SmartPA Criteria Proposal

Drug/Drug Class: Parathyroid Hormone and Bone Resorption Suppression Related Agents

First Implementation Date: December 12, 2019

Revised Date: February 6, 2020

Prepared for: MO HealthNet

Prepared by: MO HealthNet/Conduent

Criteria Status: ☒ Existing Criteria

Executive Summary

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

Why was this Issue Selected: Recombinant human parathyroid hormone and Parsabiv are both used to manage calcium levels; recombinant human parathyroid hormone is indicated to treat hypocalcemia in patients with hypoparathyroidism, and Parsabiv is indicated to treat secondary hyperparathyroidism in patients with chronic kidney disease on dialysis. Forteo, Prolia, and Tymlos are all indicated to treat osteoporosis. Forteo and Tymlos bind to the same receptors as parathyroid hormone, and mimic the effect of parathyroid hormone. Prolia binds to RANKL, preventing it from activating 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. Both Prolia and recombinant human parathyroid hormone have required REMS programs to inform patients and providers of serious risks associated with their use. In patients unable to take oral therapy, osteoporosis guidelines frequently recommend Forteo or Prolia.

Program-specific information:

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Claims (1/1/19-3/31/19)</th>
<th>Spend (1/1/19-3/31/19)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prolia</td>
<td>56</td>
<td>$10,808</td>
</tr>
<tr>
<td>Forteo®</td>
<td>53</td>
<td>$169,229</td>
</tr>
<tr>
<td>Tymlos™</td>
<td>31</td>
<td>$52,266</td>
</tr>
<tr>
<td>Natpara®</td>
<td>16</td>
<td>$154,288</td>
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<tr>
<td>Sensipar®</td>
<td>266</td>
<td>$254,880</td>
</tr>
<tr>
<td>Cinacalcet (gen Sensipar)</td>
<td>30</td>
<td>$42,930</td>
</tr>
<tr>
<td>Parsabiv™</td>
<td>327</td>
<td>$791,013</td>
</tr>
</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 and older

Approval Criteria

- Participant age 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 Prolia:
  - History of appropriate diagnosis for placing participant at high risk for fractures:
    - Post-menopausal osteoporosis in women
    - Primary or hypogonadal osteoporosis in men
    - Glucocorticoid-induced osteoporosis
    - Treatment of bone loss in men receiving androgen deprivation therapy for prostate cancer
    - Treatment of bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer
  - Documented treatment failure, contraindication, or ineffective response to a minimum 12 month trial on previous therapy with oral bisphosphonates
- For Forteo and Tymlos:
  - History of appropriate diagnosis for placing participant at high risk for fractures:
    - Post-menopausal osteoporosis in women
    - Primary or hypogonadal osteoporosis in men AND
  - Confirmation participant is receiving calcium and vitamin D supplementation if dietary intake is inadequate 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
  - Tymlos – Documented trial on Forteo or Prolia (35 days in the past 90 days)
- For Natpara:
  - Appropriate diagnosis as an adjunct to calcium and vitamin D to control hypocalcemia in participants with hypoparathyroidism
  - Subject to REMS criteria – due to the potential risk of osteosarcoma
- For Sensipar:
  - Appropriate diagnosis of secondary hyperparathyroidism in adult patients with CKD on dialysis OR
  - Hypercalcemia in adult patients with Parathyroid Carcinoma OR primary hyperparathyroidism
- For Parsabiv:
  - Appropriate diagnosis of secondary hyperparathyroidism in adult patients with CKD on hemodialysis
  - Documented trial on Sensipar (35 days in the past 90 days)
- For Reclast:
  - History of appropriate diagnosis for placing participant at high risk for fractures:
    - Post-menopausal osteoporosis in women
    - Primary or hypogonadal osteoporosis in men
    - Glucocorticoid-induced osteoporosis
    - Paget disease of bone
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

**Required Documentation**

<table>
<thead>
<tr>
<th>Laboratory results:</th>
<th>Progress notes:</th>
</tr>
</thead>
</table>

MedWatch form: | Other: 

**Disposition of Edit**

Denial: Exception Code “682” (Clinical Edit)
Rule Type: CE

**Default Approval Period**

6 months

**References:**