Drug and Biologic Coverage Policy

Effective Date 12/1/2020
Next Review Date… 12/1/2021
Coverage Policy Number 1812

Etelcalcetide

Table of Contents

Related Coverage Resources

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. 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.

Coverage Policy

Etelcalcetide (Parsabiv®) is considered medically necessary when ALL of the following criteria are met:

- Individual is 18 years and older
- Treatment of secondary hyperparathyroidism (HPT) in individuals with chronic kidney disease (CKD)
- Individual is on hemodialysis
- Documented failure/inadequate response, contraindication per FDA label, not a candidate or intolerance to cinacalcet (Sensipar).
- No concurrent use with cinacalcet

Initial and reauthorization is up to 12 months unless otherwise stated.

Etelcalcetide (Parsabiv) is considered medically necessary for continued use when the following criteria are met:

- **Initial criteria were met at start of therapy**
- **No concurrent use with cinacalcet**

Etelcalcetide (Parsabiv) is considered experimental, investigational or unproven for any other use.

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.

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

FDA Approved Indications

FDA Approved Indication

Parsabiv is a calcium-sensing receptor agonist indicated for:

- Secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on hemodialysis.

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.

Recommended Dosing

FDA Recommended Dosing

- The recommended starting dose of Parsabiv is 5 mg administered by intravenous (IV) bolus injection three times per week at the end of hemodialysis treatment
- The maintenance dose or Parsabiv 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 levels within the recommended target range and corrected serum calcium within the normal range. The lowest maintenance dose of Parsabiv is 2.5 mg three times per week, and the highest maintenance dose of Parsabiv is 15mg three times per week.

Switching from Cinacalcet to Parsabiv

- Discontinue cinacalcet for at least 7 days prior to starting Parsabiv, and initiate Parsabiv treatment at a starting dose of 5 mg. Ensure corrected serum calcium is at or above the lower limit of normal prior to Parsabiv initiation

Drug Availability

Parsabiv is a single-dose, clear, and colorless solution available as follows:

- Injection: 2.5 mg/0.5 mL solution in a single-dose vial
- Injection: 5 mg/mL solution in a single-dose vial
- Injection: 10 mg/2 mL solution (5 mg/mL) in a single-dose vial

General Background

Pharmacology

Etelcalcetide is a calcimimetic agent that allosterically modulates the calcium-sensing receptor (CaSR). Etelcalcetide binds to the CaSR and enhances activation of the receptor by extracellular calcium. Activation of the CaSR on parathyroid chief cells decreases PTH secretion.

Professional Societies/Organizations

Kidney Disease: Improving Global Outcomes (KDIGO)

Diagnosis, evaluation, prevention and treatment of chronic kidney disease-mineral and bone disorder were addressed in clinical practice guidelines in 2017 (update to the 2009 version) by Kidney Disease: Improving Global Outcomes (KDIGO). Specifics from the KDIGO Chronic Kidney Disease-Mineral and Bones Disorder (CKD-MDB) guideline recommend individuals with CKD stage 5 who are on dialysis and have an elevated or

increasing PTH should be considered for treatment with calcitriol, vitamin D analogs, calcimimetics, or a combination of calcimimetics and calcitriol or vitamin D analogs. Etelcalcetide is not specifically addressed in guidelines. (KDIGO, 2017)

The American Board of Internal Medicine's (ABIM) Foundation Choosing Wisely® Initiative

No recommendations are available for Etelcalcetide (Parsabiv).

Centers for Medicare & Medicaid Services - National Coverage Determinations (NCDs)

There are no CMS National Coverage Determinations for Etelcalcetide (Parsabiv).

Clinical Efficacy

Three randomized, double-blind trials evaluated the safety and efficacy of etelcalcetide 5 mg IV 3 times weekly after hemodialysis. One trial compared etelcalcetide with cinacalcet, while the other 2 trials were placebo-controlled. Etelcalcetide significantly reduced serum PTH concentrations by 30% or more compared with cinacalcet ($P < 0.001$) and placebo ($P < 0.001$ for both trials). (Block, 2017)

Coding/ Billing 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.

Covered when medically necessary when used to report the administration of etelcalcetide (Parsabiv):

HCPCS Codes	Description
J0606	Injection, etelcalcetide, 0.1 mg

***Current Procedural Terminology (CPT®) ©2017 American Medical Association: Chicago, IL.**

References

1. Block GA, Bushinsky DA, Cheng S, et al. Effect of Etelcalcetide vs Cinacalcet on Serum Parathyroid Hormone in Patients Receiving Hemodialysis With Secondary Hyperparathyroidism: A Randomized Clinical Trial. JAMA. 2017;317(2):156-164.
2. Block GA, Bushinsky DA, Cunningham J, et al. Effect of Etelcalcetide vs Placebo on Serum Parathyroid Hormone in Patients Receiving Hemodialysis With Secondary Hyperparathyroidism: Two Randomized Clinical Trials. JAMA. 2017;317(2):146-155.
3. 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;(113):S1-130.
4. Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD 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). Journal of the International Society of Nephrology. Volume 7. Issue 1. July 2017.
5. Parsabiv [package insert]. Thousand Oaks, CA: Amgen; 2018.