Optum Rx®

## Bomyntra® (denosumab-bnht) – New biosimilar approval

- On March 25, 2025, Fresenius Kabi announced the FDA approval of Bomyntra (denosumab-bnht), biosimilar to Amgen's Xgeva® (denosumab).
    - Bomyntra is the fourth FDA-approved biosimilar to Xgeva.
    - Sandoz's Wyost® (denosumab-bbdz), Samsung Bioepis' Xbryk™ (denosumab-dssb), and Celltrion's Osenvelt® (denosumab-bmwo) were previously approved as biosimilars to Xgeva.
- Bomyntra, Osenvelt, Xbryk, Wyost and Xgeva share the following indications:
    - Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors
    - 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
    - Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy
- The approval of Bomyntra is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Xgeva.
- Bomyntra is contraindicated in patients with:
    - Hypocalcemia: Pre-existing hypocalcemia must be corrected prior to initiating therapy with Bomyntra.
    - Hypersensitivity.
- Warnings and precautions for Bomyntra include drug products with same active ingredient; osteonecrosis of the jaw; atypical subtrochanteric and diaphyseal femoral fractures; hypercalcemia following treatment discontinuation in patients with giant cell tumor of bone and in patients with growing skeletons; multiple vertebral fractures following discontinuation of treatment; and embryo-fetal toxicity.
- The most common adverse reactions (≥ 25%) with Bomyntra use in bone metastasis from solid tumors were fatigue/asthenia, hypophosphatemia, and nausea.
- The most common adverse reactions (≥ 10%) with Bomyntra use in multiple myeloma were diarrhea, nausea, anemia, back pain, thrombocytopenia, peripheral edema, hypocalcemia, upper respiratory tract infection, rash, and headache.
- The most common adverse reactions (≥ 10%) with Bomyntra use in giant cell tumor of the bone were arthralgia, headache, nausea, back pain, fatigue, and pain in extremity.
- The most common adverse reactions (≥ 20%) with Bomyntra use in hypercalcemia of malignancy were nausea, dyspnea, decreased appetite, headache, peripheral edema, vomiting, anemia, constipation, and diarrhea.
- The recommended dosage of Bomyntra in multiple myeloma and bone metastasis from solid tumors is 120 mg administered as a subcutaneous (SC) injection every 4 weeks in the upper arm, upper thigh, or abdomen.

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- The recommended dosage of Bomyntra in giant cell tumor of the bone and hypercalcemia of malignancy is 120 mg administered SC every 4 weeks with additional 120 mg doses on days 8 and 15 of the first month of therapy.
- Fresenius Kabi's launch plans for Bomyntra are pending. Bomyntra will be available as a 120 mg/1.7 mL (70 mg/mL) solution in a single-dose vial.
    - A confidential settlement agreement signed between Amgen and Fresenius Kabi allows for launch of Bomyntra in mid-2025.