

## PARSABIV™ (ETELCALCETIDE)

Policy Number: 2019D0075B

Effective Date: March 1, 2019

[Instructions for Use](#) ⓘ

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### Related Policies

None

### COVERAGE RATIONALE

#### Initial Therapy

**Parsabiv (etelcalcetide) is proven for the treatment of secondary hyperparathyroidism with chronic kidney disease when the following criteria are met:**

- I. Diagnosis of secondary hyperparathyroidism with chronic kidney disease; **and**
- II. Patient is on dialysis; **and**
- III. Patient is not receiving Parsabiv (etelcalcetide) in combination with Sensipar (cinacalcet hydrochloride); **and**
- IV. Prescribed by or in consultation with an endocrinologist or nephrologist; **and**
- V. Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and**
- VI. Initial authorization will be for no longer than 12 months.

**Parsabiv (etelcalcetide) is medically necessary for the treatment of secondary hyperparathyroidism with chronic kidney disease when the following criteria are met:**

- I. Diagnosis of secondary hyperparathyroidism with chronic kidney disease; **and**
- II. Patient is on dialysis; **and**
- III. **All** of the following:
  - A. History of failure, contraindication, or intolerance to **one** phosphate binder (e.g., PhosLo, Fosrenol, Renvela, Renagel, etc.); **and**
  - B. History of failure, contraindication, or intolerance to **one** vitamin D analog (e.g., calcitriol, Hectorol, Zemplar, etc.); **and**
  - C. History of failure of maximum tolerated dosage, adverse reaction, or contradiction to Sensipar (cinacalcet hydrochloride);**and**
- IV. Patient is not receiving Parsabiv (etelcalcetide) in combination with Sensipar (cinacalcet hydrochloride); **and**
- V. Prescribed by or in consultation with an endocrinologist or nephrologist; **and**
- VI. Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and**
- VII. Initial authorization will be for no longer than 12 months.

#### Continuation Therapy

**Parsabiv (etelcalcetide) will be reauthorized based on all of the following criteria:**

- I. Documentation of a reduction in serum calcium from baseline; **and**
- II. Patient is not receiving Parsabiv (etelcalcetide) in combination with Sensipar (cinacalcet hydrochloride); **and**
- III. Prescribed by or in consultation with an endocrinologist or nephrologist; **and**
- IV. Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and**
- V. Reauthorization will be for no longer than 12 months.

### U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Parsabiv is a calcium-sensing receptor agonist indicated for secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on hemodialysis.<sup>1</sup>

**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.<sup>1</sup>

**For patients changing from cinacalcet to Parsabiv:** Discontinue cinacalcet for at least 7 days prior to starting Parsabiv, and initiate Parsabiv treatment at a starting dose of 5 mg. Ensure corrected serum calcium is at or above the lower limit of normal prior to Parsabiv initiation.<sup>1</sup>

## BACKGROUND

Parsabiv is a calcimimetic agent that allosterically modulates the calcium-sensing receptor (CaSR). Etelcalcetide binds to the CaSR and enhances activation of the receptor by extracellular calcium. Activation of the CaSR on parathyroid chief cells decreases PTH secretion.<sup>1</sup>

## APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

HCPCS Code	Description
J0606	Injection, etelcalcetide, 0.1 mg

## CLINICAL EVIDENCE

In 2 parallel, phase 3, randomized, placebo-controlled treatment trials, Block et al evaluated the effect of the etelcalcetide on serum parathyroid hormone (PTH) concentrations in patients receiving hemodialysis.<sup>3</sup> Study participants received etelcalcetide or placebo after each hemodialysis session for 26 weeks. The primary end point was the proportion of patients achieving greater than 30% reduction in mean PTH over baseline during weeks 20-27, while the secondary end point was the proportion of patients reaching a mean PTH of 300 pg/mL or lower. Patients randomized to etelcalcetide were significantly more likely to achieve the primary and secondary endpoints. Regarding adverse events for both trials, patients receiving etelcalcetide had more muscle spasms, as well as nausea and vomiting. The authors conclude that in patients receiving hemodialysis with moderate to severe secondary hyperparathyroidism, use of etelcalcetide vs. placebo resulted in greater reduction in serum PTH over 26 weeks.

