| CMS Manual System | Department of Health & Human Services (DHHS) |
|---|---|
| Pub 100-08 Medicare Program Integrity | Centers for Medicare & Medicaid Services (CMS) |
| **Transmittal 13356** | **Date: August 14, 2025** |
| | **Change Request 14094** |

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

**I. SUMMARY OF CHANGES:** The purpose of this Change Request (CR) is to clarify the documentation required to support payment of claims for refills of essential accessories for beneficiary-owned CPAPs, RADs, and CGMs. It also changes the terminology from replacement to refill for consistency between the manual and regulation at Subsection (§)42 Code of Federal Regulations (C.F.R.) 410.38(d)(4). As such, the date of this section has been amended to reflect the effective date of the regulation.

**EFFECTIVE DATE: January 1, 2024**
**Unless otherwise specified, the effective date is the date of service.*
**IMPLEMENTATION DATE: September 16, 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 Refills 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

| Pub. 100-08 | Transmittal: 13356 | Date: August 14, 2025 | Change Request: 14094 |
|---|---|---|---|

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## II. GENERAL INFORMATION

**A. Background:** The Centers for Medicare & Medicaid Services recently codified the documentation that would be anticipated to support payment for refills at §42 C.F.R. 410.38, durable medical equipment, prosthetics, orthotics and supplies: Scope and conditions, as detailed in paragraph (d)(4). This CR removes parts of the prior manual text, and instead, defers to that regulatory text. In addition, it changes the terminology "replacement" and instead uses "refill(s)".

**B. Policy:** §42 C.F.R. 410.38

## III. 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 | |
| 14094.1 | Contractors shall conduct medical review in accordance with the revised language in Publication 100-08, Chapter 5, Section 5.10.2. | | | | X | | | | | CERT, RAC, SMRC, UPICs |

## IV. PROVIDER EDUCATION

None

**Impacted Contractors:** None

## 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. 13356; Issued: 08-14-25)*

## Transmittals for Chapter 5

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

***(Rev. 13356; Issued: 08-14-25; Effective: 01-01-24; Implementation: 09-16-25)***

When reviewing claims for *refills* 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 *refill* 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 *refill* 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 *refill* 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.

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.