Patient Support Program
ENROLLMENT FORM

CELLTRION CONNECT® PATIENT SUPPORT PROGRAM | Stoboclo® denosumab-bmwo

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

Instructions for Enrollment - Celltrion CONNECT® offers 2 options for enrollment:

Option 1: Submit through the Portal

At www.CelltrionConnect.com/STOBOCLO/hcpportal, a healthcare provider can:

- Enroll a patient in Celltrion CONNECT
- Instruct the patient to complete electronic consent as applicable
- Inform the patient a Celltrion CONNECT Case Coordinator will contact them by phone with the next steps and to verify their information

OR

Option 2: Complete this form

- Attach both sides of the patient's insurance card(s)
- Attach the patient's demographics, chart notes, and clinical documentation
- Have the patient and prescriber sign the form
- Fax the completed form, along with attachments, to (833) 912-3707

Patients may sign the form electronically by visiting www.CelltrionConnect.com/STOBOCLO

Requested Services - Please check all that apply:

- ☐ **Select All**
- ☐ Benefit Verification
- ☐ Prior Authorization Support
- ☐ Appeals Support
- ☐ Medical Claims Support
- ☐ Co-pay Support for Commercially Insured Patients
  *For co-pay assistance only, visit **www.CelltrionCARES.com** to enroll*

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 *By providing alternate contact information, I hereby authorize the release of my protected health information to the authorized alternate contact.*

Alternate Contact Name _____ Relationship to Patient _____

Primary Phone _____ ☐ Cell ☐ Home Secondary Phone _____ ☐ Cell ☐ Home

Patient Insurance Information

Please attach a copy of the patient's insurance card(s) (both front and back). If not available, please complete the following:

☐ Patient does not have insurance. If the patient is uninsured, please complete the Patient Assistance Program application at www.CelltrionConnect.com/STOBOCLO

Primary Insurance _____ Policyholder Name _____

Primary Policy # _____ Primary Group # _____ Policyholder Date of Birth _____

Secondary Insurance _____ Policyholder Name _____

Secondary Policy # _____ Secondary Group # _____ Policyholder Date of Birth _____

Does the patient have a separate pharmacy benefit card? *(Optional)* ☐ Yes ☐ No

Cardholder Name _____ Pharmacy Benefit Name _____ Policy/Identification # _____

Rx BIN _____ Rx PCN _____ Group # _____

Please see Important Safety Information on page 4 and full Prescribing Information including BOXED WARNING.

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

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

***Primary Diagnosis**

☐ M81.0 (Age-related osteoporosis without current pathological fracture)

☐ M80.0_____ (Age-related osteoporosis with current pathological fracture)

Please provide complete code and diagnosis

Other (specify ICD-10 Code): | Please provide secondary ICD-10 Code, if applicable:

Medical History (required to complete prior authorization)

Original Diagnostic T-Score: | T-Score date: | History of osteoporotic fracture: ☐ Yes ☐ No

Patient is currently taking calcium and vitamin D supplements: ☐ Yes ☐ No | If available: Calcium level: | Calcium level date:

Prior Medications (required to complete prior authorization)

☐ Generic alendronate ☐ Fosamax® (alendronate sodium) ☐ Actonel® (risedronate sodium) ☐ Boniva® (ibandronate sodium) ☐ Other:

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

Has the patient started treatment with a denosumab product? ☐ Yes ☐ No | Anticipated date of treatment:

Fulfillment Method

Preferred Procurement Method: ☐ Medical and Pharmacy Benefit ☐ Medical Benefit (Physician Purchase)

Preferred Specialty Pharmacy *(Optional)*:

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

Product	Strength	Directions	Quantity	Refills*
☐ STOBOCLO	60 mg prefilled syringe	Inject 60 mg subcutaneously in the upper arm, upper thigh, or abdomen every 6 months. **Instruct patients to take calcium 1000 mg daily and at least 400 IU vitamin D daily**	1	

*Required for legal prescription triage

Prescriber Attestation/Authorization

I certify that the information provided in this STOBOCLO Enrollment Form is complete and accurate to the best of my knowledge. I have prescribed STOBOCLO based on my judgment of medical necessity. I certify that I have obtained my patient's written authorization in accordance with applicable state and federal law, including the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations to provide the individually identifiable health information on this form to agents and service providers of Celltrion Inc. and to the Celltrion CONNECT program for benefits eligibility, coverage authorization, coordination and dispensing of STOBOCLO, and providing my patient and me with other educational and support services associated with STOBOCLO. I agree that the Celltrion CONNECT program may contact me for additional information relating to STOBOCLO, including but not limited to via email, fax, and telephone. I authorize the Celltrion CONNECT program to transmit the above prescription to the pharmacy.

