Osenvelt®
denosumab-bmwo

Billing and Coding Guide

INDICATIONS

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

- Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors.
- Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity.
- Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

IMPORTANT SAFETY INFORMATION

Contraindications: Patients with hypocalcemia or with known clinically significant hypersensitivity to denosumab products.

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

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

OSENVELT injection, for subcutaneous use is a RANK ligand (RANKL) inhibitor biosimilar to XGEVA® (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 OSENVELT 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.

OSENVELT Formulation[1]

FOR SUBCUTANEOUS ADMINISTRATION

120 mg/1.7 mL
NDC: 72606-038-01

IMPORTANT SAFETY INFORMATION (CONTINUED)

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 OSENVELT.

Indications[1]

OSENVELT is a RANK ligand (RANKL) inhibitor indicated for:

- Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors.
- Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity.
- Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

Dosage and Administration[1]

Subcutaneous Injection: 120 mg/1.7 mL (70 mg/mL), colorless to pale yellow solution in a single-dose vial.

Indication	Strength	Recommended Dosing
Multiple Myeloma and Bone Metastasis from Solid Tumors	120 mg	• Administer 120 mg every 4 weeks as a subcutaneous injection in the upper arm, upper thigh, or abdomen
Giant Cell Tumor of Bone	120 mg	• Administer 120 mg every 4 weeks with additional 120 mg doses on Days 8 and 15 of the first month of therapy. Administer subcutaneously in the upper arm, upper thigh, or abdomen • Administer calcium and vitamin D as necessary to treat or prevent hypocalcemia
Hypercalcemia of Malignancy	120 mg	• Administer 120 mg every 4 weeks with additional 120 mg doses on Days 8 and 15 of the first month of therapy. Administer subcutaneously in the upper arm, upper thigh, or abdomen

IMPORTANT SAFETY INFORMATION (CONTINUED)

Hypocalcemia. Severe hypocalcemia can occur, and fatal cases have been reported. Monitor calcium levels and calcium and vitamin D intake.

Osteonecrosis of the Jaw (ONJ). ONJ can occur in patients on OSENVELT. A routine oral exam and appropriate preventive dentistry are recommended before starting and during treatment with OSENVELT. Good oral hygiene should be maintained. Avoid invasive dental procedures during treatment with OSENVELT. For invasive dental procedures, consider temporary discontinuation of OSENVELT. If ONJ develops, consult a dentist or oral surgeon, as extensive surgery may worsen ONJ; consider discontinuing OSENVELT based on benefit-risk assessment.

Sample Coding

This section serves as an educational reference for coding that may be appropriate for reporting OSENVELT and related services. Medical record documentation must support the codes reported on the claim. These codes may be appropriate when OSENVELT 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
Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors[2-5]	
C79.51	Secondary malignant neoplasm of bone
C90.00	Multiple myeloma not having achieved remission
C90.01	Multiple myeloma in remission
C90.02	Multiple myeloma in relapse
Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity[6]	
D48.0	Neoplasm of uncertain behavior of bone and articular cartilage
Treatment of hypercalcemia or malignancy refractory to bisphosphonate therapy[7]	
E83.52	Hypercalcemia For patients receiving treatment for hypercalcemia of malignancy, payers may also require to document the diagnosis code describing the malignancy; however, specific coding requirements vary by payer

Note: Allowable diagnosis codes may vary by payer.

National Drug Code[1,8]

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.

OSENVELT	10-Digit NDC Code	11-Digit NDC Code
120 mg	72606-038-01	72606-0038-01

IMPORTANT SAFETY INFORMATION (CONTINUED)

Atypical Subtrochanteric and Diaphyseal Femoral Fracture. Atypical femoral fracture has been reported with denosumab products. During OSENVELT 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 OSENVELT therapy should be considered, pending a benefit-risk assessment, on an individual basis.

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[9,10]	Location on CMS-1500 Form[11]	Location on CMS-1450 (UB-04) Form[12]
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.

Code Set	Code and Description[13]	Location on CMS-1500 Form[11]	Location on CMS-1450 (UB-04) Form[12]
HCPCS	J3590 Unclassified Biologics	Field 24D	Field 44

IMPORTANT SAFETY INFORMATION (CONTINUED)

Hypercalcemia Following Treatment Discontinuation in Patients with Giant Cell Tumor of Bone and in Patients with Growing Skeletons. Clinically significant hypercalcemia, sometimes requiring hospitalization and complicated by acute renal injury, has occurred in denosumab-treated patients with giant cell tumor of bone and in those with growing skeletons, often within the first year after discontinuation. After treatment discontinuation, monitor for hypercalcemia symptoms, check serum calcium periodically, reassess calcium and vitamin D needs, and manage as appropriate.

