The Office of Human Research Ethics

The University of North Carolina at Chapel Hill

Billing Coverage Analysis and the IRB

Introduction

Imagine a research participant consents to a free CT scan as part of a research study but receives a bill for the scan from the clinic. Now the participant has a stressful and unexpected problem to clear up, and the institution has a compliance issue with potentially serious consequences, such as improper billing to insurance or Medicare.

This is why a Billing Coverage Analysis, or BCA, is required for studies where participants will receive medical services potentially billable to the participant or their insurer.

A Billing Coverage Analysis (BCA) is a systematic review of research related documents to determine the Medicare billing status of the study itself, and the items and services provided to the research participants. The BCA helps protect participants from being inappropriately billed for services and to ensure the institution stays compliant with federal and local billing requirements.

IRB members play a critical role in the BCA accuracy by identifying and remedying inconsistencies between the protocol and the informed consent form (ICF), which ultimately must align with the Sponsor contract.

Learning Objectives

By the end of this video, you'll be able to:

- Explain what the BCA is and why it matters.
- Recognize the differences in terminology used to describe study-related services across the research community.
- Identify how the BCA integrates with ICF review.
- Evaluate cost language in an ICF for clarity and consistency.

What billing coverage analysis is, and why it matters

Why the BCA Matters:

- It protects participants from being inappropriately billed for research-only or sponsor-paid activities.
- It helps UNC avoid billing errors, regulatory noncompliance, and potential legal or financial penalties.
- It promotes consistency and alignment across departments, sponsors, and clinical services.
- It reinforces the ethical integrity of research by supporting transparency and fairness for participants.

The BCA analysis is based on rules defined by Medicare (primarily National Coverage Determination (NCD) 310.1: Routine Costs in Clinical Trials) as well as other federal, local and institutional billing policies. These rules determine which procedures meet the definition of 'routine costs' and may be billed to participants or their insurance, and which are considered strictly 'research only' and therefore not billable to participants or insurers.

Common Terms

Across study teams, clinical departments, sponsors, and insurers, many different terms are used to describe study-related services. These terms often sound similar and are sometimes used interchangeably, but they answer different questions about why a service is being performed and who should pay for it.

The BCA helps cut through that confusion by applying one consistent billing framework. This ensures that everyone involved is working from the same assumptions when determining how study services should be billed.

Let's look at these terms more closely.

Standard of Care (SOC) refers to care a patient would normally receive for their condition, even if they were not enrolled in a research study. For example, typical labs, imaging, or treatments that are part of routine medical care. Importantly, labeling a service as "standard of care" describes its clinical purpose. It does not automatically mean that the service can be billed to insurance during a clinical trial.

Routine costs are a billing concept. They refer to a certain subset of SOC services that are allowed to be billed to insurance while a patient is participating in a clinical trial, based largely on Medicare's Clinical Trial Policy and other Medicare rules. While many routine costs overlap with standard of care, not everything considered standard of care qualifies as a routine cost in the research setting.

Research Only procedures are services performed solely because of the study and may provide no direct clinical benefit to participants. These include things like extra blood draws for research analysis or imaging performed only to collect research data. Research only procedures should not be billed to insurance and must be paid for by the study or sponsor.

Sponsor-paid items include anything the study sponsor has agreed to cover, regardless of whether the service might otherwise be considered SOC or a routine cost. This often includes the investigational drug or device, but may also include exams, labs, imaging, or visits that could otherwise be billable. "Sponsor-paid" does not automatically mean "research only;" it simply names who is responsible for payment.

Case Study

The BCA team will go through the research protocol, ICF and contract, and designate and code all the activities based on who's paying for it.

In this example, physical exams, hematology, and MRI are part of the study. They're coded as not billable or billed to the study. Later, glucose monitoring and study drug administration are coded as routine care. Therefore, the clinic will bill the patient or patient's insurance.

A helpful way to think about this is in layers:

- Why is the service being done – is it a routine cost or only because of the study?
- Is the service allowed to be billed during a clinical trial?
- Has the sponsor agreed to pay for the service?

Based on all of that, can the service be billed to insurance or not?

Evaluating Cost Language in ICFs

Under both the Common Rule and FDA regulations, ICFs must include a description of any costs that may result from participation in the research – this does NOT mean a line-by-line analysis of every test or procedure is required. Instead, ICFs should provide participants with enough information to reasonably understand if some services may be billed to their insurance, if out-of-pocket costs such as copays or deductibles may apply, and if certain items or procedures will be covered by the study or sponsor.

Overly detailed cost breakdowns can increase confusion and introduce the risk of inaccuracies, particularly when insurance coverage varies by participant or when changes to the study design such as new procedures affect billing.

It's also important to remember that insurance coverage decisions are made by insurers—not by the research team or the IRB, so ICF language should avoid implying certainty where none exists.

From an IRB perspective, the goal is participant understanding, not billing precision.