SIGN & DATE **Prescriber Signature and Date (no stamps)** | Date

ATTN: Please submit the electronic prescription as required by your state law

Please see Important Safety Information on page 4 and full Prescribing Information including BOXED WARNING.

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 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

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.

☐ By checking this box, the patient accepts receiving SMS messages with the cell phone number(s) provided in the Patient Information section.

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 4 and full Prescribing Information including BOXED WARNING.

Indication and Important Safety Information for STOBOCLO® (denosumab-bmwo) injection, for subcutaneous use

INDICATIONS

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

- Treat osteoporosis in women after menopause who are at high risk for fracture or who cannot use or haven't responded well to other osteoporosis medicines.
- Increase bone mass in men with osteoporosis who are at high risk for fracture.
- Treat osteoporosis in men and women who will be taking corticosteroid medicines (such as prednisone) for at least 6 months and are at high risk for fracture.
- Treat bone loss in men who are at high risk for fracture receiving certain treatments for prostate cancer that has not spread to other parts of the body.
- Treat bone loss in women who are at high risk for fracture receiving certain treatments for breast cancer that has not spread to other parts of the body.

It is not known if Stoboclo is safe and effective in children. Stoboclo is not approved for use in children.

IMPORTANT SAFETY INFORMATION

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

Stoboclo can cause serious side effects including:

Increased risk of severe low calcium levels in your blood (hypocalcemia). Stoboclo may lower the calcium levels in your blood. Your doctor should treat any low calcium levels before starting Stoboclo and may prescribe calcium and vitamin D supplements—take these exactly as instructed. If you have advanced chronic kidney disease (with or without dialysis) or chronic kidney disease-mineral bone disorder (CKD-MBD), your risk of severe hypocalcemia increases, potentially leading to hospitalization, life-threatening events, or death. Your doctor may monitor your blood levels before and during treatment. Low blood calcium often has no symptoms, but call your doctor immediately if you notice muscle spasms, twitches, cramps, or numbness and tingling in your fingers, toes, or around your mouth.

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.

Severe jawbone problems (osteonecrosis). Severe jaw bone problems may happen when you take Stoboclo. 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.

Increased risk of broken bones, including broken bones in the spine, after stopping, skipping or delaying Stoboclo. Talk with your doctor before starting Stoboclo treatment. Stopping, skipping, or delaying doses can increase your risk of bone fractures, especially in your spine. This risk is higher if you've already had a spine fracture. Do not change your dosing without consulting your doctor, who may recommend other treatments if Stoboclo is stopped.

Serious infections. Stoboclo may increase your risk of serious infections in your skin, abdomen, bladder, ear, or heart (endocarditis). Your risk is higher if you have a weakened immune system or take medicines that affect immunity. You may need hospital treatment if an infection develops. Call your doctor immediately if you experience fever or chills; red, swollen, hot, or tender skin; persistent cough or shortness of breath; severe abdominal pain; or frequent, urgent, or painful urination.

Skin problems. Stoboclo may cause skin problems like dermatitis, rash, or eczema. Call your doctor if symptoms such as persistent redness, dry or leathery skin, itching, blisters that ooze or crust, small bumps or rash patches, or skin peeling worsen or do not resolve.

Severe bone, joint, or muscle pain. Some people who take denosumab products develop severe bone, joint, or muscle pain.

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

Before taking Stoboclo, tell your doctor if you:

- take other denosumab products
- have low blood calcium
- cannot take daily calcium and vitamin D supplements
- have had parathyroid or thyroid surgery
- have malabsorption syndrome (trouble absorbing minerals)
- have kidney problems or receive dialysis
- take medicines that can lower blood calcium
- plan dental surgery or tooth removal
- are pregnant, planning pregnancy, or breastfeeding. Stoboclo 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 Stoboclo 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 Stoboclo are:

For women with osteoporosis after menopause: back pain, muscle pain, pain in arms and legs, bladder infection, high cholesterol.

For men with osteoporosis: back pain, common cold (runny nose or sore throat), joint pain.

For patients with glucocorticoid-induced osteoporosis: back pain, lung infection (bronchitis), high blood pressure, headache.

For patients treated for prostate or breast cancer: joint pain, pain in arms and legs, back pain, muscle pain.

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 STOBOCLO, see full Prescribing Information including BOXED WARNING.