

PERMANENT CODING FOR BILPREVDA INJECTION, FOR SUBCUTANEOUS USE, AN INTERCHANGEABLE BIOSIMILAR TO XGEVA (DENOSUMAB)

HCPCS II Code for BILPREVDA

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

Administration Codes for BILPREVDA

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 BILPREVDA. 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 BILPREVDA 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 BILPREVDA

Code	Description
10-digit code: 78206-195-01 / 11-digit code: 78206-0195-01*	120 mg/1.7 mL single-dose vial

*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 BILPREVDA format is converted to an 11-digit code by adding a zero (0) in front of the second group of numbers, eg, 78206-0195-01. It is important to communicate with your payers to determine the appropriate NDC format requirements.

INDICATIONS AND USAGE

Multiple Myeloma and Bone Metastasis from Solid Tumors

BILPREVDA is indicated for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors.

Giant Cell Tumor of Bone

BILPREVDA is indicated for the 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.

Hypercalcemia of Malignancy

BILPREVDA is indicated for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

SELECTED SAFETY INFORMATION

CONTRAINDICATIONS

Pre-existing hypocalcemia must be corrected prior to initiating therapy with BILPREVDA. BILPREVDA is contraindicated in patients with known clinically significant hypersensitivity to denosumab products.

WARNINGS AND PRECAUTIONS

Drug Products with Same Active Ingredient

Patients receiving BILPREVDA should not receive other denosumab products concomitantly.

Hypocalcemia

Denosumab products can cause severe symptomatic hypocalcemia, and fatal cases have been reported. Pre-existing hypocalcemia must be corrected prior to initiating BILPREVDA. Monitor calcium levels throughout therapy, especially in the first weeks of initiating therapy, and administer calcium, magnesium, and vitamin D as necessary. Concomitant use of calcimimetics and other drugs that can lower calcium levels may worsen hypocalcemia risk, and serum calcium should be closely monitored. Advise patients to contact a health care provider for symptoms of hypocalcemia.

An increased risk of hypocalcemia has been observed in clinical trials of patients with increasing renal dysfunction, most commonly with severe dysfunction (creatinine clearance less than 30 mL/min and/or on dialysis), and with inadequate/no calcium supplementation. Monitor calcium levels and calcium and vitamin D intake.

Please read the next page for additional Selected Safety Information.

SELECTED SAFETY INFORMATION (CONTINUED)

Hypersensitivity

BILPREVDA is contraindicated in patients with known clinically significant hypersensitivity to denosumab products, including anaphylaxis. Reactions may include hypotension, dyspnea, upper airway edema, lip swelling, rash, pruritus, and urticaria. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue BILPREVDA therapy permanently.

Osteonecrosis of the Jaw (ONJ)

ONJ has been reported in patients receiving denosumab products, manifesting as jaw pain, osteomyelitis, osteitis, bone erosion, tooth or periodontal infection, toothache, gingival ulceration, or gingival erosion. Persistent pain or slow healing of the mouth or jaw after dental surgery may also be manifestations of ONJ. In clinical trials in patients with cancer, the incidence of ONJ was higher with longer duration of exposure.

A history of tooth extraction, poor oral hygiene, or use of a dental appliance may be predisposing factors to developing ONJ. Other risk factors for the development of ONJ include immunosuppressive therapy, treatment with angiogenesis inhibitors, systemic corticosteroids, diabetes, and gingival infections.

Perform an oral examination and appropriate preventive dentistry prior to the initiation of BILPREVDA and periodically during therapy. Advise patients regarding oral hygiene practices. Avoid invasive dental procedures during treatment with BILPREVDA. Consider temporarily interrupting therapy if an invasive dental procedure must be performed.

Patients who are suspected of having or who develop ONJ while on BILPREVDA should receive care by a dentist or an oral surgeon. In these patients, extensive dental surgery to treat ONJ may exacerbate the condition.

