Clinical Trial Billing: A Tour through the Rules (and how to get your systems to do it for you!)

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Objectives

- Understand how to apply the CMS clinical trial billing rules
- Conduct a mock review of hospital and professional claims using a coverage analysis
- Using systems to help streamline processes

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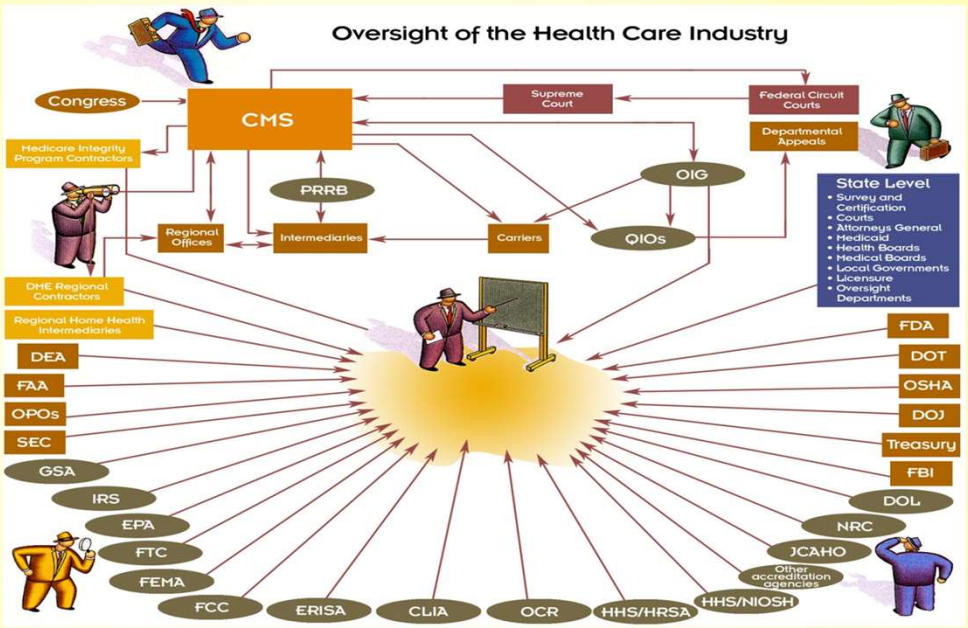

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What is Research Billing Compliance?

- Awareness and accuracy from the intake of a study, regardless of study sponsor, throughout the revenue cycle, including human subject protection, reimbursement by payer, sponsor invoicing (if applicable), payment process, claims adjudication, study funds allocation and account reconciliation.

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Primary Goals For Clinical Trial Billing

- Clinical research studies must meet federal billing compliance requirements:
  - **No double billing**
  - Documentation supporting **coding** – no more and no less
  - Research **modifiers**, diagnosis codes, **condition codes** and clinical trial number when study is **qualifying**
  - Transparent and consistent **documentation** for compliance assurance

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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

Compliant Billing

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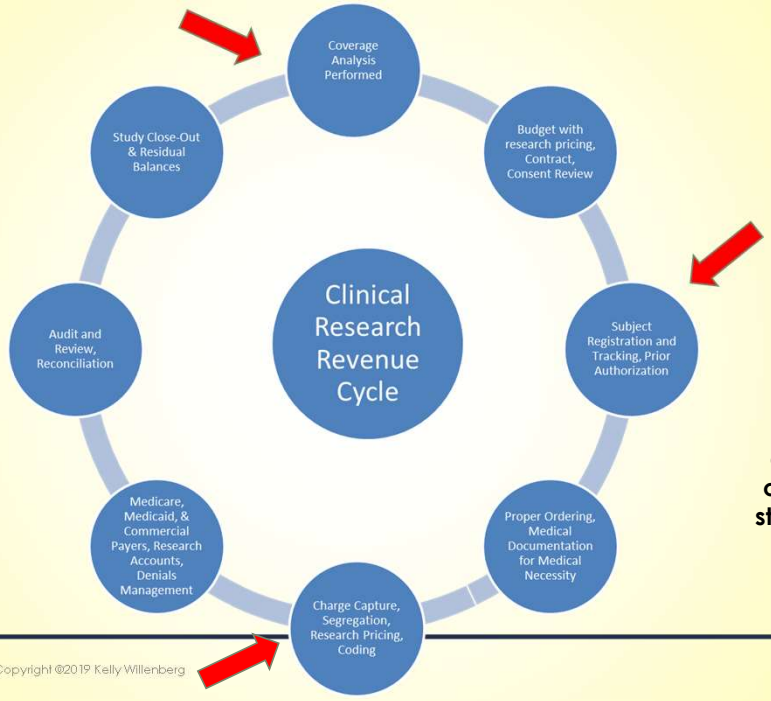

What about amendments or other changes to study documents?

