Forteo® (teriparatide) – Updated drug label

- On November 16, 2020, the FDA approved several updates to Eli Lilly's Forteo (teriparatide) drug label, including:
    - The removal of the boxed warning regarding osteosarcoma
    - Modification of the dosing and administration section to allow for longer duration of treatment in patients who remain at or return to having a high risk for fracture
    - Addition of the risk of cutaneous calcification including calciphylaxis to the existing warning regarding hypercalcemia and hypercalcemic disorders.

- Forteo is approved for:
    - Treatment of postmenopausal women with osteoporosis at high risk for fracture
    - Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture
    - Treatment of men and women with glucocorticoid-induced osteoporosis at high risk for fracture.

- The recommended dose of Forteo is 20 mcg subcutaneously once a day.

- The new recommended treatment duration section of the drug label states that the use of Forteo for more than 2 years during a patient's lifetime should only be considered if a patient remains at or has returned to having a high risk for fracture.
    - Previously, the treatment duration section stated that the safety and efficacy of Forteo had not been evaluated beyond 2 years of treatment. Consequently, use of the drug for more than 2 years during a patient's lifetime was not recommended.