

Patient Assistance Program

APPLICATION



Monday - Friday, 8 AM - 8 PM ET | Phone: (877) 812-6662 | Fax: (833) 912-3707 | www.CelltrionConnect.com

Patient Information - All fields marked with an * are required.

*First Name		MI		*Last Name			
*Address				*City		*State	
*Zip							
*Date of Birth		Sex	☐ Male ☐ Female ☐ Prefer Not to Answer	Weight	lb or kg		
*Email				Preferred Language	☐ English ☐ Other		
*Primary Phone		☐ Cell ☐ Home	Secondary Phone		☐ Cell ☐ Home		
Preferred Contact	☐ Patient ☐ Alternate Contact <i>By providing alternate contact information, I hereby authorize the release of my protected health information to the authorized alternate contact.</i>						
Alternate Contact Name				Relationship to Patient			
Primary Phone		☐ Cell ☐ Home	Secondary Phone		☐ Cell ☐ Home		

The Celltrion CONNECT® Patient Assistance Program is for uninsured patients only. Please confirm the patient does not have insurance. ☐

Patient Authorization to Share Health Information

By signing this form, the patient gives their permission for their physicians, pharmacies, laboratories, and other healthcare providers ("Healthcare Providers") and their health insurers to share their individually identifiable health information with Celltrion USA, Inc., the Celltrion Patient Assistance Foundation, and Celltrion affiliates and its vendors (collectively, "Celltrion").

The patient understands that their individually identifiable health information may include their full name, address, date of birth, demographic information, financial information, insurance information, and information related to their medical condition, treatment, care management, medication history, and prescriptions (collectively, "Health Information"), whether in written or verbal form, including portions of their medical record.

The patient's Health Information will be shared with Celltrion so that Celltrion may provide them with various support and information to help them access a Celltrion medicine, which may include the following, depending on the program (collectively, "Patient Support Activities"):

- Processing this application
- Verifying the information provided in this application
- Providing benefit investigation/verification and reimbursement support, including:
 - Assisting with identification of prior authorization requirements
 - Assisting with the identification of requirements of their insurer for appeal of a denied claim
- Determining their eligibility for and helping them access co-pay support or free drug programs
- Communicating with their Healthcare Providers about a Celltrion medicine and Patient Support Activities
- Coordinating the dispensing and delivery of medication
- Providing them with financial assistance resources and information if they are eligible
- Providing them with disease management and other educational materials, as well as information about Celltrion's products, services, and programs, may include sending them surveys about their experience with Celltrion products, services, and programs

Celltrion also may use their Health Information for auditing for compliance with Program requirements, for quality assurance purposes, and to evaluate and improve our operations and services.

The patient understands that Celltrion may de-identify their Health Information and use it in performing research, education, business analytics, marketing studies, or for other commercial purposes, including linkage with other de-identified data Celltrion receives from other sources.

The patient understands that they do not have to sign this form, and choosing not to sign will not affect their ability to receive treatment from their Healthcare Providers or payment from their health insurer. However, if they do not sign this form, Celltrion may not be able to provide them with assistance.

The patient understands that once their Health Information is shared, it may no longer be protected by federal privacy law. However, Celltrion agrees to protect their Health Information and to use it for the purposes described in this form or as required or permitted by law. Select pharmacies may receive remuneration from Celltrion in exchange for their Health Information and/or for any Patient Support Activities provided to them. The patient understands that this form will remain in effect for six (6) years from the date of their signature or shall otherwise expire at a shorter duration as required under applicable state law unless they provide written notice that they would like to withdraw their approval to share their Health Information sooner. If the patient would like to withdraw their approval, they may contact Celltrion at (877) 812-6662. This withdrawal will not affect the use or sharing of their Health Information that took place before they withdraw their approval. The patient understands that they may receive a copy of this form.

SIGN & DATE

Patient or Patient Authorized Representative Signature

Date

Patient Representative First and Last Name (print)

Relationship to Patient

Please see Important Safety Information on page 5 and full Prescribing Information.