Block GA et al evaluated the therapeutic efficacy and safety of IV etelcalcetide and oral cinacalcet in patients receiving hemodialysis with moderate to severe secondary hyperparathyroidism in a randomized, active control, double-blind phase 3 trial.<sup>2</sup> The trial compared IV etelcalcetide vs. oral placebo and oral cinacalcet vs. IV placebo in 683 patients receiving hemodialysis with serum parathyroid hormone (PTH) concentrations higher than 500 pg/mL on therapy. The patients received either etelcalcetide intravenously with oral placebo or oral cinacalcet with IV placebo for 26 weeks. Administration of the IV formulation was administered 3 times weekly with hemodialysis, while the oral formulation was administered daily. The primary end point was noninferiority of etelcalcetide at achieving more than a 30% reduction in mean predialysis PTH concentrations from baseline during weeks 20-27. Secondary end points included superiority in achieving biochemical end points (>50% and >30% reduction in PTH) as well as self-reported nausea or vomiting. Etelcalcetide was noninferior to cinacalcet on the primary end point. The estimated difference in proportions of patients achieving reduction in PTH concentrations of more than 30% between the 198 of 343 patients (57.7%) randomized to receive cinacalcet and the 232 of 340 patients (68.2%) randomized to receive etelcalcetide was -10.5%(95%CI, -17.5% to -3.5%, P for noninferiority, <.001; P for superiority, .004). One hundred seventy-eight patients (52.4%) to randomized etelcalcetide achieved more than 50% reduction in PTH concentrations compared with 138 patients (40.2%) randomized to cinacalcet (P = .001; difference in proportions, 12.2%; 95%CI, 4.7%to 19.5%). The most common adverse effect was decreased blood calcium (68.9%vs 59.8%). The authors conclude that patients with moderate to severe secondary hyperparathyroidism receiving hemodialysis, the use of etelcalcetide was not inferior to, and met superiority criteria when compare to cinacalcet. The authors state that additional studies are needed to determine clinical outcomes in addition to efficacy and safety beyond the study period.

## CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for Parsabiv (etelcalcetide). Local Coverage Determinations (LCDs) do not exist at this time.

Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. See the [Medicare Benefit Policy Manual, Chapter 15, §50 - Drugs and Biologicals](#). (Accessed May 3, 2018)

## REFERENCES

1. Parsabiv [prescribing information]. Thousand Oaks, CA; Amgen/KAI Pharmaceuticals; February 2017.
2. Block GA, Bushinsky DA, Cheng S, Cunningham J, Dehmel B, Druke TB, Ketteler M, Kewalramani R, Martin KJ, Moe SM, Patel UD, Silver J, Sun Y, Wang H, Chertow GM. Effect of Etelcalcetide vs Cinacalcet on Serum Parathyroid Hormone in Patients Receiving Hemodialysis With Secondary Hyperparathyroidism: A Randomized Clinical Trial. *JAMA*. 2017 Jan 10;317(2):156-164. doi: 10.1001/jama.2016.19468.
3. Block GA, Bushinsky DA, Cunningham J, et al. Effect of etelcalcetide on serum parathyroid hormone in patients receiving hemodialysis with secondary hyperparathyroidism: two randomized clinical trials. *JAMA*. doi:10.1001/jama.2016.19456.

## POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
03/01/2019	Reorganized policy template; simplified and relocated <i>Instructions for Use</i> and removed <i>Benefit Considerations</i> section. Archived previous policy version 2018D0075A.
07/01/2018	New policy 2018D0075A. Approved by National Pharmacy & Therapeutics Committee on 06/20/2018.

## INSTRUCTIONS FOR USE

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard benefit plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Benefit Drug Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)).

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.