

Clinical Research Billing & Compliance

SESSION 3:

Using Your Coverage Analysis for Billing & Budgets

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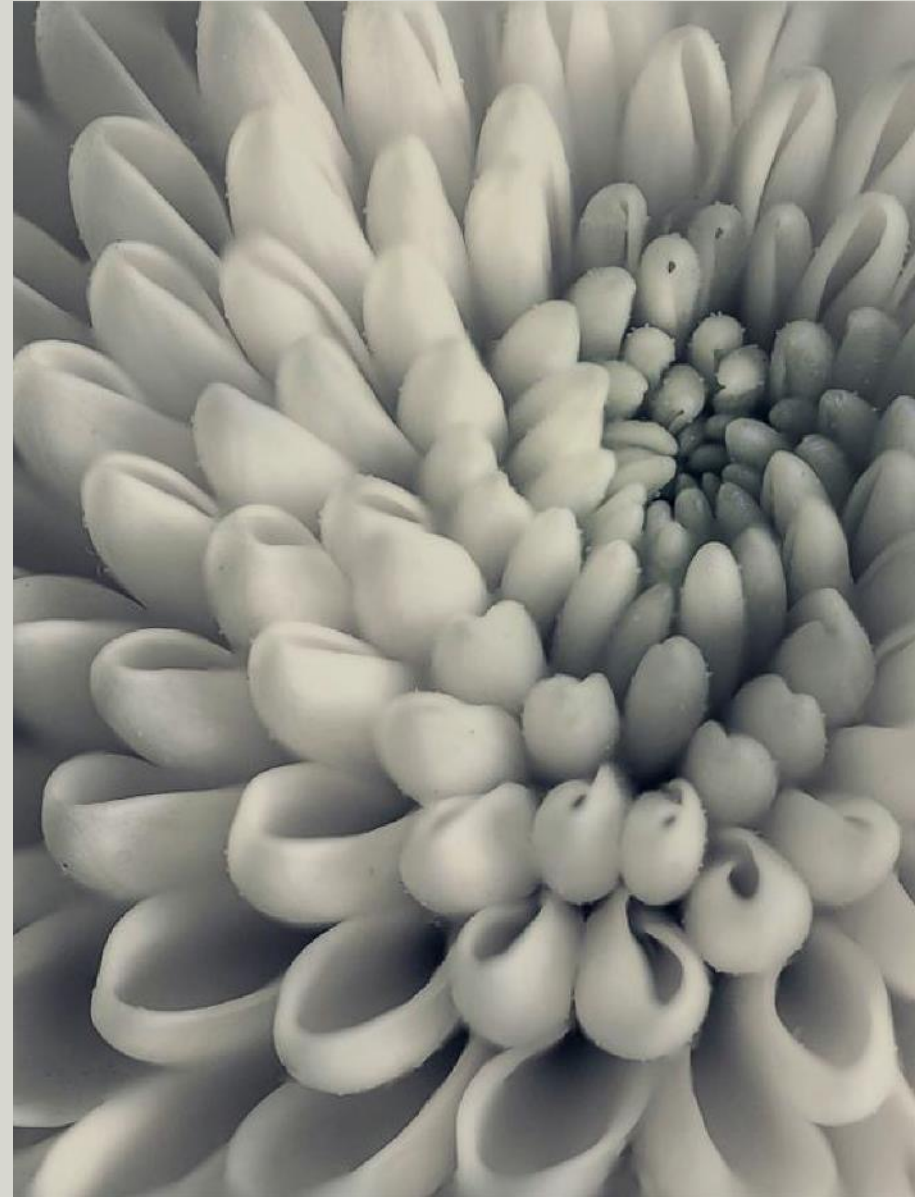
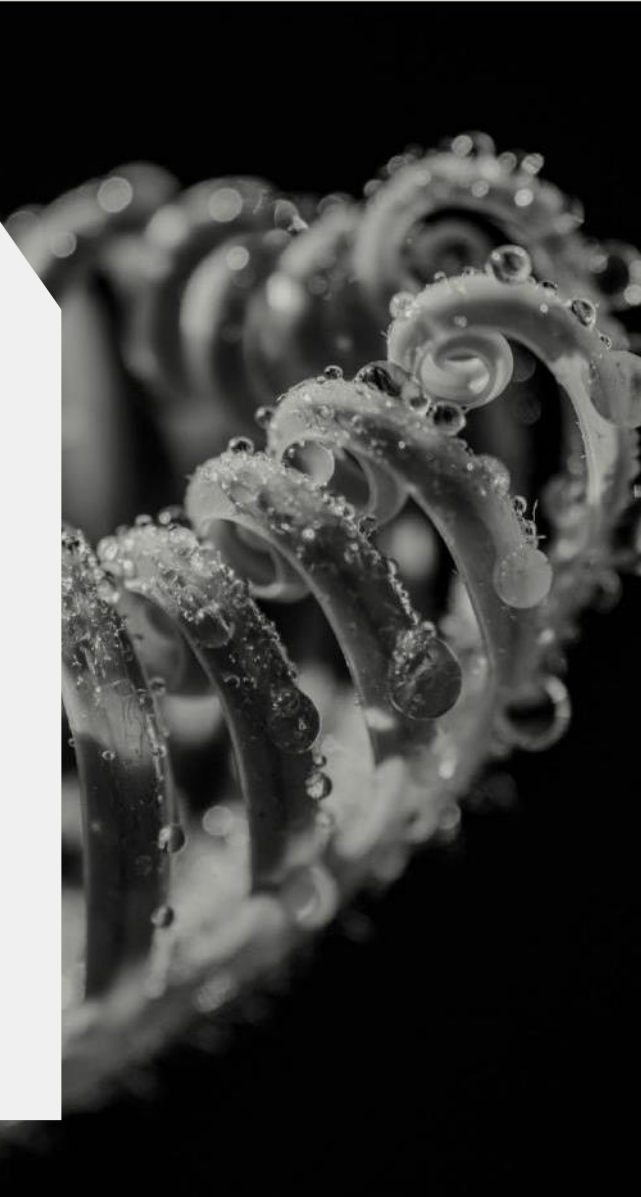


