
# Frequently Asked Questions on Billing Compliance

**Q** **Aren't most commercial payers consistent with NCD 310.1 under what they call the clinical trial policy portion of their plan?**

**A** There are nuances between commercial carriers. Some are more adamant about coverage for routine costs in trials for life-threatening diseases. Others have language more inclusive of all treatment clinical trials.

**Q** **Are central labs considered "promised free" for research billing? Should these labs be billed to sponsor if a nalyzed locally?**

**A** If a protocol calls for a blood draw and identifies central labs that will be run AND the treating investigator wants those labs for treatment purposes, they can be considered "not related to study." Central labs are typically NOT used for decision-making purposes on patient care.

**Q** **Is it truly required to continue to add research billing dx Z00.6 and modifiers once a patient is off treatment and is post-30-day follow-up and moves into long term follow-up visits?**

**A** If the clinical encounter coincides with a time point in the study, and there are study-paid services OR data will be collected from routine care performed at that visit, then yes the Z00.6 should be used. Since not on treatment there should be no use of Q0. Q1 would be used for any routine care (EKG, etc.) that is done at the visit and sponsor wants the data from that care element.

Q

**If NCD310.1 pays for the treatment of AEs...how does subject injury play into this when the sponsor offers to pay for that? Isn't it easier to be considered routine and bill insurance? How do you begin to parse out those fees when they occur?**

A

NCD 310.1 allows for the services related to diagnosis, treatment, and monitoring of research-related complications to be billed to Medicare. It is the PI's responsibility to determine whether an AE is related to investigational product, due to the underlying disease, or unrelated altogether. Research-related injury is another matter entirely!

Q

**Will NCD 310.1 "provision of the investigational product" support billing insurance for the study drug implant, and explant procedures, as well as support billing the "facility fee" for the extended hospitalization days?**

A

NCD 310.1 does allow services related to administration of the study drug to be billed to Medicare. So, if those are infusion charges, or perhaps the study drug is administered via an "implanted" pump...then yes. A pump explant becomes trickier, as it would need to follow the coverage approvals for the pump itself, but would technically fall under 310.1 as well.

Q

**Can you explain how to determine if an item is related to a research protocol when it is a standard of care item and it is not listed in the protocol? Specifically, in relationship to pediatric oncology treatment plans. Example: port removal or other labs when a patient has an adverse event.**

A

If your Principal Investigator determines the AE was caused by research, then NCD 310.1 inclusion of covering services related to diagnosis, treatment, and monitoring of complications would cover charges to treat an AE.

Q

**If Epic batches procedures (sometimes with different DOS) and only a few are study-related, is that considered split billing? For example, the physical exam is for the study, but the patient also gets a vaccine that is not for the study. Would the vaccine would be routine/standard of care rather than research?**

A

The clinical date of service for protocol required elements may be performed on different days of service. For instance, an office visit with the MD today, but patient had the study-required CT scan a week previous, so the results were available for the office visit. Both might be included in the same protocol visit based on sponsor's time and event grid. It is also common for a batch of labs to be run for patient care purposes that includes several required by the study, and others not mentioned in the protocol. Those not mentioned but desired by the physician would be "Not Study Related" even if ordered and run at same time.

Q

**Can you please discuss inpatient billing? Specifically, when Medicare is making a fixed payment for the DRG rather than reimbursing by individual CPT codes?**

A

Medicare allows reimbursements for inpatient care based on DRG reimbursement. Services done only for research purposes and not routine care should not be billed to Medicare. Pulling individual charge codes off an IP encounter and charging them to the research study (if sponsor paid) will not affect your DRG reimbursement.

Q

**We have sponsors who are not seeking Medicare approval for a device study because it is first in humans and data is not available until a certain number of subjects are enrolled. How are other institutions handling that?**

A

FDA approval will not be sought until there is enough (compelling) evidence for FDA to decide. Medicare will make an approval on coverage-whether the drug/device will be reimbursed-only AFTER approval by FDA. If the device study is being conducted under an IDE then routine costs can be billed to Medicare.

Q

**What internal research billing compliance audits are recommended? My team currently performs quality reviews on research studies (reviewing past research billing activities) but are open to performing other audits.**

A

Sounds like you are on the right path! We typically recommend random audits on any visits occurring within a time period, and for those to be routinely repeated. An example would be to audit 30 research patient encounters each quarter-randomly selected from all possible-and repeat each quarter. Plus, be on the lookout for studies to do prospective "for cause" audits based on high enrollments, coordinator changes during study, and/or multiple protocol amendments triggering budget amendments or coverage analysis versions.

Q

**Do you find common issues with coordinating with third party entities for research-covered services? For example: Radiology "read fee" charges?**

A

If you have external providers that are part of the clinical care plan (radiology, anesthesia, etc.) it is the institution's responsibility to inform those partners of which patients, service dates, and services are research-related and especially paid for by sponsor (therefore not billable). Many EPIC users send a "flat file" with such encounters identified so the medical group can properly bill. It is not the institution's responsibility to audit the group's billing, however.