) to provide intended results: **risk assessment** of entire process
- In order to evaluate existing processes, need to compare to **minimum necessary to achieve compliance** assurance: regulations, other external requirements, and organizational policies

What does clinical research billing compliance assurance require?

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Types of Clinical Trial Billing Audits

- Process / Internal Control
- Study Level
  - Document Concordance
  - Coverage Analysis Validation
  - Invoicing
- Subject Level
  - Claims
  - Denials
  - Invoicing

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Audit scope: preliminaries

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Stakeholders and auditors, internal and external

- Depends upon the **content scope**
- **Skill set** to be parallel to content: e.g., denials review requires person with denials experience
- Do **internal audit or compliance departments** have authority?
- Is Office of General Counsel to be consulted?
- Decision to go external may be related to risk assessment results

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Audit scope: preliminaries, 1

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Time span

- Are you auditing a **process improvement**?
- Do you want to see **before and after** or just after?
- Are you performing it **for cause** and need a specific time point?

Sample size

- Determining **significant sample**
- Unless reviewing a process only, number of **studies**?
- If conducting billing review, number of **patients**, number of **claims**?

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Audit scope: preliminaries, 2

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Interviewees, assistants and notifications

- Depends upon the content scope
- Will involve those according to assigned operational tasks
- **Leadership channels** to be considered

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Audit Scope: One or All of the Following

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Audit scope: one or all of the following, 1

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Coverage analysis

- Is the **coverage analysis concordant** with study documents? (protocol, ICF, budget, contract, coverage analysis)
- Does the study **qualify** for billing?
- Do the justifications support billing the subject's insurance?
- Were all costs included?

Document concordance

- Are all study **documents concordant**? (protocol, ICF, budget, contract, coverage analysis)
- Do study documents contain **clear language**?

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Audit scope: one or all of the following, 2

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Subject identification

- Are the **subjects identified** "flagged" in the systems?
- Was the "flag" applied timely?

Claims review

- Did the claim go to the **appropriate payer**? (Medicare, Medicare Advantage, Sponsor, Commercial Insurance, etc.)
- Does the claim contain **correct coding**? (Z00.6, Q1, Q0, CC30, IDE#, Rev Code 256/624, NCT#, etc.)
- Does the medical record **documentation support medical necessity**?

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Audit scope: one or all of the following, 3

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Payer selection

- Audit **Medicare/Medicaid** only or include **commercial** payers?
- If commercials payers to be included, do you want
  - A different **sample size**?
  - A **subset** of them?

Invoicing

- Did invoicing occur?
- Was invoicing **timely**?
- Was the **proper amount billed**?
- Was **overhead** included?

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Audit scope: one or all of the following, 4

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Denials

- Are research related **denials identified**?
- **What causes** research related denials?
- **Who manages** research denials?

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Areas to Understand Prior to Audit Testing

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- Operations
  - Charge Segregation
  - Registration
  - Charge Capture
  - Billing
- Financial Management
  - Budgeting, Pricing, Contracting
  - Accounts Receivable
  - Professional Fees
- Compliance Management
  - Investigations & Monitoring
  - Training
- Personnel
  - Roles & Responsibilities
  - Communication

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What areas at your organizations do you understand fully?

Summary: how to audit a clinical trial, 1

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- Take the **standard steps**:
  - Risk assessment
  - **Objectives**: what are we trying to achieve?
  - **Scope**: what and who are to be included in the audit?
  - **Approval(s)** required: Identify necessary authorities, advisors, stakeholders
- Create an **audit plan**
  - What is the objective of each step?
  - Does the step tie to the overall audit objective?

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Summary: how to audit a clinical trial, 2

- Conduct **sample selection**
- Request and **review documents**
  - Study Level – protocol / study documents, ICF, CTA, budget, CA, IND/IDE
  - Patient Level – UBs/1500s, EOBs, study accounts, subject calendars, EMR
- Perform **interviews and testing**
  - Documentation
  - Work papers
  - Data collection
- Write a report

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Document Concordance Auditing

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Term alert: document concordance

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We use "document concordance" to refer to a key and complex* practical *requirement in research billing: the consistency and accuracy of all study-initiation and continuation documents relevant to billing for protocol-specified clinical services

Without concordance,

accurate billing is impossible

(– or accidental)

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Example: document concordance and content review

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Compare **key documents**

- Contract
- Budgets (Internal and External)
- Informed Consent Form (ICF)
- Coverage Analysis
- Protocol

Are there any **discrepancies** between the documents?

Were there any discrepancies on the Coverage Analysis?

Did the budget contain **invoiceable items**?

Were there any additional **regulatory issues** identified?

- Did the contract or ICF contain language the violate the Medicare Secondary Payer Rule?
- Did the ICF contract Medicare Advantage language for drug trials?