How the BCA and IRB Intersect

So, how does the work of the BCA team and the IRB intersect?

First, the IRB reviews and approves the consent form, then the BCA team confirms that the cost language aligns with the insurer designations established in the BCA. Then study activation and participant enrollment can begin.

If any inconsistency is detected by the BCA team, they will work with the study team to resolve it, and the study team will submit to the IRB an updated ICF, if needed. This final review ensures:

- The Costs section clearly says whether participants may have any financial responsibility for study-related services.
- Any sponsor-covered procedures are described accurately and consistently.
- Statements such as "free of charge" or "the sponsor will pay" are clear, contractually supported, and aligned with the BCA, without implying guaranteed insurance coverage.

When these documents are aligned, participants receive consistent information and are less likely to face surprise bills.

Tips for IRB members when reviewing ICF cost language

If something seems unclear or inconsistent, a useful framing is: “If I were the participant, how would I interpret this language?”

Keep in mind that amendments can change study procedures and cost structures. During amendment review, consider whether new procedures or schedule changes require updates to the ICF cost language to keep it accurate over time.

Conclusion

In summary, cost accuracy is a shared responsibility. The BCA protects both UNC and our participants by aligning cost responsibility across the protocol, ICF, and contract.

During your review of the ICF, look closely at how costs are described. Remember, regulations require transparent disclosure of potential costs; not detailed, line-by-line accounting of every charge. Participants should be able to determine (before agreeing to participate) whether they may be financially responsible for any routine costs (including deductibles or copays) or whether the study or sponsor will cover all costs.

Your attention helps safeguard participants and strengthens the quality, transparency, and compliance of our research.

Thanks for watching!

BCA Example

Arm SingleArm: SingleArm: Diabetes and glucose	Version: V1 (Unreleased Budget) ProtVers1.1,6/3/2024	Protocol No.: Sample			
	Comments	Treatment			Follow Up
		Screening 1@1Days	Treatment Visits 1,7@7 days		Follow-up
		Screening	Visit 1	Visit 2	6 month
Informed Consent	This service is related to completion of documents or data collection and is not a billable event.	STUDY(EFT)			
Physical Exam	This service is performed at the CTRC and not EPIC billed.	STUDY(CT)			
Hematology	This item or service is paid by the sponsor (Budget).	STUDY		STUDY	STUDY
*- CBC W/WO diff (85025 85027) [*CBC w/o Auto Diff (85027), *Complete Blood Count (CBC), with outo differential (85025)]*		STUDY		STUDY	STUDY
MRI	This service is performed at BRIC and not EPIC billed.		STUDY(BR)		
Glucose serum	According to "Blood Sugar in Diabetics" published in Endocrine Journal (October 2, 2024) p.2 "Glucose serum should be performed in this population to measure for high sugar levels."	ROUTN1	ROUTN1		
*- GLUCOSE BLOOD TEST (82962) [*Hosp- GLUCOSE BLOOD TEST (82962 HS), *Pro- GLUCOSE BLOOD TEST (82962)]*		ROUTN1	ROUTN1		
QOL Questionnaire	This service is related to completion of documents or data collection and is not a billable event.	STUDY(EFT)	STUDY(EFT)	STUDY(EFT)	STUDY(EFT)
Study Drug (IV)	The study drug is provided by the sponsor (Protocol, Sec. 3.2).	STUDY	STUDY	STUDY	STUDY
Study Drug Administration	NCD 310.1 supports coverage for services required for the administration of the investigational item.	ROUTN1	ROUTN1	ROUTN1	ROUTN1
*- IV INFUSION INIT UP TO 1HR (96365) [*Hosp- IV INFUSION INIT UP TO 1HR (96365 HS), *Pro- IV INFUSION INIT UP TO 1HR (96365)]*		ROUTN1	ROUTN1	ROUTN1	ROUTN1
Blood Draw	Services to obtain specimens for the clinical management of the participant are billable. Venipunctures performed for research purposes are not billable.	ROUTN1	ROUTN1	STUDY	STUDY
*- VENIPUNCTURE (36415) [*Hosp-VENIPUNCTURE (36415 HS), *Pro-VENIPUNCTURE (36415)]*		STUDY(CT)	ROUTN1	STUDY	STUDY

Billing Designation Key

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ROUTN1	Bill to research participant or their insurance Routine Cost, Qualifying Clinical Trial Q1 Modifier; Z00.6 dx code
STUDY/STUDY	Bill to research study account Q0 Modifier only for the investigational item/service Please note: This font will be dark red if the service is determined to be research related, without current sponsor payment
STUDY(EFT)	Not Billable (charge will not be generated) Research study team effort only
[Grey shaded cell]	Procedure or Activity does not occur this visit
CTRC - STUDY(CT)	Bill to research study account by CTRC
BRIC - STUDY(BR)	Bill to research study account by BRIC
Routine(M)	Bill to research participant or their insurance Non-Qualifying Clinical Trial