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Research Billing

Buzz

A Newsletter from the Office of Clinical Research Billing Compliance

Volume 4 July 2019

The Importance of Research Billing Compliance

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Research Billing
 Compliance



Medicare Clinical
 Trial Regulations

All the components of running a compliant clinical trial can feel overwhelming at times. There are also many billing implications, but some of the more important are:

- Monetary penalties under the False Claims
 Act due to double billing
 - 2019 minimum penalty under the False Claims Act is \$11,463 while maximum is \$22,363 PER CLAIM
 - Any recovery amount is TRIPLED in addition to per claim penalties
- Risk of the provider removal from Medicare participation
- Loss of reputation for the provider and for Johns Hopkins

What does Medicare Cover?

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:

Is the Study Qualifying?

All of these must be true:

- The item or service falls into a Medicare benefit catetory
- 2. The study has therapeutic intent
- 3. The study enrolls participants with a diagnosed disease

AND

- 4. One of these must be true for the study to be "deemed":
- Is funded/supported by NIH, CDC, AHRQ, CMS, DOD or VA
- Is supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA
- Has an IND number: Trial conducted under an investigational new drug application (IND) reviewed by the FDA
- Trial is exempt from having an IND



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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