Understanding Research Billing Compliance: Navigating the Basics and Beyond

A Three-Part Series - Webinar 2:
Beyond the Standard Coverage Analysis: Unpacking Challenging Billing Compliance Issues During Start-Up

Introductions

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Polling Question #1:

What type of organization do you represent?

Today's Agenda

1. Start Reading the Agenda to the Audience
2. Sponsor Budget Shenanigans
3. Device Study Situations
4. Study Design Scenarios
5. State of Cell Therapy
6. Conclusion and Audience Questions

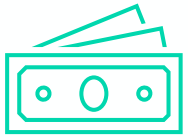
Case Study 1: Sponsor Budget Flip-Flop

Sponsor Paid Before I Did the CA

1. Look at the **sponsor budget**
2. Sponsor is **offering payment** for everything
3. Get excited about an "**easy**" coverage analysis
4. Finish said "**easy**" coverage analysis
5. Begin **negotiations**
6. Sponsor changes their mind; they don't want to pay for everything *"Ope, actually… We don't want to pay for that." – A very real quote*
7. Make a decision. Who's gonna pay up?
8. What would you do?

Polling Question #2:

What Would You Do in this Situation?



Push sponsor to pay for **everything** based on **initial document**

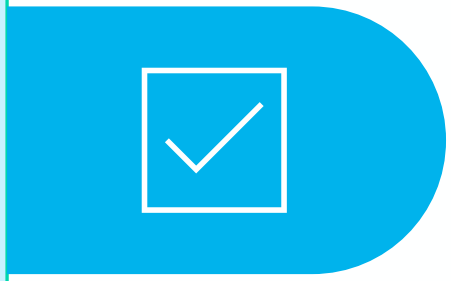
Re-analyze

I think I'll just **call it a day**

Case Study 1 Continued

1. Becoming **increasingly common**
2. Both **drug** and **device studies**
   - Most common in solid tumor studies
3. Specific to when the sponsor budget **does not include** instructions to update designations
4. ICF and contract **don't provide enough detail** to make a solid argument

What should you do?



Push Back

- Avoid costs to the patient(s)
- Several different arguments may be used

- Could result in the study being dropped
- Could result in the coverage analyst not wasting their time

Re-analyze

- Speeds up negotiations
- May cause additional costs to patients

- There might be no changes to designations
- Check to see if the sponsor still intends on paying for any items

- If you go with this approach, consider requesting additional start-up funds

Case Study 2: IDE and Seek

IDE study with

CMS approval

Sponsor expects all tests/procedures to be

billable to insurance

Their interpretation of Medicare policy is that all items are billable to insurance solely because it is an **IDE study**

Case Study 2 Continued

"Routine care items and services refers to items and services that are otherwise generally available to Medicare beneficiaries (that is, a benefit category exists, it is not statutorily excluded, and there is not a national non-coverage decision) **that are furnished during clinical study and that would be otherwise furnished even if the beneficiary were not enrolled in a clinical study**."

(MEDICARE BENEFIT POLICY MANUAL, CHAPTER 14, SECTION 20).

TLDR: Items are covered if they would standardly be done for the patient population outside of the trial

Case Study 2 Continued

Now What?

- You must first define sponsor paid items
- Once that is done, you need to verify whether any non-sponsor paid items would be performed absent a trial
  - Guidelines, NCDs, LCDs, etc.
- Quite often not all items have support for the general patient population
  - Guidelines may not have any recommendations for some protocol-required items
  - NCDs/LCDs may limit the coverage and/or require EXTREMELY specific diagnostic information

Case Study 3: Study Design

Oncology Basket Trials: Making Amends

- Protocols include **several arms** with the intent to add arms over time
- New arms may include **new indications** and/or **new drug regimen**
- Could also change indications in **existing arms**
- The preferred approach differs based on the **complexity of the amendment updates**

Case Study 3 Continued

Simple Amendments

- Amendments that don’t change inclusion criteria/drug regimen
- Retain designations from previous CA

Complex Amendments

- Most sites prefer to preserve as much of the previous analysis as possible
- Billable items will be reviewed against the new inclusion criteria
- If no patients have been enrolled, a complete re-analysis can be considered

Case Study 3 Continued

Questions to ask:

Have you **enrolled** any patients yet?

If so, **what arms** have patients enrolled? Indications?

Are you **planning to enroll** all possible indications?

Are all arms **still open** to enrollment?

Do you plan to enroll into all the **new arms**?

