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Medicare Advantage Policy Manual **Policy ID:** M-MED150

Clinical Trials and Investigational Device Exemption (IDE) Studies

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

BACKGROUND

Effective January 1, 2008, all claims submitted for patient care in clinical research studies must use the –Q0 or –Q1 modifiers for routine and investigational clinical services.

- Q0 - Investigational clinical service provided in a clinical research study that is in an approved clinical research study.
- Q1 - Routine clinical service provided in a clinical research study that is in an approved clinical research study.

Clinical research studies include:

- Studies that are certified under the Medicare Clinical Research Policy
- Investigational Device Exemption (IDE) trials, and
- Studies and registries required under a coverage with evidence development (CED) national coverage determination (NCD)."[1]

In addition to the above modifiers, claims also need to include the ICD-10 code Z00.6 (or ICD-9 code V70.7 if the services were rendered prior to October 1, 2015).

Some of these services are covered by Original Medicare (or the local Medicare Administrative Contractors, also known as "MACs") as the primary carrier, while other services would be processed by the Medicare Advantage Organization (MAO). Therefore, claims reported with these modifiers and diagnoses codes require some review to ensure accurate adjudication.

This policy is intended to aid decision-making regarding:

(1) The appropriate primary payor for the service(s) in question; and

(2) When further medical necessity review may be necessary.

DEFINITIONS AND ACRONYMS

Category A Device:	A device for which questions regarding safety and effectiveness remain because the "absolute risk" of the device type has not been established.[2]
Category B Device:	Also known as a "non-experimental/investigational" device, this is a device for which initial questions of safety and effectiveness of that device type have been resolved. This includes devices with known safety and efficacy because other manufacturers have obtained FDA premarket approval or clearance for that device type. [2]
IDE:	Investigational Device Exemption
MAC: (also seen as "A/B MACs")	Medicare Administrative Contractor, also known as a local contractor. Part A and Part B MACs process Medicare Part A and Medicare Part B claims for a defined geographic area or "jurisdiction," servicing institutional providers, physicians, practitioners, and suppliers.
MAO:	Medicare Advantage Organization. Also referred to as Medicare Advantage (MA) Plans, Medicare+Choice Organizations, or Medicare Part C.[3]
Medical Device:	Defined by the FDA as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: • Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, • Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

- Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes”[4, 5]

Important Notes:

- This policy is **not** intended to provide coverage for devices or procedures that would otherwise be excluded by Medicare (i.e., devices or procedures statutorily excluded from coverage based on CMS manuals or other regulation).
- Procedures and devices deemed experimental or investigational (and therefore not medically necessary) ***by the Medicare Advantage Organization (MAO)*** following an evidence-based review process are not addressed by this policy. These are addressed in separate Medicare Advantage medical policies specific to the service in question.
- This policy does not address Humanitarian Use Devices (HUDs) and Exemptions (HDEs).

Type of Clinical Trial, Registry, or Study	***Financial Responsibility/Where to submit claims***	***Covered / Non-Covered Items and Services***	***Party Responsible for Study Approval and/or Criteria Development***
Clinical trials not otherwise specified **Note:** *Registries* NOT part of a clinical trial or Medicare Coverage with Evidence Development (CED) policy do **not** fall under this provision.	Primary Responsibility: Local MAC or Original Medicare. Contact local MAC for confirmation. Secondary Responsibility: Submit to the MAO with the Medicare Explanation of Benefits (MEOB)	Original Medicare or local contractors cover the routine costs of qualifying clinical trials on behalf of MA members and will waive the Part A and the Part B deductibles. MAOs are then responsible for the remaining original Medicare coinsurance (minus plan's normal copays).	Medicare. Provider should call 1-800-MEDICARE to confirm Medicare-approval of the requested clinical trial/registry. The health plan does not have access to this information and relies on the inclusion of a MEOB to confirm Medicare coverage was made.
Category A and Category B Investigational Device Exemption (IDE) Study	MAO plan Documentation to support the IDE study has been approved by CMS or by the local contractor should be included.	**Effective 1/1/2015** – Routine care items and services in CMS-approved Category A and B IDE studies are approved; however, the Category A devices are statutorily excluded, while Category B devices are reimbursable.	**Effective 1/1/2015** – Medicare reviews and approves via a centralized review process. Approved IDE studies are added to CMS "Approved IDE Studies" website. **Prior to 1/1/2015** – Local MACs determined IDE coverage. If no

		Prior to 1/1/2015 – Same coverage for Category B IDEs, but MAOs are NOT responsible for ay items or services in CMS-approved Category A IDE studies.	LCD or LCA exists to address coverage, the provider will need to supply documentation of MAC approval.
Coverage with Evidence Development (CED) Studies and Registries	See Cross References for separate Medicare Advantage Medical Policy, Medicine, Policy No. 156		

NOTE: A detailed description of clinical trials, registries, and Investigational Device Exemption (IDE) Studies is below.