Administration and Billing Codes (continued)

Modifiers

Modifier	Description[14,15]	Location on CMS-1500 Form[11]	Location on CMS-1450 (UB-04) Form[12]
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 OSENVELT 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 OSENVELT.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Multiple Vertebral Fractures (MVF) Following Treatment Discontinuation. Following discontinuation of denosumab treatment, fracture risk increases, including the risk of multiple vertebral fractures. Evaluate the individual patient's risk for vertebral fractures after OSENVELT discontinuation.

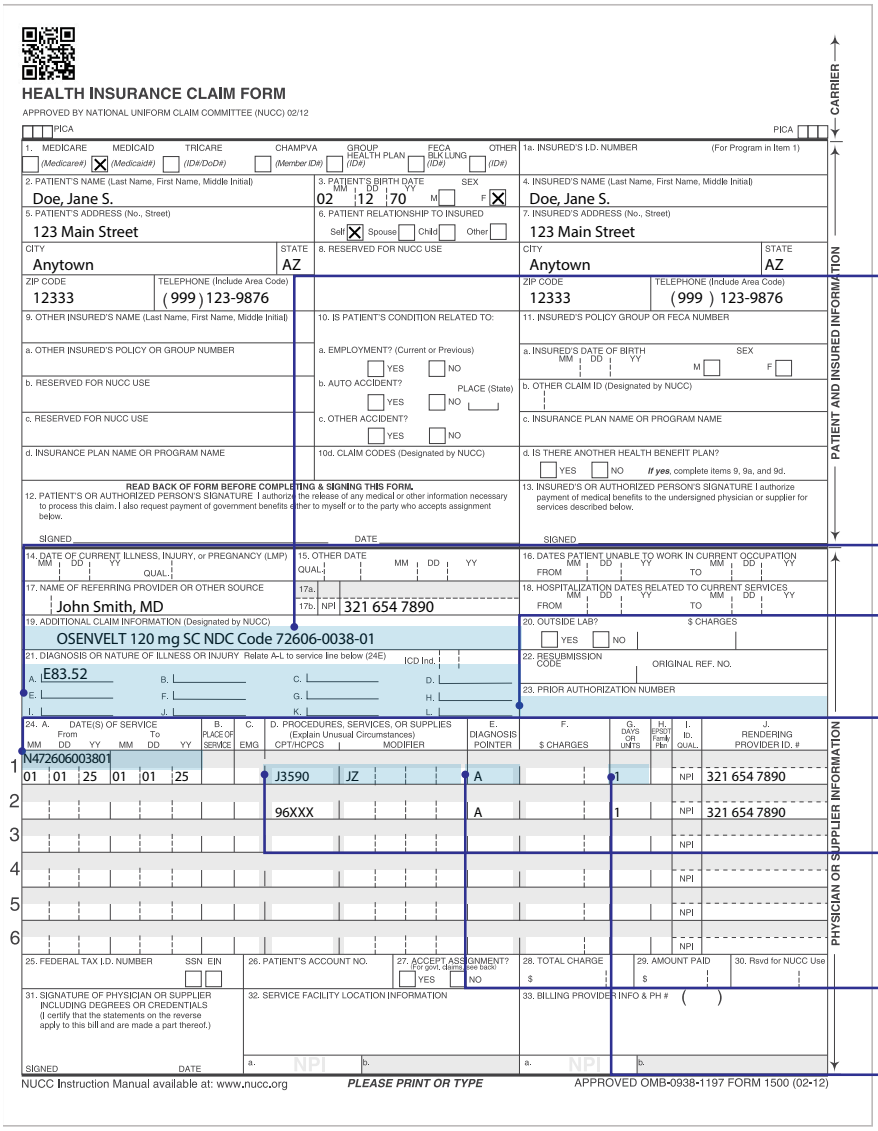
Embryo-Fetal Toxicity. Denosumab may cause fetal harm based on animal studies and its mechanism of action. Verify pregnancy status in females of reproductive potential before starting OSENVELT, and advise them to use effective contraception during treatment and for 5 months after the last dose to prevent fetal harm.

Adverse Reactions:

- **Bone Metastasis from Solid Tumors:** Most common adverse reactions (≥ 25%) were fatigue/asthenia, hypophosphatemia, and nausea.
- **Multiple Myeloma:** Most common adverse reactions (≥ 10%) were diarrhea, nausea, anemia, back pain, thrombocytopenia, peripheral edema, hypocalcemia, upper respiratory tract infection, rash, and headache.
- **Giant Cell Tumor of Bone:** Most common adverse reactions (≥ 10%) were arthralgia, headache, nausea, back pain, fatigue, and pain in extremity.
- **Hypercalcemia of Malignancy:** Most common adverse reactions (> 20%) were nausea, dyspnea, decreased appetite, headache, peripheral edema, vomiting, anemia, constipation, and diarrhea.

