Experimental Procedures and Items, Investigational Devices, and Clinical Trials

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Instructions for Use

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Related Policies
None

Coverage Rationale

Experimental and investigational procedures, items, and medications are considered not Reasonable and Necessary. Investigational Device Exemption (IDE) studies are only covered when the Medicare coverage requirements are met. Routine costs associated with Medicare approved clinical trials is Medicare's financial responsibility.

Refer to:

- Medicare Benefit Policy Manual, Chapter 14, §20 – Food and Drug Administration (FDA) – Approved Investigational Exemption (IDE) Studies
- Medicare Program Integrity Manual, Chapter 13, §13.5.4 – Reasonable and Necessary Provisions in LCDs
- Medicare Claims Processing Manual, Chapter 32, §68 – Investigational Device Exemption (IDE) Studies

Investigational Device Exemption (IDE) Studies

Category A Device

Category A (Experimental) Device refers to a device for which "absolute risk" of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective.

The Medicare Advantage Organization (MAO) is responsible for payment of Routine Care Items and Services in Centers for Medicare & Medicaid (CMS)-approved Category A IDE studies that are covered by the Medicare Administrative Contractor (MAC) with jurisdiction over the MA plan's service area. CMS will not approve Category A devices because they are statutorily excluded from coverage.

Note: CMS finalized changes to the IDE regulations (42 CFR § 405 Subpart B), effective January 1, 2015. CMS added criteria for coverage of IDE studies and changed from local MAC review and approval of IDE studies to a centralized review and approval of IDE studies. An approval for a Category A (Experimental) IDE study will allow coverage of Routine Care Items and Services furnished in the study, but not of the Category A device, which is statutorily excluded from coverage. An approval for a Category B (Nonexperimental/investigational) IDE study will allow coverage of the Category B device and the Routine Care Items and Services in the trial. A listing of all CMS-approved Category A IDE studies and Category B IDE studies is posted on the CMS Coverage website located at http://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html and published in the Federal Register.

Refer to the:

- Medicare Managed Care Manual, Chapter 4, §10.7.2 – Payment for Investigational Device Exemption (IDE) Studies.
- Medicare Benefit Policy Manual, Chapter 14, §20 – Food and Drug Administration (FDA)-Approved Investigational Device Exemption (IDE) Studies.

- Medicare Coverage Related to Investigational Device Exemption (IDE) Studies.

Category B Device

Category B (Nonexperimental/Investigational) Device refers to a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type.

MAOs are responsible for payment of claims related to members' participation in Category 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 B IDE studies. The MAO is also responsible for CMS-approved Category B devices.

Note: CMS finalized changes to the IDE regulations (42 CFR § 405 Subpart B), effective January 1, 2015. CMS added criteria for coverage of IDE studies and changed from local MAC review and approval of IDE studies to a centralized review and approval of IDE studies. An approval for a Category A (Experimental) IDE study will allow coverage of Routine Care Items and Services furnished in the study, but not of the Category A device, which is statutorily excluded from coverage. An approval for a Category B (Nonexperimental/investigational) IDE study will allow coverage of the Category B device and the Routine Care Items and Services in the trial. A listing of all CMS-approved Category A IDE studies and Category B IDE studies is posted on the CMS Coverage website located at http://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html and published in the Federal Register.

Refer to the:

- Medicare Managed Care Manual, Chapter 4, §10.7.2 – Payment for Investigational Device Exemption (IDE) Studies.
- Medicare Benefit Policy Manual, Chapter 14, §20 – Food and Drug Administration (FDA)-Approved Investigational Device Exemption (IDE) Studies.
- Medicare Coverage Related to Investigational Device Exemption (IDE) Studies.

Payment for Investigational Device Exemption (IDE) Studies

The MAO is responsible for payment of claims related to the members' 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.

Refer to the Medicare Claims Processing Manual, Chapter 32, §69.9 – Billing and Processing Fee for Service Claims for Covered Clinical Trial Services Furnished to Managed Care Enrollees.

Clinical Trials (Also Known as Clinical Research Study)

Coverage with Evidence Development (CED)

In NCDs requiring CED, Medicare covers items and services in CMS-approved CED studies. MAOs are responsible for payment of items and services in CMS-approved CED studies unless CMS determines that the significant cost threshold is exceeded for that item or service (refer to 42 CFR 422.109). Approved CED studies are posted on the CMS Coverage with Evidence Development webpage at http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html. Billing instructions are issued for each NCD.

Refer to the Medicare Managed Care Manual, Chapter 4, §10.7.3 – Payment for Clinical Studies Approved Under Coverage with Evidence Development (CED).

Payment for Clinical Studies Approved Under Coverage with Evidence Development (CED)

In NCDs requiring CED, Medicare covers items and services in CMS approved CED studies. The MAO is responsible for payment of items and services in CMS approved CED studies unless CMS determines that the significant cost threshold is exceeded for that item or service (see 42 CFR 422.109).

Refer to the Medicare Claims Processing Manual, Chapter 32, §69.9 – Billing and Processing Fee for Service Claims for Covered Clinical Trial Services Furnished to Managed Care Enrollees.

