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		

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

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

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 is a calcium-sensing receptor agonist indicated for secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on hemodialysis. Clinical trials evaluating the efficacy and safety of Parsabiv have demonstrated significant reductions in serum parathyroid hormone (PTH) levels, phosphate levels, and calcium-phosphate product. Common adverse events include hypocalcemia, muscle spasms, diarrhea, and nausea.

Initial Criteria:

- The patient is ≥ 18 years of age; AND
- The patient has a diagnosis of hyperparathyroidism secondary to chronic kidney disease; AND
- The patient 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 patient is not receiving dual therapy with a calcium-sensing receptor agonist; AND
- The patient has a documented failure, contraindication, or ineffective response at maximum tolerated doses to Sensipar(cinacalcet); AND
- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Continuation of Therapy Criteria:

- Patient is tolerating treatment; AND
- The patient has a diagnosis of hyperthyroidism secondary to chronic kidney disease; AND
- The patient is receiving hemodialysis; AND
- Documentation of a reduction in serum calcium (corrected for albumin) from baseline; AND
- The patient 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 INTEGRITY 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 INTEGRITY (Medicare-Medicaid Plan) 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.