Parsabiv® (etelcalcetide)

**Medical Guideline Disclaimer**

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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 hemodialysis**
   a. Diagnosis of secondary hyperparathyroidism with chronic kidney disease; **AND**
   b. Patient is on dialysis; **AND**
   c. **All** of the following;
      i. History of failure, contraindication, or intolerance to one phosphate binder (e.g., PhosLo, Fosrenol, Renvela, Renagel, etc.); **AND**
      ii. History of failure, contraindication, or intolerance to one vitamin D analog (e.g., calcitriol, Hectorol, Zemplar, etc.); **AND**
      iii. 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>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
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<tbody>
<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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</tbody>
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Applicable Procedure Codes

<table>
<thead>
<tr>
<th>Procedure Code</th>
<th>Applicable Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J0606</td>
<td>Injection, etelcalcetide, 0.1 mg, 1 billable unit = 0.1 mg</td>
<td></td>
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</tbody>
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Applicable NDCs

<table>
<thead>
<tr>
<th>NDC Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>55513-0740-xx</td>
<td>Parsabiv 5 mg/ml single dose vial</td>
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Applicable Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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<tbody>
<tr>
<td>E83.51</td>
<td>Hypocalcemia</td>
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<tr>
<td>N18.6</td>
<td>End stage renal disease</td>
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References