Reference number(s)
2222-A

SPECIALTY GUIDELINE MANAGEMENT

PARSABIV (etelcalcetide)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on hemodialysis

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Secondary hyperparathyroidism with CKD on hemodialysis
Authorization of 12 months may be granted for treatment of secondary hyperparathyroidism in a member with chronic kidney disease on hemodialysis who has a serum calcium level (corrected for albumin) greater than or equal to 8.3 mg/dL (see Appendix).

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when the member is experiencing benefit from therapy as evidenced by a decrease in intact parathyroid hormone (iPTH) levels from pretreatment baseline.

IV. APPENDIX

Corrected calcium = measured total calcium + 0.8(4.0 – serum albumin)

V. REFERENCES

1. Parsabiv [package insert]. Thousand Oaks, CA: Amgen, Inc.; March 2019.
2. Micromedex Solutions [database online]. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: www.micromedexsolutions.com. Accessed October 1, 2020.
3. AHFS DI (Adult and Pediatric) [database online]. Lexi-Comp, Inc. Hudson, OH. Available at: http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed October 1, 2020.
4. Clinical Pharmacology [Internet]. Elsevier. Tampa (FL). Available from: http://www.clinicalpharmacology.com. Accessed October 1, 2020.
5. Block GA, Bushinsky DA, Cunningham J, et al. Effect of etelcalcetide vs placebo on serum parathyroid hormone in patients receiving hemodialysis with secondary hyperparathyroidism: two randomized clinical trials. *JAMA*. 2017;317(2):146-155.
6. Shoback D. Hypoparathyroidism. *NEJM*. 2008;359: 391-403.