Mandatory Reporting of Clinical Trial Identifier Numbers on Claims

Q: Do organizations bill Medicare for all services related to the clinical trial and then bill Medicare Advantage (MA) plans for the difference between Medicare's and the MA's plan coinsurance/copay that would have been normally paid?

A: Medicare will reimburse qualifying clinical trial claims on behalf of MA members and will waive the Part A and the Part B deductibles. MA plans are responsible for the remaining original Medicare coinsurance minus the plan's normal member copays for the incurred types of service. Providers need to submit the bills to the appropriate A or B Medicare Administrative Contractor (A/B MAC) using the proper modifiers and ICD-9 or ICD-10 codes depending on whether the date of service is prior to October 1, 2014, or after.

Type of Clinical Trial	Where to Submit Claim
Investigational Device Exemption (IDE (Category A and Category B)	MA Plan (Coverage for the IDE item itself may not be consistent across all MA plans)
Clinical Trials that Quality for Coverage Under a Specific National Coverage Determination (NCD)	Follow the instructions for coding and submitting claims in the Change Request associated with the NCD
Clinical Trials that Qualify for Coverage under the Clinical Trial Policy	Fee-for-Service MAC (coverage may not be consistent across all MACs)

Q: If a patient is in a clinical trial, has finished active treatment and is being seen yearly for observation, do we still need to include the National Clinical Trial (NCT) identifier number?

A: Yes

Q: If a patient is in an observation-only trial (where the trial is looking at care trending and has no bearing on treatment decisions) are we required to report the NCT identifier number?

A: Yes

Q: We question when the modifier -Q0 would ever be used on a claim. If a drug that is not Food and Drug Administration- (FDA) approved is being used in a trial, said drug is provided by the study and won't be billed to insurance. So what is the purpose of using the -Q0?

A: There are times when trials are testing treatments for off-label uses, especially in the case of IDE studies. The -Q0 modifier is also used in studies required for Coverage with Evidence Development (CED).

Q: If we have a patient in a trial and the physician orders lab tests/scans not dictated by the trial (new problem) but the patient doesn't go off study, do we still include the NCT number?

A: No

Q: If a physician orders labs dictated by the study and also orders additional labs, do we put a -Q1 modifier on the study-dictated labs but not the additional labs?

A: That is correct.

Q: Are we supposed to put the -Q1 modifier on all line items or just the primary procedure code and is it acceptable to put the modifier in the second modifier slot?

A: Yes the –Q1 modifier should be on all line items. Yes the modifier can go in the secondary position.

Q: If we have a clinical trial patient who has been admitted to the hospital for a non-cancer related problem (sepsis, heart attack) and we are called in to consult, do we report the NCT number?

A: No

Q: We assume if we admit the patient to the hospital for treatment we would include the NCT number on the claim, but what if we admit them for sepsis or dehydration, pain control etc.?

A: If the sepsis, dehydration, or pain is a complication of the trial, then yes include the NCT identifier number; otherwise, no.

Q: Do all services to a patient who is in a clinical trial need to be submitted with the NCT number, or only specifically those services that are part of the trial? Or do we include all services related to the condition (diagnosis) that is part of the clinical trial?

A: Only those services that are part of the clinical trial, including routine care for the condition in the clinical trial, need to be submitted with an NCT identifier number on a Medicare claim related to the clinical trial. In other words, if the patient falls and break their leg and happens to be participating in a trial, they would not report the NCT identifier number on the claim for the broken leg.

Q: Does Transmittal 2805 dated October 30, 2013, mandating the reporting of a clinical trial number on claims for items/services provided in clinical trials that are qualified for coverage as specified in the NCD Manual apply to research studies?

A: If the study is registered on ClinicalTrials.gov and is assigned an NCT identifier number, that NCT identifier number should be reported on all related claims as long as the patient is a study participant.

Q: I am a provider participating in a registry sponsored by the manufacturer. This is not a CED required registry, but a company-sponsored registry for data reporting and tracking (no clinical end-points are being tested). The study is a post-market registry involving patients receiving many different technologies from the manufacturer. All devices are FDA approved/cleared and being used as indicated. There are no protocol-driven services - all services are standard of care. Patients are consented to participate but may be consented up to 30 days after the implant. The study sites are required to obtain Institutional Review Board approval, and the trial is registered with CMS and has an assigned NCT number. Is it necessary to report the NCT number on claims for Medicare patients enrolled in the registry? If it is required on claims for the device implant/usage, is it also required for follow-up visits in which a device may be checked or programmed?

A: What you describe is not CED, IDE, or a qualifying clinical trial as CMS describes them. However, since it is registered on ClinicalTrials.gov, registered with CMS, and is assigned an NCT identifier number, our response is that the NCT identifier number should be reported on all related claims. That would mean any post-trial service related to the trial as long as the patient is being tracked by the trial.

Q: I have some questions about the delay (mentioned in MLN Matters Number: SE1344) of the reporting of an NCT identifier number on claims for items/services provided in clinical trials. Does the delay also affect the –Q0/-Q1 modifier reporting?

A: No. Reporting modifiers –Q0/Q1 to identify trial-related items/services has been in place for many years and continues without change.

Q: SE 1344 gives hospitals permission to use the 99999999 number in place of the actual NCT identifier number on claims. Can a hospital use the NCT identifier number when they have it for some claims and use the 99999999 number when they do not have the actual number?

A: Yes, however, actual NCT identifier numbers are required/encouraged if they are known.

