Medical Coverage Policy | Calcium Sensing Receptor Agonists (etelcalcetide Parsabiv)

EFFECTIVE DATE: 01|01|2018
POLICY LAST UPDATED: 01|16|2018

OVERVIEW
Parsabiv is a calcium-sensing receptor agonist indicated for Secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on hemodialysis.

MEDICAL CRITERIA
Initial and Renewal Evaluation
Parsabiv (etelcalcetide) will be approved when ALL of the following are met:
1. The patient has a diagnosis of secondary hyperparathyroidism with chronic kidney disease
   AND
2. The patient is on hemodialysis
   AND
3. The patient's corrected serum calcium is at or above the lower limit of the normal range
   AND
4. The patient has a pre-treatment or current intact PTH (iPTH) level of greater than or equal to 300 pg/mL
   AND
5. The patient does not have any one of the following limitations to the use of Parsabiv:
   a. Parathyroid carcinoma **OR**
   b. Primary hyperparathyroidism
   AND
6. ONE of the following:
   a) The patient's medication history includes previous use of a prerequisite agent (Sensipar (cinacalcet) and had an inadequate response to treatment (inadequate reduction in IPTH) **OR**
   b) The patient has a documented intolerance, FDA labeled contraindication, or developed hypocalcemia from treatment

Length of Approval: 12 months.

PRIOR AUTHORIZATION
Prior authorization is required for BlueCHiP for Medicare and recommended for Commercial Products

POLICY STATEMENT
BlueCHiP for Medicare and Commercial Products
Etelcalcetide (Parsabiv) is medically necessary when all of the criteria have been met.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable physician administered benefits/coverage.

BACKGROUND
Secondary hyperparathyroidism (HPT) is a frequent complication in patients with chronic kidney disease (CKD). It is characterized by elevated phosphorus and vitamin D deficiency. The implications of untreated secondary HPT include renal bone disease, weakness, fractures, bone and muscle pain, as well as avascular necrosis.

Management of secondary HPT in patients with dialysis involves dietary phosphate restriction and use of a combination of phosphate binders (e.g. calcium acetate, Renagel, Renvela, Fosrenol), vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol), and/or calcimimetics (e.g. Sensipar, Parsabiv). The goal of therapy is to maintain serum level of phosphorus between 3.5 and 5.5 mg/dL.

CODING

BlueCHiP for Medicare and Commercial Products

The following code is medically necessary when the criteria are met:

J0606 Injection, etelcalcetide, 0.1 mg (New code effective 1/1/2018)

RELATED POLICIES

None

PUBLISHED

Provider Update, March 2018

REFERENCES:

1. Parsabiv prescribing information. Amgen. April 2017

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