Experimental Procedures and Items, Investigational Devices and Clinical Trials

Approved by: UnitedHealthcare Medicare Benefit Interpretation Committee  Last Review Date: 08/21/2018

Related Medicare Advantage Policy Guidelines:

- Percutaneous Left Atrial Appendage Closure (LAAC) (NCD 20.34)
- Routine Costs in Clinical Trials (NCD 310.1)

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I. COVERAGE

**Coverage Statement:** 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.

**Guidelines/Notes:**

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

   *For coverage of drugs and biologicals, refer to the [Coverage Summary for Medications/Drugs (Outpatient/Part B)](http://www.cms.gov/Medicare/Coverage/) and [Coverage Summary for Chemotherapy, and Associated Drugs and Treatments](http://www.cms.gov/Medicare/Coverage/).*

2. **Investigational Device Exemption (IDE)**
   a. **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 MAO Medicare Advantage Organization 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.

      *See the [Medicare Managed Care Manual, Chapter 4, §10.7.2 – Payment for Investigational Device Exemption (IDE) Studies](http://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html). (Accessed August 15, 2018)*

      *Also see the [Medicare Benefit Policy Manual, Chapter 14, §20 - Food and Drug Administration (FDA)-Approved Investigational Device Exemption (IDE) Studies](http://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html). (Accessed August 15, 2018)*

      *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](http://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html) and published in the Federal Register. (Accessed August 15, 2018)*

   b. **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 enrollees’ 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.
See the Medicare Managed Care Manual, Chapter 4, §10.7.2 – Payment for Investigational Device Exemption (IDE) Studies. (Accessed August 15, 2018)

Also see the Medicare Benefit Policy Manual, Chapter 14, §20 - Food and Drug Administration (FDA)-Approved Investigational Device Exemption (IDE) Studies. (Accessed August 15, 2018)

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 15, 2018)

3. Clinical Trials (also known as Clinical Research Study)
   a. 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 (MAC) 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. See the Medicare Managed Care Manual, Chapter 8, §40.4.3 - Special Rules for the September 2000 NCD on Clinical Trials. Also see the Medicare Managed Care Manual Chapter 4, §10.7.1 – Payment for Services. (Accessed August 15, 2018)

- 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 enrollees 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 enrollees 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.

For Medicare coverage information on Clinical Trials, refer to the NCD for Routine Costs
**in Clinical Trials (310.1),** (Accessed August 15, 2018)


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 15, 2018)

b. **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.

See the Medicare Managed Care Manual, Chapter 4, §10.7.3 – Payment for Clinical Studies Approved Under Coverage with Evidence Development (CED). (Accessed August 15, 2018)

c. **Complications Arising from Participating in All Qualifying Clinical Trials**

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 all qualifying clinical trials. The Clinical Trial National Coverage Determination (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 Clinical Trials. (Accessed August 15, 2018)

d. **Cost Sharing for Clinical Trials**

Medicare Advantage (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. This cost-sharing reduction requirement applies to all qualifying clinical trials. MA Organizations (MAO) cannot 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. See the Medicare Managed Care Manual, Chapter 4, §10.7.1 - Clinical Trials - Payment for Services. (Accessed August 15, 2018)

To be eligible for reimbursement, beneficiaries (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 Medicare Summary Notice (MSN). MAOs are also permitted to seek MA member Original Medicare cost-sharing information directly from clinical trial providers. Refer to the member’s Evidence of Coverage (EOC)
e. 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. See the Coverage Summary for 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.

II. 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:
1) recognized in the official National Formulary, or the U.S. Pharmacopoeia, or any supplement to them;
2) intended for the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals;
3) 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.


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, §10 – Coverage of Medical Devices. (Accessed July 26, 2018)

III. REFERENCES

See above

IV. REVISION HISTORY

04/01/2019 Updated policy introduction; added language to clarify:
- There are instances where [the Coverage Summary] 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
Experimental Procedures and Items, Investigational Devices and Clinical Trials

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08/21/2018 Annual review with the following updates:

Guideline 2.b Category B Device – in the Note section; adding the following language “CMS finalized changes to the IDE regulations (42 CFR § 405 Subpart B)," for consistency with the referenced MBPM.

Guideline 3.d Cost Sharing for Clinical Trials – Adding “for Clinical Trials” to guideline title; for consistency with the referenced MBPM.

06/19/2018 Re-review with the following updates:

Guideline 3.a (Routine Costs Associated with Medicare Approved Clinical Trial)
- Deleted references to “carriers and intermediaries”; replaced with “Medicare Administrative Contractors (MAC)”
- Moved the following language from the Note Section to the Guideline Section and added reference link to the Medicare Managed Care Manual Chapter 4, §10.7 – Clinical Trials.

Medicare MACs make payments on behalf of MA organizations directly to providers of covered clinical trial services, on a fee-for-service basis. See the Medicare Managed Care Manual, Chapter 8, §40.4.3 - Special Rules for the September 2000 NCD on Clinical Trials.

