Stoboclo®
denosumab-bmwo

Billing and Coding Guide

INDICATIONS[1]

STOBOCLO® (denosumab-bmwo) is a RANK ligand (RANKL) inhibitor indicated for treatment:

- of **postmenopausal women** with osteoporosis at high risk for fracture
- to **increase bone mass in men** with osteoporosis at high risk for fracture or in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer
- of **glucocorticoid-induced osteoporosis** in men and women at high risk for fracture
- to **increase bone mass in women** at high risk for fracture receiving a adjuvant aromatase inhibitor therapy for breast cancer

IMPORTANT SAFETY INFORMATION

WARNING: SEVERE HYPOCALCEMIA IN PATIENTS WITH ADVANCED KIDNEY DISEASE

Patients with advanced chronic kidney disease (eGFR < 30 mL/min/1.73 m^2), including dialysis-dependent patients, are at greater risk of severe hypocalcemia following denosumab products administration. Severe hypocalcemia resulting in hospitalization, life-threatening events and fatal cases have been reported.

The presence of chronic kidney disease-mineral bone disorder (CKD-MBD) markedly increases the risk of hypocalcemia in these patients.

Prior to initiating STOBOCLO in patients with advanced chronic kidney disease, evaluate for the presence of CKD-MBD. Treatment with STOBOCLO in these patients should be supervised by a healthcare provider with expertise in the diagnosis and management of CKD-MBD.

Contraindications:

- Hypocalcemia: Pre-existing hypocalcemia must be corrected before initiating therapy.
- Pregnancy: Denosumab products may cause fetal harm when administered to a pregnant woman.
- Hypersensitivity: Known hypersensitivity to denosumab products.

Introduction to STOBOCLO® (denosumab-bmwo)[1]

STOBOCLO injection, for subcutaneous use is a RANK ligand (RANKL) inhibitor and is a biosimilar to PROLIA® (denosumab).

Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. Biosimilarity of STOBOCLO has been demonstrated for the condition(s) of use (eg, indication[s]), dosing regimen[s]), strength(s), dosage form(s), and route(s) of administration described in its Full Prescribing Information.

This guide is provided for informational purposes only. Correct coding is the responsibility of the provider submitting the claim for the item or service. Please check with the payer to verify codes and specific billing requirements. Celltrion does not make any representation or guarantees concerning reimbursement or coverage for any service or item, nor does Celltrion guarantee patient assistance to the limits described.

STOBOCLO Formulation[1]

FOR SUBCUTANEOUS ADMINISTRATION

1 mL of a 60 mg/mL clear
NDC: 72606-037-01

IMPORTANT SAFETY INFORMATION (CONTINUED)

Severe Hypocalcemia and Mineral Metabolism Changes. Severe hypocalcemia can occur. Ensure adequate calcium and vitamin D supplementation.

Drug Products with Same Active Ingredient. Patients receiving STOBOCLO should not receive other denosumab products concomitantly.

Hypersensitivity. Clinically significant hypersensitivity including anaphylaxis has been reported with denosumab products. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue further use of STOBOCLO.

Indications[1]

STOBOCLO is a RANK ligand (RANKL) inhibitor indicated for treatment:

- of **postmenopausal women** with osteoporosis at high risk for fracture
- to **increase bone mass in men** with osteoporosis at high risk for fracture or in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer
- of **glucocorticoid-induced osteoporosis** in men and women at high risk for fracture
- to **increase bone mass in women** at high risk for fracture receiving a adjuvant aromatase inhibitor therapy for breast cancer

Dosage and Administration[1]

Dosage Forms and Strength	Recommended Dosing and Administration
1 mL of 60 mg/mL clear, colorless to pale yellow solution in a single-dose prefilled syringe	• Pregnancy must be ruled out prior to administration of STOBOCLO • Before initiating STOBOCLO in patients with advanced chronic kidney disease, including dialysis patients, evaluate for the presence of chronic kidney disease mineral and bone disorder with intact parathyroid hormone, serum calcium, 25(OH) vitamin D, and 1,25(OH)2 vitamin D • STOBOCLO should be administered by a healthcare provider • Administer 60 mg every 6 months as a subcutaneous injection in the upper arm, upper thigh, or abdomen • Instruct patients to take calcium 1000 mg daily and at least 400 IU vitamin D daily

If a dose of STOBOCLO is missed, administer the injection as soon as the patient is available. Thereafter, schedule injections every 6 months from the date of the last injection.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Osteonecrosis of the Jaw (ONJ). ONJ can occur in patients on STOBOCLO, particularly after tooth extraction and/or local infection with delayed healing. A routine oral exam is recommended before starting STOBOCLO, with a dental evaluation and preventive care for high-risk patients. Good oral hygiene should be maintained, and ONJ-risk drugs may heighten ONJ likelihood, especially with extended STOBOCLO exposure. For invasive dental procedures, individualize treatment based on clinical judgment. If ONJ develops, consult a dentist or oral surgeon, as extensive surgery may worsen ONJ; consider discontinuing STOBOCLO based on benefit-risk assessment.

