SmartPA Criteria Proposal

Drug/Drug Class:	Parathyroid Hormone and Bone Resorption Suppression Related Agents Clinical Edit
First Implementation Date:	December 12, 2019
Proposed Date:	June 18, 2020
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of parathyroid hormone and bone resorption suppression related agents

Why Issue Selected: Forteo, a recombinant parathyroid hormone, and Tymlos, an analog of human parathyroid hormone related peptide, bind to the same receptors as parathyroid hormone and mimic the effect of parathyroid hormone. Prolia is a subcutaneous fully human, highly specific, monoclonal antibody against receptor activator of nuclear factor kappa-beta ligand (RANKL) preventing it from activating receptors known as receptor activator of nuclear factor-kappa-beta (RANK), and ultimately, decreases bone resorption and increases bone mass and strength. Tymlos is only indicated for use in postmenopausal women; Forteo and Prolia are also indicated for treatment of osteoporosis in men and for glucocorticoid-induced osteoporosis. Prolia has the most indications, with additional indications for treatment of bone loss in women taking aromatase inhibitors and men prescribed androgen-deprivation therapy.

Natpara is an injectable parathyroid hormone for use as adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism.

Parsabiv (etelcalcetide) is an intravenous, calcimimetic and calcium-sensing receptor (CaSR) agonist indicated for secondary hyperparathyroidism in adults with chronic kidney disease on hemodialysis. Sensipar (cinacalcet) is an oral calcimimetic agent indicated for the treatment of patients with secondary hyperparathyroidism due to chronic kidney disease, hypercalcemia associated with parathyroid carcinoma, or severe hypercalcemia due to primary hyperparathyroidism who are unable to undergo parathyroidectomy.

Zolendronic acid, marketed as Zometa® and Reclast®, is an injectable bisphosphonate first approved in 2001. It is a potent inhibitor of bone resorption and also displays some antitumor activity. Reclast is FDA approved for the treatment and prevention of osteoporosis in postmenopausal woman, osteoporosis in men, treatment and prevention of glucocorticoid-induced osteoporosis, and Paget disease of bone in men and women. Zometa is FDA approved for the treatment of hypercalcemia of malignancy, for the treatment of bone metastasis associated with solid tumors, and for the treatment of multiple myeloma patients with documented osteolytic lesions. Zometa is not included in this edit and is reviewed in the Zometa Clinical Edit.

Due to the highly specific indications and cost of these agents, MO HealthNet will impose criteria to ensure appropriate utilization.

Program-Specific Information:

FORTEO 600 MCG/2.4 ML PEN	253	$834,499.65	$3,298.41	$3,480.50	NADAC
NATPARA 25 MCG CARTRIDGE	1	$195.00	$195.00	$10,016.32	MAC
NATPARA 50 MCG CARTRIDGE	19	$188,449.35	$9,918.38	$10,016.32	MAC
NATPARA 75 MCG CARTRIDGE	2	$20,051.74	$10,025.87	$10,016.32	MAC
NATPARA 100 MCG CARTRIDGE	7	$69,305.87	$9,900.83	$10,016.32	MAC
PARSABIV 2.5 MG/0.5 ML VIAL	371	$32,056.20	$86.40	$81.75	WAC
PARSABIV 5 MG/ML VIAL	887	$168,405.12	$189.85	$163.50	WAC
PARSABIV 10 MG/2 ML VIAL	126	$41,202.00	$327.00	$327.00	WAC
PROLIA 60 MG/ML SYRINGE	291	$292,024.79	$1,003.52	$1,237.68	NADAC
RECLAST 5 MG/100 ML	53	$10,532.30	$198.72	$110.00	MAC
SENSIPAR 30 MG TABLET	952	$451,285.22	$474.03	$11.61	NADAC
SENSIPAR 60 MG TABLET	394	$366,960.19	$931.37	$25.26	NADAC
SENSIPAR 90 MG TABLET	123	$167,419.18	$1,361.13	$43.94	NADAC
TERIPARATIDE 620 MCG/2.48 ML	0	-	-	$2,465.09	MAC
TYMLOS 80 MCG DOSE PEN	135	$241,352.88	$1,787.79	$1,893.62	NADAC

Type of Criteria:

☐ **Increased risk of ADE** ☐ **Preferred Drug List**
☒ **Appropriate Indications** ☒ **Clinical Edit**

Data Sources:

☐ **Only Administrative Databases** ☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Parathyroid Hormone and Bone Resorption Suppression Related Agents
- Age range: All appropriate MO HealthNet participants aged 18 years or older