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The Village

- Principal Investigator
- Clinical Research Coordinator
- IRB process
- Budget negotiators
- Clinical Trial Agreement negotiators
- Project Accounting/Grant administration
- Health Information Management/IT
- Registration/Scheduling/Authorizations/Denials
- Medical center billing and coding
- Physician professional fee billing and coding
- Offsite facilities providing Clinical Trial services
- Managed care contract negotiators ….and others!

Communication is Key!!!

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Common Billing Errors

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Common Billing Errors, 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 – **potential for duplicate 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
  - **Lack of follow-up** on denials; write-offs

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Common Billing Errors, 2

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- **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 to patients

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Consequences of Non-Compliant Billing

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Consequences of Non-Compliant Billing

- Loss of community **trust and reputation**
- Enforcement **actions, fines and penalties**
- Potential loss of **participation in Medicare/Medicaid** for the entire Health System
- Potential loss of federal grant funding
- Corporate Integrity Agreements
- Staff time lost on correcting billing errors
- **Lost revenue** both on payer side and in research
- Residual balances

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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
- Coordination 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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A TOUR THROUGH CLINICAL TRIAL BILLING RULES

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Clinical Trial Coverage & Billing Compliance Primary Rules*

1995 Medicare's Device Clinical Trial Coverage

2000 Medicare Clinical Trial NCD 310.1 (MA Device Coverage Mandate)

2007 Medicare "Clinical Trial Policy" (CTP) NCD 310.1 (reconsideration)

2014 ACA Commercial Payer Clinical Trial Mandate

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 including coding!**

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

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What is a Coverage Analysis (CA)?

- **Systematic review** of research-related documents to **determine the Medicare billing status** of both the study itself and the items and services provided to the research subjects that are outlined in the research documents over the course of the study
- Review based on thorough research, supported by **industry guidelines** which meet the "generally accepted in the medical community" standard and are compliant with government regulations
- **Provides subjects** with an accurate accounting of their **financial liability** before they enroll
- Provides an accurate assessment of the true costs of the clinical trial with potential increased revenue
- **Protects your institution** from violations of the False Claims Act and other regulations by showing due diligence

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EXAMPLE: Coverage Analysis Billing Grid

This Medicare coverage analysis is intended as a general guideline for use in determining which items and services are billable to Medicare based upon current benefit policies, coverage determinations, coverage decisions, and federal guidelines. All items and services that are billable to Medicare must be supported by medical necessity.

Protocol Related Items and Services	CPT / HCPCS (Sample codes)	Screening (Visit 1)		Cycle 1		Cycle 2		Cycle 3		Cycle 4		Cycle 5 to Discontinue		EOT - Study Term. Visit 30 days (+/- 5 days).	Comments Please address the following in the Comments and Justifications: 1. Support for Coverage under NCD, IDE or standard Billing Rules; 2. Routine costs to be justified as
		(-42 to -29)	(-28 to -1)	Day 1	Day 8	Day 1	Day 8	Day 1	Day 8	Day 1	Day 8	Day 1	Day 8		
Procedures / Evaluation Management															
Physical Exam / Vitals / Facility Fee	99201-99205, 99211-99215, G0463		S	Q1		Q1	Q1	Q1		Q1	Q1	Q1		Q1	Screening: Paid by sponsor per sponsor CTA Treatment: * Examinations during each cycle of therapy and at EOT appear performed to monitor disease and response to therapy * Medical record must justify use 'Monitoring/Follow-up: * NCCN Ovarian Cancer Guidelines (v.2.2019) support visits every 2–4 mo. for 2 y, then 3–6 mo. for 3 y, then annually after 5 y * Medical record must justify use
ECG (triplicate)	93000-93010		S												* Invoiced to sponsor per sponsor CTA
Laboratory															
Serum/Urine Pregnancy Test	84703 / 81025		S	S											* Paid by sponsor per sponsor CTA
Prothrombin time	85610		S												* Paid by sponsor per sponsor CTA
Thromboplastin time, partial (PTT)	85730		S												* Paid by sponsor per sponsor CTA
CEA								S						S	* Paid by sponsor per sponsor CTA

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NCD 310.1: What is a Qualifying Clinical Trial?

