

**Mandatory Reporting of National Clinical Trial (NCT) Identifier
Numbers on Medicare Claims – Qs & As**

Background

Medicare may pay for items and services in clinical research studies under three policies: (1) the Clinical Trial Policy (CTP), (2) the Investigational Device Exemption (IDE) policy, and, (3) Coverage with Evidence Development (CED).

- **CTP:** The CTP is a National Coverage Determination (NCD) that allows payment of routine items/services, and payment of the investigational item/service if it is covered outside the trial, in clinical trials that qualify for coverage. For details see <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&NCAId=186&bc=AiAAAAAAAgAAAA%3d%3d&>.
- **IDE:** Medicare may cover certain items/services in Food and Drug Administration (FDA)-approved IDE trials. For trials approved by the FDA before January 1, 2015, the Medicare Administrative Contractors (MACs) approve IDE studies for coverage. For trials approved by the FDA after January 1, 2015, a list of approved studies may be found at: [website]
- **CED:** Medicare may make an NCD that requires participation in certain clinical trials, longitudinal studies, or registries for coverage of an investigational item/service and routine and related items/services. All CED studies are listed on the Centers for Medicare & Medicaid Services' (CMS') CED Website at: <http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html>

Medicare coverage of clinical trials, prospective studies, and registries			
	CTP	IDE	CED
CMS approval required	No – must qualify under NCD 310.1	Yes –each specific study approved by FDA before 1/1/2015, requires MAC approval; for each specific study approved by FDA after 1/1/2015, requires CMS approval	Yes – requires CMS approval for each specific study
Public notification	No – provider determines qualification	Each specific study approved by FDA after 1/1/2015 appears on CMS IDE Website	Each specific study approved by CMS appears on CMS CED Website
Routine services (Q1)	Covered if otherwise coverable by Medicare in qualified study	Covered if study is approved by CMS and otherwise coverable by Medicare	Covered if study is approved by CMS and otherwise coverable by Medicare
Investigational item/service (Q0)	Covered if otherwise coverable by Medicare in qualified study	Covered if study is Category B, and approved by CMS	Covered if study is approved by CMS

1. 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 MAC using the proper modifiers and ICD-9 or ICD-10 codes depending on whether the date of service is prior to October 1, 2015, or after.

Type of Clinical Trial	Where to Submit Claim
IDE (Category A and Category B)	MA Plan
Clinical Trials that Qualify for Coverage Under a Specific NCD	MA plan unless CMS determines that the significant cost threshold is exceeded.
Clinical Trials that Qualify for Coverage under the CTP	Fee-for-Service MAC

2. 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, and *includes billable charges*, the NCT identifier number should be reported on all related claims as long as the patient is a study participant.

3. 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: No

4. 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: No

5. Q: We question when the modifier -Q0 would ever be used on a claim. If a drug that is not 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: See chart

6. 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

7. 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.

8. 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.

9. Q: If we have a clinical trial patient who has been admitted to the hospital for a problem not related to the clinical trial (sepsis, heart attack) and we are called in to consult, do we report the NCT number?

A: No

10. 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: No. Complications arising from participation in a clinical trial do not need an NCT number.

11. 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 breaks 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.

12. Q: MLN Article SE1344 dated January 2, 2014, gives hospitals and others 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 if they are known. If the study is an IDE study or a CED study, the NCT number is always required.

13. 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 (MM8401 and SE1344) and the CR8401, Transmittal 2805, the website includes a link for contractors to verify the validity of a clinical trial/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: No, the use of the CMS web page that includes listings of approved facilities and mentions various studies/registries does not constitute a complete list of all Medicare-approved trials, studies, and registries subject to this reporting requirement.

14. 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 if it qualifies for the CTP, is an IDE study, or is a CED study.

15. Q: If a supplier cannot/does not report a valid NCT identifier number and reports the generic number 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 but if the capabilities are there to report the actual clinical trial number that is the number that should be reported.

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.

16. 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.

17. Q: What is the difference between an approved and a qualified clinical trial? Are claims with diagnosis code 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: See chart explaining the differences between CTP, IDE, and CED studies. All of these studies require the mandatory coding as described in Transmittal 2805. The V70.7 diagnosis code 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.

18. Q: For cases where a patient is enrolled in a study/registry over a multiple year time frames, and has the study item/service (device/drug) provided on a given day at enrollment onset, do we have to report the NCT identifier number on all claims afterward?

A: The NCT identifier number is mandatory for all trial-related items/services claims that are directly related to the study throughout the life of the trial; but not for non-trial-related items/services claims. For example, a study protocol may require testing over several years. That testing should be billed under the NCT identifier number. That said, providers should use their professional judgment in determining individual items/services and what is and is not related to a given trial.

19. Q: How should control studies (symptom management or quality of life) be billed?

A: If there are items or services provided in these studies, they should be reported using the instructions in CR 8401.

20. Q: Are the requirements in CR 8401 only for Medicare patients or all patients?

A: The requirements referred to in CR 8401 pertain to Medicare approved/qualifying clinical trials/registries/studies.

21. Q: When is the NCT identifier number necessary - for just the visit or for line-by-line charges?

A: The NCT identifier number is required on the claim transmitting items/services provided relative to the trial/study/registry. The individual line-items will be identified with an appropriate -Q0 or -Q1 modifier to identify coverage.

22. Q: Does it apply to all routine care as well as specific research required procedures?

A: It only applies to routine items/services required by the study.

23. Q Do we provide the NCT identifier number with every encounter? &/or every line item? &/or just the date of the study visit?

A: The NCT identifier number is required on every trial-related item/service claim, encounter, and/or date of study visit. It is not required on every line item.

24. Q: What do you do when the care is considered routine care that they would receive regardless?

A Providers should use their professional judgment in determining Medicare coverage of individual items/services and what is and is not related to a given trial.

25. Q: Does this apply to cancer control if it is or is not deemed a qualifying trial? Cancer control trials are generally focused on management of cancer symptoms and treatment. The interventions may be drug or behavioral in nature.

A: Determine whether the study qualifies for the CTP before billing for services for this type of trial.

26. Q: What about Pediatrics and Children's Oncology Group (COG) trials? Our institution says yes to all across the board but others say no. Is this relevant to Medicare patients only?

A: These policies apply to all Medicare beneficiaries regardless of age.

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