Using your CA for CTA's, ICF's, Budget's and Billing

How does the ICF and CTA affect your
Coverage Analysis

Using your Coverage Analysis to Budget

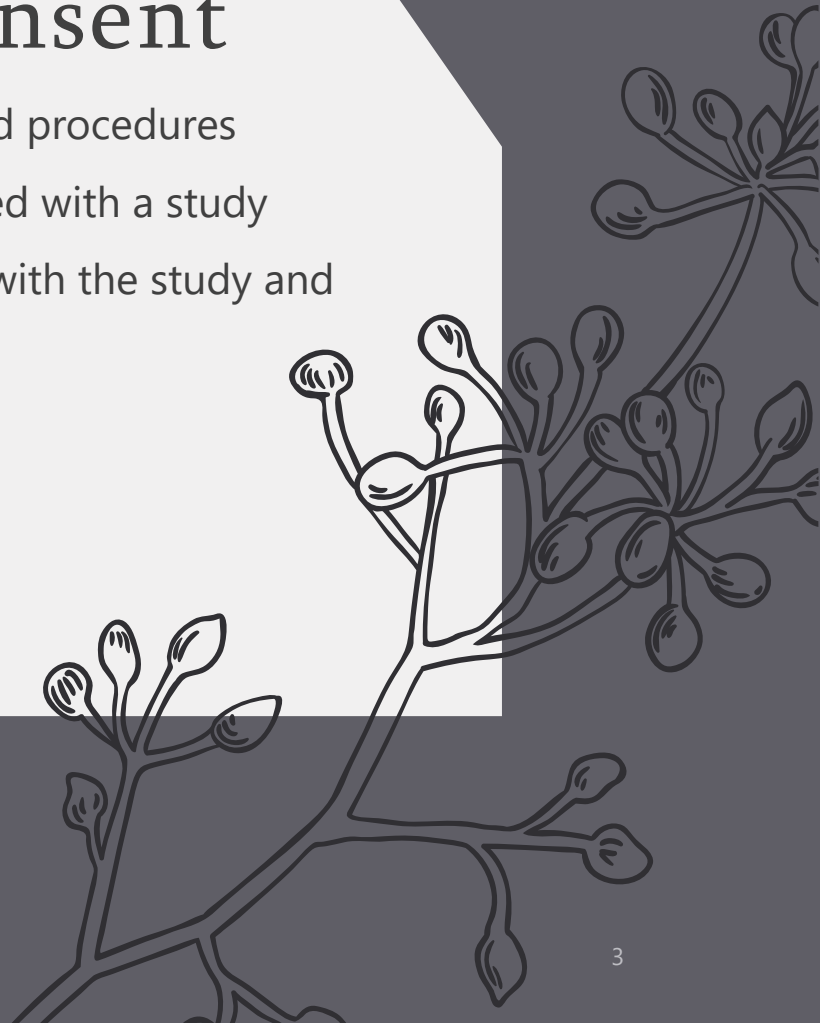
Review the use of Modifier's, ICD-10, and
NCT





Informed Consent

- Description of study related procedures
- Benefits and risks associated with a study
- Potential costs associated with the study and patient responsibility





