MEDICAL MUTUAL®

Drug Policy

Policy:	**201714**	**Initial Effective Date: 11/10/2017** **Annual Review Date: 04/01/2019** **Policy Retirement Date: 04/01/2019**
Code(s):	**HCPCS J0606**	
SUBJECT:	**Parsabiv (etelcalcetide)**	

As of 4/1/2019, Prior approval is not required for the procedure codes listed in this Corporate Drug Policy.

OVERVIEW

Etelcalcetide is an intravenously administered calcium-sensing receptor agonist that is indicated for secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on hemodialysis. The drug achieves its therapeutic effect by decreasing (parathyroid hormone) PTH secretion and leveling serum calcium and phosphorus levels amongst patients with secondary HPT on hemodialysis.

POLICY STATEMENT

This policy involves the use of Parsabiv. Prior authorization is recommended for pharmacy and medical benefit coverage of Parsabiv. Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy**, and **Labs/Diagnostics** for the diagnosis provided. **Waste Management** applies for all covered conditions that are administered by a healthcare professional. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Parsabiv as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Parsabiv be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Parsabiv is recommended in those who meet the following criteria:

1. **Secondary Hyperparathyroidism (HPT) in adults with Chronic Kidney Disease (CKD) on hemodialysis**
   Criteria. *Patient must meet the following criteria (A, B, C and D):*

   A. Patient is 18 years of age or older; AND
   B. Patient has been diagnosed with secondary HPT with CKD and is on hemodialysis; AND
   C. Patient has a corrected serum calcium level at or above the lower limit of normal prior to initiation; AND

D. If patient is on oral Sensipar, Sensipar will be discontinued at least 7 days prior to initiation of Parsabiv

Dosing in Parsabiv. *Dosing must meet the following:*
Recommended dosage of Parsabiv:
Initial dose of 5 mg IV bolus 3 times per week at the end of hemodialysis

- Titration in increments of 2.5-5 mg no more frequently than every 4 weeks to a dose that maintains PTH levels within the recommended target range and corrected serum calcium within the normal range
- Maximum dose of 15 mg 3 times per week
- Conversion from Sensipar: discontinue Sensipar at least 7 days prior to initiating Parsabiv

Initial Approval/ Extended Approval.
A) *Initial Approval: 1 year*
B) *Extended Approval: 1 year if patient has shown improvement or beneficial response to therapy.*

Duration of Therapy in Parsabiv. Indefinite**.**

Labs/Diagnostics. Corrected serum calcium and PTH levels, per the following recommendations:
Corrected serum calcium levels: Prior to initiation and 1 week after dose initiation or adjustment. After the maintenance dose is established, monitor every 4 weeks.
PTH levels: Prior to initiation and 4 weeks after dose initiation or adjustment. After the maintenance dose is established, monitor per clinical practice.

Waste Management for All Indications.
Solution, Intravenous [preservative free]:
Parsabiv: 5 mg/mL (1 mL); 10 mg/2 mL (2 mL); 2.5 mg/0.5 mL (0.5 mL)

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Parsabiv has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Parathyroid carcinoma, primary hyperparathyroidism, or patients with CKD who are not on hemodialysis.** Parsabiv has not been studied in adults with parathyroid carcinoma, primary hyperparathyroidism, or CKD who are not on hemodialysis. Therefore, use is not recommended in these patient populations.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not

medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Parsabiv ® injection [prescribing information]. Thousand Oaks, CA: Amgen Pharmaceuticals; August 2018.
2. Etelcalcetide. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 21 August 2018. Accessed on 16 September 2018.

FOR MEDICAL BENEFIT COVERAGE REQUESTS:

Prior approval is required for HCPCS Codes J0606

HCPCS Code(s):	
J0606	Injection, etelcalcetide, 0.1 mg (Parsabiv)