Clinical Policy: Etelcalcetide (Parsabiv)

Reference Number: CP.PHAR.379
Effective Date: 03.20.18
Last Review Date: 08.25
Line of Business: Commercial, 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 HPT, 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. 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, at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;^
   ^For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395
   a. Generic cinacalcet (Sensipar®)*;
   b. One vitamin D analog *(see Appendix B)*;
   **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 either of the following (a and b):
   a. 15 mg three times per week;
   b. 3 mL three times per week.

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
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 either of the following (a and b):
   a. 15 mg three times per week;
   b. 3 mL three times per week.

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, 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 – CP.CPA.09 for commercial, 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
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	Oral: 20 mcg 3 times weekly

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	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	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

- 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, 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 single-dose vials for injection: 2.5 mg/0.5 mL, 5 mg/mL, 10 mg/2 mL

VII. References

1. Parsabiv Prescribing Information. Wilmington, DE: KAI Pharmaceuticals, Inc.; January 2025. Available at: 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	P&T Approval Date
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
Template changes applied to other diagnoses/indications and continued therapy section.	09.22.22	
3Q 2023 annual review: no significant changes; references reviewed and updated.	04.11.23	08.23
3Q 2024 annual review: no significant changes; references reviewed and updated.	05.10.24	08.24
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; added Commercial line of business and approval duration to 6 months or member's renewal date, whichever is longer; references reviewed and updated. Added step therapy bypass for IL HIM per IL HB 5395.	06.26.25	08.25

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.