Sample CMS-1500 Claim Form—Physician Office[11]

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.



HEALTH INSURANCE CLAIM FORM

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

PICA

1. MEDICARE (Medicare#) ☒ 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 ☒

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 ☒ 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 SEX

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) QUAL.

15. OTHER DATE QUAL.

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM TO

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

17a.

17b. NPI 321 654 7890

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC): OSENVELT 120 mg SC NDC Code 72606-0038-01

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. E83.52 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 N472606003801 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.

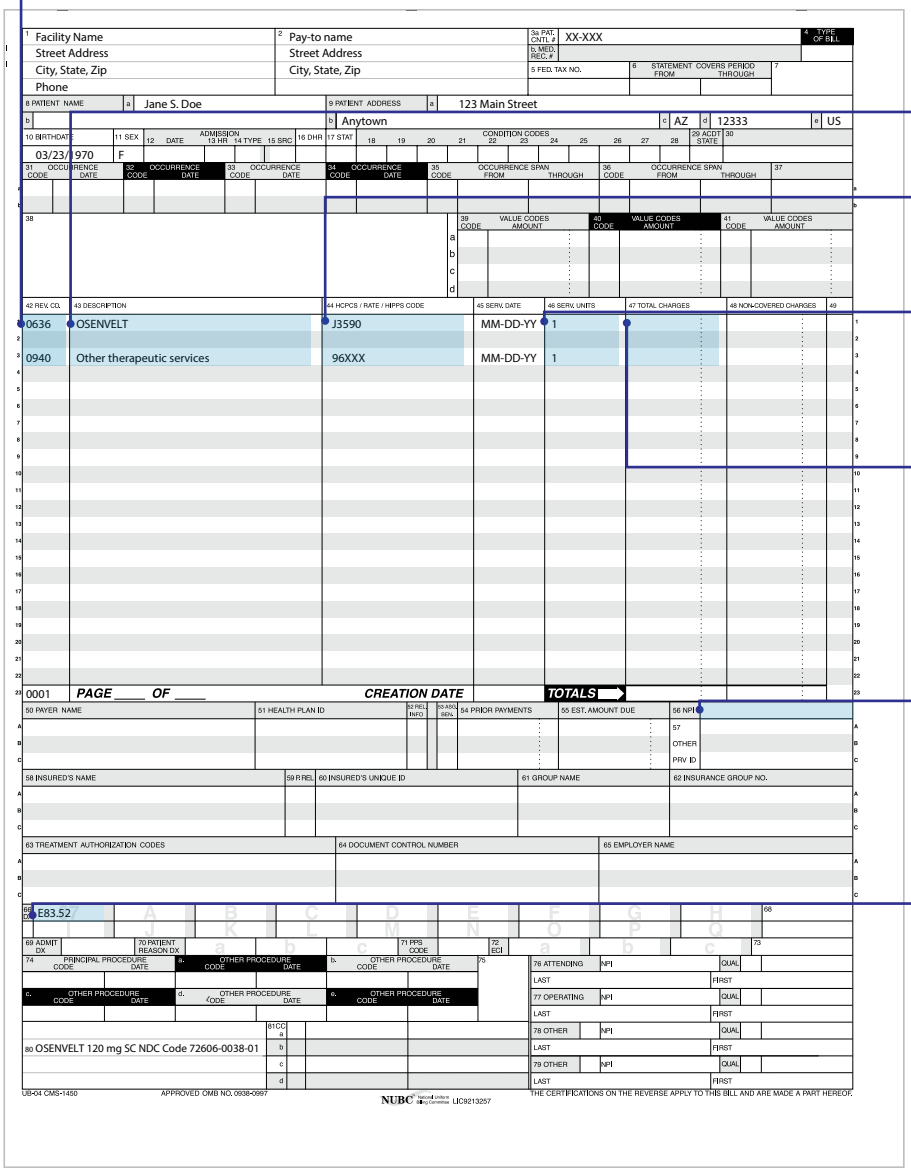
Field 24D: Indicate appropriate HCPCS as required by the payer. Include the appropriate CPT® code (eg, 96372 or 96401) to report the administration procedure.

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[12]

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.



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.

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

Contraindications: Patients with hypocalcemia or with known clinically significant hypersensitivity to denosumab products.

Drug Products with Same Active Ingredient. Patients receiving OSENVELT 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 OSENVELT.

Hypocalcemia. Severe hypocalcemia can occur, and fatal cases have been reported. Monitor calcium levels and calcium and vitamin D intake.

