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 17, 2021
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.

Evenity® is an anabolic agent indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. FDA approved in April 2019, it is the first and only bone builder with a dual effect that both increases bone formation and decreases bone loss. Full course of Evenity is 12 monthly doses administered by a healthcare provider.

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

Program-Specific Information:

Date Range FFS 4-1-2020 to 3-31-2021			
Drug	**Claims**	**Spend**	**Avg spend per claim**
EVENITY 105 MG/1.17 ML SYR	0	-	-
EVENITY 210 MG/2.34 ML SYR	29	$36,258.30	$1,250.28
FORTEO 620 MCG/2.48 ML PEN	308	$989,732.62	$3,213.41
NATPARA 25 MCG CARTRIDGE	0	-	-
NATPARA 50 MCG CARTRIDGE	0	-	-
NATPARA 75 MCG CARTRIDGE	0	-	-
NATPARA 100 MCG CARTRIDGE	0	-	-
PARSABIV 2.5 MG/0.5 ML VIAL	491	$39,628.25	$80.70
PARSABIV 5 MG/ML VIAL	596	$114,695.25	$192.44
PARSABIV 10 MG/2 ML VIAL	312	$102,024.00	$327.00
PROLIA 60 MG/ML SYRINGE	321	$329,386.38	$1,026.12
RECLAST 5 MG/100 ML	25	$4,411.16	$176.44
SENSIPAR 30 MG TABLET	1,155	$348,373.93	$301.62
SENSIPAR 60 MG TABLET	638	$323,927.00	$507.72
SENSIPAR 90 MG TABLET	200	$217,252.20	$1,086.26
TYMLOS 80 MCG DOSE PEN	115	$185,241.20	$1,610.79

Type of Criteria:

☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **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 or Tymlos:**
  - Documented diagnosis of osteoporosis **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 **a teriparatide agent** or Prolia (35 out of 90 days)

- **For Prolia:**
  - History of appropriate diagnosis placing participant at high risk for fractures:
    - Documented diagnosis of osteoporosis **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 **AND**
  - Documented diagnosis of hypocalcemia **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 **OR**
  - Documented diagnosis of hypercalcemia with:
    - Documented diagnosis of parathyroid carcinoma **OR**
    - Documented diagnosis of primary hyperparathyroidism
- **For Parsabiv:**
  - Documented diagnosis of secondary hyperparathyroidism with chronic kidney disease on dialysis **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 **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
- **For Evenity:**
  - **Documented diagnosis of osteoporosis**
  - **Documented treatment failure, contraindication, or ineffective response to a minimum 12 month trial on previous therapy with oral bisphosphonates**
  - **Documented adequate therapeutic trial of Prolia**
  - **Participant has not received Evenity therapy in excess of 12 doses in total**

Denial Criteria

- Therapy will be denied if no approval criteria are met
- Claim exceeds approvable quantity limitations:
  - Forteo: 1 pen every 20 days
  - Natpara: 2 cartridges (1 package) every 20 days
  - **Prolia: 1 syringe every 152 days**
  - Reclast: 1 vial every 304 days
  - **Teriparatide 620mcg: 1 pen every 20 days**
  - **Tymlos: 1 pen every 20 days**

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; November 2020.
- TYMLOS® (abaloparatide) injection [package insert]. Waltham, MA: Radius Health, Inc.; October 2020.
- 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.; July 2020.
- PARSABIV® (etelcalcetide) injection [package insert]. Thousand Oaks, CA: Amgen Inc.; February 2021.
- 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.
- EVENITY® (romosozumab-appg) [package insert]. Thousand Oaks, CA: Amgen; 2019
- 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.