CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1818	**Date: September 18, 2009**
	Change Request 6512

This transmittal rescinds and replaces Transmittal 1773 to remove code J3490 from business requirement 6512.2. All other information remains the same.

SUBJECT: Revised Processing of Osteoporosis Drugs Under the Home Health Benefit

I. SUMMARY OF CHANGES: This transmittal creates a new edit in Medicare systems to more accurately enforce existing coverage criteria for osteoporosis drugs under the home health benefit.

New / Revised Material
Effective Date: January 1, 2010
Implementation Date: January 4, 2010

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

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	10/90/Medical and Other Health Services Not Covered Under the Plan of Care (Bill Type 34X)
R	10/90.1/Osteoporosis Injections as HHA Benefit

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

SECTION B: 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

Unless otherwise specified, the effective date is the date of service.

Attachment – Business Requirements

Pub. 100-04	Transmittal: 1818	Date: September 18, 2009	Change Request: 6512

This transmittal rescinds and replaces Transmittal 1773 to remove code J3490 from business requirement 6512.2. All other information remains the same.

SUBJECT: Revised Processing of Osteoporosis Drugs Under the Home Health Benefit

Effective Date: January 1, 2010
Implementation Date: January 4, 2010

I. GENERAL INFORMATION

A. Background: Sections 1861(m) and 1861(kk) of the Social Security Act provide Medicare coverage of injectable osteoporosis drugs if certain criteria are met. These criteria include:

- Eligibility for coverage of home health services;
- Physician certification that the individual sustained a bone fracture related to post-menopausal osteoporosis; and
- Physician certification that the female patient is unable to learn the skills needed to self-administer the drug or is otherwise physically or mentally incapable of administering the drug, and that her family or caregivers are unable or unwilling to administer the drug.

Currently, the second and third criteria are enforced to the extent possible through Medicare systems by edits that require the beneficiary is female and that the diagnosis code 733.01 (post-menopausal osteoporosis) is present. However, the first criterion that the beneficiary must be covered under the home health benefit is only partially enforced. If an osteoporosis claim is received, and a home health episode of care is on file, Medicare systems require that the provider number of the HHA submitting the osteoporosis claim is the same as the provider number on the episode record. But there is no system requirement to ensure that a home health episode is present to correspond with all osteoporosis claims received by Medicare. This transmittal revises Medicare systems to fully enforce this criterion. Pub. 100-04, Medicare Claims Processing Manual, chapter 10, section 90.1.C has contained a description of current enforcement and is revised by this transmittal.

B. Policy: This transmittal contains no new policy. This transmittal simply ensures that the coverage requirements of Sections 1861(m) and 1861(kk) of the Social Security Act and Pub. 100-02, Medicare Benefit Policy Manual, chapter 7, section 50.4.3 are fully enforced.

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6512.1	Medicare systems shall require that the date of service on a home health claim falls within the start and end dates of									X	

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	an existing home health episode if the claim contains: • type of bill 34x; • HCPCS codes J0630, J3110 or J3490; and • Covered charges corresponding to these HCPCS codes.										
6512.1.1	Medicare systems shall reject the claim if the criteria in requirement 6512.1 are not met.	X				X	X				
6512.2	Medicare systems shall require that HCPCS codes J0630 or J3110 are only billed on type of bill 34x.						X				
6512.2.1	Medicare systems shall reject the line if the criteria in requirement 6512.2 are not met.	X		X		X	X				
6512.3	When rejecting claims because the criteria in requirement 6512.1 or 6512.2 are not met, Medicare systems shall use MSN message 6.5, which reads, "Medicare cannot pay for this injection because one or more requirements for coverage were not met."	X		X		X	X				
6512.4	When rejecting claims because the criteria in requirement 6512.1 or 6512.2 are not met, Medicare systems shall use claim adjustment reason code 177, which reads, "Patient has not met the required eligibility requirements."	X		X		X	X				

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6512.5	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and	X		X		X					

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	administering the Medicare program correctly.										

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below:
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
N/A	

B. For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

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Post-Implementation Contact(s): Appropriate Regional Office

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs),* and/or *Carriers*:
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

B. *For Medicare Administrative Contractors (MAC)*:
The Medicare Administrative Contractor (MAC) is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as changes to the MAC Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts specified 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.

90 - Medical and Other Health Services Not Covered Under the Plan of Care (Bill Type 34X)

(Rev. 1818; Issued: 09-18-09; Effective Date: 01-01-2010; Implementation Date: 01-04-2010)

HHAs may submit claims for certain Part B medical and other health services for which the HHA may receive payment outside of the prospective payment system. (See the Medicare Benefit Policy Manual, chapter 7). Refer to instructions in chapter 20 of this manual for submitting claims under arrangement with suppliers.

