

Ospomyv[™] (denosumab-dssb) – New biosimilar approval

- On February 14, 2025, the FDA approved Samsung Bioepis' [Ospomyv \(denosumab-dssb\)](#), biosimilar to Amgen's [Prolia[®] \(denosumab\)](#).
 - Ospomyv is the second FDA-approved biosimilar to Prolia. Sandoz' [Jubbonti[®] \(denosumab-bbdz\)](#) was the first biosimilar approved to Prolia.
 - In addition, Samsung Bioepis received FDA approval for unlabeled denosumab-dssb.
- Ospomyv, Jubbonti and Prolia share the following indications:
 - Treatment of postmenopausal women with osteoporosis at high risk for fracture
 - Treatment to increase bone mass in men with osteoporosis at high risk for fracture
 - Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture
 - Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer
 - Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.
- The approval of Ospomyv is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Prolia.
- Like Prolia, Ospomyv carries a boxed warning for severe hypocalcemia in patients with advanced kidney disease.
- Ospomyv is contraindicated in patients with:
 - Hypocalcemia: Pre-existing hypocalcemia must be corrected prior to initiating therapy with Ospomyv.
 - Pregnancy: Denosumab products may cause fetal harm when administered to a pregnant woman.
 - Hypersensitivity: Reactions have included anaphylaxis, facial swelling, and urticaria.
- Warnings and precautions for Ospomyv include severe hypocalcemia and mineral metabolism changes; concomitant use with drug products with the same active ingredient; osteonecrosis of the jaw; atypical subtrochanteric and diaphyseal femoral fractures; multiple vertebral fractures following discontinuation of treatment; serious infections; dermatologic adverse reactions; musculoskeletal pain; suppression of bone turnover; and hypercalcemia in pediatric patients with osteogenesis imperfecta.
- The most common adverse reactions (> 5% and more common than placebo) with Ospomyv use in postmenopausal osteoporosis were back pain, pain in extremity, hypercholesterolemia, musculoskeletal pain, and cystitis.
- The most common adverse reactions (> 5% and more common than placebo) with Ospomyv use in male osteoporosis were back pain, arthralgia, and nasopharyngitis.
- The most common adverse reactions (> 3% and more common than active-control group) with Ospomyv use in glucocorticoid-induced osteoporosis were back pain, hypertension, bronchitis, and headache.

- The most common adverse reactions (> 5% and more common than placebo) with Ospomyv use in male osteoporosis were back pain, arthralgia, and nasopharyngitis.
- The most common adverse reactions (≥ 10% and more common than placebo) with Ospomyv use in patients with bone loss due to hormone ablation for cancer were arthralgia and back pain.
- The recommended dosage of Ospomyv is 60 mg administered as a single subcutaneous injection once every 6 months.
 - Ospomyv should be administered by a healthcare professional.
 - All patients should receive calcium 1,000 mg daily and at least 400 IU vitamin D daily.
- Samsung Bioepis' launch plans for Ospomyv are pending. Ospomyv will be available as a 60 mg/mL solution in a single-dose prefilled syringe.



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