Osteonecrosis of the Jaw (ONJ). ONJ can occur in patients on OSENVELT. A routine oral exam and appropriate preventive dentistry are recommended before starting and during treatment with OSENVELT. Good oral hygiene should be maintained. Avoid invasive dental procedures during treatment with OSENVELT. For invasive dental procedures, consider temporary discontinuation of OSENVELT. If ONJ develops, consult a dentist or oral surgeon, as extensive surgery may worsen ONJ; consider discontinuing OSENVELT based on benefit-risk assessment.

Atypical Subtrochanteric and Diaphyseal Femoral Fracture. Atypical femoral fracture has been reported with denosumab products. During OSENVELT 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 OSENVELT therapy should be considered, pending a benefit-risk assessment, on an individual basis.

Hypercalcemia Following Treatment Discontinuation in Patients with Giant Cell Tumor of Bone and in Patients with Growing Skeletons. Clinically significant hypercalcemia, sometimes requiring hospitalization and complicated by acute renal injury, has occurred in denosumab-treated patients with giant cell tumor of bone and in those with growing skeletons, often within the first year after discontinuation. After treatment discontinuation, monitor for hypercalcemia symptoms, check serum calcium periodically, reassess calcium and vitamin D needs, and manage as appropriate.

Multiple Vertebral Fractures (MVF) Following Treatment Discontinuation. Following discontinuation of denosumab treatment, fracture risk increases, including the risk of multiple vertebral fractures. Evaluate the individual patient's risk for vertebral fractures after OSENVELT discontinuation.

Embryo-Fetal Toxicity. Denosumab may cause fetal harm based on animal studies and its mechanism of action. Verify pregnancy status in females of reproductive potential before starting OSENVELT, and advise them to use effective contraception during treatment and for 5 months after the last dose to prevent fetal harm.

Adverse Reactions:

- **Bone Metastasis from Solid Tumors:** Most common adverse reactions (≥ 25%) were fatigue/asthenia, hypophosphatemia, and nausea.
- **Multiple Myeloma:** Most common adverse reactions (≥ 10%) were diarrhea, nausea, anemia, back pain, thrombocytopenia, peripheral edema, hypocalcemia, upper respiratory tract infection, rash, and headache.
- **Giant Cell Tumor of Bone:** Most common adverse reactions (≥ 10%) were arthralgia, headache, nausea, back pain, fatigue, and pain in extremity.
- **Hypercalcemia of Malignancy:** Most common adverse reactions (> 20%) were nausea, dyspnea, decreased appetite, headache, peripheral edema, vomiting, anemia, constipation, and diarrhea.

For more information about OSENVELT, please see full Prescribing Information.

References

1. OSENVELT [prescribing information]. Celltrion USA, Inc.; 2025. **2.** 2025 ICD-10-CM Diagnosis Code C79.51. ICD10Data.com. Accessed March 25, 2025. https://www.icd10data.com/ICD10CM/Codes/C00-D49/C76-C80/C79-/C79.51 **3.** 2025 ICD-10-CM Diagnosis Code C90.00. ICD10Data.com. Accessed March 25, 2025. https://www.icd10data.com/ICD10CM/Codes/C00-D49/C81-C96/C90-/C90.00 **4.** 2025 ICD-10-CM Diagnosis Code C90.01. ICD10Data.com. Accessed March 25, 2025. https://www.icd10data.com/ICD10CM/Codes/C00-D49/C81-C96/C90-/C90.01 **5.** 2025 ICD-10-CM Diagnosis Code C90.02 ICD10Data.com. Accessed March 25, 2025. https://www.icd10data.com/ICD10CM/Codes/C00-D49/C81-C96/C90-/C90.02 **6.** 2025 ICD-10-CM Diagnosis Code D48.0. ICD10Data.com. Accessed March 25, 2025. https://www.icd10data.com/ICD10CM/Codes/C00-D49/D37-D48/D48-/D48.0 **7.** 2025 ICD-10-CM Diagnosis Code E83.52. ICD10Data.com. Accessed March 25, 2025. https://www.icd10data.com/ICD10CM/Codes/E00-E89/E70-E88/E83-/E83.52 **8.** National Drug Codes explained. Drugs.com. Updated June 12, 2024. Accessed March 25, 2025. https://www.drugs.com/ndc.html **9.** 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 **10.** 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_oIvb6IhwerfSdn0egiSI **11.** CMS.gov. CMS-1500. Accessed March 25, 2025. https://www.cms.gov/medicare/cms-forms/cms-forms/cms-forms-items/cms1188854 **12.** CMS.gov. CMS-1450. Accessed March 25, 2025. https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing-items/cms-1450 **13.** 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 **14.** 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 **15.** 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