Atypical Subtrochanteric and Diaphyseal Femoral Fractures. Atypical low energy or low trauma fractures of the shaft have been reported in patients receiving denosumab products. During STOBOCLO treatment, patients should be advised to report new or unusual thigh, hip, or groin pain. Patients with thigh or groin pain should be evaluated for an atypical femur fracture, including assessment for potential fractures in the contralateral limb. Interruption of STOBOCLO therapy should be considered, pending a benefit-risk assessment, on an individual basis.

Sample Coding

This section serves as an educational reference for coding that may be appropriate for reporting STOBOCLO and related services. Medical record documentation must support the codes reported on the claim. These codes may be appropriate when STOBOCLO is administered to patients in the physician's office or a hospital setting.

Diagnosis Codes (ICD-10-CM Codes)

This list is for informational purposes only. One or more codes may be appropriate on a claim. Please review payer policy requirements for guidance on diagnosis codes.

Code	Description
Osteoporosis	
Primary Diagnosis Codes[2]	
M80.0_ _ _	Age-related osteoporosis with current pathological fracture To ensure specificity, 3 additional characters should follow M80.0 to describe laterally, anatomic site, and encounter type. See page 5 for coding details for patients with current osteoporotic fracture
The following primary diagnosis codes may be appropriate for patients *without* current osteoporotic fracture treated with STOBOCLO[3]	
M81.0	Age-related osteoporosis without current pathological fracture
M81.8	Other osteoporosis without current pathological fracture
The following secondary diagnosis code may be appropriate to describe patients with a personal history of healed osteoporosis fracture[4]	
Z87.310	Personal history of healed osteoporosis fracture
The following secondary diagnosis code may be appropriate to describe patients for glucocorticoid-induced osteoporosis[5]	
Z79.52	Long-term (current) use of systemic steroids
Cancer Treatment-Induced Bone Loss[6]	
C61	Malignant neoplasm of prostate, or Provider to determine appropriate site and laterality for breast cancer diagnosis ICD-10 code
Use of Androgen Deprivation Therapy[7]	
Z79.818[a]	Long-term [current] use or other agents affecting estrogen receptors and estrogen levels
Use of Aromatase Inhibitor Therapy[8]	
Z79.811	Long-term [current] use of aromatase inhibitors
Bone Codes That May Be Used (consult individual payer requirements)[2,3,9]	
M85.9	Disorder of bone density and structure, unspecified
M81.0	Age-related osteoporosis without current pathologic fracture
M81.8	Other osteoporosis without pathologic fracture
M80.0	Age-related osteoporosis with current pathologic fracture
M80.8	Other osteoporosis with current pathological fracture

[a]Diagnosis code Z79.818 may be used for males receiving androgen deprivation therapy (eg, leuprolide acetate or goserelin acetate) for prostate cancer.[7]

Examples of ICD-10-CM Codes Relevant for Patients With Current Osteoporotic Fracture

Age-related osteoporosis with current pathological fracture[2]

M80.0_ _ _ [laterality] [anatomic site] [encounter type][a]