Celltrion CONNECT does not guarantee coverage or reimbursement. Coverage and reimbursement decisions are made by insurance companies following the receipt of claims.

Patient Name Patient Date of Birth

Patient Assistance Program (PAP) Consent

I certify that I cannot afford my medication, and I affirm that my answers and my proof-of-income documents are complete, true, and accurate to the best of my knowledge. I will promptly contact the Celltrion Patient Assistance Program within thirty (30) days if my financial status or health insurance coverage changes. I will not seek to have this medicine or any cost from it counted in my Medicare Part D out-of-pocket expenses for prescription drugs. I will not seek reimbursement or credit for the medicine(s) from my prescription insurance provider, payor, or government health benefit program, including Medicare Part D plans, for Celltrion medications that I receive from the Celltrion Patient Assistance Foundation. I will notify my insurance provider of the receipt of any medicines through the Celltrion Patient Assistance Program. I have a signed copy of a current and completed Patient Authorization to Share Health Information on record with my healthcare provider so that my healthcare provider may share health information about me with Celltrion's assistance programs, Celltrion USA, Inc., and the Celltrion Patient Assistance Foundation.

I understand that the information I provide will be used by Celltrion, the Celltrion Patient Assistance Foundation, and parties acting on their behalf to determine eligibility, to manage and improve Celltrion's assistance programs, to communicate with me about my experience with Celltrion's assistance programs, to help me understand my insurance coverage and help me access certain Celltrion medicines through my insurance, and/or to send materials and other helpful information and updates relating to Celltrion programs.

I understand that: Completing this enrollment form does not guarantee that I will qualify for Celltrion's assistance programs. Celltrion may contact my insurer, to help me understand my insurance coverage for certain products and may provide me with support to obtain coverage through my insurer, including prior authorization and appeals support (if necessary and available). Celltrion may verify the accuracy of the information I have provided and may ask for more financial and insurance information. Any medicines supplied by Celltrion's assistance programs shall not be sold, traded, bartered, or transferred. Celltrion reserves the right to change or cancel Celltrion's assistance programs, or terminate my enrollment, at any time. The support provided through this program is not contingent on any future purchase. If I decide to enroll in a Medicare Part D plan and am eligible for the Celltrion Patient Assistance Program, I will inform the Celltrion Patient Assistance Foundation by calling 1-877-81CONN (1-877-812-6662). If I receive notice that I have been auto enrolled in a Medicare Part D plan, I will immediately notify the Celltrion Patient Assistance Foundation.

☐ By checking this box, the patient agrees to PAP consent and agrees to the Terms and Conditions specified here.

Patient Authorization to Telephone Consumer Protection Act (TCPA) Information

By signing up for text messages from Celltrion, the patient agrees that they are the primary owner of the phone number(s) provided and consent to receiving promotional communications in the form of phone calls or text messages relating to Celltrion products and services and/or their condition or treatment at the phone number(s) provided. These communications may be sent from an automated system for the selection and dialing of telephone numbers, including an automatic telephone dialing system, or may use an artificial or pre-recorded voice, including recording messages or pre-recorded voicemails.

Your agreement and consent is not required as a condition for the purchase of any goods or services. Message and data rates may apply. Unsubscribe at any time by replying STOP or clicking the unsubscribe link (where available). Text HELP for help. Message frequency varies. To the maximum extent permitted by law: (i) all information contained in SMS text messages is provided "as is" without warranty of any kind, either express or implied, including but not limited to the implied warranties of merchantability, fitness for a particular purpose, or noninfringement; and (ii) Celltrion expressly excludes any liability for any direct, indirect, or consequential loss or damage incurred by any user in connection with the receipt, use, failure of, or inability to use SMS text messages.

The patient also gives their permission to receive communications from Celltrion and parties acting on its behalf, including calls or messages made with an automated system for the selection and dialing of telephone numbers, including an automatic telephone dialing system, or may use an artificial or pre-recorded voice, including recorded messages or prerecorded voicemails at the phone number(s) provided to determine their eligibility and provide benefits verification, prior authorization/appeals assistance, and financial assistance resources and information, such as co-pay support or free drug programs, and/or other nonmarketing purposes. The patient understands that they can opt out of these telephonic communications concerning Patient Support Activities at any time by contacting Celltrion at (877) 812-6662, Monday - Friday, 8 AM - 8 PM ET.

