CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 12860	Date: October 2, 2024
	Change Request 13829

SUBJECT: Technical Revision Only to the Medicare Benefit Policy (MBP) Manual, Publication (Pub) 100-02, Chapter 15, section 50.4.2

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to announce a technical change made to the Medicare Benefit Policy Manual, (Pub) 100-02, Chapter 15, section 50.4.2.

EFFECTIVE DATE: January 9, 2025
*Unless otherwise specified, the effective date is the date of service.
IMPLEMENTATION DATE: January 9, 2025

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	15/50/50.4.2/Unlabeled Use of Drug

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. 100-02	Transmittal: 12860	Date: October 2, 2024	Change Request: 13829

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**I.	SUMMARY OF CHANGES:** The purpose of this Change Request (CR) is to announce a technical change made to the Medicare Benefit Policy Manual, (Pub) 100-02, Chapter 15, section 50.4.2.

**II.	GENERAL INFORMATION**

**A.	Background:** CMS has identified a typo in the MBP Manual, Chapter 15, section 50.4.2 (Unlabeled Use of Drug).

**B.	Policy:** For purposes of clarity, consistency, and accuracy, CMS is making a technical revision to the MBP Manual, Chapter 15, section 50.4.2. 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. The proposed manual change includes a typo within section 50.4.2. The manual text reference is being revised from 50.5 (Self-Administered Drugs and Biologicals) to 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

**III.	BUSINESS REQUIREMENTS TABLE**

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13829.1	Contractors shall be aware of the technical revisions to the MBP Manual as noted above. No policy is affected by this revision.	X	X							

**IV.	PROVIDER EDUCATION TABLE**

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13829.2	CR as Provider Education: MACs shall use the content in the CR to develop relevant education material. Provide a link to the entire instruction in the education content. You can also supplement with local information that would help your provider community bill and administer the Medicare Program correctly.	X	X			

V.   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

VI. CONTACTS

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

VII. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
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ATTACHMENTS: 0

50.4.2 - Unlabeled Use of Drug
(Rev.12860; Issued:10-02-24; Effective:01-09-25; Implementation:01-09-25)

An unlabeled use of a drug is a use that is not included as an indication on the drug's label as approved by the FDA. FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the A/B MAC (B) determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. In the case of drugs used in an anti-cancer chemotherapeutic regimen, unlabeled uses are covered for a medically accepted indication as defined in §*50.4.5.*