If you don't ask these questions, you could spend **several days** updating the CA, budget, CTMS build, etc. for no reason

Study Design - Blinded Device Studies

- Many sponsors are unaware of the billing complexity
- Coding may unblind the trial
- Some blinded procedures do have CPT codes that may help with billing challenges
- Tend to get caught up in the start-up process due to other issues that need to be resolved
  - Preventing chart notes from being released to the patients
  - Other logistical challenges that may lead to unblinding
- Some of these trials have easier solutions than others

Case Study 4a: Blinded Device

Easy

Same surgery

- Routine care valve implant

Different devices implanted

- Approved model and sponsor-provided model

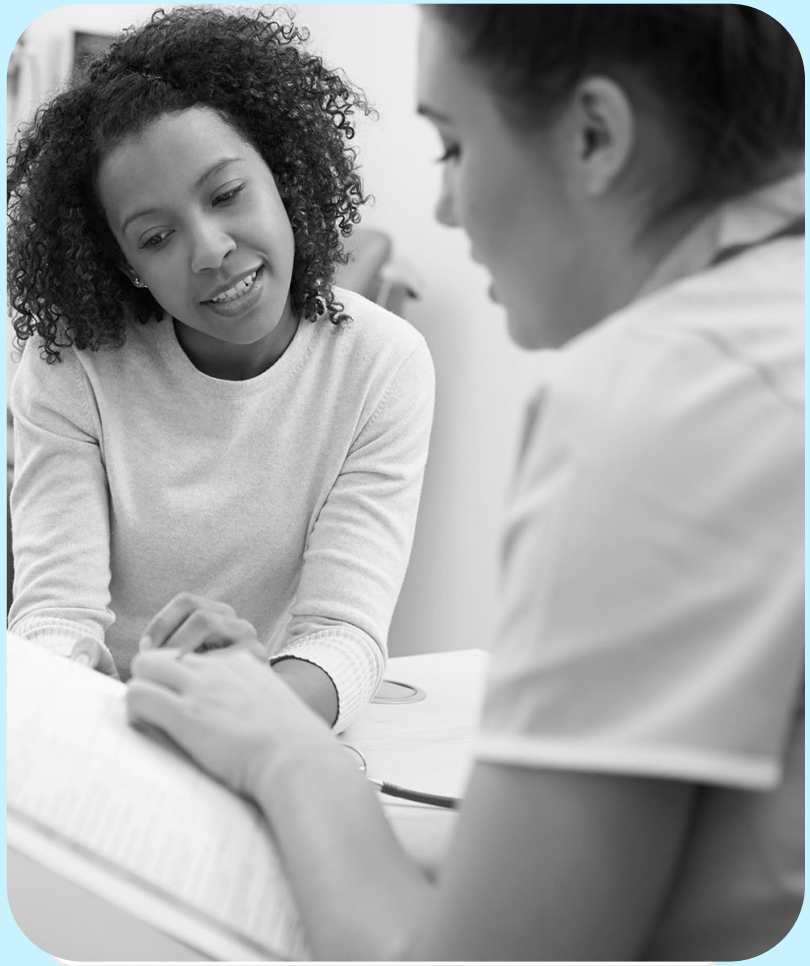
Solution

- Don’t bill the device in either arm
- Implant is still billable as it is routine care

Case Study 4b (or not 4b)

