Clinical Policy Title:	etelcalcetide
Policy Number:	RxA.443
Drug(s) Applied:	Parsabiv®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

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

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
etelcalcetide (Parsabiv®)	Secondary HPT	Intravenous: Initial: 5 mg intravenous bolus 3 times per week administered at the end of hemodialysis; adjust in 2.5 or 5 mg increments every 4 weeks to maintain target PTH levels and normal serum calcium levels.	15 mg three times per week

Dosage Forms

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

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

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

1. Diagnosis of secondary hyperparathyroidism 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 contraindicated or clinically significant adverse effects are experienced;
   *Prior authorization may be required for Sensipar®
7. Member is not receiving other calcimimetics;
8. Dose does not exceed 15 mg three times per week.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
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
Commercial: 12 months
Medicaid: 12 months

III. Appendices

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
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Maximum Dose
cinacalcet (Sensipar®)	30 mg orally 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 orally once daily.	180 mg/day
calcitriol (Rocaltrol®)	Oral: 0.25 mcg orally once daily or every other day; may increase dose by 0.25 mcg/day at 4 to 8 week intervals. Intravenous: 1 to 2 mcg/day intravenously 3 times weekly on approximately every other day; may increase by 0.5 to 1 mcg/dose at 2 to	Oral: 1 mcg/day Intravenous: 4

Drug Name	Dosing Regimen	Maximum Dose
	4 week intervals.	mcg/day
doxercalciferol (Hectorol®)	Oral: 10 mcg orally 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. Intravenous: 4 mcg intravenous 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 Intravenous: 18 mcg/week
paricalcitol (Zemplar®)	1 mcg orally daily if baseline iPTH level is 500 picogram/mL or less; 2 mcg orally daily if baseline iPTH level is greater than 500 picogram/mL; may titrate dose at 2 to 4 week intervals.	0.24 mcg/kg

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

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.
- 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.

References

1. Parsabiv® Prescribing Information. Wilmington, DE: Amgen Pharmaceuticals, Inc.; February 2021. Available at: www.parsabiv.com . Accessed July 02, 2021.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Truven Health Analytics. Updated periodically. Available at: https://www.micromedexsolutions.com/micromedex2/librarian/ssl/true . Accessed July 02, 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: https://kdigo.org/wp-content/uploads/2017/02/2017-KDIGO-CKD-MBD-GL-Update.pdf . Accessed July 02, 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Line of Business Policy Applies to was updated to all lines of business. 3. Initial and Continued approval duration was updated to include Medicaid, Commercial & HIM approval duration. 4. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 5. References were reviewed and updated.	7/22/2020	7/14/2020
Policy was reviewed: 1. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 2. Initial Approval Criteria I.A.1 was	07/02/2021	09/14/2021

updated from “hyperparathyroidism associated with CKD” to “hyperparathyroidism with CKD.” 3. Initial Approval Criteria and Continued Therapy Approval Criteria were updated to remove HIM approval duration. 4. Continued Therapy Approval Criteria II.A.1 was rephrased to " Member is currently receiving the medication that has been authorized by..." 5. Therapeutic Alternatives verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..". 6. Statement about drug listing format in Appendix B is updated to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 7. References were reviewed and updated.		