Drug Coverage Policy

Effective Date.....5/1/2025
Coverage Policy Number.....IP0718
Policy Title.....Parsabiv

Hyperparathyroidism – Parsabiv

- Parsabiv® (etelcalcetide intravenous infusion – Amgen)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Parsabiv, a calcium-sensing receptor agonist, is indicated for the treatment of secondary hyperparathyroidism in adults with chronic kidney disease (CKD) on hemodialysis.[1]

Limitations of use: Parsabiv has not been studied in patients with parathyroid carcinoma, primary hyperparathyroidism, or CKD who are not on hemodialysis.[1] Use of Parsabiv is not recommended for these patients.

Dosing Information.
Prior to initiation of Parsabiv, dose increase, or re-initiation of Parsabiv (after a dosing interruption), serum calcium should be corrected to at or above the lower limit of normal.[1] The recommended starting dose of Parsabiv is 5 mg 3 times a week at the end of hemodialysis treatment. The maintenance dose is individualized and determined by titration based on parathyroid hormone (PTH) and corrected serum calcium response; the maintenance dose is the dose that maintains PTH within the recommended target range and corrected serum calcium within the normal range. Dose ranges from 2.5 mg 3 time a week to 15 mg 3 times a week.

Disease Overview
Secondary hyperparathyroidism is a frequent complication of CKD caused by a reduction in circulating calcitriol levels and disturbances in calcium and phosphorous metabolism.[2] This leads to increases in the parathyroid hormone (PTH) levels, which then leads to osteoclastic activity resulting in bone resorption and marrow fibrosis.

Parathyroid carcinoma, a rare malignant cancer, is an uncommon cause of primary hyperparathyroidism.[3] The condition is associated with higher serum calcium and PTH levels than primary hyperparathyroidism due to benign adenoma. The primary cause of morbidity in patients with parathyroid carcinoma is due to complications of hypercalcemia (e.g., cardiac arrhythmias, renal failure). Surgical resection of the malignancy may relieve symptoms and reduce serum calcium levels. Medical therapy with cinacalcet and intravenous bisphosphonates are useful adjunct therapies to control hypercalcemia.

Guidelines
The Kidney Disease: Improving Global Outcomes (KDIGO) clinical practice guidelines (2009; updated 2017) for the treatment of CKD-mineral bone disorder (CKD-MBD) consider calcimimetics (cinacalcet), calcitriol, or vitamin D analogs (or a combination of these agents) as reasonable first-line options for patients with CKD stage 5D who require PTH-lowering therapy.[4,5] If intact parathyroid hormone (iPTH) levels fall below two times the upper limit of normal for the assay, these products should be reduced or discontinued. Parsabiv is not specifically addressed in the guidelines.

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POLICY STATEMENT
Prior Authorization is required for prescription benefit coverage of Parsabiv. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Parsabiv as well as the monitoring required for adverse events and long-term efficacy, approval requires Parsabiv to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Parsabiv is considered medically necessary when the following criteria are met:

FDA Approved Indication

1. **Secondary Hyperparathyroidism.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
   A) Patient is ≥ 18 years of age ; AND

B) Patient has chronic kidney disease; AND
C) Patient is receiving hemodialysis; AND
D) Prior to initiation, dose increase, or re-initiation of Parsabiv, corrected serum calcium level is at or above the lower limit of normal as defined by the laboratory reference; AND
E) According to the prescriber, the patient has inadequate efficacy or significant intolerance to cinacalcet tablets; AND
F) The medication being prescribed by or in consultation with a nephrologist or endocrinologist.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage

Parsabiv for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Concomitant Use with Cinacalcet (Sensipar®, generic).** Both cinacalcet and Parsabiv are calcimimetics; there is no evidence to support concomitant use.

2. **Patient with Parathyroid Carcinoma.** Parsabiv has not been studied in patients with parathyroid carcinoma.[1]

3. **Patient with Primary Hyperparathyroidism.** Parsabiv has not been studied in patients with primary hyperparathryoidism.[1]

Coding Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J0606	Injection, etelcalcetide, 0.1 mg

References

1. Parsabiv intravenous infusion [prescribing information]. Thousand Oaks, CA: Amgen; February 2021.
2. Crockell YJ. Management of chronic kidney disease: An emphasis on delaying disease progression and treatment options. *Formulary.* 2012;47:228-236.
3. Sharretts JM, Kebebew E, Simonds WF. Parathyroid Cancer. *Semin Oncol.* 2010;37:580-590.
4. Kidney Disease: Improving Global Outcomes (KDIGO) CKD – MBD Work Group, KDIGO clinical practice guideline for the diagnosis, evaluation, prevention, and treatment of chronic kidney disease-mineral and bone disorder (CKD-MBD). *Kidney Int Suppl.* 2009;76(Suppl 113):S1-S130.

5. 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). *Kidney Int Suppl.* 2017;7:1-59.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**Policy Title:** **Updated from "**Etelcalcetide" to "Hyperparathyroidism – Parsabiv" **Removed** "Etelcalcetide (Parsabiv) is considered medically necessary for continued use when the following criteria are met: Initial criteria were met at start of therapy." **Secondary Hyperparathyroidism:** **Updated** criteria **from** "Individual is 18 years and older" **to "**Patient is ≥ 18 years of age." **Updated** criteria **from** "Treatment of secondary hyperparathyroidism (HPT) in individuals with chronic kidney disease (CKD)" **to** "Patient has chronic kidney disease." **Updated** criteria **from** "Individual is on hemodialysis" **to** "Patient is receiving hemodialysis." **Updated** criteria **from** "Documented failure/ inadequate response, contraindication per FDA label, not a candidate or intolerance to cinacalcet (Sensipar)" **to** "According to the prescriber, the patient has inadequate efficacy or significant intolerance to cinacalcet tablets." **Added** "Prior to initiation, dose increase, or re-initiation of Parsabiv, corrected serum calcium level is at or above the lower limit of normal as defined by the laboratory reference." **Added** "The medication being prescribed by or in consultation with a nephrologist or endocrinologist." **Added** "Patient with Parathyroid Carcinoma and Patient with Primary Hyperparathyroidism" to Parsabiv use considered not medically necessary.	5/1/2025

The policy effective date is in force until updated or retired.

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