CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal: 12590	**Date: April 25, 2024**
	Change Request 13597

SUBJECT: Technical Revision Only to the National Coverage Determination (NCD) Manual, Publication (Pub) 100-03, Chapter 1, Part 4, section 310.1

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to announce a technical change that was made to the National Coverage Determination (NCD) Manual, Publication 100-03, Chapter 1, Part 4, section 310.1

EFFECTIVE DATE: May 27, 2024
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: May 27, 2024

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/Part4/310/310.1/Routine Costs in Clinical Trials (Effective July 9, 2007)

III. FUNDING:

For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-03	Transmittal: 12590	Date: April 25, 2024	Change Request: 13597

SUBJECT: Technical Revision Only to the National Coverage Determination (NCD) Manual, Publication (Pub) 100-03, Chapter 1, Part 4, section 310.1

EFFECTIVE DATE: May 27, 2024
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: May 27, 2024

I. GENERAL INFORMATION

A. Background: The purpose of this Change Request (CR) is to announce a technical change that was made to the National Coverage Determination (NCD) Manual. CMS has identified a deprecated website in section 310.1 Routine Costs in Clinical Trials of the National Coverage Determination (NCD) Manual, Publication (Pub) 100-03, Chapter 1, Part 4.

B. Policy: For purposes of clarity, consistency, and accuracy, CMS is making a technical revision to the NCD Manual, Chapter 1, Part 4. Currently, section 310.1 references LMRP.net which is a deprecated website. Local medical review policies (LMRPs) no longer exist and were phased out by local coverage determinations (LCDs). There is nothing included in this update that revises current coverage policy and that has not already been conveyed to the public via previous CRs.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
13597.1	Contractors shall be aware of the technical revision to the NCD Manual as noted above. No policy is affected by this revision.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	None					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

Medicare National Coverage Determinations Manual

Chapter 1, Part 4 (Sections 200 – 310.1)
Coverage Determinations

Table of Contents
(Rev. 12590; Issued: 04-25-24)

Transmittals for Chapter 1, Part 4

310.1 - Routine Costs in Clinical Trials (Effective July 9, 2007)

(Rev. 12590; Issued: 04-25-24; Effective: 05-27-24; Implementation: 05-27-24)

Effective for items and services furnished on or after July 9, 2007, Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.

Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except:

- The investigational item or service, itself unless otherwise covered outside of the clinical trial;
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
- Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.

Routine costs in clinical trials include:

- Items or services that are typically provided absent a clinical trial (e.g., conventional care);
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service--in particular, for the diagnosis or treatment of complications.

This policy does not withdraw Medicare coverage for items and services that may be covered according to local coverage determination (LCDs) or the regulations on category B investigational device exemptions found in 42 CFR 405.201-405.215, 411.15, and 411.406. For information about *LCDs,* refer to *https://www.cms.gov/medicare-coverage-database/search.aspx* a searchable database of *Medicare Administrative Contractor* local policies.

For non-covered items and services, including items and services for which Medicare payment is statutorily prohibited, Medicare only covers the treatment of complications arising from the delivery of the non-covered item or service and unrelated reasonable and necessary care. However, if the item or service is not covered by virtue of a national non-coverage policy in Pub. 100-03, National Coverage Determination (NCD) Manual, and is the focus of a qualifying clinical trial, the routine costs of the clinical trial (as defined above) will be covered by Medicare but the non-covered item or service, itself, will not.