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Sample checklist

IRB #: 12-00000 **PI Name: MD**
Study Name: XYZ Study **Consistency Checklist Date:**

Issue	Agreement / Budget Date	ICF Version/Date:	Protocol	Reviewer
A. Confidentiality Describe how data or information will be shared between INSTITUTION, or sites and the research sponsor.	N/A	YES	YES	XXX
B. Benefits of Taking Part in the Study Describe benefits of participating for the subject and/or others in the context of therapeutic intent.				XXX
C. Research vs. Conventional Care The procedures that will be performed during the course of the trial that are considered to be part of the subjects' conventional care and that would be performed anyway notwithstanding the research study are differentiated from the procedures that will be performed during the course of the study that are for research purposes only.	N/A	YES	N/A	XXX
D. Additional Costs Subjects will be required to bear additional costs beyond those associated with their conventional care as a result of participating in the study.	N/A	N/A	N/A	XXX
E. Subject Compensation Subjects will be compensated for agreeing to participate in the trial.	N/A	N/A	N/A	XXX
F. Research Related Injury Identify the individual or entity responsible for the costs of any research-related injuries to subjects.	N/A	N/A	N/A	XXX
G. Future Use Of Data Are subjects asked or expected to donate data, materials, samples etc. to databases or tissue repositories and if the sponsor receive any future rights to the data or materials collected in the course of the study?	N/A	YES	YES	XXX
H. Study is registered at clinicaltrials.gov and statement is in the ICF (Input Registration Number)				XXX
I. Medicare Advantage statement included in the ICF				XXX

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Insurance Claims Review & Exercises

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Billing grid/sponsor budget review
Exercise
What's missing/incorrect?

S = Sponsor Paid
M = Medicare/ 3rd Party Payer

Blue = billing grid; orange = sponsor budget

Procedure/Event	CPT/HCPCS Codes	Billing Designation
CT Scan Abd/Pelvis w/ Contrast incl RECIST	74177, Q9967	S
CMP	80053	S
Chemo Admin	96413	M
Chemo Study Drug	J9999	S
Procedure/Event	**CPT/HCPCS Codes**	**Amount Paid**
CT Scan Abd/Pelvis w/ Contrast	74177	$3000.00
Port Draw	36591	$50.00
CMP	80053	$30.00
Chemo Admin	96413	Routine

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Billing grid/claim
Exercise
What's missing/incorrect?

S = Sponsor Paid
M = Medicare/ 3rd Party Payer

Blue = billing grid; orange = payer claim

Procedure/Event	CPT/HCPCS Codes	Billing Designation
CT Scan Abd/Pelvis w/ Contrast incl RECIST	74177	S
CMP	80053	S
Chemo Admin	96413	M
Chemo Study Drug	J9999	S
Charge Description	**CPT/HCPCS Code**	**Charge Amount**
CT Scan Abd/Pelvis w/ Contrast	74177	$5000.00
CT Contrast	Q9967	$150.00
Port Draw	36591	$200.00
CMP	80053	$100.00
Chemo Admin	96413	$500.00

What if Medicare Advantage was the payer?

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Data Collection & Error Rates

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Data collection during a claims review audit

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General

- Subject identifier
- Payer Type – Primary, Secondary and Tertiary
- Visit #, DOS

Claim Information

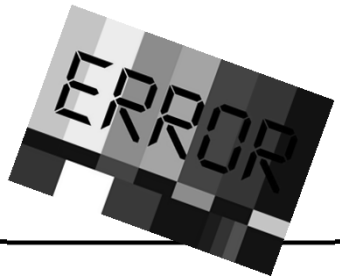
- Claim type
- Encounter Number
- Claim Number
- Item / Service Description
- CPT/HCPCS Codes
- Coding: NCT#, Modifiers, Dx code, IDE#, CC 30 , CC53

Documentation requirements

Amount billed and amount paid

Overpayments / Underpayments

- Calculate overpayments
- Calculate underpayments
- Calculate error rates



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CMS Error Rate Data – A/B MACs

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Improper Payment Rate Scores/Rankings:

- **1 0.0% - 3.9% (Oh Yeah!)**
- **2 4.0% - 7.9% (Getting Better)**
- **3 8.0% - 11.9% (Tighten Up)**
- **4 12.0% - 15.9% (Processes?)**
- **5 16.0% and above (Uh-OH!)**

Focused monitoring and corrective actions help organizations get to an acceptable ranking

Source:

- https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/MedicareFFSJurisdictionErrorRateContributionData.html

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Error Rate Calculations - Examples

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Payment Error Rate

- Total dollars paid in error / total dollars paid
  - EX: $195,000 / $500,000 = **39% payment error rate**

Claim Error Rate

- Total # of claims billed to the incorrect payer / Total # of claims reviewed
  - EX: 90 / 500 = **18% claim error rate**

Line Item Error Rate

- Total # of line items billed to incorrect payer / Total # of line items reviewed
  - EX: 975 / 5000 = **20% line item error rate**

Coding Error Rate

- Total # of claims billed to correct payer, incorrect coding / Total # of claims reviewed. Coding errors count as 1 error per claim.
  - EX: 200 / 500 = **40% coding error rate**

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Common findings

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Auditing clinical trial billing and finance: common findings, 1