Atypical Subtrochanteric and Diaphyseal Femoral Fracture

Atypical femoral fracture has been reported with denosumab products. These fractures can occur anywhere in the femoral shaft from just below the lesser trochanter to above the supracondylar flare and are transverse or short oblique in orientation without evidence of comminution.

Atypical femoral fractures most commonly occur with minimal or no trauma to the affected area. They may be bilateral and many patients report prodromal pain in the affected area, usually presenting as dull, aching thigh pain, weeks to months before a complete fracture occurs. A number of reports note that patients were also receiving treatment with glucocorticoids (eg, prednisone) at the time of fracture. During BILPREVDA 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. Patients presenting with an atypical femur fracture should also be assessed for symptoms and signs of fracture in the contralateral limb. Interruption of BILPREVDA therapy should be considered, pending a risk/benefit assessment, on an individual basis.

Hypercalcemia Following Treatment Discontinuation in Patients with Giant Cell Tumor of Bone (GCTB) and in Patients with Growing Skeletons

Clinically significant hypercalcemia requiring hospitalization and complicated by acute renal injury has been reported in denosumab-treated patients with GCTB and in patients with growing skeletons. Hypercalcemia has been reported within the first year after treatment discontinuation. After treatment is discontinued, monitor patients for signs and symptoms of hypercalcemia, assess serum calcium periodically, reevaluate the patients' calcium and vitamin D supplementation, and treat appropriately.

Multiple Vertebral Fractures (MVF) Following Treatment Discontinuation

MVF have been reported following discontinuation of treatment with denosumab products. Patients at higher risk for MVF include those with risk factors for or a history of osteoporosis or prior fractures. When BILPREVDA treatment is discontinued, evaluate the individual patient's risk for vertebral fractures.

Embryo-Fetal Toxicity

Based on data from animal studies and its mechanism of actions, denosumab products can cause fetal harm when administered to a pregnant woman.

Verify the pregnancy status of females of reproductive potential prior to the initiation of BILPREVDA. Advise females of reproductive potential to use effective contraception during therapy, and for at least 5 months after the last dose of BILPREVDA. Advise pregnant women and females of reproductive potential that exposure to BILPREVDA during pregnancy or within 5 months prior to conception can result in fetal harm.

ADVERSE REACTIONS

The most common adverse reactions (incidence $\geq 25\%$) in patients with bone metastasis from solid tumors were fatigue/asthenia, hypophosphatemia, and nausea. The most common serious adverse reaction was dyspnea. The most common adverse reactions resulting in discontinuation were osteonecrosis and hypercalcemia.

The most common adverse reactions (incidence $\geq 10\%$) in patients with multiple myeloma were diarrhea, nausea, anemia, back pain, thrombocytopenia, peripheral edema, hypocalcemia, upper respiratory tract infection, rash, and headache. The most common serious adverse reaction was pneumonia. The most common adverse reaction resulting in discontinuation was osteonecrosis of the jaw.

The most common adverse reactions (incidence $\geq 10\%$) in patients with GCTB were arthralgia, back pain, pain in extremity, fatigue, headache, nausea, nasopharyngitis, musculoskeletal pain, toothache, vomiting, hypophosphatemia, constipation, diarrhea, and cough. The most frequent serious adverse reactions were osteonecrosis of the jaw, bone giant cell tumor, anemia, pneumonia, and back pain. The most common adverse reaction resulting in discontinuation was osteonecrosis of the jaw.

The most common adverse reactions (incidence $>20\%$) in patients with hypercalcemia of malignancy were nausea, dyspnea, decreased appetite, headache, peripheral edema, vomiting, anemia, constipation, and diarrhea.

Before prescribing BILPREVDA, please read the accompanying **Prescribing Information**.

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



HAVE BILLING AND CODING QUESTIONS?

Visit organonaccessprogram-bilprevda.com

OR

Call 1-866-809-9515

Monday-Friday, 8 AM to 8 PM ET