Anatomic Site and Laterality	Encounter Type[b]					
	Initial encounter for fracture	Subsequent encounter for fracture with routine healing	Subsequent encounter for fracture with delayed healing	Subsequent encounter for fracture with nonunion	Subsequent encounter for fracture with malunion	Sequela
UNSPECIFIED SITE	M80.00XA	M80.00XD	M80.00XG	M80.00XK	M80.00XP	M80.00XS
SHOULDER						
Right	M80.011A	M80.011D	M80.011G	M80.011K	M80.011P	M80.011S
Left	M80.012A	M80.012D	M80.012G	M80.012K	M80.012P	M80.012S
Unspecified	M80.019A	M80.019D	M80.019G	M80.019K	M80.019P	M80.019S
HUMERUS						
Right	M80.021A	M80.021D	M80.021G	M80.021K	M80.021P	M80.021S
Left	M80.022A	M80.022D	M80.022G	M80.022K	M80.022P	M80.022S
Unspecified	M80.029A	M80.029D	M80.029G	M80.029K	M80.029P	M80.029S
FOREARM						
Right	M80.031A	M80.031D	M80.031G	M80.031K	M80.031P	M80.031S
Left	M80.032A	M80.032D	M80.032G	M80.032K	M80.032P	M80.032S
Unspecified	M80.039A	M80.039D	M80.039G	M80.039K	M80.039P	M80.039S
HAND						
Right	M80.041A	M80.041D	M80.041G	M80.041K	M80.041P	M80.041S
Left	M80.042A	M80.042D	M80.042G	M80.042K	M80.042P	M80.042S
Unspecified	M80.049A	M80.049D	M80.049G	M80.049K	M80.049P	M80.049S
FEMUR[c]						
Right	M80.051A	M80.051D	M80.051G	M80.051K	M80.051P	M80.051S
Left	M80.052A	M80.052D	M80.052G	M80.052K	M80.052P	M80.052S
Unspecified	M80.059A	M80.059D	M80.059G	M80.059K	M80.059P	M80.059S
LOWER LEG						
Right	M80.061A	M80.061D	M80.061G	M80.061K	M80.061P	M80.061S
Left	M80.062A	M80.062D	M80.062G	M80.062K	M80.062P	M80.062S
Unspecified	M80.069A	M80.069D	M80.069G	M80.069K	M80.069P	M80.069S
ANKLE AND FOOT						
Right	M80.071A	M80.071D	M80.071G	M80.071K	M80.071P	M80.071S
Left	M80.072A	M80.072D	M80.072G	M80.072K	M80.072P	M80.072S
Unspecified	M80.079A	M80.079D	M80.079G	M80.079K	M80.079P	M80.079S
PELVIS						
Right	M80.0B1A	M80.0B1D	M80.0B1G	M90.0B1K	M80.0B1P	M80.0B1S
Left	M80.0B2A	M80.0B2D	M80.0B2G	M80.0B2K	M80.0B2P	M80.0B2S
Unspecified	M80.0B9A	M80.0B9D	M80.0B9G	M80.0B9K	M80.0B9P	M80.0B9S
VERTEBRA(E)	M80.08XA	M80.08XD	M80.08XG	M80.08XK	M80.08XP	M80.08XS
OTHER SITE	M80.0AXA	M80.0AXD	M80.0AXG	M80.0AXK	M80.0AXP	M80.0AXS

For other osteoporosis with or without current pathological fracture, refer to ICD-10 reference.

[a]According to the ICD-10-CM Official Guidelines for Coding and Reporting, M80.0 codes are for patients who have a current pathologic fracture at the time of an encounter. The codes under M80 identify the site of the fracture. A code from category M80, not a traumatic fracture code, should be used for any patient with known osteoporosis who suffers a fracture, even if the patient had a minor fall or trauma, if that fall or trauma would not usually break a normal, healthy bone.[10]

[b]According to the ICD-10-CM Official Guidelines for Coding and Reporting, seventh character A is for as long as the patient is receiving active treatment for the fracture. Assignment of the seventh character is based on whether the patient is undergoing active treatment and not whether the provider is seeing the patient for the first time. Seventh character D is to be used for encounters after the patient has completed active treatment. The other seventh characters, listed under each subcategory in the Tabular List, are to be used for subsequent encounters for treatment of problems associated with healing, such as malunions, nonunions, and sequelae.[10]

[c]Osteoporotic fracture of femur is the approximate synonym of osteoporotic fracture of the hip.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Serious Infections. In a trial of women with postmenopausal osteoporosis, serious infections were more frequent with denosumab than placebo, including skin, abdominal, urinary, ear infections, and endocarditis. Overall infection rates were similar between groups. Advise patients to seek medical attention for severe infection symptoms like cellulitis. Those on immunosuppressants or with weakened immune systems may face higher risks. Assess the benefit-risk profile before starting STOBOCLO, and reconsider its use if serious infections develop.

Sample Coding (Continued)

National Drug Code[11]

The National Drug Code (NDC) is required on the claim form. While the FDA uses a 10-digit format when registering NDCs, payers often require an 11-digit NDC format on claim forms for billing purposes. The NDC unit of measure qualifier and quantity may also be required. Check payer-specific reporting requirements.

STOBOCLO	10-Digit NDC Code	11-Digit NDC Code
60 mg	72606-037-01	72606-0037-01

Administration and Billing Codes

This section reviews general coding guidelines for drug administration services coded by physician offices using the CMS-1500 claim form and by hospital outpatient departments using the CMS-1450 (UB-04) claim form.

CPT® Code

Drug administration services are reported on claims forms in both the physician office and hospital outpatient sites of care using the Current Procedural Terminology (CPT®) coding system.

Code Set	Code and Description[12,13]	Location on CMS-1500 Form[14]	Location on CMS-1450 (UB-04) Form[15]
CPT	96372 Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	Field 24D	Field 44
CPT	96401 Chemotherapy administration, subcutaneous or intramuscular; non-hormonal antineoplastic	Field 24D	Field 44

HCPCS Level II Code(s)

Drugs are typically reported using product-specific Healthcare Common Procedure Coding System (HCPCS) codes (eg, J-codes) assigned by the CMS. HCPCS units are determined by the specific HCPCS descriptor.