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it may result in a delay of reimbursement or an incorrect denial:

- The name of the trial, registry, or study;
- The clinical trial number, or NCT number (**Note:** While registries not part of a clinical trial or Medicare Coverage with Evidence Development (CED) policy are **not** subject to the Medicare clinical trial rules, we encourage inclusion of the NCT number to confirm the registry the member is enrolled in);
- The name of the device (if applicable);
- For an IDE study approved ***prior to*** January 1, 2015, documentation to support the IDE study was approved by the local MAC must be submitted. While not mandatory, a copy of the FDA-approval letter provided to the sponsor or manufacturer of the device is also beneficial and may help to expedite claim processing. The category assignment (Category A or Category B IDE) should be represented on this FDA letter.

CLINICAL TRIALS

Costs Associated with Clinical Trials

"For clinical trials covered under the Clinical Trials National Coverage Determination (NCD) (NCD manual, Pub. 100-3, Part 4, Section 310), Medicare covers the routine costs of qualifying clinical trials for all Medicare enrollees, including those enrolled in MA plans, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participating in qualifying clinical trials. All other Medicare rules apply.

"…MA plans pay the enrollee the difference between original Medicare cost-sharing incurred for qualified clinical trial items and services and the MA plan's in-network cost-sharing for the same category of items and services."[6]

Routine costs are covered by Original Medicare unless they are otherwise excluded as a non-covered Medicare benefit, or are non-covered based on a national coverage decision. NCD 310.1 provides details regarding what services are considered "routine" costs, and what services are not considered routine costs. Table 1 below outlines who holds primary financial responsibility for various services when a member is enrolled in a qualifying clinical trial:

Table 1. Financial Liability for Costs of a Qualifying Clinical Trial	
Original Medicare (or Medicare Administrative Contractor)	**Medicare Advantage Organizations (MAOs, or MA Plans)**
• Items or services typically provided absent a clinical trial (e.g., conventional care); • Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; • Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications.	• The remaining original Medicare coinsurance minus the plan's normal member copays appropriate for the type of service rendered (the Medicare deductibles are waived[7]). (MEOB required) • Services *to diagnose conditions* that may be covered in the context of a clinical trial. (Expected to be performed prior to trial enrollment, so MEOB not required.) • Services provided as *follow-up care* to clinical trial services when medically necessary. (If the member has completed the clinical trial, MEOB is not required.) • Services and/or complications *unrelated* to the clinical trial, as long as the services are medically reasonable and necessary. (MEOB not required)

Not all services are considered "routine" costs. NCD 310.1 provides additional details regarding what services are NOT considered "routine" costs. Examples include, but are not limited to: (a) The investigational item or service, itself unless otherwise covered outside of the clinical trial; (b) Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); or (c) Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.

When a claim is submitted to the MAO for services that are part of a qualifying clinical trial, the claim should be accompanied with the Medicare Explanation of Benefits (MEOB). The MAO will then process the claim as the secondary carrier according to Medicare guidelines described above. Claims submitted without the MEOB will be denied, with a message instructing the provider to submit the claim to Original Medicare.

NOTE: If a clinical trial is not approved by Medicare, then it is not considered a "qualifying clinical trial." This means the trial and its related services would not be covered by either Medicare or the MAO. This Medicare-approval requirement is outlined in the member benefit contract or Evidence of Coverage (EOC).

While prior authorization for clinical trial services is not required, for the member's financial protection, the health plan recommends members or providers confirm with Medicare first that a clinical trial has been approved by Medicare. The CMS web page of approved registries, trials, and facilities does not constitute a complete list of all Medicare-approved trials, studies, and registries.[8] Therefore, if a trial/registry/study is not listed on the CMS website as Medicare-approved, the approval-status information for that study is not available to the MAO. The provider or member should call 1-800-MEDICARE to confirm Medicare approval status.

REGISTRIES

For registries required under a national Coverage with Evidence Development (CED) policy, please see the related policy in Cross References.

