RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Forteo (teriparatide) is used to treat osteoporosis in women after menopause who are at high risk for fracture (broken bone) and cannot use another osteoporosis medicine or other osteoporosis medicines did not work well. Forteo may also be used to increase bone mass in men with primary or hypogonadal osteoporosis; and treat men and women with osteoporosis associated with sustained systemic glucocorticoid therapy (1).

Tymlos (abaloparatide) is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture 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. In postmenopausal women with osteoporosis, Tymlos reduces the risk of vertebral fractures and nonvertebral fractures (2).

Regulatory Status
FDA-approved indications:

Forteo
Forteo is recombinant human parathyroid hormone analog (1-34), [rhPTH(1-34)] indicated for: (1)
1. Treatment of postmenopausal women with osteoporosis at high risk for fracture
2. Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture
3. Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture

Tymlos
Tymlos is a human parathyroid hormone related peptide [PTHrP(1-34)] analog indicated for: (2)
1. Treatment of postmenopausal women with osteoporosis at high risk for fracture

The Forteo and Tymlos labels includes a boxed warning citing the risk of osteosarcoma dependent on dose and treatment duration. Forteo and Tymlos should not be prescribed for patients who are at increased baseline risk for osteosarcoma including those with Paget’s disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, or prior external beam or implant radiation therapy involving the skeleton (1-2).
Because of the unknown relevance of the rodent osteosarcoma findings to humans, cumulative use of parathyroid hormone analogs including Forteo (teriparatide) and Tymlos (abaloparatide) for more than 2 years during a patient's lifetime is not recommended (1-2).

Caution should be used in prescribing Forteo in patients with severe renal impairment. In 5 patients with severe renal impairment (CrCl<30 mL/min), the AUC and T1/2 of teriparatide were increased by 73% and 77%, respectively (1).

The safety and effectiveness of Forteo and Tymlos in pediatric patients has not been established (1-2).

**Summary**

Forteo (teriparatide) is used to treat osteoporosis in women after menopause who are at high risk for fracture (broken bone) and may also be used to increase bone mass in men with primary or hypogonadal osteoporosis; and treat men and women with osteoporosis associated with sustained systemic glucocorticoid therapy. Tymlos (abaloparatide) is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture 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. These agents should not be prescribed for patients who are at increased baseline risk for osteosarcoma including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, or prior external beam or implant radiation therapy involving the skeleton. The safety and effectiveness of Forteo and Tymlos in pediatric patients has not been established (1-2).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Forteo and Tymlos while maintaining optimal therapeutic outcomes.

**References**