The descriptor is not necessarily the same as the package or therapeutic dose, so the dose must be converted to billable HCPCS units to accurately complete a claim.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Dermatologic Adverse Reactions. Epidermal and dermal adverse events such as dermatitis, eczema, and rashes have been reported in patients treated with denosumab. Consider discontinuing STOBOCLO if severe symptoms develop.

Musculoskeletal Pain. In postmarketing experience, severe and occasionally incapacitating bone, joint, and/or muscle pain has been reported in patients taking denosumab products. Consider discontinuing use if severe symptoms develop.

Suppression of Bone Turnover. In clinical trials in women with postmenopausal osteoporosis, denosumab significantly suppressed bone remodeling, with unknown long-term effects that may lead to osteonecrosis of the jaw, atypical fractures, or delayed fracture healing; patients should be monitored for these outcomes.

Hypercalcemia in Pediatric Patients with Osteogenesis Imperfecta. STOBOCLO is not indicated for use in pediatric patients. Hypercalcemia has been reported in pediatric patients with osteogenesis imperfecta treated with denosumab products. Some cases required hospitalization.

Administration and Billing Codes (Continued)

HCPCS Level II Code(s) (Continued)

Code Set	Code and Description[16]	Location on CMS-1500 Form[14]	Location on CMS-1450 (UB-04) Form[15]
HCPCS	J3590 Unclassified Biologics	Field 24D	Field 44

Modifiers

Modifier	Description[17,18]	Location on CMS-1500 Form[14]	Location on CMS-1450 (UB-04) Form[15]
JZ	No amount of drug was discarded from a single-vial/dose drug and not administered to any patient	Field 24D	Field 44
JW	Amount of drug discarded/not administered to any patient	Field 24D	Field 44
JG	Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes	Field 24D	Field 44
TB	Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes for select entities	Field 24D	Field 44

Note on product and administration coding:

If you order STOBOCLO through a specialty pharmacy or the Celltrion CONNECT® Patient Assistance Program (PAP), you should not seek reimbursement for the product; however, your patient's health plan may still require that you include the HCPCS code on the claim with a zero or nominal charge in order for them to reimburse the drug administration procedure.

Remember to submit a claim for reimbursement for services associated with STOBOCLO.

IMPORTANT SAFETY INFORMATION (CONTINUED)

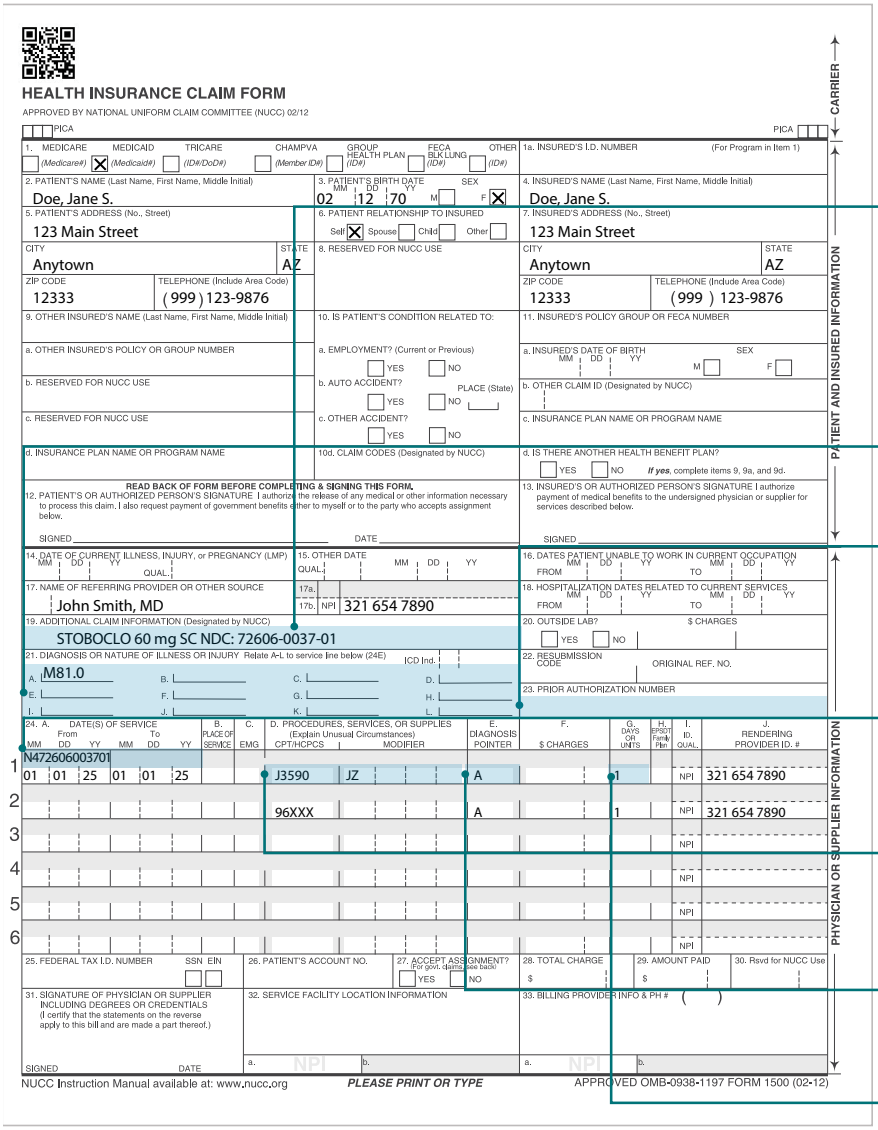
Adverse Reactions:

