CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 10274	**Date: August 7, 2020**
	Change Request 11846

SUBJECT: Update to Osteoporosis Drug Codes Billable on Home Health Claims

I. SUMMARY OF CHANGES: This change request adds instructions for billing and payment of additional codes for osteoporosis drugs under the home health benefit.

EFFECTIVE DATE: January 1, 2021 - Claims received on and after this date.
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 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
R	10/90.1/Osteoporosis Injections as HHA Benefit

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. 100-04	Transmittal: 10274	Date: August 7, 2020	Change Request: 11846

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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 a home health agency 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). Coverage requirements for osteoporosis drugs are found in Pub. 100-02, Medicare Benefit Policy Manual, chapter 7, section 50.4.3. Coverage requirements for the home health benefit in general are found in Pub. 100-02, Medicare Benefit Policy Manual, chapter 7, section 30.

B. Policy: Medicare may cover denosumab, romosozumab-aqqg, or abaloparatide when provided by an HHA to female beneficiaries who meet the criteria established in Pub. 100-02, Medicare Benefit Policy Manual, section 50.4.3 and the coverage criteria for the home health benefit established in Pub. 100-02, Medicare Benefit Policy Manual, section 30. Like the calcitonin based osteoporosis drug and teriparatide, denosumab, romosozumab-aqqg, and abaloparatide is paid on a cost basis and is subject to deductible and coinsurance. 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.

II. 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	
11846.1	The contractor shall accept osteoporosis drugs with HCPCS codes J0897, J3111 and J3590 on Type of Bill (TOB) 034x.			X		X				
11846.2	The contractor shall make payment on a cost basis on HCPCS codes J0897, J3111 and J3590 when reported					X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	on TOB 034x.									
11846.3	The contractor shall apply Part B deductible and 20% coinsurance to payments for HCPCS codes J0897, J3111 and J3590 when reported on TOB 034x.					X				
11846.4	The contractor shall add HCPCS codes J0897, J3111 and J3590 to the edit requiring that osteoporosis drug HCPCS codes be only billed on TOB 034x.					X				
11846.5	The contractor shall add HCPCS codes J0897, J3111 and J3590 to the edit requiring that the date of service on a home health claim falls within the start and end dates of an existing home health episode if the claim contains: 1. TOB 034x; 2. osteoporosis drug HCPCS codes; and 3. Covered charges corresponding to these HCPCS codes.								X	

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
11846.6	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the "MLN Matters" listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.			X		

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:
.5	This edit was created by business requirement 6512.1.
.4	This edit was created by business requirement 6512.2.

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

V. CONTACTS

Pre-Implementation Contact(s): Wil Gehne, wilfried.gehne@cms.hhs.gov

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

VI. FUNDING

Section A: 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.

ATTACHMENTS: 0

Medicare Claims Processing Manual
Chapter 10 - Home Health Agency Billing

Table of Contents
(Rev.10274, Issued: 08-07-2020)

90.1 - Osteoporosis Injections as HHA Benefit

*(Rev.**10274, Issued: 08-07-2020**, Effective: 01-01-2021, Implementation: 01-04-2021)*

A. Billing Requirements

The administration of the drug is included in the charge for the skilled nursing visit billed using TOB 032x. The cost of the drug is billed using TOB 034x, using revenue code 0636. *These drugs are paid on a reasonable cost basis, using the provider's submitted charges to make initial payments, which are subject to annual cost settlement.*

Coverage requirements for osteoporosis drugs are found in Pub. 100-02, Medicare Benefit Policy Manual, chapter 7, section 50.4.3. Coverage requirements for the home health benefit in general are found in Pub. 100-02, Medicare Benefit Policy Manual, chapter 7, section 30.

Drugs that have the ingredient calcitonin are billed using HCPCS code J0630. HCPCS code J0630 is defined as up to 400 units. Therefore, the provider must calculate units for the bill as follows:

Units Furnished During Billing Period	Units of Service Entry on Bill
100-400	1
401-800	2
801-1200	3
1201-1600	4
1601-2000	5
2001-2400	6

Drugs that have the ingredient teriparatide may be billed using HCPCS code J3110, if all existing guidelines for coverage under the home health benefit are met. HCPCS code J3110 is defined as 10 mcg. Providers should report 1 unit for each 10 mcg dose provided during the billing period.

Drugs that have the ingredient denosumab are billed using HCPCS code J0897, if all existing guidelines for coverage under the home health benefit are met. HCPCS code J0897 is defined as 1 mg. Providers should report 1 unit for each 1 mg dose provided during the billing period.

Drugs that have the ingredients romosozumab-aqqg are billed using HCPCS code J3111, if all existing guidelines for coverage under the home health benefit are met. HCPCS code J311 is defined as 1 mg. Providers should report 1 unit for each 1 mg dose provided during the billing period.

Drugs that have the ingredient abaloparatide are billed using HCPCS code J3590 (unclassified biologics), if all existing guidelines for coverage under the home health benefit are met. As an unclassified code, HCPCS code J3590 does have not a standard definition for units. Providers should report 1 unit for each 80 mcg dose provided during the billing period.

All other osteoporosis drugs that are FDA approved and are awaiting a HCPCS code must use the miscellaneous code of J3490 until a specific HCPCS code is approved for use.

B. Edits

Medicare system edits require that the date of service on a 034x claim for covered osteoporosis drugs falls within the start and end dates of an existing home health PPS episode. Once the system ensures the service dates on the 034x claim fall within an HH PPS episode that is open for the beneficiary on CWF, CWF edits to assure that the provider number on the 034x claim matches the provider number on the episode file. This

is to reflect that although the osteoporosis drug is paid separately from the HH PPS episode rate it is included in consolidated billing requirements (see §10.1.25 regarding consolidated billing).

Claims are also edited to assure that if the claim is an HH claim (TOB 034x), the beneficiary is female and that the diagnosis code for post-menopausal osteoporosis is present.