Wyost® (denosumab-bbdz) – New first-time interchangeable biosimilar approval

- On March 5, 2024, the FDA approved Sandoz's Wyost (denosumab-bbdz), biosimilar and *interchangeable* to Amgen's Xgeva® (denosumab).
    - Wyost is the first FDA-approved biosimilar to Xgeva.
- 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 Wyost is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Xgeva.
- Evidence also demonstrated that Wyost met the other legal requirements to be *interchangeable* with Xgeva at the pharmacy level.
- Wyost is contraindicated in patients with:
    - Hypocalcemia: Pre-existing hypocalcemia must be corrected prior to initiating therapy with Xgeva.
    - Hypersensitivity.
- Warnings and precautions for Wyost 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 Wyost use in bone metastasis from solid tumors were fatigue/asthenia, hypophosphatemia, and nausea.
- The most common adverse reactions (≥ 10%) with Wyost 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 Wyost 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 Wyost use in hypercalcemia of malignancy were nausea, dyspnea, decreased appetite, headache, peripheral edema, vomiting, anemia, constipation, and diarrhea.
- The recommended dosage of Wyost 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 Wyost 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.

- Sandoz's launch plans for Wyost are pending. Wyost will be available as a 120 mg/1.7 mL (70 mg/mL) solution in a single-dose vial.