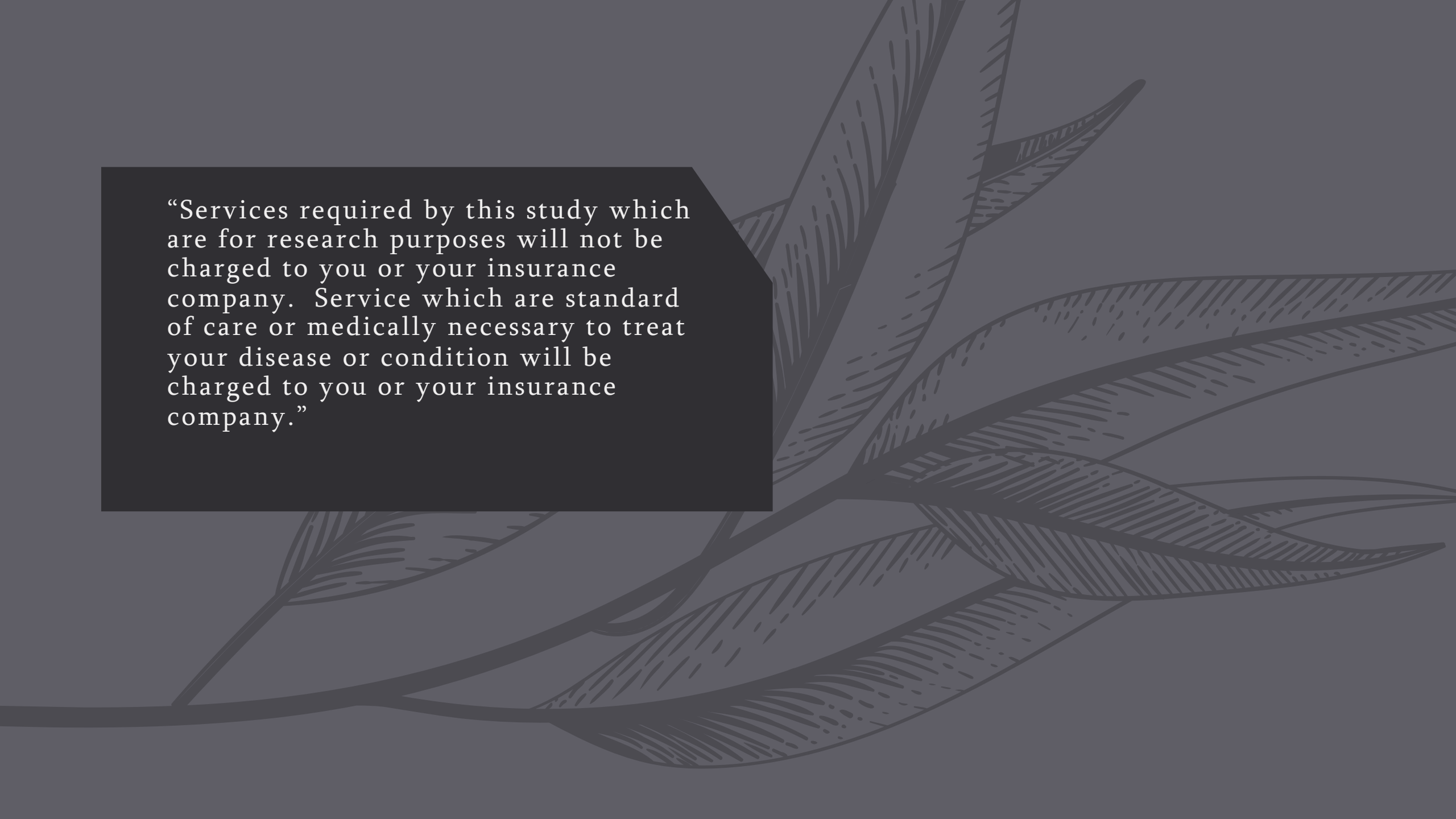
Interpreting the Informed Consent

Patient is not responsible for “study activities” is interpreted to mean any services required as part of the study (i.e., all services)

Patient is not responsible for “research service” is interpreted to mean any services performed solely for research (i.e., those services that do not qualify as a routine cost)

“You will not benefit from any services required by this research study” is interpreted to indicate there is no therapeutic intent.

“You may not benefit from any services required by this research study” is interpreted neutrally.



“Services required by this study which are for research purposes will not be charged to you or your insurance company. Service which are standard of care or medically necessary to treat your disease or condition will be charged to you or your insurance company.”

CTA Basics

The CTA and the Budget are in the same document

They are NOT two different documents
Language in one impacts the other

The provider cannot bill for items and services paid for by the sponsor.

This includes services that sponsor is obligated to pay but has not yet paid.

