Policy: Experimental Procedures and Items, Investigational Devices, and Clinical Trials	**Policy Number: CL-05**
Department: Claims	**Original Issue Date: 01/01/2025**
Approver: Melissa Heath, RN/Director, Utilization Management **Dependencies: Mass Advantage Mass Advantage Definitions, Abbreviations and Acronyms** **Date Approved: 12/02/2024**	☐ **Date Last Reviewed / Revised [mm/dd/yyyy] OR** ☐ **Date Last Reviewed / No Revisions [mm/dd/yyyy] OR** ☒ **New Policy / N/A** **Effective Date: 01/01/2025**

PURPOSE

To ensure the Plan (Mass Advantage) and/or its delegated entities processes are consistent and compliant with Centers for Medicare and Medicaid Services (CMS) for investigational devices and procedures.

POLICY

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 responsibility.

SCOPE

This policy impacts the following departments and workflows:

Departments: Claims

Workflows: Claims, Utilization Management

PROCEDURES

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 (initial questions of safety and effectiveness have not been resolved) and the Food and Drug Administration (FDA) is unsure whether the device type can be safe and effective.
- Mass Advantage is responsible for payment of Routine Care Items and Services in CMS-approved Category A IDE studies that are covered by the Medicare Advantage Contractor (MAC) with jurisdiction over our plan's service area.

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 (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 other manufacturers have obtained FDA premarket approval or clearance for that device type.
  Note: the local MAC with jurisdiction over the Medicare Advantage (MA) plan's service area determines coverage of IDE studies. A listing of all CMS-approved Category A IDE studies and Category B IDE studies is posted on the CMS Coverage website located at Approved IDE Studies - CMS.

Clinical Trials

Routine Costs Associated with Medicare Approved Clinical Trials

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

- MACs will directly pay providers for clinical trial services furnished to a Mass Advantage member.
- MACs make payments on behalf of MA organizations directly to providers of covered clinical trial services, on a fee-for-service basis.
  - If Mass Advantage receives a bill with clinical trial codes, these bills will not be paid but will be returned to the provider. Mass Advantage 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.

Note: 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 Mass Advantage is required.

Coverage with Evidence Development (CED)

- Medicare covers items and services in CMS-approved CED studies. Mass Advantage 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. Approved CED studies are posted on the CMS Coverage with Evidence Development webpage at Coverage with Evidence Development - CMS.

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 qualifying clinical trials. The National Coverage Determination (NCD) on clinical trials defines what routine costs mean and clarifies when items and services are reasonable and necessary.

REGULATORY CITATIONS AND POLICY REFERENCES

- Medicare Benefit Policy Manual, Chapter 14 – Food and Drug Administration (FDA) – Approved Investigational Exemption (IDE) Studies
- Medicare Managed Care Manual, Chapter 4 – Payment for Investigational Device Exemption (IDE) Studies
- Medicare Managed Care Manual, Chapter 4 – Payment for Services
- NCD 310.1 – NCD for Routine Costs in Clinical Trials

VERSION AND REVIEW HISTORY

Version #	Action (Original Issue, Reviewed, Revised)	Description of Changes	Policy Owner/ Business Lead Name/Title	Approving Committee Or Business Lead Approver	Committee or Business Lead Approval Date
v1	Original Issue	Policy Origination	MHeath/Director, Utilization Management	MHeath	12/30/2024