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 women, 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.

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Program-Specific Information</th>
<th>Total Cost</th>
<th>Average Cost per Claim</th>
<th>Average Cost per Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>FORTEO 600 MCG/2.4 ML PEN</td>
<td>$834,499.65</td>
<td>$3,298.41</td>
<td>$3,480.50 NADAC</td>
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<td>NATPARA 25 MCG CARTRIDGE</td>
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<td>PARSABIV 2.5 MG/0.5 ML VIAL</td>
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<td>PARSABIV 5 MG/ML VIAL</td>
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<td>PARSABIV 10 MG/2 ML VIAL</td>
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<td>RECLAST 5 MG/100 ML</td>
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<td>SENSIPIAR 30 MG TABLET</td>
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<td>SENSIPIAR 60 MG TABLET</td>
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<td>SENSIPIAR 90 MG TABLET</td>
<td>$167,419.18</td>
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<td>TERIPARATIDE 620 MCG/2.48 ML</td>
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<td>TYMLOS 80 MCG DOSE PEN</td>
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</tbody>
</table>

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:

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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
  o Documented treatment failure, contraindication, or ineffective response to a minimum 12 month trial with oral bisphosphonates

- For Natpara:
  o Documented diagnosis of hypoparathyroidism in the past 2 years AND
  o Documented diagnosis of hypocalcemia in the past 2 years AND
  o Participant is on concurrent calcium and vitamin D therapy AND
  o Prescriber attests to compliance with the Natpara REMS program

- For Sensipar:
  o Documented diagnosis of secondary hyperparathyroidism with chronic kidney disease on dialysis in the past 2 years OR
  o 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:
  o Documented diagnosis of secondary hyperparathyroidism with chronic kidney disease on dialysis in the past 2 years AND
  o Documented adequate therapeutic trial of Sensipar (defined as 35 days in the past 90 days)

- For Reclast:
  o 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
  o 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 criteria are met
- **Claim exceeds approvable quantity limitations:**
  o Forteo: 1 pen per 28 days
  o Natpara: 2 cartridges (1 package) per 28 days
  o 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.