IMPORTANCE REMINDER: The health plan’s Medicare Advantage Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with the member Evidence of Coverage (EOC) booklet. Benefit determinations are based in all cases on any applicable EOC language and any applicable CMS policy. To the extent there may be any conflict, applicable EOC language or applicable CMS policy take precedence over the health plan’s Medicare Advantage Medical Policy.

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).

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. This includes "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)
• 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.

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 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.

**Associated Clinical Documentation:**
It is critical that the list of information below is submitted for review to determine if the policy guidelines 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.
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:** 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”\(^{(4, 5)}\)
# MEDICARE MEDICAL POLICY CRITERIA

<table>
<thead>
<tr>
<th>Type of Clinical Trial, Registry, or Study</th>
<th>Financial Responsibility/Where to submit claims</th>
<th>Covered / Non-Covered Items and Services</th>
<th>Party Responsible for Study Approval and/or Criteria Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical trials not otherwise specified</td>
<td>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)</td>
<td>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).</td>
<td>Medicare. Provider should call 1-800-MEDICARE to confirm Medicare-approval of the requested clinical trial/registry.</td>
</tr>
<tr>
<td><strong>Note:</strong> Registries NOT part of a clinical trial or Medicare Coverage with Evidence Development (CED) policy do not fall under this provision.</td>
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<tr>
<td>Category A and Category B Investigational Device Exemption (IDE) Study</td>
<td>MAO plan Documentation to support the IDE study has been approved by CMS or by the local contractor should be included.</td>
<td><strong>Effective 1/1/2015</strong> – 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. <strong>Prior to 1/1/2015</strong> – Same coverage for Category B IDEs, but MAOs are NOT responsible for any items or services in CMS-approved Category A IDE studies.</td>
<td><strong>Effective 1/1/2015</strong> – Medicare reviews and approves via a centralized review process. Approved IDE studies are added to CMS “Approved IDE Studies” website. <strong>Prior to 1/1/2015</strong> – Local MACs determined IDE coverage. If no LCD or LCA exists to address coverage, the provider will need to supply documentation of MAC approval.</td>
</tr>
<tr>
<td>Coverage with Evidence Development (CED) Studies and Registries</td>
<td>See Cross References for separate Medicare Advantage Medical Policy, Medicine, Policy No. 156</td>
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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

<table>
<thead>
<tr>
<th>Original Medicare (or Medicare Administrative Contractor)</th>
<th>Medicare Advantage Organizations (MAOs, or MA Plans)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Items or services typically provided absent a clinical trial (e.g., conventional care);</td>
<td>• The remaining original Medicare coinsurance minus the plan’s normal member copays appropriate for the type of service rendered (the Medicare deductibles are waived).</td>
</tr>
<tr>
<td>• 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;</td>
<td>• Services to diagnose conditions that may be covered in the context of a clinical trial.</td>
</tr>
<tr>
<td>• 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.</td>
<td>• Services provided as follow-up care to clinical trial services when medically necessary.</td>
</tr>
<tr>
<td></td>
<td>• Services and/or complications unrelated to the clinical trial, as long as the services are medically reasonable and necessary.</td>
</tr>
</tbody>
</table>

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.*

*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) (i.e., enrollment in a clinical registry such as the Registry for Prostate Cancer Radiosurgery, or RPCR, may qualify stereotactic body radiation therapy [SBRT] for coverage as a treatment for prostate cancer under Noridian LCD L34151).

**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 IDE studies and for routine care items and services, as well as the Category B device under study in Category B IDE studies.”

REFERENCES
4. Medicare Benefit Policy Manual, Chapter 14 - Medical Devices, §10 - Coverage of Medical Devices
5. Food and Drug Administration (FDA) website: http://www.fda.gov/AboutFDA/Transparency/Basics/ucm211822.htm
6. Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, §10.7 – Clinical Trials, §10.7.1 – Payment for Services
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, §68.5 – Contractor Review of Category B IDEs
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):
19. Noridian Local Coverage Determination (LCD) for Non-Covered Services (L35008)
   (This LCD can be found on the Medicare Coverage Database website)
20. Medicare “Mandatory Reporting of National Clinical Trial (NCT) Identifier Numbers on Medicare Claims – Qs & As” Document

CROSS REFERENCES

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

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

<table>
<thead>
<tr>
<th>CODES</th>
<th>NUMBER</th>
<th>DESCRIPTION</th>
</tr>
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<tbody>
<tr>
<td>Note:</td>
<td></td>
<td>Services for clinical trials 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)</td>
</tr>
<tr>
<td>CPT</td>
<td>N/A</td>
<td></td>
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<tr>
<td>HCPCS</td>
<td>N/A</td>
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