Understanding Research Billing Compliance: Navigating the Basics and Beyond

A Three-Part Series - Webinar 1:
Research Billing Compliance & Coverage Analysis 101

Introductions

Nice to meet you, where you been?

Amanda Miller

Training Manger, WCG

Caroline Klemme

Senior Coverage Analyst, WCG

Polling Question:

What type of organization do you represent?

Today's Agenda – Are you ready for it?

1. Research Billing Compliance Rules
2. Research Billing Compliance and Coverage Analysis Process
3. Coverage Analysis in Use
4. Conclusion and Audience Questions
5. Bonus – Can you identify the theme of this presentation?

Where do we begin?

Have I known you for 20 seconds or 20 years?

Must know Medicare research billing rules:

1. NCD 310.1
2. Medicare Benefit Policy Manual Chapter 14 (IDE)
3. Coverage with Evidence Development

How Did We Get Here?

The Eras of Research Billing Compliance

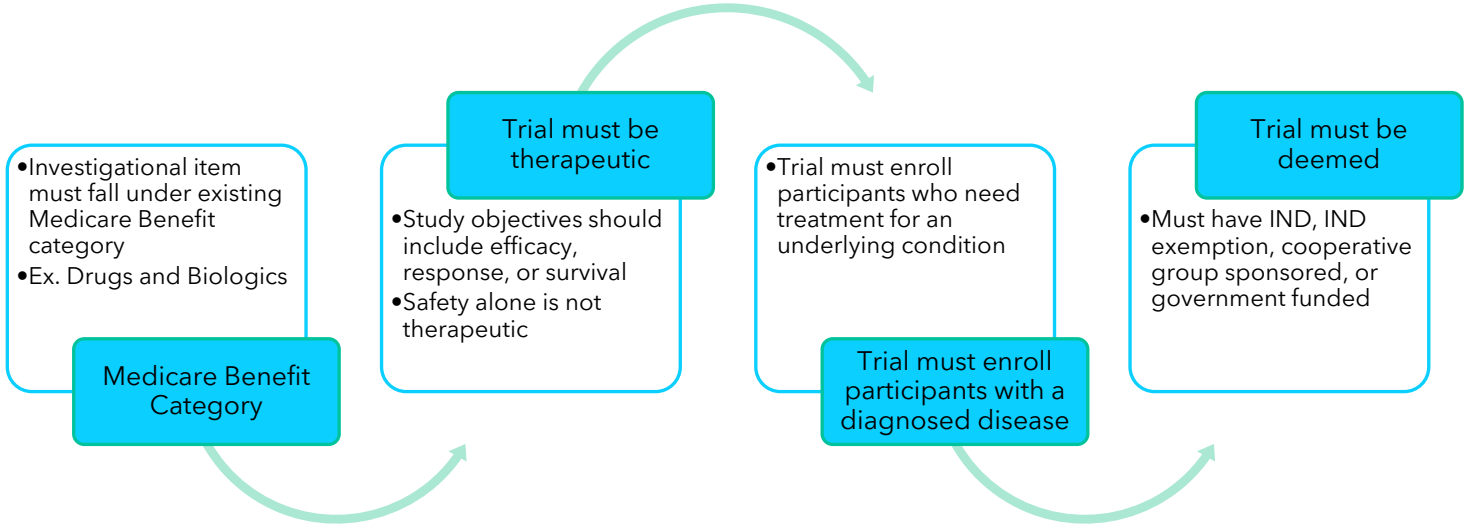
	Rules were released	IDE Devices – 1994 NCD 310.1 – 2000 with minor updates in 2007
	Sites didn't have a process in place to address these rules – sites were billing study participants and receiving payments from sponsors	
	Large settlements for Rush and Emory in the 2000s/2010s put research billing compliance on the radar	
	2010s - Enter the coverage analysis and research billing compliance era at sites	
	2020 – focus on technology and challenges with more complex trials	

Research Billing Compliance Key Rules

NCD 310.1 – My one condition is…

- **Applies to most trials that are not IDE studies**
- **Provides Medicare coverage for routine services in qualifying trials**

- Medicare requires the trial to **qualify** for coverage. The qualification process **is up to the research to determine**.
- In order to qualify the trial must meet all four conditions listed here:



Research Billing Compliance Key Rules

NCD 310.1 – We got bills to pay

If the trial qualifies, then Medicare will pay for the following items:

- Items that are considered **conventional care** for the medical condition
  - Participant would have the test performed regardless of clinical trial
  - National guidelines are used to determine this – ex. A physical exam is recommended prior to starting a new chemotherapy regimen and every 3 months following treatment

- Items **required for the provision of the investigational item or service**
  - Administration of study product – most commonly, IV administration
  - Can apply to items such as central lines or other services required to safely administer study product

- Items used to **prevent complications and monitor side effects** of the study therapy
  - Testing to monitor known side effects of the study regimen
  - Example: A CBC once per cycle for a new chemotherapy drug known to change white blood cell counts

Research Billing Compliance Key Rules

NCD 310.1 – You're on your own kid

NCD 310.1 includes items that are not covered by Medicare

- Items provided free of charge by the study sponsor – AKA **DOUBLE BILLING**

- Items used only for data collection and **not the direct management of the patient**
  - Example given by Medicare- they will not pay for follow-up scans when only a single diagnostic scan is required
  - Everything billed in a trial requires medical necessity and documentation the item falls under Medicare coverage rules (including NCD 310.1!)

