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**The Importance of Research
Billing Compliance**

In this Issue

- **Research Billing
Compliance**

Medicare is the driving force for clinical trial coverage ([NCD 310.1](#)) and many private payors follow Medicare guidelines as well.

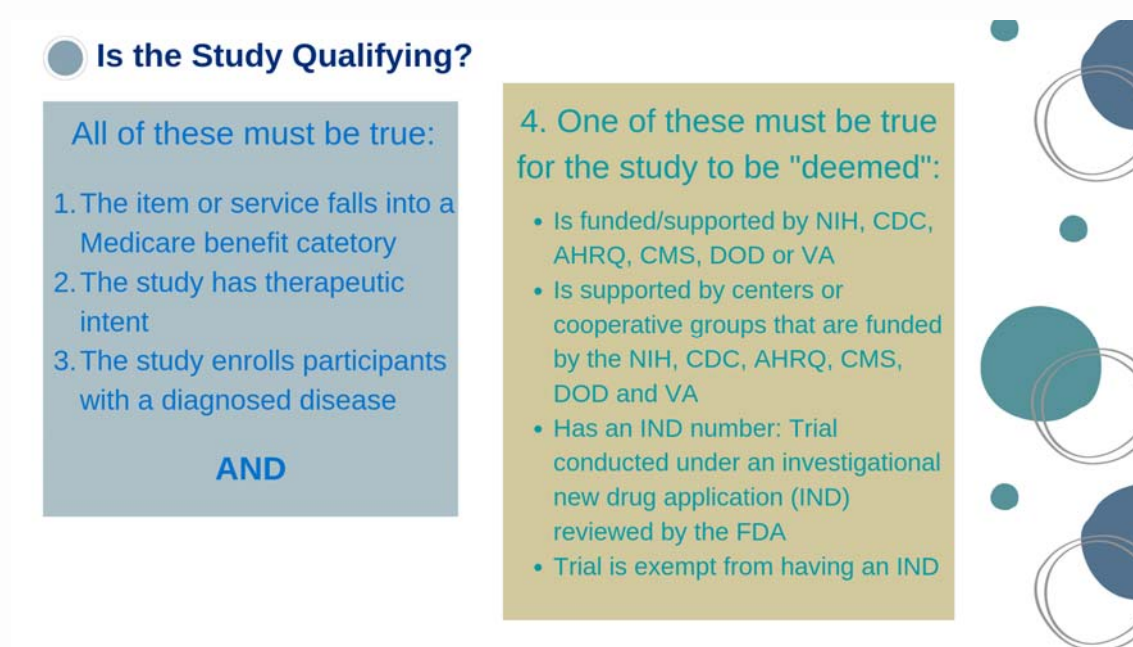
Medicare will cover those routine costs of qualifying clinical trials and the cost of items and services that are "reasonable and necessary" to diagnose and treat complications arising from participation in all clinical trials.

What does "reasonable and necessary means"? Some commonly ordered tests may not be considered "reasonable and necessary" under the NCD, or may be reasonable and necessary at some frequency less than that required by the sponsor in a protocol. Keep in mind that necessary does not mean covered.

Thus, the study must be qualifying in order for Medicare to pay for the associated routine cost.

What is a Qualifying Study?

Please see the graphic below for a quick overview:



Please note that all of these must be true for the study to be considered "qualifying" by Medicare.

How do we Know what is Billable to Medicare?

Most of the Medical Academic Centers (AMC) that perform research have a *Coverage Analysis* that delineates the services and items in the research protocol and who is responsible for paying for them (insurance/participant, sponsor/grant or both).

In Hopkins, if a study has ANY possibility for generating a charge in our billing systems a *Prospective Reimbursement Analysis* (PRA) is created by the Office of Clinical Research Support Services (CRSS). We will look more in depth as this process in a future issue of Clinical Research Billing Buzz.

How is this Related to Billing?

CRBC needs to:

- Follow the PRA and clinical documentation to bill to either the participant or his/her insurance, or to the research study. We call this process "adjudication" of charges
- Follow Medicare billing guidelines, coding and documentation rules
- Medicare also requires the claims to have certain diagnosis code and modifiers that serve as our attestation that the study is *qualifying*

If you want to learn more about research revenue cycle, look in MyLearning for the in-person training titled *A Complete Guide to Clinical Research Billing Compliance*

Need Help?

If you need help, have questions or want to suggest topics for future newsletters you can email us at:

CLINIRESBILLING@exchange.johnshopkins.edu

For more information, visit the **Research Revenue Cycle Website**

[Research Rev Cycle Website](#)



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