CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-20 One-Time Notification	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 10763	**Date: May 11, 2021**
	Change Request 12199

SUBJECT: Correction to Osteoporosis Drug Processing

I. SUMMARY OF CHANGES: This Change Request removes drugs that can be used for other indications from an edit requiring osteoporosis drugs to be billed only by home health agencies.

EFFECTIVE DATE: October 1, 2021 - Claims received on or after this date.
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 4, 2021

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
N/A	

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:
One Time Notification

Attachment - One-Time Notification

Pub. 100-20	Transmittal: 10763	Date: May 11, 2021	Change Request: 12199

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I. GENERAL INFORMATION

A. Background: Sections 1861(m) and 1861(kk) of the Social Security Act provide for coverage of Food and Drug Administration (FDA) approved injectable drugs for osteoporosis provided by a Home Health Agency (HHA) to female beneficiaries who meet certain criteria. Initially, the only FDA approved injectable drug for osteoporosis was calcitonin. Effective for dates of services on or after January 1, 2005, Medicare also began covering teriparatide (brand named Forteo), an injectable drug approved by the FDA for use in treating osteoporosis. Since that time, there have been additional drugs approved for use in treating osteoporosis that would be covered under the Medicare home health benefit if provided by an HHA to eligible female beneficiaries. These include osteoporosis drugs that have the ingredient denosumab (brand names Xgeva and Prolia), romosozumab-aqqg (brand name Evenity) or abaloparatide (brand name, Tymlos).

Like the calcitonin based osteoporosis drug and teriparatide, denosumab, romosozumab-aqqg, and abaloparatideare are paid on a cost basis and are subject to deductible and coinsurance in the home health setting. Denosumab may be billed using Healthcare Common Procedure Coding System (HCPCS) code J0897. Romosozumab-aqqg may be billed using HCPCS code J3111. Abaloparatide may be billed using HCPCS code J3590.

These three new HCPCS codes were implemented by Change Request (CR) 11846, for claims received on and after January 01, 2021. The codes were included in all the appropriate systems edits to ensure compliant billing by home health agencies. However, they were included in error in an edit that restricts drug codes to home health agency claims only. These drugs can be used for indications other than osteoporosis and billed by other provider types. This CR revises Medicare systems to correct the error.

Additionally, Home Health and Hospice (HH&H) MACs and the FISS maintainer have reported a requirement error in the implementation of CR 11855, Penalty for Delayed Request for Anticipated Payment (RAP) Submission. Line items subject to low utilization payment adjustment (LUPA) payments, should not be paid if the RAP is not timely and the line items fall within the period between the claim From date and the RAP receipt date. The CR 11855 requirement failed to include the criterion that the RAP is not timely, so lines being denied in error any time they fall between the From date and the RAP receipt date. The requirements below also correct this error.

B. Policy: This Change Request contains no new policy. It corrects the implementation of existing policy.

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	
12199.1	The contractor shall remove HCPCS codes J0897, J3111 and J3590 from the edit requiring that osteoporosis drug HCPCS codes be billed only on TOB 034x. Note: This is FISS reason code 32453.					X				
12199.2	The contractors shall reactivate FISS reason code 32453 in their claims processing system as of the implementation date.	X		X						
12199.3	When applying LUPA payment amounts to line items on Type of Bill 032x, the contractor shall reduce the payment to zero if the RAP receipt date is greater than 5 days later than the claim From date and the line item date of the visit falls within the span of days between the From date and the RAP receipt date (excluding a date of 99999999) and the OVERRIDE-IND is N.					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:

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
.3	This BR revises reason code 37363, created by BR 11855.13, to add the criterion "if the RAP receipt date is greater than 5 days later than the claim From date."
.3	Example:

X-Ref Requirement Number	Recommendations or other supporting information:
	Claim From date 02/10/21 Claim Through date 02/28/21 RAP receipt date 02/16/21 Visit line items dated 02/10, 02/11, 02/12, 02/13, 02/14, or 02/15 would receive $0 payment. FISS reason code 37363 would assign on the line The RAP is timely on the From date and any of the five following days (i.e., in counting to 5, the From date is day 0). In this example, 2/15 would be day 5. If the receipt date is 2/16 or later , all LUPA visit lines would be paid $0. If it is 2/15 or earlier, all LUPA visit lines would be paid.

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

V. CONTACTS

Pre-Implementation Contact(s): Wil Gehne, wilfried.gehne@cms.hhs.gov , Carla Douglas, carla.douglas@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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ATTACHMENTS: 0