Policy Title:	Parsabiv (etelcalcetide) (intravenous)		
		Department:	PHA
Effective Date:	06/01/2020		
Review Date:	03/18/2020, 06/10/2021, 4/14/2022		

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.

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
- Dosing is in accordance with the United States Food and Drug Administration approved labeling;
- 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; AND
- Dosing is in accordance with the United States Food and Drug Administration approved labeling

Coverage durations:

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

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable.***

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.