

Parsabiv™ (etelcalcetide) Injection

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

FDA-approved indication

Parsabiv is indicated for the treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on hemodialysis.

Approved Off-label Compensial use(s)

None

Coverage Guidelines

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 cinacalcet (Sensipar®)
- Has corrected serum calcium level 7.5 mg/dL or greater
- Does not have any signs or symptoms of hypocalcemia
- For an initial authorization request, the parathyroid hormone (PTH) level is 300 pg/mL or greater
- For a reauthorization request, the parathyroid hormone (PTH) level is 100 pg/mL or greater

Dosing Recommendation

The recommended starting dose is 5 mg via intravenous bolus injection three times per week at the end of hemodialysis treatment. *(The lowest maintenance dose is 2.5 mg three times per week, and the highest maintenance dose is 15 mg three times per week.)*

Approval duration (initial and renewal): 12 months

References

1. Parsabiv prescribing information. Thousand Oaks, CA.; Amgen. February 2017.
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
5. Progression, and Therapeutic Options. *Clin J Am Soc Nephrol* 6:913-921.