Policy Title:	Parsabiv (etelcalcetide) (intravenous)		
		Department:	PHA
Effective Date:	06/01/2020		
Review Date:	03/18/2020, 06/10/2021, 4/14/2022, 1/26/2023, 12/07/2023, 01/04/2024, 05/14/2025, 03/10/2026		

Purpose: To support safe, effective, and appropriate use of Parsabiv (etelcalcetide).

Scope: Medicaid, Commercial, Medicare

Policy Statement:

Parsabiv (etelcalcetide) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Parsabiv (etelcalcetide) will be reviewed prospectively via the prior authorization process based on criteria below.

Summary of Evidence:

Parsabiv (etelcalcetide) is an intravenous calcimimetic indicated for the treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease who are on hemodialysis, and it is not recommended for patients with primary hyperparathyroidism, parathyroid carcinoma, or CKD patients not receiving hemodialysis. Its clinical studies have demonstrated effectiveness in lowering parathyroid hormone (PTH) levels, with dose adjustments based on PTH and corrected serum calcium measurements as outlined in prescribing information and placebo-controlled/active-controlled trials evaluating safety, efficacy, and treatment-emergent adverse events in dialysis patients. Common adverse effects include hypocalcemia, muscle spasms, diarrhea, nausea, headache, and paresthesia.

Initial Criteria:

- The member is ≥ 18 years of age; AND
- The member has a diagnosis of hyperparathyroidism secondary to chronic kidney disease; AND
- The member is receiving hemodialysis; AND
- Documentation of serum calcium (corrected for albumin) ≥8.4 mg/dL; AND
- Documentation of pre-treatment parathyroid hormone level >400 pg/mL; AND
- The member is not receiving dual therapy with a calcium-sensing receptor agonist; AND
- The member has a documented failure, contraindication, or ineffective response at maximum tolerated doses to Sensipar(cinacalcet); AND

- Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Continuation of Therapy Criteria:

- Member is tolerating treatment; AND
- The member has a diagnosis of hyperthyroidism secondary to chronic kidney disease; AND
- The member is receiving hemodialysis; AND
- Documentation of a reduction in serum calcium (corrected for albumin) from baseline; AND
- The member is not receiving dual therapy with a calcium-sensing receptor agonist;

Coverage durations:

- Initial coverage: 6 months
- Continuation of therapy coverage: 6 months

Per §§ 42 CFR 422.101, this clinical medical policy only applies to Medicare in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

Policy Rationale:
Parsabiv was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Parsabiv according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

Dosage/Administration:

Indication	**Dose**	**Maximum dose (1 billable unit = 0.1 mg)**
Secondary hyperparathyroidism	2.5-15 mg three times a week	150 billable units three times a week

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists

to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J0606	Injection, etelcalcetide, 0.1mg

References:

1. Parsabiv [package insert]. Thousand Oaks, CA: Amgen, Inc.; February 2021. Accessed May 2025.