Parsabiv® (etelcalcetide) intravenous solution

Humana

Pharmacy Coverage Policy

Effective Date: January 01, 2019
Revision Date: March 22, 2023
Review Date: March 15, 2023
Line of Business: Medicare, Commercial, Medicaid - South Carolina, Medicaid - Ohio
Policy Type: Prior Authorization

Products Affected

Parsabiv intravenous solution

Listed Indications

Secondary Hyperparathyroidism in CKD
Secondary Hyperparathyroidism in CKD - Reauthorization

Secondary Hyperparathyroidism in CKD

Does the member meet all of the following criteria?	
Criteria #1	The member is = 18 years of age
Criteria #2	Has a diagnosis of secondary hyperparathyroidism due to CKD
Criteria #3	Currently receiving hemodialysis
Criteria #4	Has a corrected serum calcium = 8.3 mg/dL
Criteria #5	Has had previous treatment, contraindication or intolerance with a generic vitamin D analog (i.e. calcitriol, paricalcitol OR doxercalciferol)
For continuation of therapy requests, does the member meet all of the following renewal criteria?	
Renewal Criteria #1	The member is = 18 years of age
Renewal Criteria #2	Has a diagnosis of secondary hyperparathyroidism due to CKD
Renewal Criteria #3	Currently receiving hemodialysis
Renewal Criteria #4	PTH hormone has NOT consistently been below the target range
Renewal Criteria #5	Has a corrected serum calcium = 7.5 mg/dL
Does the member have any of the following exclusions? If yes, approval may not be appropriate. NOTE: Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.	
Exclusion #1	Adult patients with parathyroid carcinoma, primary hyperparathyroidism, or with CKD who are not on hemodialysis
Approval Duration	
Initial	Parsabiv (etelcalcetide) will be approved in plan year duration or as determined through clinical review.

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Secondary Hyperparathyroidism in CKD - Reauthorization

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Background

This is a prior authorization policy about Parsabiv (etelcalcetide).

- Secondary hyperparathyroidism due to chronic kidney disease is characterized by progressive kidney dysfunction resulting in calcitriol deficiency and hyperphosphatemia, both of which lead to hypocalcemia. These abnormalities play a significant role in the disorders of mineral and bone metabolism that are commonly associated with chronic kidney disease.
- Parsabiv (etelcalcetide) is not indicated in patients that are not currently receiving hemodialysis.
- Excessive administration of calcimetics, including Parsabiv, can cause hypocalcemia. Severe hypocalcemia can cause paresthesias, myalgias,

muscle spasms, seizures, QT prolongation and ventricular arrhythmias. Patients predisposed to any of the aforementioned conditions may be at increased risk and require close monitoring. Furthermore, all patients should be educated on the symptoms of hypocalcemia.
- Reductions in corrected serum calcium may be associated with congestive heart failure. Patients with heart failure should be closely monitored for worsening signs and symptoms of heart failure.
- Patients with risk factors for upper GI bleeding may be at increased risk. Monitor and promptly evaluate and treat any suspected GI bleeding.
- Adynamic bone may develop if PTH levels are chronically suppressed. Reduce the dose or discontinue Parsabiv if PTH levels decrease below the recommended range

Parsabiv (etecalcitide) is a calcium-sensing receptor agonist.

Parsabiv (etelcalcetide) 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 (PTH).

Parsabiv (etelcalcetide) is indicated for secondary hyperparathyroidism (HPT) in adults with chronic kidney disease (CKD) on hemodialysis.

Limitations of Use: Parsabiv has not been studied in adult patients with parathyroid carcinoma, primary hyperparathyroidism, or with CKD who are not on hemodialysis and is not recommended for use in these populations.

Etelcalcetide injection is available as Parsabiv in 2.5mg/0.5mL, 5mg/mL and 10mg/2mL single-dose vials.

Provider Claim Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Parsabiv; etelcalcetide; secondary hyperparathyroidism; chronic kidney disease; dialysis; pharmacy

References

1. Clinical Pharmacology [database online]. Philadelphia, PA: Elsevier, Inc.; URL: https://www.clinicalkey.com/pharmacology/. Updated periodically.
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3. KDIGO clinical practice guideline for the diagnosis, evaluation, prevention, and treatment of chronic kidney disease-mineral and bone disorder (CKD-MBD). Kidney International supplements 2017; 7, 1-59.
4. Parsabiv [package insert]. Thousand Oaks, CA; Amgen Inc. Mar 2019.

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