- Items **not otherwise covered by Medicare**
  - If Medicare has existing non-coverage policy (ex: NCDs, LCDs, etc.), a qualifying trial doesn't lead to coverage

- **Investigational item**

Medicare Benefit Policy Manual Chapter 14

IDE Devices – I should not be left to my own devices…

Investigational (IDE) Devices Have Their Own Medicare Policy – Study Must Qualify for Coverage

Qualification Process

- **Document IDE Status**
  - Should have FDA letter stating Category A or B IDE device
- **CMS Approval (website and letter)**
  - Study sponsor submits study to CMS for review and approval
  - Posted on Approved IDE webpage and sponsor can provide a letter
  - Some regions may need to notify their local contractor in addition to national approval

Medicare Benefit Policy Manual Chapter 14

IDE Devices – They say the road gets hard and you get lost

Medicare coverage in IDE Trials

- **Medicare will cover items considered routine care**
  - Item is **"otherwise available" to Medicare beneficiaries**
  - Item is recommended by national guidelines, National Coverage Determinations (NCD), or Local Coverage Determinations (LCDs)

- **Device Coverage**
  - Category A IDE Device: Must be provided by the sponsor
  - Category B IDE Device: Can be billed to Medicare as a routine cost

Coverage with Evidence Development

Say you'll remember me

Clinical Trial Participation Requirement for Coverage

- Medicare provides coverage for newer/investigational therapies while collecting additional data for long term coverage decisions
- Trials will **need CMS approval for coverage** – may also fall under NCD 310.1 or IDE policies
- Common procedures in trials: TAVR, TEER, some stem cell transplants, Alzheimer's monoclonal antibodies

Medicare Claims Processing Manual Chapter 32

Next chapter

Full Instructions on How to Process Claims Under the Research Policies Discussed

- Research Q1 (routine cost) modifier and Q0 (investigational item) modifier requirements
- NCT Number Requirement
- Z00.6 ICD-10 code
- Field-by-field details for completing inpatient and outpatient claims
- Many sites automate the requirements from this chapter in their billing systems

Violations Most Commonly Fall Under:

Now we got problems and I don't know that we can solve 'em

False Claims Act

- Most research billing violations fall under the False Claims Act
- Impacts more than the research department at the site

Medicare Secondary Payer Rule

- By law, Medicare is the payer of last resort
- Any language in budgets, contracts, and consents indicating the sponsor will only pay after Medicare/insurance must be removed

How do you apply these rules?

It's our house and we make the rules

- Research sites need to have a billing compliance process in place to ensure compliance with the rules
- Process should cover activities from start-up through close-out – much more than the coverage analysis alone
- Compliance ultimately falls on the site, not the sponsor or CRO
- Touches many more departments than billing
- How do I tie this process together in a single document?

Real Life Billing Compliance

Enter the coverage analysis – It's me, hi!

- **Meet the coverage analysis:**
  - Developed early in start-up for every trial that involves billing insurance
    - Guideline for the study budget development, billing throughout the trial, and will service as both internal and external audit documentation
  - Documentation of items and services by visit
  - Billing determination (bill to Medicare, bill to study sponsor)
  - Important players:
    - Study budget
    - ICF, IB
    - Contract
    - Applicable Medicare research billing rules

Coverage Analysis Process

Development – The dominoes cascaded in a line

When and How is the Coverage Analysis Developed?

- **When?**
  - Once site is selected and has protocol, budget, contract, and usually ICF available (Draft versions are acceptable!)
  - Prior to budget negotiations!!!
- **Step 1- Qualification**
  - Determine which research policy the trial will fall under
  - Complete the qualification process
- **Step 2 – Build out the study grids**
  - List the study visits from the schedule of events
  - List each activity required by the protocol at the visits
  - Important to break out the items by CPT codes for next steps in the process

Coverage Analysis Process – Promises of Payment

I searched aurora borealis green

- **Once the study billing grids are built, document items that are promised free**
  - **Review the study budget**
    - Per patient budget, invoiceables, and payment terms
    - If the sponsor is offering $ for an item, should not bill insurance for that item
  - **Review the ICF**
    - Does the costs section promise specific items free of charge or all items free of charge?
    - Document any items promised in the ICF
  - **Review the contract and payment terms**
    - Should align with the study budget
    - May indicate the study product is promised free, must be purchased (IDE device), or may indicate the sponsor will provide the equipment for an activity (ex. ECG)

Coverage Analysis Process – Routine Care

Now, did you think it all through?

