

Clinical Policy Title:	etelcalcetide
Policy Number:	RxA.443
Drug(s) Applied:	Parsabiv®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
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	IV: Initial: 5 mg IV 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.

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;

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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

HIM: 6 months

II. Continued Therapy Approval

A. Secondary Hyperparathyroidism (must meet all):

1. 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

HIM: 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

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.	180 mg/day
calcitriol (Rocaltrol®)	Oral: 0.25 mcg PO once daily 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	Oral: 1 mcg/day
		IV: 4 mcg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	increase by 0.5 to 1 mcg/dose at 2 to 4 week intervals.	
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 picogram/mL or less; 2 mcg PO 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 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.
- 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, 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.

References

1. Parsabiv Prescribing Information. Wilmington, DE: Amgen Pharmaceuticals, Inc.; March 2019. Available at: www.parsabiv.com . Accessed July 22, 2020.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Truven Health Analytics. Updated periodically. Accessed July 22, 2020.
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-GLUpdate.pdf>. Accessed July 22, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: <ol style="list-style-type: none"> 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