Medium

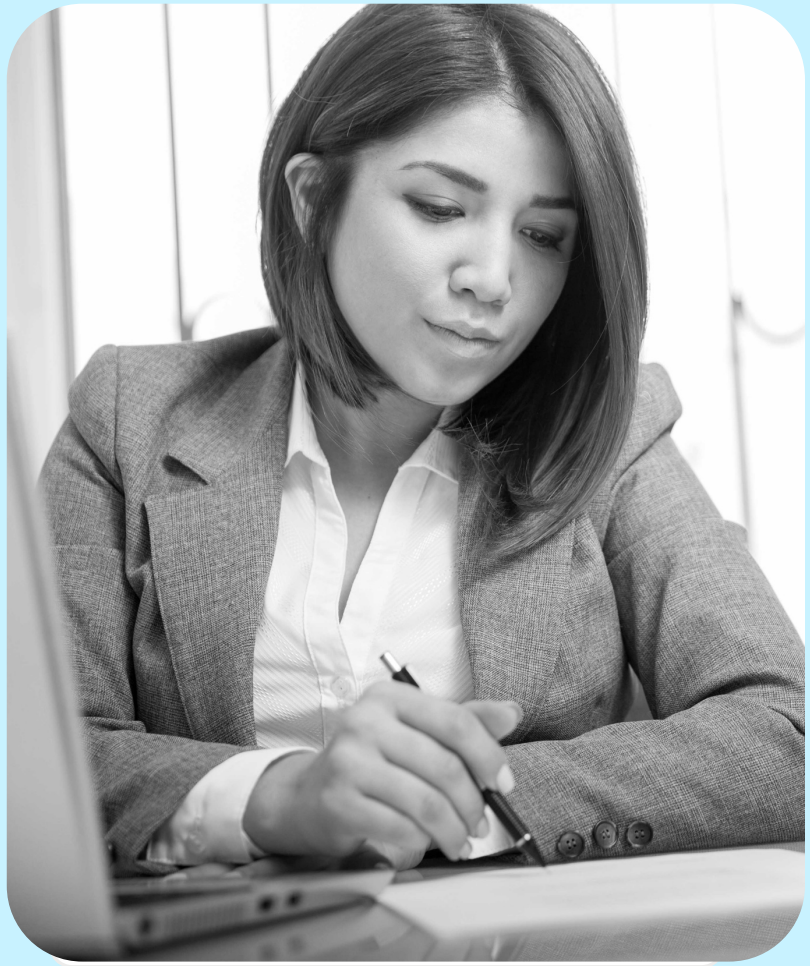
- Similar procedures, but different coding
- Both procedures have guideline support
- If this wasn't blinded, we'd be on our way to paradise
- If standard billing is followed, the claim will unblind the trial
- Some sites may require the sponsor to pay for both procedures in order to maintain the blind (good luck)
- Worked with sites that have changed the CPT code description so that the claim will not unblind the trial



Case Study 4c

Tough

- Device implant procedure and sham procedure
- Many sponsors anticipate that sham procedures and tests will be billable to insurance
- Figure out what the sham procedure is in comparison to the device implant procedure
- Device implant is an add-on code to the sham procedure
  - Routine care angiography
  - Billed the angiography in both arms, but could not bill the add on code for device placement
- Sham procedure is not therapeutic
  - Angiography is only billable if performed with the device implant
  - PI agrees that the sham angiography is not billable and they cannot document medical necessity
  - Most sites request sponsor payment for the procedure in both arms



Oncology Cell Therapy

CAR-T, CAR-NK, TIL, ABCDEFG?

CAR-T

- NCD 110.24
- Has specific recommendations in the NCCN Guidelines
- This may seem like an “ordinary” treatment, but the CA approach is not ordinary
- May require leukapheresis and lymphodepletion
- Commonly used lymphodepletion drugs are not FDA approved for this purpose

The Rest Of Them

- No national guidelines/ guideline support
- No approved products (yet)
- Still shares a few similarities with CAR-T
- How do I analyze?
- Underlying condition
- Study product side effects (probably not)

Stem Cell Transplant in Oncology

- NCD 110.23 includes a very detailed list of supported indications
- Vary between allogeneic and autologous
- Is the stem cell transplant the investigational item, or are patients already planning on undergoing transplant?
- If patients are already planning on undergoing the transplant:
  - Assume transplant is billable independent of the study and that all billing criteria of NCD 110.23 will be met
- If stem cell transplant is the investigational item:
  - If in NCD: transplant and associated items are all billable to insurance
  - If not in NCD: Nothing associated directly with the transplant is billable to insurance
- Additional indications may be covered under Coverage with Evidence Development

But wait – there's more!

Non-Oncology CAR-T and Stem Cell Transplant

- NCDs are specific to cancer (at this point in time)
- It's only half-past twelve: This type of treatment is still in its infancy
- The current trend is that everything associated with the treatment/transplant should be sponsor-paid
  - Hospitalization
  - Supportive medications
  - Lymphodepletion
  - Site requirements for CAR-T therapy/transplant

Case Study 5: Drug Analysis

Solid Tumors, Not So Solid Analysis

- Solid tumor study that requires Pembrolizumab
- The sponsor wants this to be billable to insurance
- Some studies have enough inclusion information to allow drug analysis (but not this one)
- Typically begin by requesting that the sponsor pays for, or provides, Pembrolizumab
- If you need to make Pembrolizumab billable to insurance:
  - PI and study team must only enroll patients that are indicated to receive this drug
  - This would most likely result in the elimination of some patients not being able to be enrolled
  - This approach requires additional discussion outside of the billing team due to potentially limiting enrollment

Audience Questions

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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 #3:

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

Join us for our Coverage Analysis Q&A webinar on March 28th

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

Thank you!

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