Celltrion CONNECT®: View our privacy policy: <https://www.celltrionconnect.com/patient-privacy-policy> | View our terms of use: <https://www.celltrionconnect.com/terms-of-use/>

By signing below, the patient expressly consents to the terms of this section.

 **SIGN & DATE** Patient or Patient Authorized Representative Signature Date
Cell Phone ☐ By checking this box, the patient accepts receiving SMS messages with the cell phone number(s) provided in the Patient Information section.

Patient Financial Verification Authorization

I understand that by checking the "I Agree" box immediately following this notice, I am providing "written instructions" to Celltrion CONNECT® and/or its agents and contractors under applicable federal and/or state law authorizing them to perform electronic income verification by obtaining information from my personal credit profile or other information from Experian Health. I authorize Celltrion CONNECT® and/or their agents and contractors to obtain such information solely to validate my income for the purposes of determining my eligibility for patient assistance. As a soft credit check, it will not impact my credit score.

☐ I AGREE to the terms above for electronic income verification using Experian Health.

☐ I DO NOT AGREE with the terms above and do not wish to have my income verified by using Experian Health. I understand that I will be asked to provide supporting documentation to authenticate my income and eligibility. If additional income documentation is required, the following documents are acceptable for income verification:

- Social Security/Disability benefit statement, monthly check, or 1099
- Previous year tax return or W-2 statement
- Unemployment or disability determination letter

Patient Income Verification

Annual Gross Income (Including salary/wages, Social Security income, disability income, and any other income): Household Size (Number of members including you):
☐ By checking this box, the patient agrees to income information specified here.

Please see Important Safety Information on page 5 and full Prescribing Information.

Celltrion CONNECT does not guarantee coverage or reimbursement. Coverage and reimbursement decisions are made by insurance companies following the receipt of claims.

Patient Name Patient Date of Birth

Prescriber Information - All fields required.

Prescriber First Name MI Prescriber Last Name Prescriber NPI
Tax ID # Medicare PTAN # Prescriber Address
City State Zip Phone Fax
Practice Name Practice Contact Name
Practice Contact Title Phone Practice Contact Email Address

OSENVELT® (denosumab-bmwo) Prescribing Information - All fields required.

Has the patient started treatment with a denosumab product? ☐ Yes ☐ No Anticipated date of treatment: Diagnosis:
Location of Injection: ☐ Prescriber's Office ☐ Hospital Outpatient ☐ Other
Shipping Information for Therapy (Note: Shipments cannot be sent to PO boxes) Name
Address City State Zip
Phone

Diagnosis	Directions	Quantity	Refills
☐ Multiple Myeloma and Bone Metastasis From Solid Tumors	Administer 120 mg every 4 weeks as a subcutaneous injection in the upper arm, upper thigh, or abdomen.		
☐ Giant Cell Tumor of Bone	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.		
☐ Hypercalcemia of Malignancy	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.		

Prescriber Attestation/Authorization

By signing this document the prescriber attests that they have obtained any and all authorizations and consents from the patient or the patient's authorized personal representative necessary under HIPAA and state law to release protected health information, including that contained on this form, to Celltrion and its employees or agents for the purposes relating to Celltrion's patient support program, including, assisting the patient with benefits verification, prior authorization/appeals assistance, dispensing and delivery of the medication, financial assistance resources and information, such as co-pay support or free drug programs, for which the patient may be eligible, and other support for Celltrion's medication.

The provider certifies that they have obtained consent from the patient or the patient's caregiver to be contacted by Celltrion, Celltrion CONNECT®, and parties acting on their behalf at the phone number(s) provided regarding the purposes described above and for other non-marketing purposes.

The provider certifies that they are the prescriber of OSENVELT to the patient and that the therapy is medically necessary. The provider authorizes Celltrion to act on their behalf to transmit this prescription by any means necessary to the pharmacy chosen by the patient.

