Permanent Coding for BILDYOS Injection, for Subcutaneous Use, an Interchangeable Biosimilar to PROLIA (denosumab)

HCPCS II Code for BILDYOS

Coding System	Code	Description
HCPCS II	Q5162	Injection, denosumab-nxxp (BILDYOS/BILPREVDA), biosimilar, 1 mg

Administration Codes for BILDYOS

Type	Code	Description
CPT	96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
	96401	Chemotherapy administration, subcutaneous or intramuscular; non- hormonal anti-neoplastic

Diagnosis Codes:
The codes above may be relevant when submitting a claim for BILDYOS. Please consult with the applicable payer to understand the payer's specific billing requirements. Health care professionals are solely responsible for selecting codes that appropriately reflect the patient's diagnosis, the services rendered, and the applicable payer's guidelines. Included are lists of codes that may be relevant for BILDYOS and its administration. This information is current as of January 2026. The information provided here is compiled from sources believed to be accurate, but Organon makes no representation that it is accurate.
CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System.

National Drug Code (NDC) Code for BILDYOS

Code	Description
10-digit code: 78206-193-01 / 11-digit code: 78206-0193-01*	60 mg/mL single-dose prefilled syringe

*Please note that although the FDA uses a 10-digit format when registering NDCs, payers often require an 11-digit NDC number on claim forms for billing purposes. The 10-digit BILDYOS format is converted to an 11-digit code by adding a zero (0) in front of the second group of numbers, eg, 78206-0193-01. It is important to communicate with your payers to determine the appropriate NDC format requirements.

INDICATIONS AND USAGE

Treatment of Postmenopausal Women with Osteoporosis at High Risk for Fracture
BILDYOS is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, BILDYOS reduces the incidence of vertebral, nonvertebral, and hip fractures.

Treatment to Increase Bone Mass in Men with Osteoporosis
BILDYOS is indicated for treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

Treatment of Glucocorticoid-Induced Osteoporosis
BILDYOS is indicated for the treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months. High risk of fracture is defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

Treatment of Bone Loss in Men Receiving Androgen Deprivation Therapy for Prostate Cancer
BILDYOS is indicated as a treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy (ADT) for nonmetastatic prostate cancer. In these patients, denosumab products also reduced the incidence of vertebral fractures.

Treatment of Bone Loss in Women Receiving Adjuvant Aromatase Inhibitor Therapy for Breast Cancer
BILDYOS is indicated as a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

SELECTED SAFETY INFORMATION

SEVERE HYPOCALCEMIA IN PATIENTS WITH ADVANCED KIDNEY DISEASE

Patients with advanced chronic kidney disease (eGFR <30mL/min/1.73m^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 BILDYOS in patients with advanced chronic kidney disease, evaluate for the presence of CKD-MBD. Treatment with BILDYOS in these patients should be supervised by a health care provider with expertise in the diagnosis and management of CKD-MBD.

CONTRAINDICATIONS

BILDYOS is contraindicated in patients with hypocalcemia. Pre-existing hypocalcemia must be corrected prior to initiating BILDYOS. BILDYOS is contraindicated in women who are pregnant and may cause fetal harm when administered to a pregnant woman. In women of reproductive potential, pregnancy testing should be performed prior to initiating treatment with BILDYOS. BILDYOS is contraindicated in patients with a history of systemic hypersensitivity to any component of the product. Reactions have included anaphylaxis, facial swelling, and urticaria.

WARNINGS AND PRECAUTIONS

Severe Hypocalcemia and Mineral Metabolism Changes
Denosumab products can cause severe hypocalcemia and fatal cases have been reported. Pre-existing hypocalcemia must be corrected prior to initiating therapy with BILDYOS. Adequately supplement all patients with calcium and vitamin D.

In patients without advanced chronic kidney disease who are predisposed to hypocalcemia and disturbances of mineral metabolism (eg, treatment with other calcium lowering drugs), assess serum calcium and mineral levels (phosphorus and magnesium) 10 to 14 days after BILDYOS injection.

Drug Products with Same Active Ingredient
The active ingredient in BILDYOS is denosumab. Patients receiving BILDYOS should not receive other denosumab products concomitantly.

Hypersensitivity
Clinically significant hypersensitivity, including anaphylaxis, has been reported with denosumab products. Symptoms have included hypotension, dyspnea, throat tightness, facial and upper airway edema, pruritus, and urticaria. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue further use of BILDYOS.

Please read the next page for additional Selected Safety Information.

SELECTED SAFETY INFORMATION *(continued)*

Osteonecrosis of the Jaw (ONJ)
ONJ, which can occur spontaneously, is generally associated with tooth extraction and/or local infection with delayed healing. ONJ has been reported in patients receiving denosumab products. A routine oral exam should be performed by the prescriber prior to initiation of BILDYOS. A dental examination with appropriate preventive dentistry is recommended prior to treatment in patients with risk factors for ONJ such as invasive dental procedures (eg, tooth extraction, dental implants, oral surgery), diagnosis of cancer, concomitant therapies (eg, chemotherapy, corticosteroids, angiogenesis inhibitors), poor oral hygiene, and co-morbid disorders (eg, periodontal and/or other pre-existing dental disease, anemia, coagulopathy, infection, ill-fitting dentures). Good oral hygiene practices should be maintained during treatment with BILDYOS. Concomitant administration of drugs associated with ONJ may increase the risk of developing ONJ. The risk of ONJ may increase with duration of exposure to denosumab products.