08/15/2017 Guideline 2.a (Category A Device) –
- Updated language to reflect the Medicare Managed Care Manual, Chapter 4, §10.7.2 – Payment for Investigational Device Exemption (IDE) Studies.

Definitions
- Experimental Procedures and Items- deleted from Coverage Summary; unable to find same language in any CMS reference.

08/16/2016 Annual review with the following updates:

Guideline 2.a (Category A Device) –
- Deleted the following verbiage “Medicare covers routine care items and services furnished in an FDA-approved Category A IDE study if CMS (or its designated entity) determines that the Medicare coverage IDE study criteria are met. Category A devices are statutorily not covered by Medicare.”
- Updated with the following verbiage from the Medicare Managed Care Manual, Chapter 4, Section 10.7.2 “The MAO Medicare Advantage Organization is responsible for payment of routine care items and services in CMS-approved Category IDE studies that are covered by the MAC with jurisdiction over the MA plan’s service area.”
- Added the following to the Note: “CMS finalized changes to the IDE regulations (42 CFR § 405 Subpart B),”

Guideline 2.b (Category B) - Deleted the following verbiage “Medicare may make payment for a Category B IDE device and routine care items and services furnished in an FDA-approved Category B IDE study if CMS (or its designated entity) determines prior to the submission of the first related claim that the Medicare
coverage IDE are met. The MAO is responsible for payment of routine care items and services in CMS-approved Category B IDE studies, as well as the Category B device under study in Category B IDE studies.” Updated with the following verbiage from the Medicare Managed Care Manual, Chapter 4, Section 10.7.2 “MAOs are responsible for payment of claims related to enrollees’ 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.”

09/15/2015 Annual review without any updates.

04/21/2015 Coverage Statement
• Updated the coverage statement, deleted “FDA Category B Devices”, replaced with “Investigational Device Exemption (IDE) studies.

Guideline 2.a (Category A Device)
• Updated coverage guideline based on the updated Medicare Managed Care Manual, Chapter 4, Section 10.7.2 Payment for Investigational Device Exemption (IDE) Studies) and Medicare Benefit Policy Manual, Chapter 14, Section 20 - Food and Drug Administration (FDA) Approved Investigational Device Exemption (IDE) Studies.

Guideline 2.b (Category B Device)
• Updated coverage guideline based on the updated Medicare Managed Care Manual, Chapter 4, Section 10.7.2 Payment for Investigational Device Exemption (IDE) Studies) and Medicare Benefit Policy Manual, Chapter 14, Section 20 - Food and Drug Administration (FDA)-Approved Investigational Device Exemption (IDE) Studies.

Guideline 3.b (Coverage with Evidence Development)
• Updated coverage guideline based on the updated Medicare Managed Care Manual, Chapter 4, Section 10.7.3 – Payment for Clinical Studies Approved Under Coverage with Evidence Development (CED).

Definitions
• Medical Device (FDA Definition) - changed the reference link from FDA to Medicare Benefit Policy Manual, Chapter 14, Section 10 – Coverage of Medical Devices
• FDA-Category A Devices (Experimental/Investigational) - moved to Guideline 2.a (Category A Device)
• FDA Category B Devices (Non-Experimental/and/or Investigational) - moved to Guideline 2.b (Category B Device)
• Routine Care Items and Service - added definition.

09/16/2014 Annual review with the following updates:
Guideline #3.e (Evaluation for Clinical Trial) - revised the guidelines to indicate:
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.
Definitions: Updated the definition of Medical Device based on the FDA definition.

04/15/2014 Guideline #2.a (Category A Devices) – added as not covered by Medicare unless they are part of a qualifying clinical trial.

Definitions – updated the definition of FDA Category A based on the Medicare Benefit Policy Manual; also updated the definition of FDA Category B Devices based on the Federal Register Final Rule dated December 10, 2013.

10/24/2013 Annual review with the following updates:

Guideline #2 (Investigational Devices) – added reference links for accessing FDA approved Category B devices.

Guideline #3 (Clinical Trials) - added reference links to the CMS approved clinical trials/clinical research studies website.

04/29/2013 Annual review; Added clarification that Medicare Advantage (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.

10/31/2012 Guidelines #3 (Clinical Trials) updated to include clarification that Clinical Trials are also known as Clinical Research Study; also added a note to further clarify Coverage with Evidence Development (CED).

02/27/2012 Annual review; Guidelines #3 (Clinical Trials) updated to include a note to clarify the UHC MA Plan benefit coverage for the evaluation for clinical trial.

06/14/2011 Guidelines #3 Clinical Trials updated to include the updated Medicare coverage language on clinical trials based on the Medicare Managed Care Manual Chapter 4, §10.13 Clinical Trials (effective 05-20-11).

02/21/2011 Annual review; Guidelines #2.d updated to include additional coverage information pertaining to FDA-approved IDE Category B devices.

08/26/2010 Reference and links to the NCD and the Medicare Managed Care Manual updated.