CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 13049	**Date: January 16, 2025**
	Change Request 13919

SUBJECT: Documentation for Claims for Replacement of Essential Accessories for Beneficiary-Owned Continuous Glucose Monitors (CGMs)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update Chapter 5, Section 5.10.2 of Publication 100-08 - Program Integrity Manual to clarify the documentation required to support the replacement of essential accessories for beneficiary-owned CGMs.

EFFECTIVE DATE: February 18, 2025
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: February 18, 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	5/5.10/5.10.2/Suppliers Documentation for Claims for Replacement of Essential Accessories for Beneficiary-Owned Continuous Positive Airway Pressure (CPAP), Respiratory Assist Devices (RADs), and Continuous Glucose Monitors (CGMs)

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

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II. GENERAL INFORMATION

A. Background: Contractors do not need to determine that the requirements for the provision of CGMs, as when it was originally ordered, were met. However, the documentation from the treating practitioner that indicates the replacement accessories/supplies continues to be medically necessary is required.

B. Policy: There are no legislative, statutory, or regulatory impacts associated with this CR.

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	
13919.1	Contractors shall apply the instructions outlined in Chapter 5, Section 10.2 of Pub. 100-08 in their review of CGM accessories/supplies.									CERT, JA DME MAC, JB DME MAC, JC DME MAC, JD DME MAC, RAC, SMRC, UPICs

IV. PROVIDER EDUCATION

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. You don't need to separately track and report on this education.

Impacted Contractors: DME MAC

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

Medicare Program Integrity Manual

Chapter 5 – Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items and Services Having Special DME Review Considerations

Table of Contents

(Rev. 13049; Issued: 01-16-25)

Transmittals for Chapter 5

5.10.2 - Suppliers Documentation for Claims for Replacement of Essential Accessories for Beneficiary-Owned Continuous Positive Airway Pressure (CPAP), Respiratory Assist Devices (RADs), *and Continuous Glucose Monitors (CGMs)*

(Rev. 13049; Issued: 01-16-25; Effective: 02-18-25; Implementation: 02-18-25)

When reviewing claims for replacement of essential accessories for beneficiary-owned CPAP*,* RADs, *and CGMs,* the contractor shall review for continued medical necessity of the DME and necessity of the replacement accessory. Contractors are not required to determine that the requirements for provision of the CPAP*,* RAD*, and CGM* as when it was originally ordered were met. For example, even though a face-to-face encounter is required for the initial provision of the CPAP device, it is not needed for replacement of a CPAP mask for a patient-owned CPAP device covered by Medicare in the past. However, documentation from the treating practitioner that indicates the CPAP or RAD which requires replacement accessories*/supplies* continues to be medically necessary is required. Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in the policy. *Likewise, for CGM supplies, contractors would not need to see the initial qualifying documentation but will need to verify that medical need for continuing coverage, as prescribed in applicable policy (e.g., Local Coverage Determination) is met.*

In addition, the contractor shall ensure that the supplier's record includes the reason why the accessory(s) need to be replaced to meet the Medicare beneficiary's medical need. The contractor shall also ensure that the supplier's record includes the reason why any new accessories (e.g., heated humidifier or heated tubing) need to be furnished to meet the Medicare beneficiary's medical need. *In regard to CGMs, we note that the contractor prescribed monthly allowance need not be documented to be taken into consideration by the reviewer (e.g., the CGM supply allowance is one unit of service per month).* These instructions do not replace or alter other longstanding instructions related to coverage and payment for reasonable and necessary accessories for patient-owned DME. Contractors shall continue to adhere to these program policies and procedures.