Approval Criteria

- Participant aged 18 years or older **AND**
- **Participant demonstrates compliance to current therapy:**
  - **For Prolia: at least one claim in the past year**
  - **For all other agents: 90 out of 120 days of therapy OR**
- **For Forteo, Teriparatide 620mcg, or Tymlos:**
  - Documented diagnosis of osteoporosis in the past 2 years **AND**
  - Participant is on concurrent calcium and vitamin D therapy **AND**
  - Participant is not at increased risk for osteosarcoma **AND**
  - Participant has not received therapy with parathyroid hormone analogs or receptor agonist in excess of 24 months in total **AND**
  - Documented treatment failure, contraindication, or ineffective response to a minimum 12 month trial on previous therapy with oral bisphosphonates
  - **For Teriparatide 620mcg: Clinical Consultant Review required for medical necessity of therapy**
  - For Tymlos: Documented adequate therapeutic trial on Forteo or Prolia (35 days in the past 90 days)
- **For Prolia:**
  - History of appropriate diagnosis placing participant at high risk for fractures:

        - Documented diagnosis of osteoporosis in the past 2 years **OR**
        - Documented diagnosis of prostate cancer in the past year with androgen deprivation therapy **OR**
        - Documented diagnosis of breast cancer in the past year with adjuvant aromatase inhibitor therapy **AND**
    - Documented treatment failure, contraindication, or ineffective response to a minimum 12 month trial with oral bisphosphonates
- **For Natpara:**
    - Documented diagnosis of hypoparathyroidism in the past 2 years **AND**
    - Documented diagnosis of hypocalcemia in the past 2 years **AND**
    - Participant is on concurrent calcium and vitamin D therapy **AND**
    - Prescriber attests to compliance with the Natpara REMS program
- **For Sensipar:**
    - Documented diagnosis of secondary hyperparathyroidism with chronic kidney disease on dialysis in the past 2 years **OR**
    - Documented diagnosis of hypercalcemia in the past 2 years with:
        - Documented diagnosis of parathyroid carcinoma in the past 2 years **OR**
        - Documented diagnosis of primary hyperparathyroidism in the past 2 years
- **For Parsabiv:**
    - Documented diagnosis of secondary hyperparathyroidism with chronic kidney disease on dialysis in the past 2 years **AND**
    - Documented adequate therapeutic trial of Sensipar (defined as 35 days in the past 90 days)
- **For Reclast:**
    - **History of appropriate diagnosis for placing participant at high risk for fractures:**
        - **Documented diagnosis of osteoporosis in the past 2 years OR**
        - **Documented diagnosis of Paget's disease of bone in the past year AND**
    - **Documented treatment failure, contraindication, or ineffective response to a minimum 12 month trial on previous therapy with oral bisphosphonates**

Denial Criteria

- Therapy will be denied if no approval crieria are met
- **Claim exceeds approvable quantity limitations:**
    - **Forteo: 1 pen per 28 days**
    - **Natpara: 2 cartridges (1 package) per 28 days**
    - **Reclast: 1 vial per year**

Required Documentation

Laboratory Results:		Progress Notes:	
MedWatch Form:		Other:	X

Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)
Rule Type: CE

Default Approval Period

1 year

References

- FORTEO® (teriparatide injection) [package insert]. Indianapolis, IN: Lilly USA, LLC; April 2020.
- TERIPARATIDE injection [package insert]. Morristown, NJ: Alvogen, Inc.; November 2019.
- TYMLOS® (abaloparatide) injection [package insert]. Waltham, MA: Radius Health, Inc.; October 2018.
- PROLIA® (denosumab) injection [package insert]. Thousand Oaks, CA: Amgen Inc.; March 2020.
- NATPARA® (parathyroid hormone) for injection [package insert]. Lexington, MA: Shire-NPS Pharmaceuticals, Inc.; December 2018.
- PARSABIV® (etelcalcetide) injection [package insert]. Thousand Oaks, CA: Amgen Inc.; March 2019.
- SENSIPAR® (cinacalcet) tablets [package insert]. Thousand Oaks, CA: Amgen Inc.; December 2019.
- RECLAST® (zoledronic acid) injection [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2020.
- Qaseem A, Forciea MA, McLean RM, Denberg TD; Clinical Guidelines Committee of the American College of Physicians. Treatment of low bone density or osteoporosis to prevent fractures in men and women: a clinical practice guideline update from the American College of Physicians. Ann Intern Med. 2017;166(11):818-839.
- Buckley L, Guyatt G, Fink HA, et al. 2017 American College of Rheumatology guideline for the prevention and treatment of glucocorticoid-induced osteoporosis. Arthritis Rheumatol. 2017;69(8):1521-1537.
- Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis- 2016. Endocr Pract. 2016;22(Suppl 4):1-42.