For registries that are not part of a clinical trial or national CED policy, Medicare does not consider the patient to be participating in a clinical research study, and ordinary Medicare claim coding and processing will apply. However, we encourage the submission of the NCT number to confirm the registry the member is enrolled in, especially when a registry may allow coverage for a service under a local coverage determination (LCD). For example, the Noridian local coverage determination (LCD) L34151 allows coverage for stereotactic body radiation therapy [SBRT] as a treatment for prostate cancer with enrollment in a clinical registry, such as the Registry for Prostate Cancer Radiosurgery (RPCR; this registry is just an example, it is not all-inclusive of relevant registries).

INVESTIGATIONAL DEVICE EXEMPTION (IDE) STUDIES

Medicare may cover certain devices provided in Food and Drug Administration (FDA)-approved IDE studies. These studies include Category A and Category B devices. According to the *Medicare Managed Care Manual, Chapter 4 – Benefits and Beneficiary Protections, §10.7.2 – Payment for Investigational Device Exemption (IDE) Studies*, "MAOs are responsible for payment of claims related to enrollees' participation in both Category A and B IDE studies that are covered by the MAC with jurisdiction over the MA plan's service area. The MAO is responsible for payment of routine care items and services in CMS-approved Category A and Category B IDE studies. The MAO is also responsible for CMS-approved Category B devices. CMS will not approve Category A devices because they are statutorily excluded from coverage."

CROSS REFERENCES

Investigational (Experimental) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services, Medicine, Policy No. M-149

Coverage with Evidence Development (CED) Studies and Registries, Medicine, Policy No. M-156

REFERENCES

1. CMS Manual System Change Request (CR) 5805, dated January 18, 2008
2. *Medicare Benefit Policy Manual, Chapter 14 - Medical Devices,* §20 – Food and Drug Administration (FDA)-Approved Investigational Device Exemption (IDE) Studies
3. *Medicare National Coverage Determination (NCD) Manual*, Routine Costs in Clinical Trials (310.1)
4. *Medicare Benefit Policy Manual, Chapter 14 - Medical Devices, §10 - Coverage of Medical Devices*
5. *Food and Drug Administration (FDA) website:* https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device#step1 [Last Cited 11/24/2024]**Error! Hyperlink reference not valid.***Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections*, *§10.7 – Clinical Trials,* §10.7.1 – Payment for Services
6. Noridian webpage for *Clinical Trials*; Available at: https://med.noridianmedicare.com/web/jfb/topics/clinical-trials [Last Cited 11/24/2024*]*
7. Medicare webpage *"Medicare Approved Facilities/Trials/Registries"*
8. Medicare webpage "Medicare Clinical Trial Policies"
9. *Medicare Claims Processing Manual, Chapter 32 - Billing Requirements for Special Services*, §68.1 – Billing Requirements for Providers Billing for Routine Care Items and Services in Category A IDE Studies
10. *Medicare Claims Processing Manual, Chapter 32 - Billing Requirements for Special Services*, §68.4 - Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category B IDE
11. *Medicare Claims Processing Manual, Chapter 32 - Billing Requirements for Special Services*, §68.2 – Contractor Review of Category B IDEs
12. *Medicare Benefit Policy Manual, Chapter 14 - Medical Devices,* §20.1 - Medicare Requirements for Coverage of Items and Services in FDA-approved Category A and B IDE Studies
13. *Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections*, *§10.7 – Clinical Trials,* §10.7.2 – Investigational Device Exemption (IDE)
14. *Medicare Managed Care Manual, Chapter 8 - Payments To Medicare Advantage Organizations*, §40.4.3 - Special Rules for the September 2000 NCD on Clinical Trials
15. *Medicare Managed Care Manual, Chapter 8 - Payments To Medicare Advantage Organizations*, §40.4.4 - Category B Investigational Device Exemption (IDE) Trials
16. Medicare webpage "*Medicare Coverage Related to Investigational Device Exemption (IDE) Studies*"
17. NCT number searches: http://www.clinicaltrials.gov/
18. Product Classification searches (Class I, Class II, or Class III): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm
19. Medicare "*Mandatory Reporting of National Clinical Trial (NCT) Identifier Numbers on Medicare Claims – Qs & As*" Document

20. Noridian Article for Investigational Device Exemptions (IDE) - IDE Documentation Requirements for Studies with an FDA Approval dated January 01, 2015 or later (A54917)

CODING

NOTE: Services for clinical trials, registries, and IDEs are recognized by the use of the applicable clinical trial number, the modifiers –Q0 and –Q1, and the use of ICD-9 diagnosis code V70.7/ICD-10 diagnosis code Z00.6 (in either the primary/secondary positions)

Codes	Number	Description
CPT	N/A	
HCPCS	N/A	

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*