

## Clinical Policy: Etelcalcetide (Parsabiv)

Reference Number: PA.CP.PHAR.379

Effective Date: 10/2018

Last Review Date: 07/2025

### Description

Etelcalcetide (Parsabiv™) is a calcium-sensing receptor agonist which binds to the calcium-sensing receptor (CaSR) on chief cells of the parathyroid gland.

### FDA Approved Indication(s)

Parsabiv is indicated for the treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease (CKD) on hemodialysis.

Limitation(s) of use: Parsabiv has not been studied in adult patients with parathyroid carcinoma, primary hyperparathyroidism, or with CKD who are not on hemodialysis and is not recommended for use in these populations.

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of PA Health & Wellness® that Parsabiv is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Secondary Hyperparathyroidism (must meet all):

1. Diagnosis of secondary hyperparathyroidism associated with CKD;
2. Prescribed by or in consultation with a nephrologist or endocrinologist;
3. Age  $\geq$  18 years;
4. Member is on hemodialysis;
5. One of the following (a or b):
  - a. Lab results over the previous 3-6 months show trending increase in iPTH level;
  - b. Current (within the last 30 days) labs show iPTH above the normal levels;
6. Failure of both of the following (a and b):
  - a. Generic cinacalcet (Sensipar®);
  - b. One vitamin D analog (*see Appendix B*), at up to maximally indicated doses unless clinically significant adverse effects are experienced or all are contraindicated;

*\*Prior authorization may be required for Sensipar*
7. Parsabiv is not prescribed concurrently with other calcimimetics (e.g., cinacalcet [Sensipar]);
8. At the time of request, member does not have serum calcium less than the lower limit of the normal range;
9. Dose does not exceed one of the following (a or b):
  - a. 15 mg three times per week;
  - b. 3mLs three times per week.

**Approval duration: 6 months**

**B. Other diagnoses/indications**

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

**II. Continued Therapy**

**A. Secondary Hyperparathyroidism (must meet all):**

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy as evidenced by a decrease in iPTH;
3. Parsabiv is not prescribed concurrently with other calcimimetics (e.g., cinacalcet [Sensipar]);
4. If request is for a dose increase, new dose does not exceed one of the following (a or b):
  - a. 15 mg three times per week;
  - b. 3 mLs three times per week.

**Approval duration: 12 months**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.PHARM.01) applies.  
**Approval duration: Duration of request or 6 months (whichever is less);** or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

CaSR: calcium-sensing receptor

CKD: chronic kidney disease

HPT: hyperparathyroidism

iPTH: intact parathyroid hormone

PTH: parathyroid hormone

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
cinacalcet (Sensipar)	30 mg PO once daily; titrate as necessary no more frequently than every 2 to 4 weeks through sequential doses of 60 mg, 90 mg, 120 mg, and 180 mg PO once daily	300 mg/day
calcitriol (Rocaltrol <sup>®</sup> )	Oral: 0.25 mcg PO QD or QOD; may increase dose by 0.25 mcg/day at 4 to 8 week intervals IV: 1 to 2 mcg/day IV 3 times weekly on approximately every other day; may increase by 0.5 to 1 mcg/dose at 2 to 4 week intervals	Oral: 1 mcg/day IV: 4 mcg/day
doxercalciferol (Hectorol <sup>®</sup> )	Oral: 10 mcg PO 3 times weekly at dialysis; increase dose as needed at 8 week intervals in 2.5 mcg increments if iPTH is not lowered by 50% and fails to reach the target range IV: 4 mcg IV bolus 3 times weekly at the end of dialysis, increase dose as needed at 8 week intervals by 1 to 2 mcg increments if iPTH is not lowered by 50% and fails to reach the target range	Oral: 20 mcg 3 times weekly IV: 18 mcg/week
paricalcitol (Zemplar <sup>®</sup> )	1 mcg PO daily if baseline iPTH level is 500 picog/mL or less; 2 mcg PO daily if baseline iPTH level is greater than 500 picog/mL; may titrate dose at 2 to 4 week intervals	0.24 mcg/kg

Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): known hypersensitivity to etelcalcetide or any of its excipients
- Boxed warning(s): none reported

*Appendix D: General Information*

- Serum calcium levels should be measured 1 week after initiation of therapy or dosage adjustment, and every 4 weeks thereafter for maintenance. PTH should be measured 4 weeks after initiation of therapy or dose adjustment. In individuals with PTH levels below the target range, reduce the dose of Parsabiv or temporarily stop the therapy. Once PTH and serum calcium levels return to the target range, therapy will be initiated at a lower dose. Among individuals with a corrected serum calcium of at least 7.5 mg/dL but below target range and without symptoms of hypocalcemia, consider reducing the dose, temporarily stopping therapy, or adding on therapies to increase serum calcium. If therapy is stopped, reinstate at a lower dose when PTH and serum calcium levels return to the target range. If the corrected serum calcium falls below 7.5 mg/dL, or if patient is experiencing symptomatic hypocalcaemia, stop the therapy and treat hypocalcaemia.
- Cinacalcet should be discontinued for at least 7 days prior to starting Parsabiv.
- If serum calcium falls below 7.5 mg/dl or if patient reports symptoms of hypocalcemia, therapy should be discontinued.

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
Secondary HPT	Initial: 5 mg IV bolus 3 times per week administered at the end of hemodialysis; adjust in 2.5 or 5 mg increments no more frequently than every 4 weeks to maintain target PTH levels and normal serum calcium levels.	15 mg three times per week

**VI. Product Availability**

Solution in a single-dose vial for injection: 2.5 mg/0.5 mL, 5 mg/mL, 10 mg/2mL

**VII. References**

1. Parsabiv Prescribing Information. Wilmington, DE: KAI Pharmaceuticals, Inc.; January 2025. Available at: [www.parsabiv.com](http://www.parsabiv.com). Accessed April 14, 2025.
2. Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Update Work Group. KDIGO 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease–Mineral and Bone Disorder (CKD-MBD). Available at: <http://kdigo.org/wp-content/uploads/2017/02/2017-KDIGO-CKD-MBD-GL-Update.pdf>.
3. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Truven Health Analytics. Updated periodically. Accessed April 30, 2025.

**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0606	Injection, etelcalcetide, 0.1 mg

Reviews, Revisions, and Approvals	Date
Policy created	10/2018
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/2019
3Q 2020 annual review: added age limit; added to Section I requirement that member does not have serum calcium less than the lower limit of the normal to align with prescribing information and similar Sensipar criteria requirements; references reviewed and updated.	07/2020
3Q 2021 annual review: no significant changes; references reviewed and updated.	07/2021
3Q 2022 annual review: no significant changes; references reviewed and updated.	07/2022

<b>Reviews, Revisions, and Approvals</b>	<b>Date</b>
3Q 2023 annual review: no significant changes; references reviewed and updated.	07/2023
3Q 2024 annual review: no significant changes; references reviewed and updated.	07/2024
3Q 2025 annual review: clarified redirection to Sensipar should be to generic cinacalcet; included cinacalcet as an example of a calcimimetic that should not be prescribed concurrently with Parsabiv; references reviewed and updated.	07/2025