Complications Arising From Participating in All Qualifying Clinical Trials

Medicare covers the routine costs of qualifying clinical trials for all Medicare members, 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 all qualifying clinical trials. The Clinical Trial NCD defines what routine costs means and also clarifies when items and services are Reasonable and Necessary. All other Medicare rules apply.

Refer to the Medicare Managed Care Manual, Chapter 4, §10.7.1, Payment for Services.

Cost Sharing for Clinical Trials

MAOs pay the member 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. This cost-sharing reduction requirement applies to all qualifying clinical trials. MAOs may not choose the clinical trials or clinical trial items and services to which this policy applies. The MAO owes this difference even if the member has not yet paid the clinical trial provider. Additionally, the member's in-network cost-sharing portion must also be included in the plan's out-of-pocket maximum calculation.

To be eligible for reimbursement, members (or providers acting on their behalf) must notify their plan that they have received qualified clinical trial services and provide documentation of the cost-sharing incurred, such as a provider bill. MAOs are also permitted to seek MA member original Medicare cost-sharing information directly from clinical trial providers.

Refer to the Medicare Managed Care Manual, Chapter 4, §10.7.1, Payment for Services.

Refer to the member's evidence of coverage (EOC) for additional information.

Routine Costs Associated with Medicare Approved Clinical Trial

Medicare has outlined the following payment rules for qualified clinical trials:

- In accordance with applicable Medicare fee-for-service rules, MACs will directly pay providers for routine services associated with a qualified clinical trial furnished to a UnitedHealthcare Medicare member.
- Medicare MACs make payments on behalf of MA organizations directly to providers of covered routine services associated with a qualified clinical trial.
  Note: If UnitedHealthcare receives a bill with clinical trial codes, these bills will not be paid but will be returned to the provider. UnitedHealthcare will inform the provider that the bill should be sent to the appropriate MAC.
- The member is not responsible for meeting either Part A or Part B deductibles for routine services obtained through qualified clinical trials.
- The member is liable for the coinsurance amounts applicable to services paid under traditional Medicare rules when participating in a qualified clinical trial.

Notes:

- CMS will make payments for MA members on a fee-for-service basis for covered clinical trial costs under the September 2000 NCD. This policy is in effect until further notice. In CY 2000, CMS determined that the cost of covering these new benefits was not included in the 2001 MA capitated payment rates, and since this cost met the threshold for "significant cost" under 42 CFR 422.109(a), Medicare paid for covered clinical trial services outside of the capitated payment rate. CMS continues the policy of making payments on a fee-for-service basis for covered clinical trial items and services provided MA members until further notification, because the capitation rates have not been appropriately adjusted to account for costs of this NCD, as required under §1853(c)(7) of the Social Security Act (the Act).
- Member should be directed to call 1-800-MEDICARE to determine if a clinical trial is approved by Medicare and for additional information on Clinical Trials. No prior authorization by UnitedHealthcare MA Plan is required.

Refer to the Medicare Managed Care Manual, Chapter 8, §40.4.3 – Special Rules for the September 2000 NCD on Clinical Trials.

For Medicare coverage information on Clinical Trials and list of applicable Medicare benefit categories for routine costs associated with Medicare approved clinical trials (**Note**: This may not be an exhaustive list of all applicable Medicare benefit categories), refer to the NCD for Routine Costs in Clinical Trials (310.1).

Also refer to the Medicare Clinical Trial Policies at: https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies.

To access the list of CMS approved clinical trials/clinical research studies, go to Medicare Approved Facilities/Trials/Registries. Select the applicable Facility/Trial/Registry from the list on the left column to view the approved clinical trials/clinical research studies.

Definitions

Category A (Experimental) Device: A device for which "absolute risk" of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective. 42 Code of Federal Regulations (CFR) § 405 Subpart B.

Category B (Nonexperimental/Investigational) Device: A device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type. 42 Code of Federal Regulations (CFR) § 405 Subpart B.

Coverage with Evidence Development (CED): CED is a pathway whereby, after a CMS and AHRQ review, Medicare covers items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data. CMS and AHRQ established CED based on section 1862(a)(1)(E) of the Act in 2006 and have used the NCD process to provide public notice and to obtain the public's input. Medicare Coverage Document - Coverage with Evidence Development.

Investigational Device Exemption (IDE): An FDA-approved IDE application that permits a device, which would otherwise be subject to marketing approval or clearance, to be shipped lawfully for the purpose of conducting a clinical study in accordance with 21 U.S.C. 360j(g) and 21 CFR part 812. 42 Code of Federal Regulations (CFR) § 405 Subpart B.

Routine Care Items and Service: Items and services that are otherwise generally available to Medicare beneficiaries (that is, a benefit category exists, it is not statutorily excluded, and there is no national noncoverage decision) that are furnished during a clinical study and that would be otherwise furnished even if the beneficiary were not enrolled in a clinical study. Medicare Benefit Policy Manual, Chapter 14, §20 – Food and Drug Administration (FDA) – Approved Investigational Exemption (IDE) Studies.

