Xgeva® (denosumab) – New warning

- On January 24, 2018, the FDA approved an update to the *Warnings and Precautions* section of the Xgeva (denosumab) 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.