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Section:	Prescription Drugs	**Effective Date:**	October 1, 2023
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	March 3, 2017
Subject:	Parsabiv	**Page:**	1 of 4

Last Review Date: September 8, 2023

Parsabiv

Description

Parsabiv (etelcalcetide)

Background
Parsabiv (etelcalcetide) is a calcimimetic agent that increases the sensitivity of the calcium-sensing receptor to activation by extracellular calcium. These calcium-sensing receptors are on the parathyroid hormone gland and are the principal regulators of PTH (parathyroid hormone) synthesis and secretion. By increasing the sensitivity of the calcium sensing receptors, a reduction in PTH secretion is achieved. Reductions in PTH are associated with a decrease in bone turnover and bone fibrosis in patients with CKD (chronic kidney disease) on hemodialysis and uncontrolled secondary hyperparathyroidism (HPT) (1).

Regulatory Status
FDA-approved indication: Parsabiv is a calcium-sensing receptor agonist indicated for treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on hemodialysis (1).

Limitations 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 (1).

Initial treatment with Parsabiv is contraindicated if serum calcium is less than the lower limit of the normal range. Life threatening events and fatal outcomes were reported due to hypocalcemia. Hypocalcemia can prolong QT interval, lower the threshold for seizures, and

cause hypotension, worsening heart failure, and/or arrhythmia. Monitor serum calcium carefully for the occurrence of hypocalcemia during treatment. Once the maintenance dose has been established, serum calcium should be measured monthly for patients with secondary hyperparathyroidism with CKD on hemodialysis (1).

In patients with secondary hyperparathyroidism with chronic kidney disease who are on hemodialysis, serum calcium should be measured within 1 week of starting Parsabiv, and intact parathyroid hormone (iPTH) should be measured 4 weeks after initiation or dose adjustment of Parsabiv (1). Consider decreasing or temporarily discontinuing PARSABIV or use concomitant therapies to increase corrected serum calcium in patients with a corrected serum calcium below the lower limit of normal but at or above 7.5 mg/dL without symptoms of hypocalcemia. The goals of therapy are symptom control and a serum albumin-corrected total calcium level at the lower end of the normal range approximately 8.5 to 10.5 mg per deciliter (2).

Safety and effectiveness in pediatric patients have not been established (1).

Related policies
Natpara, Sensipar

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Parsabiv may be considered **medically necessary** if the conditions indicated below are met.

Parsabiv may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Secondary hyperparathyroidism (HPT) with chronic kidney disease (CKD)
    a. **MUST** be on hemodialysis

b. iPTH level greater than 300 pg/mL

AND ALL of the following:

1. Serum calcium level (corrected for albumin) greater than or equal to 7.5mg/dL
2. Prescriber agrees to monitor serum calcium levels periodically throughout therapy
3. **NO** dual therapy with a calcium-sensing receptor agonist

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Secondary hyperparathyroidism (HPT) with chronic kidney disease (CKD)
   a. **MUST** be on hemodialysis

AND ALL of the following:

1. Serum calcium level (corrected for albumin) greater than or equal to 7.5mg/dL
2. Prescriber agrees to monitor serum calcium levels periodically throughout therapy
3. **NO** dual therapy with a calcium-sensing receptor agonist

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 3 months

Prior – Approval *Renewal* Limits

Duration 12 months

Rationale

Summary
Parsabiv (cinacalcet) is a calcimimetic agent that increases the sensitivity of the calcium-sensing receptor to activation by extracellular calcium. Parsabiv is indicated for treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on hemodialysis. 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 (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Parsabiv while maintaining optimal therapeutic outcomes.

References

1. Parsabiv [package insert]. Thousand Oaks, CA: Amgen, Inc.; February 2021.
2. Shoback D. Hypoparathyroidism. *NEJM*. 2008;359: 391-403

Policy History

Date	Action
March 2017	Addition to PA
June 2017	Annual review
November 2018	Annual review. Changes to background paragraph per SME
December 2019	Annual review and reference update
December 2020	Annual review
September 2021	Annual review and reference update
September 2022	Annual review
September 2023	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 8, 2023 and is effective on October 1, 2023.