For patients requiring invasive dental procedures, clinical judgment of the treating physician and/or oral surgeon should guide the management plan of each patient based on individual benefit-risk assessment.

Patients who are suspected of having or who develop ONJ while on BILDYOS should receive care by a dentist or an oral surgeon. Extensive dental surgery to treat ONJ may exacerbate the condition. Discontinuation of BILDYOS should be considered based on individual 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. Causality has not been established as these fractures also occur in osteoporotic patients who have not been treated with antiresorptive agents.

During BILDYOS treatment, patients should be advised to report new or unusual thigh, hip, or groin pain. Any patient who presents with thigh or groin pain should be suspected of having an atypical fracture and should be evaluated to rule out an incomplete femur fracture. Interruption of BILDYOS 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. New vertebral fractures occurred as early as 7 months (on average 19 months) after the last dose of denosumab. Prior vertebral fracture was a predictor of multiple vertebral fractures after denosumab product discontinuation. Evaluate an individual's benefit-risk before initiating treatment. If BILDYOS treatment is discontinued, patients should be transitioned to an alternative antiresorptive therapy.

Serious Infections
In a clinical trial of over 7800 women with postmenopausal osteoporosis, serious infections leading to hospitalization were reported more frequently in the denosumab group than in the placebo group. Serious skin infections, as well as infections of the abdomen, urinary tract, and ear, were more frequent in patients treated with denosumab products. Endocarditis was also reported more frequently in denosumab-treated patients. The incidence of opportunistic infections and the overall incidence of infections were similar between the treatment groups. Advise patients to seek prompt medical attention if they develop signs or symptoms of severe infection, including cellulitis.

Patients on concomitant immunosuppressant agents or with impaired immune systems may be at increased risk for serious infections. Consider the benefit-risk profile in such patients before treating with BILDYOS. In patients who develop serious infections while on BILDYOS, prescribers should assess the need for continued BILDYOS therapy.

Dermatologic Adverse Reactions
In a clinical trial of over 7800 women with postmenopausal osteoporosis, epidermal and dermal adverse events such as dermatitis, eczema, and rashes occurred at a significantly higher rate with denosumab treatment compared to placebo. Most of these events were not specific to the injection site. Consider discontinuing BILDYOS if severe symptoms develop.

Musculoskeletal Pain
In postmarketing experience, severe and occasionally incapacitating bone, joint, and/or muscle pain has been reported in patients during denosumab treatment. Onset of symptoms varied from one day to several months after starting denosumab products. Consider discontinuing use if severe symptoms develop.

Suppression of Bone Turnover
In clinical trials in women with postmenopausal osteoporosis, treatment with denosumab resulted in significant suppression of bone remodeling as evidenced by markers of bone turnover and bone histomorphometry. The significance of these findings and the effect of long-term treatment with denosumab products are unknown. Monitor patients for consequences, including ONJ, atypical fractures, and delayed fracture healing.

Hypercalcemia in Pediatric Patients with Osteogenesis Imperfecta
BILDYOS is not approved for use in pediatric patients. Hypercalcemia has been reported in pediatric patients with osteogenesis imperfecta treated with denosumab products.

ADVERSE REACTIONS

The most common adverse reactions (>5% and more common than placebo) reported with denosumab products in women with postmenopausal osteoporosis are back pain, pain in extremity, musculoskeletal pain, hypercholesterolemia, and cystitis.

The most common adverse reactions (>5% and more common than placebo) reported with denosumab products in men with osteoporosis are back pain, arthralgia, and nasopharyngitis. Pancreatitis has been reported with denosumab products.

The most common adverse reactions (>3% and more common than active-control group) reported with denosumab products in patients with glucocorticoid-induced osteoporosis are back pain, hypertension, bronchitis, and headache.

The most common (per patient incidence ≥10%) adverse reactions reported with denosumab products in patients with bone loss receiving androgen deprivation therapy for prostate cancer or adjuvant aromatase inhibitor therapy for breast cancer are arthralgia and back pain. Pain in extremity and musculoskeletal pain have also been reported in clinical trials.

The most common adverse reactions leading to discontinuation of denosumab products in patients with postmenopausal osteoporosis are back pain and constipation.

Denosumab is a human monoclonal antibody. As with all therapeutic proteins, there is potential for immunogenicity.

Before prescribing BILDYOS, please read the accompanying Prescribing Information, including the Boxed Warning about severe hypocalcemia. The Medication Guide also is available.

Please note, BILDYOS is part of the Risk Evaluation and Mitigation Strategy (REMS) program.

For additional copies of the Prescribing Information, please call 844-674-3200, visit BILDYOSPro.com, or contact your Organon representative.