 **SIGN & DATE** Prescriber Signature and Date (no stamps) Dispense as Written/Brand Medically Necessary Date
May Substitute/Product Selection Permitted Date

CA, MA, NC, and PR: Interchange is mandated unless the prescriber writes the words "No Substitution" HERE
ATTN: Please submit the electronic prescription as required by your state law

Patients Eligible for the Celltrion CONNECT® Patient Assistance Program (PAP)

The Celltrion CONNECT PAP is designed to provide free product to qualified individuals who are uninsured. Celltrion CONNECT will help activate the PAP for eligible participants.

To receive PAP benefits, the patient must enroll in the program and meet the following eligibility requirements:

- Patient has no insurance:
 - Uninsured includes all payor types
 - The patient must have tried all other insurance options for coverage. Some examples of other insurance coverage include private insurance, HMOs, Medicaid, Medicare, state pharmacy assistance programs, veterans assistance, and any other social service agency support.
 - This program excludes patients whose medication is reimbursed in whole or in part by any type of government insurance (eg, Medicare, Medicaid, TRICARE, or any other federal or state program). Patients who have Medicare Parts A and B only (no Medicare Part D) are still excluded.
- Patient must have a valid prescription from a licensed healthcare provider (HCP) for an on-label indication.
- Patient must have an adjusted annual household income of ≤400% of the federal poverty level (FPL).
- Income verification:
 - Electronic income verification (eIV) will be conducted by the program. No asset review will be required; however, patients will need to provide proof of income if eIV does not match what the patient has reported (proof of income could include one of the following: W-2s, tax returns (1040, 1099), 3 months of pay stubs).
- Patient must show proof of residency by providing a valid United States or the Commonwealth of Puerto Rico address, and product must be administered and shipped to locations in the United States or the Commonwealth of Puerto Rico. Patient must have lived in the United States or the Commonwealth of Puerto Rico for at least 6 months.
- Diagnosis and dosing are consistent with FDA-approved indication for OSENVELT.
- Patients with insurance plans or employers participating in an alternate funding program (also sometimes referred to as patient advocacy programs, specialty networks, SHARx, Paydhealth, or Payer Matrix, among other names) are not eligible for PAP.
 - These programs require patients to apply to a manufacturer's PAP or otherwise pursue specialty drug prescription coverage through an alternate funding vendor as a condition of, requirement for, or prerequisite to coverage of relevant products, or that otherwise denies, restricts, eliminates, delays, alters, or withholds any insurance benefits or coverage contingent upon application to, or denial of eligibility for, specialty drug prescription coverage through the alternate funding program.
 - Patients must promptly contact the Celltrion CONNECT PAP if their financial status or insurance coverage changes.
- Electronic benefits verification (eBV) will be conducted by the program every 6 months to determine coverage changes.
- You may not seek payment for the value of medicines received from this program from any health plan, patient assistance foundation, flexible spending account, or healthcare savings account.
- This program offer may not be used with any other coupon, discount, prescription savings card, free trial, or other offer. Offer good only in the United States or the Commonwealth of Puerto Rico. Void where prohibited, taxed, or limited by law.
- Program terms will expire at the end of each calendar year and may change or end without notice.
- Eligibility rules are subject to change at any time.

Please see Important Safety Information on page 5 and full [Prescribing Information](#).

Celltrion CONNECT does not guarantee coverage or reimbursement. Coverage and reimbursement decisions are made by insurance companies following the receipt of claims.

Indications and Important Safety Information for OSENVELT® (denosumab-bmwo) injection, for subcutaneous use

INDICATIONS

Osenvelt (denosumab-bmwo) is a prescription medicine used to:

- Help prevent bone complications in patients with multiple myeloma and in patients whose cancer from solid tumors has spread to the bones.
- Treat adults and adolescents (whose bones have stopped growing) with giant cell tumor of bone that cannot be removed with surgery, or when surgery could cause severe complications.
- Treat high blood calcium caused by cancer (hypercalcemia of malignancy) that has not improved after treatment with bisphosphonates.

