

Parsabiv™ (etelcalcetide) Injection

When requesting Parsabiv (etelcalcetide), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indication

Treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) undergoing hemodialysis.

Coverage Guidelines

Secondary hyperparathyroidism

The individual must meet **all** of the following criteria for approval:

- Has a diagnosis of secondary hyperparathyroidism with chronic kidney disease;
- Currently receiving hemodialysis treatment;
- Parsabiv will not be used in combination with or within 7 days after stopping cinacalcet (Sensipar®);
- Has a corrected serum calcium level of 7.5 mg/dL or greater; AND
- Has no signs or symptoms of hypocalcemia (e.g., facial twitching, numbness in fingers or toes, muscle weakness).

For initial authorization, the individual must meet all of the criteria above AND have a parathyroid hormone (PTH) level of 300 pg/mL or greater.

For reauthorization, the individual must meet all of the criteria above AND have a parathyroid hormone (PTH) level of 100 pg/mL or greater.

Dosing Recommendation

Approve up to a maximum dose of 15mg, administered via intravenous bolus injection, up to three times per week at the end of the hemodialysis treatment.

Approval duration: 12 months

References

1. Parsabiv prescribing information. Thousand Oaks, CA.; Amgen. Revised March 2019. [Accessed Sept. 2020].
2. Block GA, Bushinsky DA, Cunningham J, et al. Effect of Etelcalcetide vs Placebo on Serum Parathyroid Hormone in Patients Receiving Hemodialysis with Secondary Hyperparathyroidism. *JAMA*. 2017;317(2):146-155.
3. Saliba W, El-Haddad B. Secondary Hyperparathyroidism: Pathophysiology and Treatment. *J Am Board Fam Med*. 2009;22:574-581.
4. Cunningham J, Locatelli F, and Rodriguez M. Secondary Hyperparathyroidism: Pathogenesis, Disease Progression, and Therapeutic Options. *Clin J Am Soc Nephrol* 6:913-921.