Clinical Policy: Etelcalcetide (Parsabiv)

Reference Number: CP.PHAR.379
Effective Date: 03.20.18
Last Review Date: 08.22
Line of Business: HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 (HPT) 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 Centene Corporation® 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 HPT 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 for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
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 Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid.

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 policy – HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid, or evidence of coverage documents.

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 for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
cinacalcet (Sensipar®)	30 mg PO QD; 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 QD	300 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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
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.
- 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/2 mL

VII. References

1. Parsabiv Prescribing Information. Wilmington, DE: Amgen Pharmaceuticals, Inc.; February 2021. Available at: www.parsabiv.com. Accessed May 17, 2022.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Truven Health Analytics. Updated periodically. Accessed May 17, 2022.
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.

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	03.20.18	08.18
3Q 2019 annual review: added the requirement to the Continued Therapy section that Parsabiv not be used concomitantly with any other calcimimetic agents for consistency with the Initial Approval Criteria section; references reviewed and updated.	05.10.19	08.19

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2020 annual review: 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; modified HIM-Medical Benefit to HIM line of business; references reviewed and updated.	04.29.20	08.20
3Q 2021 annual review: no significant changes; revised HIM.PHAR.21 to HIM.PA.154; references reviewed and updated.	04.21.21	08.21
3Q 2022 annual review: no significant changes; references reviewed and updated.	05.17.22	08.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to

recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.