A Patient Not Under A Home Health Plan Of Care

The HHA submits claims with type of bill (TOB) 34X to bill for certain Part B "medical and other health services" when there is no home health plan of care. Specifically the HHA may bill using TOB 34X for the following services. (There must be a physician's certification on file.):

- Surgical dressings, splints, casts, and other devices used for reduction of fractures and dislocations. (See chapter 20 for billing enteral and parenteral supplies and equipment.)
- Rental or purchase of DME. (See chapter 20 for billing enteral and parenteral supplies and equipment.)
- Prosthetic devices. (See chapter 20 for billing enteral and parenteral supplies and equipment.)
- Leg, arm, back, and neck braces, trusses, and artificial legs, arms, and eyes.
- Outpatient physical therapy services. (See the Medicare Benefit Policy Manual, chapter 15 and the Medicare Claims Processing Manual, chapter 5.)
- Outpatient speech-language pathology services. (See the Medicare Benefit Policy Manual, chapter 15 and the Medicare Claims Processing Manual, chapter 5.)
- Outpatient occupational therapy services. (See the Medicare Benefit Policy Manual, chapter 15 and the Medicare Claims Processing Manual, chapter 5.)
- Diabetes Outpatient Self-Management Training (DSMT). (See the Medicare Benefit Policy Manual, chapter 15, section 300.5.1)

Bills for services not under a home health plan of care should be submitted only after services are delivered. They should be submitted on a periodic basis, e.g., monthly, without regard to an episode of care. These items are not reimbursed under HH PPS.

B The Patient is Under a Home Health Plan of Care

If a patient is receiving home health services under a plan of care, the agency may bill for the following services on *TOB* 34X. All other services are home health services and should be billed as a*n* HH PPS episode with Bill Type 32X.

- A covered osteoporosis drug, and
- Pneumococcal pneumonia, influenza virus, and hepatitis B vaccines.

DME, orthotic, and prosthetics can be billed as a home health service or as a medical and other health service on bill types 32X, 33X, and 34X as appropriate.

C Billing Spanning Two Calendar Years

The agency should not submit a Part B medical and other health services bill (bill type 34X only) for an inclusive period beginning in 1 calendar year and extending into the next. If the agency does not bill on a calendar month basis, it prepares two bills. The first covers the period ending December 31 of the old year; the second, the period beginning January 1 of the new year. This permits the FI to apply the appropriate deductible for both years. HH PPS claims (TOB 32X or 33X) may span the calendar year since they represent 60-day episodes, and episodes should be attributed to the Federal fiscal year or calendar year in which they end.

D Billing For Laboratory Services

HHAs may provide laboratory services only if issued a CLIA number and/or having a CLIA certificate of waiver. HHAs do not report laboratory services, even when on the HH plan of care, on the PPS claim *to a Medicare contractor using an institutional claim format*. These services are billed to Medicare *contractors* using *a professional claim format*. To submit such claims, the HHA must have a CLIA number and a *professional* billing number. HHAs should contact the State Survey Agency to obtain a CLIA number. HHAs should contact the appropriate *contractor* to obtain a billing number. The survey process is used to validate that laboratory services in an HHA facility are being provided in accordance with the CLIA certificate.

90.1 - Osteoporosis Injections as HHA Benefit

(Rev. 1818; Issued: 09-18-09; Effective Date: 01-01-2010; Implementation Date: 01-04-2010)

A - Billing Requirements

The administration of the drug is included in the charge for the skilled nursing visit billed under bill type 32X or 33X, as appropriate. The cost of the drug is billed under bill type 34X, using revenue code 0636. Drugs that have the ingredient calcitonin are billed using HCPCS code J0630. 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. All other osteoporosis drugs that are FDA approved and are awaiting an HCPCS code must use the miscellaneous code of J3490 until a specific HCPCS code is approved for use.

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

HCPCS code J3110 is defined as 10 mcg. Providers should report 1 unit for each 10 mcg dose provided during the billing period.

These codes 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.

B - Denial Messages

If the claim for an osteoporosis drug is denied because it was not an injectable drug approved by the FDA, the *Medicare contractor* shall use the appropriate message below on the MSN:

- MSN Message 6.2: "Drugs not specifically classified as effective by the Food and Drug Administration are not covered."

If the claim for an osteoporosis injection is denied because the patient did not meet the requirements for coverage, the *Medicare contractor* shall use:

- MSN message 6.5, which reads, "Medicare cannot pay for this injection because one or more requirements for coverage were not met."

C - Edits

Medicare system edits require that the date of service on a 34X 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 34X 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 34X 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 *the claim is an HH claim (type of bill 34X),* the beneficiary is female and that the diagnosis code 733.01 (post-menopausal osteoporosis) is present.