- **Postmenopausal osteoporosis:** Most common adverse reactions (> 5%) were: back pain, pain in extremity, hypercholesterolemia, musculoskeletal pain, and cystitis. Pancreatitis has been reported in clinical trials.
- **Male osteoporosis:** Most common adverse reactions (> 5%) were: back pain, arthralgia, and nasopharyngitis.
- **Glucocorticoid-induced osteoporosis:** Most common adverse reactions (> 3%) were: back pain, hypertension, bronchitis, and headache.
- **Bone loss due to hormone ablation for cancer:** Most common adverse reactions (≥ 10%) were: arthralgia and back pain. Pain in extremity and musculoskeletal pain have also been reported in clinical trials.

Sample CMS-1500 Claim Form—Physician Office[14]

The sample claim form provided below is only an example. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, payment policies, and fee schedules.

Example for Osteoporosis



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) X | MEDICAID (Medicaid#) | TRICARE (ID#/DoD#) | CHAMPVA (Member ID#) | GROUP HEALTH PLAN (ID#) | FECA BLK LUNG (ID#) | OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial): Doe, Jane S.

3. PATIENT'S BIRTH DATE: 02 12 70 | SEX: M | F X

4. INSURED'S NAME (Last Name, First Name, Middle Initial): Doe, Jane S.

5. PATIENT'S ADDRESS (No., Street): 123 Main Street

6. PATIENT RELATIONSHIP TO INSURED: Self X | Spouse | Child | Other

7. INSURED'S ADDRESS (No., Street): 123 Main Street

CITY: Anytown | STATE: AZ

8. RESERVED FOR NUCC USE

CITY: Anytown | STATE: AZ

ZIP CODE: 12333 | TELEPHONE (Include Area Code): (999)123-9876

ZIP CODE: 12333 | TELEPHONE (Include Area Code): (999) 123-9876

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES | NO

a. INSURED'S DATE OF BIRTH MM DD YY | SEX M | F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES | NO | PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES | NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES | NO | If yes, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED _____ DATE _____

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED _____

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO MM DD YY

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE: John Smith, MD

17a.

17b. NPI 321 654 7890

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO MM DD YY

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC): STOBOCLO 60 mg SC NDC: 72606-0037-01

20. OUTSIDE LAB? YES | NO | $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. M81.0 B. C. D. E. F. G. H. I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 N472606003701 01 01 25	01 01 25			J3590	JZ	A		1		NPI	321 654 7890
2				96XXX		A		1		NPI	321 654 7890
3										NPI	
4										NPI	
5										NPI	
6										NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES | NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

Field 19: Payers require drug name, route of administration, NDC, and total dosage. Check with your payer to verify specific requirements, including use of the 10-digit or 11-digit NDC. **Note:** Some payers may also request the wholesale acquisition cost (WAC) price to be included.

Field 21: Indicate the most medically appropriate diagnosis code (ICD-10-CM).

Field 23: If required, report the prior authorization number here.

Field 24A: If a line item NDC information is required, it will be entered in the shaded portion of item 24A. NDC codes must be billed with the N4 qualifier before the NDC code.

Field 24D: Indicate appropriate HCPCS as required by the payer. Include the appropriate CPT® code (eg, 96372 or 96401) to report the administration procedure.