Q: When implantable cardiac defibrillators (ICDs) are implanted on-label for primary prevention, the data is included in a registry as part of the coverage criteria. However, these patients are not provided services subject to CED (or a related registry part of CED), a clinical trial or Category B IDE. Would the NCT identifier number need not be included on such primary prevention cases?

A: If an ICD is implanted as primary prevention and has nothing to do with a trial, a study, a registry, CED, or Category B IDE trials, but the ICD is registered as part of the coverage criteria only, those claims would not require an NCT identifier number.

Q: For clinical trials that are qualified for coverage as specified in the NCD Manual, Pub. 100-03, section 310.1, does mandatory reporting of the NCT identifier number also apply to drug clinical trials? In both the MedLearn Matters (CR 8401 revised, effective 1/1/14) and the Change Request, Transmittal 2805, the website includes a link for contractors to verify the validity of a clinical trial or registry. The related registries are also included. Does this mean the new mandatory reporting of the NCT identifier number only applies to the registries listed on this page and the studies associated with these registries?

A: Yes, reporting of an NCT identifier number applies to drug trials as well.

No, the use of the CMS web page that includes listings of approved facilities and mention of various studies and registries does not constitute a complete list of all Medicare-approved trials, studies, and registries subject to this reporting requirement.

Q: In the scenario where a patient is enrolled in a national clinical trial and also part of a demonstration, which number should be reported in the REF02 segment on a claim? Both of these numbers require use of the same field L2300-REF02 when REF01 is P4, but it seems unlikely that we should send both. In the case where there is overlap, which should take precedence? Or, is there an alternate spot we should report one of these numbers?

A: The NCT identifier number is required for all trial/registry/study-related claims. It is not a matter of precedence as long as both numbers are reported on the claim using the appropriate fields. We question why and how often a claim for any given day would cross over both a trial and a demo that are unrelated.

Q: If a supplier cannot/does not report a valid NCT identifier number and reports the generic will the claims be denied? Do suppliers have the option to use either the generic number or the actual clinical trial number?

A: Claims should not be denied as long as there is a valid or generic number in the appropriate field of the trial-related claim

The workaround is designed for those providers that don't have a current mechanism/process in place to report a valid NCT identifier number at this time. It was not designed to instruct providers that are already reporting the valid number to go ahead and start reporting the generic number or do anything different than they're already

doing. It was also not designed to afford providers the ability to slack an entire year on these requirements, but to afford those with the inability to report the actual number additional time and assist them with any hardships surrounding this reporting. Yes suppliers theoretically have an option based on our instructions but they should be reporting an actual number if they've already been doing so and are currently able to do so. We aren't looking for providers to regress. We are looking to see less and less generic numbers reported on a regular, moving forward basis.

Q: Do we need to report the NCT identifier number on all patient's in a recruiting, active, or not recruiting clinical trial for any services being billed to Medicare? This would include any service billed by the hospital or the physician as outlined in the Clinical Trial Protocol.

A: Yes. Any items/services provided to the participating beneficiary relative to the trial should be reported with the corresponding NCT identifier number.

Q: What is the difference between an approved and a qualified clinical trial? Are claims with V70.7 only for qualified clinical trial numbers, or are there cases where you use the V70.7 that would not be for a qualified clinical trial?

A: You are correct an approved/qualified clinical trial meets CMS criteria for coverage purposes. As for the V70.7, it is attached to trial-related claims to indicate the items/services are provided in connection with a Medicare approved/qualified trial. Hence, use of V70.7 for non-Medicare approved/qualified trials would not be appropriate.

Q: We have AICD implant patients implanted for primary prevention and registered into the National ICD Registry Database. Claims are frequently being denied for MA50 Remittance Code (IDE# for FDA Clinical Trial Services). We don't have an IDE number – we only have our participant ID number.

A: If the device is implanted in an approved IDE trial, the claims must contain the IDE number. If the device is not part of an IDE trial, then there does not have to be an IDE number. Since it's also part of the ICD NCD, the claims must also contain the mandatory NCT identifier number. All items and services provided in CED studies and IDE trials must be coded with the -Q0 modifier for the item being tested and the -Q1 modifier for the related items and services.

Q: For cases where a patient is enrolled in a study/registry over a multiple year time frames, and has the study service (device/drug) provided on a given day at enrollment onset, do we have to report the NCT identifier number on all claims afterward? Say a patient goes in for an x-ray/lab work/office visit that is not study-related, but is still enrolled in the study when these non-study services were rendered, do we need to include the NCT identifier number on those claims? Does this continue through the end of the enrollment, even though no other study related services were rendered?

If a patient comes in for a standard of care work-up for an upcoming clinical trial service, or comes in post-clinical trial service for a standard of care follow-up related to the clinical trial service, would the claims in either case require the trial number?

A: The NCT identifier number is mandatory for all trial-related items/services claims throughout the life of the trial. It is not required for non-trial-related items/services claims. While including the NCT identifier number has been optional for several years, it is a mandatory requirement beginning January 1, 2014. In both scenarios you refer to, the services are related to a trial – those claims require the NCT identifier number. That said, providers are expected to use their professional judgment in determining individual items/services and what is and is not related to a given trial.

Q: We have 2 Medicare patients who are scheduled to have the same procedure, and both come in for standard of care pre-procedure work-up (EKG, labs), then both have the same procedure (1 with an already approved for commercial use device and 1 with an IDE device), then both return post-procedure for standard of care follow-up. Do we need to use the clinical trial number on any claim except the one involving the use of the IDE device?

A: No, but you do need to use both the NCT identifier number and the IDE number on the IDE device claims.

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