Prolia® (denosumab) – New indication

- On May 21, 2018, Amgen announced the FDA approval of Prolia (denosumab) for the treatment of glucocorticoid-induced osteoporosis (GIOP) in men and women at high risk for fracture.
    - This includes men and women who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months. High risk of fracture is defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.
- Prolia is also indicated for treatment:
    - Of postmenopausal women with osteoporosis at high risk for fracture
    - To increase bone mass in men with osteoporosis at high risk for fracture
    - To increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer
    - To increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.
- The efficacy and safety of Prolia in the treatment of 795 patients with GIOP were assessed in the 12-month primary analysis of a 2-year study. Patients were randomized to risedronate 5 mg orally once daily or Prolia 60 mg subcutaneously (SC) once every 6 months for one year.
    - In the group receiving glucocorticoids for < 3 months at the beginning of the study, Prolia significantly increased lumbar spine bone mineral density (BMD) vs. risedronate (4.4% vs. 2.3%; difference = 2.2%; $p < 0.001$).
    - In the group receiving glucocorticoids for ≥ 3 months at the beginning of the study, Prolia significantly increased lumbar spine BMD vs. risedronate (3.8% vs. 0.8%; difference = 2.9%; $p < 0.001$).
- The most common adverse reactions (≥ 3% and more common than the active-control group) with Prolia use in GIOP were back pain, hypertension, bronchitis, and headache.
- The recommended dosage of Prolia for all indications is 60 mg administered as a single SC injection once every 6 months in the upper arm, upper thigh, or abdomen. Prolia should be administered by a healthcare professional.