Prior Authorization Review Panel

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CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 08/01/2021**
Policy Number: PA.CP.PHAR.379	**Effective Date: 10/2018** **Revision Date: 07/2021**
Policy Name: Etelcalcetide (Parsabiv)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

3Q 2021 annual review: no significant changes; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Etelcalcetide (Parsabiv)

Reference Number: PA.CP.PHAR.379
Effective Date: 10/2018
Last Review Date: 07/2021

Coding Implications
Revision Log

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 health plans affiliated with 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 ≥ 18 years;
4. Member is on hemodialysis;
5. Lab results over the previous 3-6 months show trending increase in iPTH level or current (within the last 30 days) labs show iPTH above the normal levels;
6. Failure of Sensipar® and a 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. Member is not receiving other calcimimetics;
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 15 mg 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 Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy as evidenced by a decrease in iPTH;
3. Member is not receiving other calcimimetics;
4. If request is for a dose increase, new dose does not exceed 15 mg three times per week.

Approval duration: 12 months

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.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
PTH: parathyroid hormone
CKD: chronic kidney disease
HPT: hyperparathyroidism
iPTH: intact 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 for all relevant lines of business 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®)	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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
doxercalciferol (Hectorol®)	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®)	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® (generic) when the drug is available by brand name only and generic (Brand name®) 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

- Secondary hyperparathyroidism (HPT) is most commonly seen in patients with chronic kidney disease (CKD). These patients present with elevated levels of parathyroid hormone (PTH) and an enlarged parathyroid gland. Increased levels of PTH result from vitamin D deficiency, hypocalcemia and hyperphosphatemia; all attributed to kidney failure. Over time, as kidney function deteriorates, secondary HPT becomes more severe and may lead to abnormalities in bone mineralization and turnover and soft tissue and vascular calcifications.3
- Parsabiv treats secondary HPT in patients with CKD who are on dialysis. The maintenance dose of Parsabiv is individualized and titrated based on PTH and corrected serum calcium response. The dose may be increased by 2.5-5 mg no more frequently than every 4 weeks. Serum calcium levels should be measured 1 week after initiation of therapy or dosage adjustment, and every 4 weeks thereafter for maintenance. Also, 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, reinitiate 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: Amgen Pharmaceuticals, Inc.; February 2021. Available at: www.parsabiv.com. Accessed April 21, 2021.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Truven Health Analytics. Updated periodically. Accessed April 21, 2021.
3. 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. Accessed May 10, 2019.

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	P&T Approval Date
Policy created	10/18	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	
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	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2021 annual review: no significant changes; references reviewed and updated.	07/2021	