The Budget must always be read as part of the CTA

The Budget Exhibit is a sub-part of the overall CTA

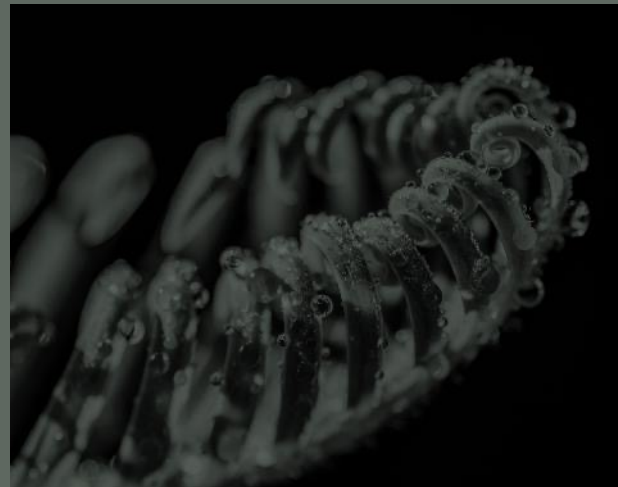
For a CA to be used in billing the final CTA Budget must be reviewed and applied.

A final sync of the CA must be performed if budget neutral or draft documents were used in the original CA.





CTAs and Budgets are negotiable-like all service arrangements



Modifiers, ICD-10's, NCT Oh My

Modifier Q1: Routine clinical service provided in a clinical research study that is an approved clinical research study

Z00.6: Encounter for examination for normal comparison and control in clinical research program

NCT #: Mandatory 8-digit clinical trial number found on clinicaltrials.gov

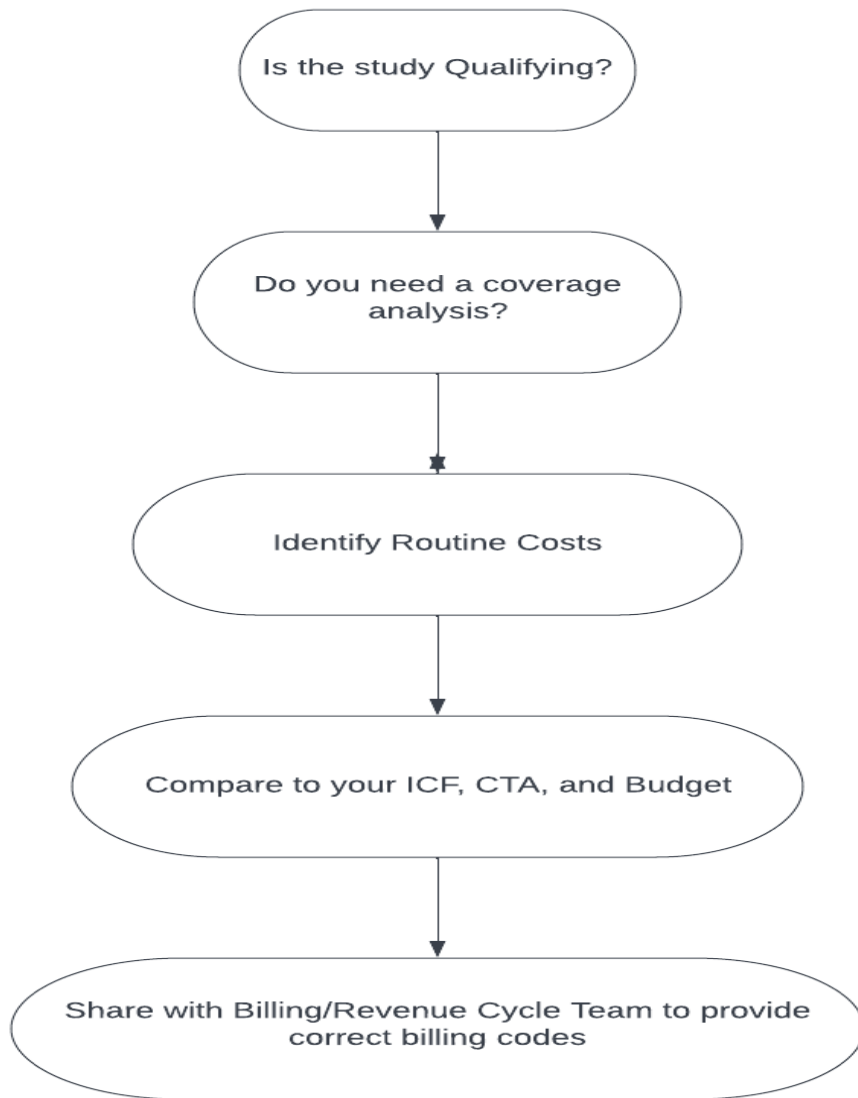
Q0: Investigational clinical service provided in a clinical research study that is an approved clinical research study

Medicare Advantage Plans (MAP)

Medicare must be billed as primary insurance for routine costs of qualifying clinical trials.

MAP plan becomes the secondary payor

If charges occurring for study and not for study on same day – bills must be split so that charges can go to correct payor.



Thank you

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