CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10492	**Date: November 25, 2020**
	Change Request 11997

SUBJECT: Clarifying The Use of As-Needed/PRN Orders for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to revise section 5.11 in Chapter 5 of Publication (Pub.) 100-08 to account for a recent regulatory change that removed frequency as a required element of the Standard Written Order for DMEPOS.

EFFECTIVE DATE: January 1, 2020 - The effective date is 1-1-2020 to align with the effective date of CMS Regulation 1713-F.
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: December 29, 2020

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	5/5.11/Evidence of Medical Necessity

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: 10492	Date: November 25, 2020	Change Request: 11997

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I. GENERAL INFORMATION

A. Background: Effective for dates of service on or after January 1, 2020, CMS amended its order requirements for items of DMEPOS via recent regulation CMS-1713-F. The rule provides a standard written order with set elements required to be included for payment purposes. Since frequency is no longer a required element, we are updating section 5.11 in Chapter 5 of Pub. 100-08 to remove the language stating that "PRN" or "as-needed" are not acceptable frequencies to be included on a Standard Written Order.

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

II. 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	
11997.1	Contractors shall be aware of the revisions in section 5.11 of Chapter 5 in Pub. 100-08, which are reflective of recent regulation CMS-1713-F.				X					CERT, RAC, SMRC, UPICs
11997.2	Contractors shall be aware, when conducting medical reviews, that frequency is no longer a				X					CERT, RAC, SMRC, UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	required element of the DMEPOS standard written order.									
11997.2.1	Contractors shall note that while frequency is no longer required, medical documentation must objectively support the quantity ordered by the treating practitioner's standard written order and rendered by the supplier.				X					CERT, RAC, SMRC, UPICs
11997.3	Contractors shall note that while frequency is no longer required as a separate element from quantity on the face of the order, practitioners may use frequency as a means of documenting quantity ordered for medications and contractors should use frequency to calculate the quantity ordered by the treating practitioner and rendered by the				X					CERT, RAC, SMRC, UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	supplier. Note: Contractors shall still abide by any coverage limitations or preclusions, including quantity and dosing limitations, as outlined in National and/or Local Coverage Determinations.									
11997.3.1	Contractors shall, if the frequency is provided as PRN/as-needed and the contractor is able to calculate the quantity (i.e., the treating practitioner order documents the dosing amount and specified potential frequency), use such information to calculate quantity to the maximum potential dosing/usage prescribed based on the assumption that the beneficiary will be utilizing the prescribed drug “as needed” at the				X					CERT, RAC, SMRC, UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	maximum amount prescribed —so long as it does not exceed dosing limitations in the applicable local coverage determination. For example, an order might state Albuterol 0.83%/3ml vial every 6-hours PRN, suppliers would dispense and contractors would provide payment for 120 unit dose vials (so long as coverage requirements are met), which would support the maximum potential usage.									
11997.4	Contractors shall note that nothing in this instruction changes the requirements found in Pub. 100-08, Chapter 5, related to refills.				X					CERT, RAC, SMRC, UPICs
11997.5	Contractors shall note that the use of the terms PRN/as-needed, alone, do not provide sufficient information to				X					CERT, RAC, SMRC, UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	allow calculation of quantity. Note: If PRN usage is in addition to a scheduled frequency, contractors should not assume the same dosing/frequency applies to the PRN prescription. Practitioners must objectively document quantity for the PRN portion of the prescription as outlined above.									
11997.6	Contractors shall, if quantity is not objectively documented as described above, deny or adjust the claim based on CMS-1713-F Standard Written Order requirements.				X					CERT, RAC, SMRC, UPICs

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
11997.7	CR as Provider Education: Contractors shall post this entire instruction, or a direct link to this instruction, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the entire instruction must be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement it with localized information that would benefit their provider community in billing and administering the Medicare program correctly.				X	

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

Pre-Implementation Contact(s): Nabil Ladipo, 410-786-8034 or nabil.ladipo@cms.hhs.gov , Jennifer Phillips, 410-786-1023 or jennifer.phillips@cms.hhs.gov , Maria Ciccanti, 410-786-3107 or maria.ciccanti@cms.hhs.gov

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

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
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immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

Medicare Program Integrity Manual

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

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(Rev. 10492; Issued: 11-25-2020)

5.11- Evidence of Medical Necessity

(Rev. 10492; Issued: 11-25-20; Effective: 12-01-20; Implementation: 12-29-20)

If replacement supplies are needed for the therapeutic use of purchased DMEPOS, the treating practitioner must specify on the standard written order, or on the CMN, the type of supplies needed*, in such a manner that the supplier may calculate the necessary disbursement and assess the continued need for refill with the beneficiary.* DME MACs, UPICs*, and other contractors* evaluate supply utilization information as part of the*ir* medical necessity *and coverage* determination*s* for DMEPOS.

Absent a State law to the contrary or a supply utilization problem, the standard written order or CMN submitted for the DMEPOS may also serve as medical evidence for supply replacement claims. However, when a standard written order for DMEPOS is renewed or revised, supply utilization information must be specified or updated by the treating practitioner on the CMN. DME MACs, UPICs*, and other contractors* assess the continuing medical necessity.

The DME MACs, UPICs*, and other contractors* must establish procedures for monitoring the utilization of replacement supplies. Suppliers must have documentation to support the medical necessity of changes in the equipment, device, or supply utilization requirements. Absent such notification, DME MACs, UPICs*, and other contractors* do not allow claims for unexplained increases in supply utilization above the usage level they previously determined as medically necessary. Suppliers shall make this information available to the DME MACs, UPICs*, and other contractors* on request.

If necessary or appropriate for a medical necessity determination, the DME MAC, UPIC*, or other contractor* must ask the supplier to obtain documentation from the treating practitioner, establishing the severity of the patient's condition and the immediate and long term need for the equipment and the therapeutic benefits the patient is expected to realize from its use. A claim of therapeutic effectiveness or benefit based on speculation or theory alone cannot be accepted. When restoration of function is cited as a reason for use of DMEPOS, the exact nature of the deformity or medical problem should be clear from the medical evidence submitted. Also, the manner in which the equipment or device will restore or improve the bodily function should be explained by the treating practitioner.

If the DME MAC, UPIC*, or other contractor* is unsuccessful in obtaining medical information from the supplier for non-assigned claims, it gives the beneficiary the opportunity to obtain the desired information from the supplier. If, after obtaining the requested information, a question of medical necessity remains, the DME MAC, UPIC*, or other contractor* must resolve the issue.