Parsabiv® (etelcalcetide)

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**Definition**

Parsabiv mimics calcium binding to the calcium-sensing receptor (CaSR) on chief cells of the parathyroid gland, which activates the receptor and decreases secretion of parathyroid hormone.

**Length of Authorization**

Coverage will be provided for 12 months and may be renewed.

**Dosing Limits**

Max Units (per dose and over time) [Medical Benefit]:

- 45 mg per 7 days

**I. INITIAL APPROVAL CRITERIA**

*Parsabiv* may be considered medically necessary if the below condition is met AND use is consistent with the medical necessity criteria that follows:

1. **Secondary hyperparathyroidism in adult patients with chronic kidney disease on hemodyalysis**
   
   a. Diagnosis of secondary hyperparathyroidism with chronic kidney disease; **AND**
   
   b. Patient is on dialysis; **AND**
   
   c. **All** of the following;
      
      i. Patient is 18 years of age or older; **AND**
      
      ii. History of failure, contraindication, or intolerance to one phosphate binder (e.g., PhosLo, Fosrenol, Renvela, Renagel, etc.); **AND**
iii. History of failure, contraindication, or intolerance to one vitamin D analog (e.g., calcitriol, Hectorol, Zemplar, etc.); AND

iv. History of failure of maximum tolerated dosage, adverse reaction, or contradiction to Sensipar (cinacalcet hydrochloride); AND
d. Patient is not receiving Parsabiv (etelcalcetide) in combination with Sensipar (cinacalcet hydrochloride); AND
e. Prescribed by or in consultation with an endocrinologist or nephrologist

Limitations/Exclusions
1) Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. RENEWAL CRITERIA
• Patient continues to meet INITIAL APPROVAL CRITERIA.

Dosage/Administration

<table>
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<tr>
<th>Indication</th>
<th>Dose</th>
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<tr>
<td>Secondary hyperparathyroidism in adult patients with chronic kidney disease on hemodyalysis</td>
<td>– Initial, 5 mg IV bolus 3 times per week administered at the end of hemodialysis; adjust in 2.5 or 5 mg increments every 4 weeks to maintain target parathyroid hormone levels and normal serum calcium levels; MAX 15 mg 3 times per week</td>
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Applicable Procedure Codes
- J0606 Injection, etelcalcetide, 0.1 mg, 1 billable unit = 0.1 mg

Applicable NDCs
- 55513-0740-xx Parsabiv 5 mg/ml single dose vial

Applicable Diagnosis Codes
- E83.51 Hypocalcemia
- N18.6 End stage renal disease

Review History
- 03/30/2020 Annual Review: added 18 years of age and older to Initial Approval Criteria.

References