BILPREVDA®
(denosumab-nxxp)
injection 120 mg/1.7 mL

POTENTIAL CODING INSTRUCTIONS FOR BILPREVDA® (DENOSUMAB-NXXP) DURING NOC PERIOD

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

J3590	J3490	J9999	C9399	96372	96401
Unclassified biologics	**Unclassified drugs**	**Not otherwise classified, antineoplastic drugs**	**Unclassified drugs or biologics**	**Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular**	**Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic**
Health Care Professional (HCP) Office			*Hospital Outpatient Department (HOPD)*	*Possible Administration Codes*	

Biosimilars without a permanent code may be often billed using a Not Otherwise Classified (NOC) Healthcare Common Procedure Coding System (HCPCS) code (eg, J3590–"Unclassified biologics"). Centers for Medicare and Medicaid Services (CMS) may then assign a permanent Q code to facilitate long-term biosimilar reimbursement. There may be payer-specific guidance on what additional information should be included on a claim form when billing NOC codes.

You are solely responsible for determining the appropriate codes and for any action you take in billing. The information provided here is not intended to be definitive or exhaustive and is not intended to replace the guidance of a qualified professional advisor. Organon and its agents make no warranties or guarantees, expressed or implied, concerning the accuracy or appropriateness of this information for your particular use given the frequent changes in public and private payer billing. The use of this information does not guarantee payment or that any payment received will cover your costs. Diagnosis codes should be selected only by a health care professional.

National Drug Code (NDC) and Packaging Information:

- BILPREVDA 120 mg/1.7 mL vial (label): 78206-195-99
- BILPREVDA 120 mg/1.7 mL vial (outer carton containing 1 vial): 78206-195-01

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, 78206-0195-99. It is important to communicate with your payers to determine the appropriate NDC format requirements.

INDICATIONS AND USAGE

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

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.

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

Please see additional safety information on next pages.

SELECTED SAFETY INFORMATION FOR BILPREVDA® (DENOSUMAB-NXXP)

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.

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.

Please see additional safety information on next page.

HAVE BILLING AND CODING QUESTIONS?

Visit organonaccessprogram-bilprevda.com OR Call 855-459-9965 Monday-Friday, 8 am to 8 pm ET

SELECTED SAFETY INFORMATION FOR BILPREVDA® (DENOSUMAB-NXXP) (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

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 ≥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 hypocalcemia.

The most common adverse reactions (incidence ≥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 ≥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.

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