IMPORTANT SAFETY INFORMATION

If you receive Osenvelt, you should not receive other denosumab products at the same time.

Osenvelt can cause serious side effects including:

Serious allergic reactions. Serious allergic reactions have occurred with denosumab products. Call your doctor or seek emergency care immediately if you experience symptoms such as low blood pressure (hypotension), rash, difficulty breathing, itching, throat tightness, hives, or swelling of your face, lips, or tongue.

Low blood calcium (Hypocalcemia). Osenvelt can lower your blood calcium levels, which can become severe or even life-threatening. Your doctor will check your calcium levels before and during treatment, especially in the first few weeks. You may need to take calcium, magnesium, and vitamin D supplements as instructed by your doctor. Your risk may be higher if you have kidney problems or take other medicines that lower blood calcium. Call your doctor immediately if you experience symptoms of low blood calcium, such as muscle spasms or cramps, numbness or tingling in fingers, toes, or around your mouth, twitching or stiffness.

Severe jawbone problems (osteonecrosis). Severe jaw bone problems may happen when you take Osenvelt. Your doctor should examine your mouth before starting treatment and may advise seeing a dentist. Practice good oral care and consult your doctor or dentist if needed.

Unusual thigh bone fractures. Symptoms include new or unusual pain in your hip, groin, or thigh.

High Blood Calcium After Stopping Treatment. If you have giant cell tumor of bone or are still growing, stopping Osenvelt can lead to high calcium levels in your blood (hypercalcemia). This condition can become severe, require hospitalization, and affect your kidneys. Your doctor will monitor your calcium levels after stopping treatment. Call your doctor right away if you notice symptoms of high blood calcium, such as nausea or vomiting, increased thirst or urination, confusion or tiredness, muscle weakness or pain. Follow your doctor's instructions carefully, and keep all scheduled appointments for calcium monitoring.

Multiple Spine Fractures After Stopping Osenvelt. After stopping treatment with Osenvelt, some patients have experienced multiple spine fractures. Your risk is higher if you have osteoporosis, previous fractures, or other risk factors. Your doctor will assess your individual fracture risk when stopping Osenvelt.

Risk to Unborn Babies. Osenvelt may harm your unborn baby if you take it while pregnant or within 5 months before becoming pregnant. Animal studies have shown serious harm, including pregnancy loss, birth defects, abnormal bone growth, missing lymph nodes, and slow growth after birth. Your doctor will check if you are pregnant before starting Osenvelt. Tell your doctor immediately if you become pregnant or think you may be pregnant during treatment.

Do not take Osenvelt if you have low blood calcium, are pregnant or planning pregnancy, or if you're allergic to denosumab or any ingredients in Osenvelt.

Before taking Osenvelt, tell your doctor if you:

- take other denosumab products
- have low blood calcium
- cannot take daily calcium and vitamin D supplements
- take medicines that can lower blood calcium
- plan dental surgery or tooth removal
- are pregnant, planning pregnancy, or breastfeeding. Osenvelt may harm an unborn baby; a pregnancy test is required before treatment; use effective birth control during treatment and for 5 months after your last dose; inform your doctor immediately if pregnancy occurs. It is unknown if Osenvelt passes into breast milk; do not breastfeed during treatment.

Tell your doctor of all medicines, vitamins, and herbal supplements you take. Keep an updated list to share with healthcare providers.

The most common side effects of Osenvelt are:

For patients with Bone Metastasis from Solid Tumors: fatigue or weakness, low phosphate levels, and nausea.

For patients with Multiple Myeloma: diarrhea, low phosphate, nausea, fatigue, low calcium, shortness of breath, and anemia.

For patients with Giant Cell Tumor of Bone: joint pain, headache, nausea, back pain, fatigue, and pain in arms or legs.

For patients with Hypercalcemia of Malignancy: nausea, trouble breathing, decreased appetite, and headache.

Tell your doctor if side effects are bothersome or persistent. These are not all possible side effects. Call your doctor for advice on side effects or report them to the FDA at 1-800-FDA-1088.

For more information about OSENVELT, see full [Prescribing Information](#).