Experimental Procedures and Items, Investigational Devices, and Clinical Trials

Policy Number: MCS109.01
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Instructions for Use

Table of Contents **Page**

Related Policies
None

Coverage Guidelines

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

(Accessed January 18, 2024)

Definitions

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 January 18, 2024)

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
(Accessed January 18, 2024)

Policy History/Revision Information

Effective Date	Summary of Changes
04/01/2024	• New Medicare Advantage Coverage Summary

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 is required where applicable. UnitedHealthcare follows Medicare coverage guidelines found in statutes, regulations, NCDs, and LCDs to determine coverage.

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