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).

Limitation 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** for patients 18 years of age or older with one of the following: secondary hyperparathyroidism (HPT) with chronic kidney disease (CKD) patient must be on hemodialysis and if the conditions indicated below are met.

Parsabiv may be considered **investigational** in patients less than 18 years of age and 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 7.5 mg/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 7.5 mg/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
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
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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.