

Experimental Procedures and Items, Investigational Devices and Clinical Trials

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[Instructions for Use](#)

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Related Medicare Advantage Policy Guidelines
• Percutaneous Left Atrial Appendage Closure (LAAC) (NCD 20.34)
• Routine Costs in Clinical Trials (NCD 310.1)

Coverage Guidelines

Experimental and investigational procedures, items and medications are not covered. 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.

Experimental and Investigational Procedures

Experimental and investigational procedures, items and medications are not covered.

For coverage of drugs and biologicals, refer to the Coverage Summaries titled [Medications/Drugs \(Outpatient/Part B\)](#) and [Chemotherapy, and Associated Drugs and Treatments](#)

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 CMS-approved Category A IDE studies that are covered by the 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: The local MAC(s) with jurisdiction over the MA plan’s service area determines coverage of IDE studies. CMS finalized changes to the IDE regulations (42 CFR § 405 Subpart B), effective January 1, 2015. A listing of all CMS-approved Category A IDE studies and Category B IDE studies will be posted on the CMS Coverage webpage site located at <http://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html> and published in the Federal Register. (Accessed August 2, 2021)

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](#)

Accessed August 2, 2021)

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: The local MAC(s) with jurisdiction over the MA plan's service area determines coverage of IDE studies. CMS finalized changes to the IDE regulations (42 CFR § 405 Subpart B), effective January 1, 2015, a listing of all CMS-approved Category A IDE studies and Category B IDE studies will be posted on the CMS Coverage webpage site located at <http://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html> and published in the Federal Register.

(Accessed August 2, 2021)

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](#)

(Accessed August 2, 2021)

Clinical Trials (also known as Clinical Research Study)

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, Medicare Administrative Contractors (MACs) will directly pay providers for clinical trial services 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.
Note: If UnitedHealthcare Medicare receives a bill with clinical trial codes, these bills will not be paid but will be returned to the provider. UnitedHealthcare Medicare 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 Medicare fee-for-service 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](#). (Accessed August 2, 2021)

For Medicare coverage information on Clinical Trials, refer to the [NCD for Routine Costs in Clinical Trials \(310.1\)](#). (Accessed August 2, 2021)

Also refer to the Medicare Clinical Trial Policies at:

<http://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/index.html?redirect=/ClinicalTrialPolicies/>. (Accessed August 2, 2021)

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. (Accessed August 2, 2021)

Coverage with Evidence Development (CED)

In national coverage determinations (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 (see 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. (Accessed August 2, 2021)

Refer to the [Medicare Managed Care Manual, Chapter 4, §10.7.3 – Payment for Clinical Studies Approved Under Coverage with Evidence Development \(CED\)](#). (Accessed August 2, 2021)

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](#). (Accessed August 2, 2021)

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 – Clinical Trials -Payment for Services](#). (Accessed August 2, 2021)

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

Evaluation for Clinical Trial

- The UnitedHealthcare Medicare Advantage Plan or its delegate(s) will cover for one (1) specialist referral for evaluation (in-network or out-of-network) of possible treatment of member, including a referral to determine if a member is a candidate for a Medicare approved clinical trial or set of trials. Refer to the Coverage Summary titled [Second and Third Opinions](#).

- The UnitedHealthcare Medicare Advantage Plan or its delegate(s) will not cover the cost of services and tests solely for the purpose for the member to qualify for the clinical trial as they would not be considered routine costs under the definition of the NCD.
- Once a member signs a Medicare approved clinical trial consent form, Original Medicare is responsible for all subsequent routine clinical trial costs.

Definitions

Medical Device (FDA Definition): An instrument, apparatus, implement, machine, contrivance, implant, in-vitro reagent, or other similar or related article, including any component or part of accessory that is:

- Recognized in the official National Formulary, or the U.S. Pharmacopoeia, or any supplement to them;
- Intended for the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals;
- Intended to affect the structure or any function of the body of man or other animals, and which does not achieve 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.

[Medicare Benefit Policy Manual, Chapter 14, §10 – Coverage of Medical Devices](#). (Accessed August 2, 2021)

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](#). (Accessed August 2, 2021)

Policy History/Revision Information

Date	Summary of Changes
08/17/2021	<ul style="list-style-type: none"> • Routine review; no change to coverage guidelines • Archived previous policy version MCS033.01

Instructions for Use

This information is being distributed to you for personal reference. The information belongs to UnitedHealthcare and unauthorized copying, use, and distribution are prohibited. This information is intended to serve only as a general reference resource 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. Each benefit plan contains its own specific provisions for coverage, limitations, and exclusions as stated in the Member's Evidence of Coverage (EOC)/Summary of Benefits (SB). If there is a discrepancy between this policy and the member's EOC/SB, the member's EOC/SB provision will govern. The information contained in this document is believed to be current as of the date noted.

The benefit information in this Coverage Summary is based on existing national coverage policy; however, Local Coverage Determinations (LCDs) may exist and compliance with these policies are required where applicable.

There are instances where this document may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG). In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)).

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