Once All Sponsor Paid Items are Documented, it's Time to Determine if the Remaining Items are Considered Routine Care

- **All trials – NCD 310.1, IDE, CED**
  - Find national guidelines and look for testing recommendations
  - If recommended by the guidelines at timing required by the protocol, then the items can be billed
- **All trials – NCD 310.1, IDE, CED**
  - Review National and Local Coverage Determinations for the protocol required items
  - Check the indications and limitations for coverage and cite where applicable
  - May lead to some differences by region
- **NCD 310.1 Trials**
  - Review study product risks from ICF, IB, and/or prescribing information
  - Look for study drug administrations

Do I need a coverage analysis for all studies?

I gotta have you

There is limited funding or no budget for the study

- Routine care determinations are part of billing compliance
- Must determine if items/services meet criteria for billing – rare for every item to meet routine care criteria

The study doesn't enroll the Medicare population

- Many private insurance companies follow Medicare, so it's a good idea to have a coverage analysis
- Should not bill participants for items paid for by the sponsor or not considered routine regardless of insurer

The study is data collection/chart review only

- Many sites create a quick coverage analysis to document no billable items
- Some sites may skip –especially chart review trials with waiver of consent

Most common approach:
If the trial includes a potentially billable item (aka item has billing codes), then a coverage analysis should be on file

You finish the CA –you're done, right?

Are we out of the woods?

- Rare to finish a CA without any clarifications required
  - Drug supply for non-SOC comparator drugs – are they invoiced? Are they provided?
  - Is this test central or local?
  - Does this line item in the budget apply to dispensing or the drug itself

- Additional context or clarification is provided by the sponsor that leads to an item changing to SOC

- Item needs to be invoiced instead of included in the per patient

- Sponsor is not really intending to pay for the items, so they need to be re-analyzed- more on this in part 2!

ICF AND CONTRACT – CA + COMPLIANCE LANGUAGE

Amanda, I know where it all went wrong

ICF and Contract Must Be Reviewed for Billing Compliance Concerns Early in Start-up!

What to flag:

- Any references to costs or items provided free that don't align or contradict other study documents
- All "if denied by insurance language" or reference to the sponsor paying *after* insurance – violates Medicare Secondary Payer language
- "If not SOC" language in the contract

At the end of study start-up:

- Any language around billing items and subject injury must align between the coverage analysis, ICF, and contract
- All language with secondary payer issues should be removed at this point

Before finalizing documents in start-up

I check it once, I check it twice

- Compare the **final negotiated budget** to the coverage analysis
  - All billing designations between documents must align
  - Check invoiceables
- Review **items that needed confirmation** when CA was first developed-do you have the answers?
  - CMS approval in IDE studies
  - Drug supply
  - Payment language and required budget edits
- Ensure **CTMS and EMR builds** align with the coverage analysis
- Check **consent and CTA** language around costs and subject injury one more time

Using the Coverage Analysis

Everything will be alright if you keep me next you

- **Billing**
  - All claims for research participants should be reviewed against the coverage analysis!
- **Invoicing**
  - Some items may be invoiced under certain circumstances – if the budget isn't clear, the CA needs to be referenced
- **Insurance and Cost Conversations with Participants**
  - CA must be referenced if participants ask specific questions about costs and insurance
- **Internal and External Audits**
  - Document is used for auditing – routine internal research billing audits should be part of your research program!

Using the Coverage Analysis

A simple miscommunication leads to fall out . . .

- The most important factor in successful research billing compliance programs
  - **COMMUNICATION**
- The coverage analysis and budget documents are complicated – don't expect everyone to know exactly what to do
- There will be mistakes if there is not communication between the coverage analysis contacts, budget contacts, billing team, patient care team, and insurance teams!
- Set up contacts for billing questions and concerns – hand out friendship bracelets, if you need to
- Set up trainings for staff on billing compliance-become a familiar name and face
- Should have a process in place for correcting mistakes – up to 12 months for Medicare – you ***can*** go back to December

Amendments

Everything was red

- From a compliance perspective:
  - Keep billing determinations from original coverage analysis consistent – preserve what you can from the original version
  - Do redline and keep a redlined version of the coverage analysis available – redlines will be helpful for updating other documents (aka budget, consent) and systems (CTMS, EMR, accounting)
  - New items –follow new and current documentation
  - New arms
    - Keep similar to existing arms if same indications and medications
    - Can update to new policies/current practices if entirely new patient population and medications
- Always ask if patients have been enrolled when starting an amendment – if you've enrolled, preservation is important!

This is not where the storyline ends

Join us for two more webinars on more advanced coverage analysis topics and a Q&A on March 7th & March 28th.

Visit our website at www.wcgclinical.com/solutions/study-start-up to learn more.

Audience Questions

The lingering question kept me, 2AM, how do I analyze

wcg™

Looking for more Billing Compliance training?

Join us at the WCG MAGI Clinical Research Conference in New Orleans on April 14-17th.

Get 15% off your registration with the code Billing15 at wcgclinical.com/MAGI

Polling Question:

Would you like to learn more about WCG's coverage analysis and billing compliance services for research sites?

Thank you!

wcgclinical.com