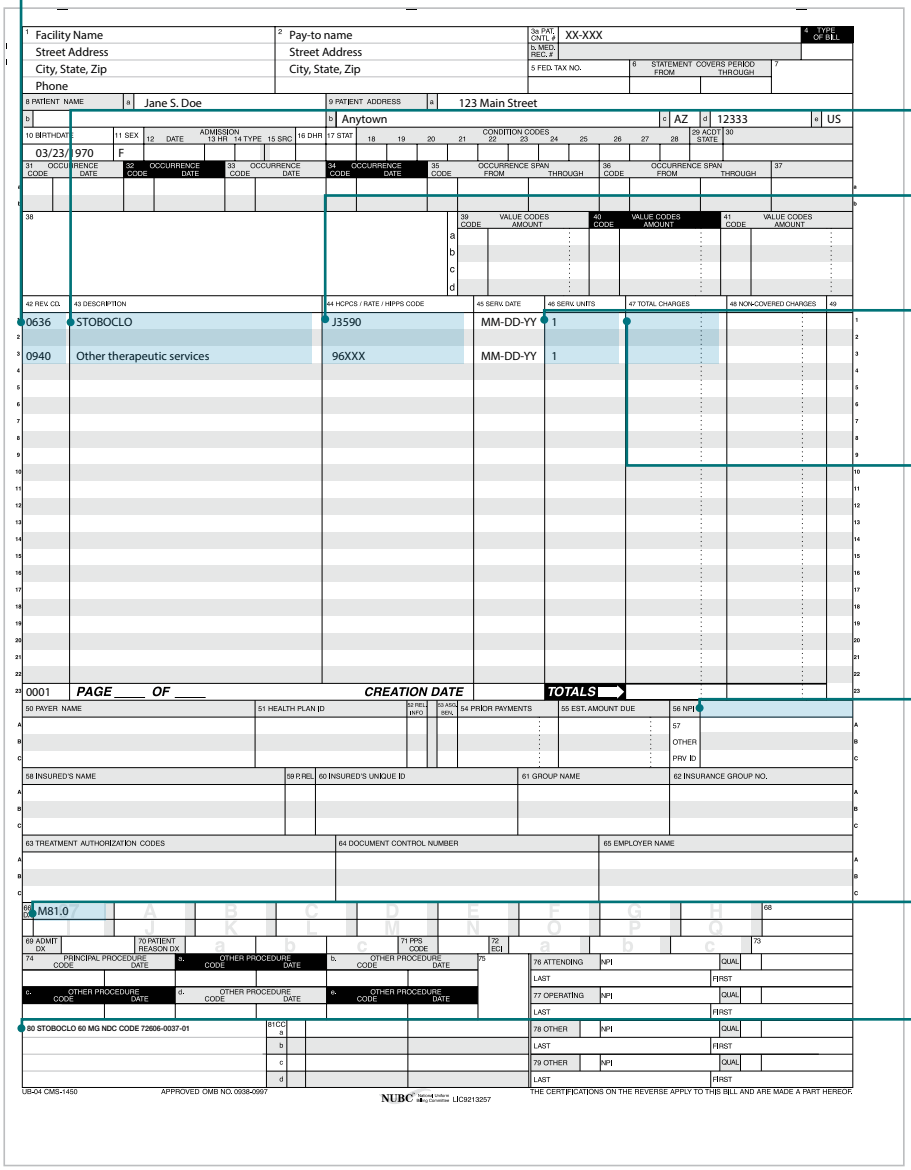
Field 24E: Enter the diagnosis code reference letter as shown in box 21. Enter only 1 diagnosis pointer.

Field 24G: Enter the number of HCPCS units.

CMS-1450 (UB-04) Claim Form—Hospital Outpatient Departments[15]

The claim form provided below is only an example. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, payment policies, and fee schedules.

Example for Osteoporosis



Field 42: Include appropriate revenue codes corresponding with the HCPCS code in box 44. Then enter the appropriate revenue code corresponding with the CPT® code in box 44.

Field 43: Provide drug product name, strength, NDC, and quantity.

Field 44: Indicate appropriate HCPCS and CPT® codes (eg, 96372 or 96401) and modifiers as required by the payer.

Field 46: Enter the number of HCPCS units.

Field 47: Indicate total charges.

Field 56: Indicate the appropriate NPI number.

Field 66: Indicate the most medically appropriate diagnosis code.

Field 80: Payers require drug name, route of administration, NDC, and total dosage. Check with your payer to verify specific requirements, including use of the 10-digit or 11-digit NDC. This is a necessary field.

Patient Support Programs Created to Provide Treatment Access to as Many Eligible Patients as Possible

CELLTRION CONNECT
PATIENT SUPPORT PROGRAM

Celltrion CONNECT helps hub-enrolled patients understand and navigate their insurance coverage and identify resources that may help them afford their treatment

CELLTRION CARES®
CO-PAY PROGRAM

Commercially insured patients may be able to receive financial assistance through Celltrion CARES® Co-Pay Assistance Program

CELLTRION inFORM
ACCESS SOLUTIONS FOR PATIENTS & PRACTICES

A dedicated team of Field Reimbursement Managers (FRMs) to assist patients and providers navigate all aspects of medication access

Comprehensive Patient Support Offered by Celltrion CONNECT®

CELLTRION CONNECT
PATIENT SUPPORT PROGRAM

Financial Assistance

- Patient insurance benefit verifications (BV)
- Prior authorization (PA) assistance
- Appeal support
- Co-Pay Assistance Program (Celltrion CARES®) for your commercially insured patients
- Financial support for qualified eligible patients

Healthcare Provider Resources

- Online portal
- Sample letters of Medical Exception and Appeal
- Downloadable brochures
- Downloadable Enrollment Form
- Downloadable Billing and Coding Guide

www.celltrionconnect.com

1-877-81CONNC (1-877-812-6662)

IMPORTANT SAFETY INFORMATION

WARNING: SEVERE HYPOCALCEMIA IN PATIENTS WITH ADVANCED KIDNEY DISEASE

Patients with advanced chronic kidney disease (eGFR < 30 mL/min/1.73 m^2), including dialysis-dependent patients, are at greater risk of severe hypocalcemia following denosumab products administration. Severe hypocalcemia resulting in hospitalization, life-threatening events and fatal cases have been reported.