Reasonable and Necessary: Evidence exists to consider an item or service to be Reasonable and Necessary if it is:

- Safe and effective;
- Not experimental or investigational (Exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered Reasonable and Necessary); and
- Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
  - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
  - Furnished in a setting appropriate to the patient's medical needs and condition;
  - Ordered and furnished by qualified personnel;
  - One that meets, but does not exceed, the patient's medical need; and
  - At least as beneficial as an existing and available medically appropriate alternative.

Medicare Program Integrity Manual, Chapter 13, §13.5.4 – Reasonable and Necessary Provisions in LCDs.

Policy History/Revision Information

Date	Summary of Changes
04/01/2026	**Coverage Rationale** ***Investigational Device Exemption (IDE) Studies*** Payment for Investigational Device Exemption (IDE) Studies • Added language to indicate: ○ The Medicare Advantage Organization (MAO) is responsible for payment of claims related to the members' participation in both Category A and B Investigational Device Exemption (IDE) studies that are covered by the Medicare Administrative Contractor (MAC) with jurisdiction over the Medicare Advantage (MA) plan's service area

Date	Summary of Changes
	○ 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 ○ Centers for Medicare & Medicaid (CMS) will not approve Category A devices because they are statutorily excluded from coverage ▪ Added instruction to refer to the *Medicare Claims Processing Manual, Chapter 32, §69.9 – Billing and Processing Fee for Service Claims for Covered Clinical Trial Services Furnished to Managed Care Enrollees* ***Clinical Trials (Also Known as Clinical Research Study)*** Payment for Clinical Studies Approved Under Coverage with Evidence Development (CED) • Added language to indicate: ○ In National Coverage Determinations (NCDs) requiring Coverage with Evidence (CED), Medicare covers items and services in CMS approved CED studies ○ The MAO is responsible for payment of items and services in CMS approved CED studies unless CMS determines that the significant cost threshold is exceeded for that item or service (refer to *Code of Federal Regulations, Title 42 CFR 422.109*) • Added instruction to refer to the *Medicare Claims Processing Manual, Chapter 32, §69.9 – Billing and Processing Fee for Service Claims for Covered Clinical Trial Services Furnished to Managed Care Enrollees* Routine Costs Associated with Medicare Approved Clinical Trial • Replaced language indicating: ○ "In accordance with applicable Medicare fee-for-service rules, Medicare Administrative Contractors (MACs) will directly pay providers for *clinical trial services* furnished to a UnitedHealthcare Medicare member" with "in accordance with applicable Medicare fee-for-service rules, MACs will directly pay providers for *routine services associated with a qualified clinical trial* furnished to a UnitedHealthcare Medicare member" ○ "Medicare MACs make payments on behalf of MA organizations directly to providers of covered *clinical trial services, on a fee-for-service basis*" with "Medicare MACs make payments on behalf of MA organizations directly to providers of covered *routine services associated with a qualified clinical trial*" ○ "The member is liable for the coinsurance amounts applicable to services paid under *Medicare fee-for-service* rules when participating in a qualified clinical trial" with "the member is liable for the coinsurance amounts applicable to services paid under *traditional* Medicare rules when participating in a qualified clinical trial" **Definitions** • Added definition of: ○ Category A (Experimental) Device ○ Category B (Nonexperimental/Investigational) Device ○ Coverage with Evidence Development (CED) ○ Investigational Device Exemption (IDE) **Supporting Information** • Archived previous policy version MMP393.04

Instructions for Use

The Medicare Advantage Policy documents are generally used to support UnitedHealthcare coverage decisions. It is expected providers retain or have access to appropriate documentation when requested to support coverage. This document may be used as a guide to help determine applicable:

- Medical necessity coverage guidelines; including documentation requirements, and/or
- Medicare coding or billing requirements.

Medicare Advantage Policies are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates. This Policy is provided for informational purposes and does not constitute medical advice. It is intended to serve only as a general reference and is not intended to address every aspect of a clinical situation. Physicians and patients should not rely on this information in making health care decisions. Physicians and patients must exercise their independent clinical discretion and judgment in determining care. Treating physicians and healthcare providers are solely

responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes this policy. For more information on a specific member's benefit coverage, call the customer service number on the back of the member ID card or refer to the Administrative Guide.

Medicare Advantage Policies are developed as needed, are regularly reviewed, and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policies at any time by publishing a new version on this website. Medicare source materials used to develop these policies may include, but are not limited to, CMS statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and manuals. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. The information presented in this Policy is believed to be accurate and current as of the date of publication. Where there is a conflict between this document and Medicare source materials, the Medicare source materials apply. Medicare Advantage Policies are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

Providers are responsible for submission of accurate claims. Medicare Advantage Policies are intended to ensure that coverage decisions are made accurately. UnitedHealthcare Medicare Advantage Policies use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

For members in UnitedHealthcare Medicare Advantage plans where a delegate manages utilization management and prior authorization requirements, the delegate’s requirements need to be followed.