Qualifying Clinical Trial Analysis			
Requirement	**Yes**	**No**	**Comment**
Does the investigational item or service fall into a Medicare benefit category? Note: The subject or purpose of the trial must be the evaluation of an item or service that falls within a benefit category and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).			
Does the study have therapeutic intent stated in the study objective(s) or aim(s) and is consistent with Institutional policy?			
Does the study enroll patients with diagnosed diseases?			
Is the study a deemed trial? (Study funded by NIH, CDC, AHRQ, CMS, DOD, or the VA or supported by cooperative groups funded by NIH, CDC, AHRQ, CMS, DOD, or the VA or Provided under BLA / BB IND / IND # or IND Exempt as verified by the FDA or IRB)			
Is the study a qualifying clinical trial? **(All questions must be answered "Yes" to qualify)**			

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NCD 310.1: What are Routine Costs?

- "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**."

Must determine what are research only costs versus routine care costs!

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Research Billing Compliance Assurance

Although there are many nuances, in a nutshell:

- **Do not bill patient/insurance** for services that are:
  - Not medically necessary
  - Otherwise not allowable / non-covered services / statutorily excluded
  - Promised by the sponsor (contract) / budget
  - Provided solely to satisfy data collection
  - Promised by the consent form
- Apply the Medicare-specified **research modifications** as applicable
- Follow all other Medicare rules

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More Rules…..

- **All Medicare rules apply**
  - National Coverage Determinations (NCDs)
  - Local Coverage Determinations (LCDs)
    - Medicare Administrative Contractor (MAC) – First Coast
  - Special device coverage rules
- **Medicare Advantage Pla**ns cannot be billed as primary payer for qualifying drug trials
- Two federal statutes **prohibiting waivers of co-payments**
  - Beneficiary Inducement Statute 42 U.S.C. 1320a-7a
  - Medicare Anti-Kickback Statute, 42 U.S.C. 1320a-7b(b)
- Medicare coverage and **off-label use**
  - Off-Label use for non-cancer – MAC Determination
  - Off-label use for cancer – NCCN Drug Compendia

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Mock Review:
Coverage Analysis & Claims Review

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Document Concordance in Clinical Trial Billing Compliance

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Term Alert: Document Concordance

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)

Documents must be concordant.... all singing from the same page!

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Document Concordance and Content Review

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?
- Was there a **waiver of co-payments or deductibles** in any documents?

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Using Systems to Help Streamline Processes

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What Can Systems do to Help?

- Create logic/functionality with the Electronic Medical Record (EMR), Clinical Trial Management System (CTMS), etc. to streamline and automate research functionality
  - Update logic to reduce billing compliance risk
  - Roster Reports – EMR, CTMS, Spreadsheets
  - 100% Bill Hold
  - Flag only the study types that require review

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What Can Systems do to Help?

- Interface systems to minimize duplicate (triplicate…) entry and reduce errors
- Narrow a report down to a specific scope to review specific items/services

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What Can Systems do to Help?

- Hold claims for line item review
- Validate Claim Scrubber mirrors EMR – many time the scrubber strips of research coding
- Ensure data transfers to external vendors include research information
- Sync CTMS and EMR to work together

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Where can you start and YOUR organization?

- Ask:
  - How are clinical trial patients identified in the EMR & billing system?
  - Do we perform coverage analysis?
    - Dose the PI sign-off on coverage analysis?
    - Who uses the coverage analysis?
  - How are clinical research related denials worked?
  - Who performs clinical trial coding? How are research related claims coded?
  - Who makes sure the informed consent is consistent with the contract, budget, and research protocol?

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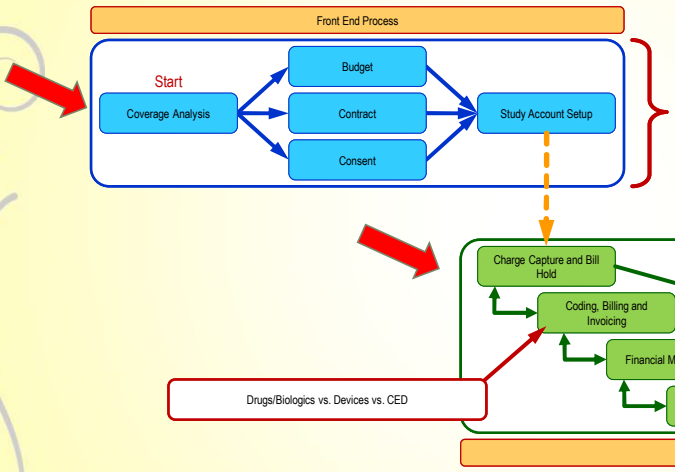
Clinical Trial Revenue Cycle & Main System Impact



Systems:

- CTMS
- EMR
- Billing / Coding
- Claims Scrubber

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Summary

- Training is Key!
- Research billing compliance is a complex topic
- Determine who the stakeholders are at your institution
- Communicate, Communicate, Communicate
- Remember this takes a Village

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Thank You!

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Contact us

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Clinical Trial Coding Requirements

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Summary: Medicare Requirements – Drug Trials

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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

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

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