Clinical Research Billing Compliance at IU

A Team Effort

Clinical research billing compliance is complex and requires collaboration for continual improvement. Indiana University (IU) and Indiana University Health (IU Health) partner to make clinical research studies available to patients from our community as well as from many other parts of the state and country. As partners, IU and IU Health have a shared responsibility to ensure compliant billing for all patients participating in clinical research. Previously, IU research staff were asked to submit a paper Grant Charge Form (GCF), which notified IU Health Revenue Cycle Services of study procedures occurring within an IU Health facility that should be invoiced to a research study account. This process did not provide the complete billing plan and led to confusion surrounding charge entry for these procedures. Together, IU and IU Health collaborated to create a more robust process, which has been in effect for all new projects since December 1, 2020. The OnCore Research Billing Notification process uses data entered into OnCore (IU and IU Health's chosen Clinical Research Management System) to communicate the information required for compliant billing for all included studies and participants.

So why the change?

Compliant research billing is not as simple as ensuring that items and services budgeted to be paid by the study sponsor are directed to the study account. Certainly, this is one important piece of the puzzle. However, the Centers for Medicaid & Medicare Services (CMS) has set forth guidance on when protocol directed billable procedures would qualify for coverage by CMS. Those procedures must be flagged to ensure claims go out the door with required codes and modifiers:

- The ***Condition Code 30*** tells CMS that this is a patient participating in a Qualifying Clinical Trial.
- The ***NCT Number***, required on claims since 2014, allows them to find more information on the trial.
- The ***Z00.6 diagnosis code*** is required on claims containing procedures completed as part of a Qualifying Clinical Trial.
- And the Q modifiers, required only on outpatient claims, identify the individual items/services as ***Q0*** (Investigational clinical service provided in a qualified clinical research trial) or ***Q1*** (Routine clinical service provided in a qualified clinical research trial).

While the paper GCF process was focused on directing charges for items and services to the research study, IU research staff were also asked to provide a monthly spreadsheet to IUH Revenue Cycle Services that contained information for all patients participating in a clinical trial. The manual process to keep these spreadsheets up-to-date was time-consuming for both parties and duplicated the effort for study teams already entering patient data into OnCore. With the new OnCore Research Billing Notification process, IU Health Revenue Cycle Services receives a daily data feed out of OnCore that provides study, patient, and billing data relevant to

the clinical research billing process. With this information, they have the complete billing plan to ensure charges are directed to the study when needed or billed to the patient with all the required codes and modifiers.

Penalty for Non-Compliance?

Providing a positive experience for our research participants is important to all of us, and accurate billing for services provided during their participation is a big part of this. But, there can be more severe consequences for non-compliant clinical research billing. *Submitting claims without any of the required research codes and modifiers is a violation of 31 U.S. Code § 3729 – False Claims.* False Claims charges, followed by audits from CMS have resulted in millions of dollars in fines for some academic research institutions. The dollar amount of these fines is calculated in accordance with the False Claims Act including $5,000-$10,000 (adjusted for inflation) per claim, along with three times the amount of the claim.

Moreover, the potential fallout from institutions implicated in False Claims Act audits has been presented at national conferences. Some institutions have reported difficulty when applying for federally funded grants, including NIH.

CMS can also suspend and/or revoke any hospital network's enrollment in the Medicare program for submitting claims which include false or misleading information in accordance with 42 CFR 424.535. Not including research codes and modifiers in research claims can be interpreted as providing false or misleading information and needs to be avoided at all costs.

While the primary focus of a Coverage Analysis is compliance with the rules and guidelines established by CMS, IU Health includes these codes and modifiers on claims to all third-party payers unless explicitly instructed to exclude them. Specific policies and consequences for non-compliance will vary by payer. Contracts between commercial insurers and hospital networks require the use of proper codes when submitting claims, and often follow the same general guidelines set forth by CMS. Failure to follow the contractual agreement could result in the commercial insurer voiding the contract with the hospital network.

IU and IU Health Response

As awareness of these requirements and the potential penalties grows, research institutions are taking a closer look and implementing process improvements to help ensure compliance. The Office of Clinical Research (OCR) is coordinating the efforts between IU and IU Health to obtain the highest level of research billing compliance.

Since 2018, the centralized Coverage Analysis Team has been providing a complete and consistent research billing review for clinical research studies opened by Indiana University investigators. This team works with study teams to document and justify the billing plan for each study directly in OnCore.

In collaboration, IU Health Corporate Compliance is completing audits that include a detailed review of the research subject's billing encounters as compared to the Cerner medical record, the Coverage Analysis, and the tracked patient calendar in OnCore. This audit ensures that all

clinical research billing processes and procedures are being followed by all parties and provides a feedback loop for continual process improvement.

Moving Forward

The OCR remains committed to working together with our healthcare partners to facilitate compliant clinical research billing through the OnCore Research Billing Notification Process. We understand process updates may be needed and we will do our best to keep the IU research community informed.

Questions about Coverage Analysis or Clinical Research Billing Compliance can be directed to ocrfin@iu.edu.

References

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