**MP 5.01.652**
**Etelcalcetide (Parsabiv) for Secondary Hyperparathyroidism**

**Last Review:** 03/21/2019  
**Effective Date:** 03/21/2019  
**Section:** Prescription Drug  

**DISCLAIMER/INSTRUCTIONS FOR USE**

Medical Policy provides general guidance for applying Blue Cross of Idaho benefit plans (for purposes of Medical Policy, the terms “benefit plan” and “member contract” are used interchangeably). Coverage decisions must reference the member specific benefit plan document. The terms of the member specific benefit plan document may be different than the standard benefit plan upon which this Medical Policy is based. If there is a conflict between a member specific benefit plan and the Blue Cross of Idaho’s standard benefit plan, the member specific benefit plan supersedes this Medical Policy. Any person applying this Medical Policy must identify member eligibility, the member specific benefit plan, and any related policies or guidelines prior to applying this Medical Policy. Blue Cross of Idaho Medical Policies are designed for informational purposes only and are not an authorization, explanation of benefits or a contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the member specific benefit plan coverage. Blue Cross of Idaho reserves the sole discretionary right to modify all its Policies and Guidelines at any time. This Medical Policy does not constitute medical advice.

**POLICY**

**INITIAL CRITERIA**

Etelcalcetide may be considered **medically necessary** if the following criteria are met:

1. the patient is diagnosed with chronic kidney disease (CKD); **AND**
2. the patient is currently receiving hemodialysis three times weekly for at least the previous three months; **AND**
3. the patient has a diagnosis of moderate to severe hyperparathyroidism (PTH greater than or equal to 400 mg/ml); **AND**
4. the patient is at least 18 years of age; **AND**
5. the patient must have a corrected calcium level at or above the lower limit of normal prior to initiation. (equal to or greater and 8.3 mg/dl); **AND**
6. the patient must be taking stable doses of active vitamin D analogs or calcium supplements or phosphate binders.

All other uses of etelcalcetide are considered **investigational**.

Length of Approval: 6 months

**RENEWAL CRITERIA**

Etelcalcetide will be approved when the following criteria are met:

1. the patient has at least 30% reduction from baseline in mean parathyroid hormone; **AND**
2. the patient has been previously approved through Blue Cross of Idaho prior authorization process; **AND**
3. the member does not have any unacceptable toxicity to Parsabiv (including severe hypocalcemia, ventricular arrhythmia, seizures, heart failure, and upper GI bleeding)

Length of Approval: 6 months

**POLICY GUIDELINES**

Note: Ensure corrected serum calcium is at or above the lower limit of normal prior to initiation, a dose increase, or re-initiation of therapy after a dosing interruption.

Hyperparathyroidism, secondary (chronic kidney disease patients on hemodialysis): IV: Initial: 5 mg IV bolus 3 times per week at the end of hemodialysis.

Dosage adjustments: Titrate dose in 2.5 mg or 5 mg increments not more frequently than every 4 weeks to a dose that maintains PTH levels within recommended target range and corrected serum calcium within the normal range; maximum maintenance dose: 15 mg three times per week; minimum maintenance dose: 2.5 mg three times per week.

Conversion from cinacalcet: Discontinue cinacalcet for at least 7 days prior to initiating etelcalcetide.

**BENEFIT APPLICATION**

**BLUECARD/NATIONAL ACCOUNT ISSUES**

State or federal mandates (eg, Federal Employee Program) may dictate that certain U.S. Food and Drug Administration–approved devices, drugs, or biologics may not be considered investigational, and thus these devices may be assessed only by their medical necessity.

**BACKGROUND**

Parsabiv (etelcalcetide) is a calcimimetic agent that increases the sensitivity of the calcium-sensing receptor to activation by extracellular calcium. These calcium-sensing receptors are on the parathyroid hormone gland and are the principal regulators of PTH (parathyroid hormone) synthesis and secretion. By decreasing extracellular calcium (through increasing the sensitivity of the calcium sensing receptors), reduction in PTH is achieved. Reductions in PTH are associated with a decrease in bone turnover and bone fibrosis in patients with CKD (chronic kidney disease) on hemodialysis and uncontrolled secondary hyperparathyroidism (HPT).

FDA approved indication: Parsabiv is a calcium-sensing receptor agonist indicated for treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on hemodialysis.

**RATIONALE**

FDA approval was based on two placebo controlled phase III studies that found etelcalcetide showed significant reduction in parathyroid hormone secretions. In two randomized trials, etelcalcetide was compared with placebo among 1023 hemodialysis patients with hyperparathyroidism. It was more effective than placebo in reducing PTH at 27 weeks. Another randomized trial compared etelcalcetide to oral cinacalcet. Etelcalcetide was superior in reducing PTH and reducing fibroblast growth factor 23. Because of the favorable effects on laboratory parameters, etelcalcetide therapy could lead to improved important patient outcomes. In addition, the IV route of administration may improve adherence which could potentiate benefits.
However, interventions to increase serum calcium concentrations could lead to positive calcium balance and worse cardiovascular outcomes, and prolongation of corrected QT intervals caused by etelcalcetide could increase the risk of sudden death.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

Not applicable.

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable.

MEDICARE NATIONAL COVERAGE

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

ESSENTIAL HEALTH BENEFITS

The Affordable Care Act (ACA) requires fully insured non-grandfathered individual and small group benefit plans to provide coverage for ten categories of Essential Health Benefits (“EHBs”), whether the benefit plans are offered through an Exchange or not. States can define EHBs for their respective state.

States vary on how they define the term small group. In Idaho, a small group employer is defined as an employer with at least two but no more than fifty eligible employees on the first day of the plan or contract year, the majority of whom are employed in Idaho. Large group employers, whether they are self-funded or fully insured, are not required to offer EHBs, but may voluntary offer them.

The Affordable Care Act requires any benefit plan offering EHBs to remove all dollar limits for EHBs.

REFERENCES


CODES

<table>
<thead>
<tr>
<th>Codes</th>
<th>Number</th>
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<tbody>
<tr>
<td>HCPCS</td>
<td>J0606</td>
<td>Injection, etelcalcetide, 0.1 mg to ESRD beneficiaries, ESRD facilities will not be responsible for furnishing calcimimetics to individuals with AKI.</td>
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POLICY HISTORY

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>03/29/18</td>
<td>New Policy</td>
<td>Blue Cross of Idaho adopted new policy with literature review through 03/27/2018; added to Prescription Drug section. Effective date 06/19/2018.</td>
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<tr>
<td>03/21/19</td>
<td>Replace policy</td>
<td>Blue Cross of Idaho annual review; no change to policy.</td>
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