The presence of chronic kidney disease-mineral bone disorder (CKD-MBD) markedly increases the risk of hypocalcemia in these patients.

Prior to initiating STOBOCLO in patients with advanced chronic kidney disease, evaluate for the presence of CKD-MBD. Treatment with STOBOCLO in these patients should be supervised by a healthcare provider with expertise in the diagnosis and management of CKD-MBD.

Contraindications:

- Hypocalcemia: Pre-existing hypocalcemia must be corrected before initiating therapy.
- Pregnancy: Denosumab products may cause fetal harm when administered to a pregnant woman.
- Hypersensitivity: Known hypersensitivity to denosumab products.

Severe Hypocalcemia and Mineral Metabolism Changes. Severe hypocalcemia can occur. Ensure adequate calcium and vitamin D supplementation.

Drug Products with Same Active Ingredient. Patients receiving STOBOCLO should not receive other denosumab products concomitantly.

Hypersensitivity. Clinically significant hypersensitivity including anaphylaxis has been reported with denosumab products. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue further use of STOBOCLO.

Osteonecrosis of the Jaw (ONJ). ONJ can occur in patients on STOBOCLO, particularly after tooth extraction and/or local infection with delayed healing. A routine oral exam is recommended before starting STOBOCLO, with a dental evaluation and preventive care for high-risk patients. Good oral hygiene should be maintained, and ONJ-risk drugs may heighten ONJ likelihood, especially with extended STOBOCLO exposure. For invasive dental procedures, individualize treatment based on clinical judgment. If ONJ develops, consult a dentist or oral surgeon, as extensive surgery may worsen ONJ; consider discontinuing STOBOCLO based on benefit-risk assessment.

Atypical Subtrochanteric and Diaphyseal Femoral Fractures. Atypical low energy or low trauma fractures of the shaft have been reported in patients receiving denosumab products. During STOBOCLO treatment, patients should be advised to report new or unusual thigh, hip, or groin pain. Patients with thigh or groin pain should be evaluated for an atypical femur fracture, including assessment for potential fractures in the contralateral limb. Interruption of STOBOCLO therapy should be considered, pending a benefit-risk assessment, on an individual basis.

Multiple Vertebral Fractures (MVF) Following Discontinuation of Treatment. Following discontinuation of denosumab treatment, fracture risk increases, including the risk of multiple vertebral fractures. Prior vertebral fracture was a predictor of multiple vertebral fractures after denosumab discontinuation. Evaluate an individual's benefit-risk before initiating treatment with STOBOCLO. If STOBOCLO treatment is discontinued, patients should be transitioned to an alternative antiresorptive therapy.

Serious Infections. In a trial of women with postmenopausal osteoporosis, serious infections were more frequent with denosumab than placebo, including skin, abdominal, urinary, ear infections, and endocarditis. Overall infection rates were similar between groups. Advise patients to seek medical attention for severe infection symptoms like cellulitis. Those on immunosuppressants or with weakened immune systems may face higher risks. Assess the benefit-risk profile before starting STOBOCLO, and reconsider its use if serious infections develop.

Dermatologic Adverse Reactions. Epidermal and dermal adverse events such as dermatitis, eczema, and rashes have been reported in patients treated with denosumab. Consider discontinuing STOBOCLO if severe symptoms develop.

Musculoskeletal Pain. In postmarketing experience, severe and occasionally incapacitating bone, joint, and/or muscle pain has been reported in patients taking denosumab products. Consider discontinuing use if severe symptoms develop.

Suppression of Bone Turnover. In clinical trials in women with postmenopausal osteoporosis, denosumab significantly suppressed bone remodeling, with unknown long-term effects that may lead to osteonecrosis of the jaw, atypical fractures, or delayed fracture healing; patients should be monitored for these outcomes.

Hypercalcemia in Pediatric Patients with Osteogenesis Imperfecta. STOBOCLO is not indicated for use in pediatric patients. Hypercalcemia has been reported in pediatric patients with osteogenesis imperfecta treated with denosumab products. Some cases required hospitalization.

