

SmartPA Criteria Proposal

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|-----------------------------------|--|
| Drug/Drug Class: | Parathyroid Hormone and Bone Resorption Suppression Related Agents Clinical Edit |
| First Implementation Date: | December 12, 2019 |
| Proposed Date: | June 16, 2022 |
| Prepared for: | MO HealthNet |
| Prepared by: | MO HealthNet/Conduent |
| Criteria Status: | <input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> 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.

Zoledronic 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 4-1-2021 to 3-31-2022 | | | | |
|--------------------------------------|--------|----------------|---------------------|--|
| Drug | Claims | Spend | Avg spend per claim | |
| EVENITY 105 MG/1.17 ML SYR | 0 | - | - | |
| EVENITY 210 MG/2.34 ML SYR | 47 | \$85,103.07 | \$1,810.70 | |
| FORTEO 620 MCG/2.48 ML PEN | 319 | \$1,102,670.32 | \$3,456.64 | |
| 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 | 47 | \$3997.81 | \$85.06 | |
| PARSABIV 5 MG/ML VIAL | 466 | \$92,853.37 | \$199.25 | |
| PARSABIV 10 MG/2 ML VIAL | 261 | \$86,528.45 | \$331.52 | |
| PROLIA 60 MG/ML SYRINGE | 371 | \$359,760.56 | \$969.70 | |
| RECLAST 5 MG/100 ML | 41 | \$3,021.76 | \$73.70 | |
| SENSIPAR 30 MG TABLET | 1,677 | \$33,046.83 | \$19.70 | |
| SENSIPAR 60 MG TABLET | 865 | \$105,058.27 | \$121.45 | |
| SENSIPAR 90 MG TABLET | 428 | \$79,330.80 | \$185.35 | |
| TYMLOS 80 MCG DOSE PEN | 74 | \$144,724.50 | \$1,955.73 | |

- 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 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**

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- Documented treatment failure, contraindication, or ineffective response to a minimum 12 month trial on previous therapy with oral bisphosphonates
- For Tymlos: Documented adequate therapeutic trial on a teriparatide agent or Prolia (35 out of 90 days)
- **For Prolia:**
 - 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 **OR**
 - Documented diagnosis of osteoporosis
 - 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**
- **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:**
 - Documented diagnosis of Paget's disease of bone in the past year **OR**
 - Documented diagnosis of osteoporosis
 - 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
- **For Reclast: Documented diagnosis of end stage renal disease**
- Claim exceeds approvable quantity limitations:
 - Evenity: 2 syringes every 20 days
 - 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:

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MedWatch Form:

Other:

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 2021.
- TYMLOS® (abaloparatide) injection [package insert]. Boston, MA: Radius Health, Inc.; December 2021.
- PROLIA® (denosumab) injection [package insert]. Thousand Oaks, CA: Amgen Inc.; May 2021.
- NATPARA® (parathyroid hormone) for injection [package insert]. Lexington, MA: Shire-NPS Pharmaceuticals, Inc.; April 2022.
- 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; April 2020.
- Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists/ American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis—2020 Update. *Endocr Pract.* 2020;26(Suppl 1):1-46. doi:10.4158/GL-2020-0524SUPPL
- Shoback D, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Guideline Update. *J Clin Endocrinol Metab.* 2020;105(3):dgaa048. doi:10.1210/clinem/dgaa048

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