

## Xgeva® (denosumab) – New warning

- On January 24, 2018, the <u>FDA approved</u> an update to the *Warnings and Precautions* section of the <u>Xgeva (denosumab)</u> drug label regarding multiple vertebral fractures (MVF) following treatment discontinuation.
- Xgeva is indicated for the following:
  - 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.
- MVF have been reported following discontinuation of treatment with denosumab.
  - Patients at higher risk for MVF include those with risk factors for or a history of osteoporosis or prior fractures.
  - When Xgeva treatment is discontinued, evaluate the individual patient's risk for vertebral fractures.



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