Adverse Reactions:

- **Postmenopausal osteoporosis:** Most common adverse reactions (> 5%) were: back pain, pain in extremity, hypercholesterolemia, musculoskeletal pain, and cystitis. Pancreatitis has been reported in clinical trials.
- **Male osteoporosis:** Most common adverse reactions (> 5%) were: back pain, arthralgia, and nasopharyngitis.
- **Glucocorticoid-induced osteoporosis:** Most common adverse reactions (> 3%) were: back pain, hypertension, bronchitis, and headache.
- **Bone loss due to hormone ablation for cancer:** Most common adverse reactions (≥ 10%) were: arthralgia and back pain. Pain in extremity and musculoskeletal pain have also been reported in clinical trials.

For more information about STOBOCLO, please see full Prescribing Information including BOXED WARNING.

References

1. STOBOCLO [prescribing information]. Celltrion USA, Inc.; 2025. **2.** Osteoporosis with current pathological fracture M80. ICD10Data.com. Accessed March 25, 2025. **3.** 2025 ICD-10-CM Diagnosis Code M81.0. ICD10Data.com. Accessed March 25, 2025. **4.** 2025 ICD-10-CM Diagnosis Code Z87.310. ICD10Data.com. Accessed March 25, 2025. https://www.icd10data.com/ICD10CM/Codes/Z00-Z99/Z77-Z99/Z87-/Z87.310 **5.** 2025 ICD-10-CM Diagnosis Code Z79.52. ICD10Data.com. Accessed March 25, 2025. **6.** 2025 ICD-10-CM Diagnosis Code C61. ICD10Data.com. Accessed March 25, 2025. https://www.icd10data.com/ICD10CM/Codes/C00-D49/C60-C63/C61-/C61 **7.** 2025 ICD-10-CM Diagnosis Code Z79.818. ICD10Data.com. Accessed March 25, 2025. https://www.icd10data.com/ICD10CM/Codes/Z00-Z99/Z77-Z99/Z79-/Z79.818 **8.** 2025 ICD-10-CM Diagnosis Code Z79.811. ICD10Data.com. Accessed March 25, 2025. https://www.icd10data.com/ICD10CM/Codes/Z00-Z99/Z77-Z99/Z79-/Z79.811 **9.** 2025 ICD-10-CM Diagnosis Code M85. ICD10Data.com. Accessed March 25, 2025. https://www.icd10data.com/ICD10CM/Codes/M00-M99/M80-M85/M85-/M85.9 **10.** Centers for Medicare & Medicaid Services. ICD-10-CM Official Guidelines for Coding and Reporting. Published 2015. Accessed March 25, 2025. https://www.cms.gov/medicare/coding/icd10/downloads/icd10cm-guidelines-2015.pdf **11.** National Drug Codes explained. Drugs.com. Updated June 12, 2024. Accessed March 25, 2025. https://www.drugs.com/ndc.html **12.** CPT code 96372: injection of drug/substance under skin or onto muscle. American Medical Association. Accessed February 19, 2025. https://www.ama-assn.org/practice-management/cpt/cpt-code-96372-injection-drugsubstance-under-skin-or-muscle **13.** Nordley B. Breaking down complexities in chemotherapy injection coding. MedLearn Publishing. Published December 30, 2022. Accessed March 25, 2025. https://medlearn.com/breaking-down-complexities-in-chemotherapy-injection-coding/?srsltid=AfmBOor6b2fKJU1VmUJYnFr47ZdEEvSf6ak_olvb6lhwerfSdn0egiSI **14.** CMS.gov. CMS-1500. Accessed March 25, 2025. https://www.cms.gov/medicare/cms-forms/cms-forms/cms-forms-items/cms1188854 **15.** CMS.gov. CMS-1450. Accessed March 25, 2025. https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing-items/cms-1450 **16.** Part B unlisted drugs and biologicals. Palmetto GBA. Published February 15, 2021. Accessed February 19, 2025. https://www.palmettogba.com/palmetto/jmb.nsf/DIDC/BY6RTU8205~Specialties~Drugs%20and%20Biologicals **17.** American Academy of Ophthalmology. Fact Sheet: JW and JZ Modifiers. Published June 5, 2023. Accessed Accessed February 19, 2025. https://www.aao.org/Assets/a82e22ae-3045-4abd-8a28-f653f6d61597/638212325906530000/modifiers-jw-jz-fs-pdf?inline=1#:~:text=Report%20JZ%20modifier%20when%20the,up%20to%20the%20nearest%20unit **18.** 340B Update for hospitals: CMS publishes FAQs clarifying use of modifiers in connection with 340B program reimbursement cut on part B drugs. K&L Gates. Published December 18, 2017. Accessed February 19, 2025. https://www.klgates.com/340B-Update-for-Hospitals-CMS-Publishes-FAQs-Clarifying-Use-of-Modifiers-in-Connection-with-340B-Program-Reimbursement-Cut-on-Part-B-Drugs-12-18-2017

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