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- Non-employed physician group **not notified of clinical trial / subject**
- **Under** budgeting
- **Lack of fund** accounting
- **Excessive residual** balances and no residual funds policy
- **Claims submission errors**
  - Misdirection of charges – **double billing**
  - **Denials**
    - For example: pre-authorization, investigational article
  - **Coding errors** and mismatches
    - IDE, NCT numbers on claim no CC or Q-modifiers
    - IV administration with no study drug on claim
  - **No follow-up** on denials; write-offs

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Auditing clinical trial billing and finance: common findings, 2

- **Charges not posted** in billing systems
- Billing of professional (pro) and technical (tech) **charges not coordinated**. For example, pro charge is billed:
  - to insurance and tech charge is billed to sponsor/research
  - to Medicare and tech charge is billing to Medicare Advantage
  - with clinical trial coding but the tech charge lacks coding
- **"Off the books"** research activities
- **Patient reimbursements** held or not paid

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Contact Us

Wendy Portier, MSN, RN, CHRC, CHC, CCM
Consultant
Kelly Willenberg and Associates, LLC
wendy@kellywillenberg.com
504-782-1328

Kelly Willenberg, DBA, MBA, BSN, CHRC, CHC, CCRP
Owner, Kelly Willenberg and Associates, LLC

P 864.473.7209

kelly@kellywillenberg.com

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Appendices

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Summary: Medicare requirements – drug trials

Claim Type	Coding Requirements	Location on Claim

Technical UB-04 (CMS1450)	- Z00.6 – Secondary Diagnosis
	- Modifier Q0 & Q1 as needed (Outpatient Only)
	  - Q0 – Investigational Clinical Service (Drug)
	  - Q1 – Routine Costs
	- Condition Code 30 "Qualifying Clinical Trial"
	- Rev Code 256 – Drug Trial
	- NCT # (www.clinicaltrials.gov)
		- Field 66
		- Field 44
		
		- Field 18 - 28
		- Field 42
		- Field 39; D4 & Value Code = 8 digit NCT#

Professional CMS1500	- Z00.6 – Secondary Diagnosis
	- Modifier Q0 & Q1 as needed
	  - Q0 – Investigational Clinical Service
	  - Q1 – Routine Costs
	- NCT # (www.clinicaltrials.gov)
		- Field 21
		- Field 24.D – Modifier
		
		- Field 19 (Use CT pre-fix on paper claim only)

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Summary: Medicare requirements – device trials

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Claim Type	Coding Requirements	Location on Claim

Technical UB-04 (CMS1450)	- Z00.6 – Secondary Diagnosis
	- Modifier Q0 & Q1 (Outpatient Only)
	  - Q0 – Investigational Clinical Service (Procedure)
	  - Q1 – Routine Costs
	- Condition Code 30 "Qualifying Clinical Trial"
	- Condition Code 53 – Free Devices (Outpatient only)
	- NCT # (www.clinicaltrials.gov)
	- Value Code FD (Free Device as part of a trial, Outpatient Only)
	- Rev Code 0624 – Device Trial
	  - Device charge – list as non-covered (token) charge if device is provided at no cost
	- Rev Code 278 – Medical/Surgical Supplies: Other Implants
	- IDE Number
	- Category B IDE device HCPCS code, as applicable
	- Generally, Category A not reported on institutional claim. Follow Medicare's specific instructions for the trial
		- Field 66
		- Field 44
		
		- Field 18 - 28
		- Field 18 - 28
		- Field 39; D4 & Value Code = 8 digit NCT#
		- Field 39; Credit amount for device
		- Field 42
		- Field 47 & 48
		
		- Field 42
		- Field 43
		- Field 44

Professional CMS1500	- Z00.6 – Secondary Diagnosis
	- Modifier Q0 & Q1 as needed
	  - Q0 – Investigational Clinical Service (Procedure)
	  - Q1 – Routine Costs
	- NCT # (www.clinicaltrials.gov)
	
	- IDE Number
		- Field 21
		- Field 24.D – Modifier
		
		- Field 19; Use CT pre-fix on paper claim only
		- Field 23

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Medicare Q&A 2014

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Mandatory Reporting of NCT# Identifier on Medicare Claims*

Medicare coverage of clinical trials, prospective studies, and registries			
	CTP	IDE	CED
CMS approval required	No – must qualify under NCD 310.1	Yes –each specific study approved by FDA before 1/1/2015, requires MAC approval; for each specific study approved by FDA after 1/1/2015, requires CMS approval	Yes – requires CMS approval for each specific study
Public notification	No – provider determines qualification	Each specific study approved by FDA after 1/1/2015 appears on CMS IDE Website	Each specific study approved by CMS appears on CMS IDE Website
Routine services (Q1)	Covered if otherwise coverable by Medicare in qualified study	Covered if study is approved by CMS and otherwise coverable by Medicare	Covered if study is approved by CMS and otherwise coverable by Medicare
Investigational item/ service (Q0)	Covered if otherwise coverable by Medicare in qualified study	Covered if study is Category B, and approved by CMS	Covered if study is approved by CMS

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*https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Downloads/Mandatory-Clinical-Trial-Identifier-Number-QsAs.pdf