

STEP THERAPY POLICY

- POLICY:** Vitamin D Analog (Oral) Step Therapy Program
- Hectorol® (doxercalciferol capsules – Genzyme; generics)
 - Rayaldee® (calcifediol extended-release capsule – OPKO)
 - Rocaltrol® (calcitriol capsules and oral solution – Validus; generics)
 - Zemplar® (paricalcitol capsules – Abbvie; generics)

REVIEW DATE: 08/26/2020

OVERVIEW

Doxercalciferol capsules are indicated for the treatment of secondary hyperparathyroidism in adult patients with Stage 3 or Stage 4 chronic kidney disease (CKD) and adult patients with CKD on dialysis.

Rayaldee capsules are indicated for the treatment of secondary hyperparathyroidism in adult patients with stage 3 or 4 CKD and serum total 25-hydroxyvitamin D levels < 30 ng/mL.

Calcitriol capsules and oral solution are indicated for the following:

- Management of secondary hyperparathyroidism and resultant metabolic bone disease in patients with moderate to severe chronic renal failure (creatinine clearance 15 to 55 mL/min) not yet on dialysis.
- Management of hypocalcemia and the resultant metabolic bone disease in patients undergoing chronic renal dialysis.
- Management of hypocalcemia and its clinical manifestations in patients with postsurgical hypoparathyroidism, idiopathic hypoparathyroidism, and pseudohypoparathyroidism.

Paricalcitol capsules are indicated for the following:

- Prevention and treatment of secondary hyperparathyroidism associated with CKD stages 3 and 4 in adults and pediatric patients ≥ 10 years of age.
- Prevention and treatment of secondary hyperparathyroidism associated with CKD Stage 5 in patients in adults and pediatric patients ≥ 10 years of age on hemodialysis or peritoneal dialysis.

Vitamin D analogs are therapeutic options for the reduction of elevated parathyroid hormone (PTH) levels in patients with chronic kidney disease (CKD) who have secondary hyperparathyroidism (SHPT).¹ SHPT is a common complication of CKD, affecting nearly all of the more than 400,000 patients receiving dialysis (CKD Stage 5D classification) in the US.^{2,3} It may also affect CKD patients not yet on dialysis.^{2,3} SHPT is associated with increased PTH levels and alterations in calcium and phosphorus levels.² These alterations can then lead to bone disease, bone pain and fractures, and vascular and soft tissue calcifications which may lead to cardiovascular (CV) morbidity and mortality.

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 drug prior to the use of a Step 2 drug. If the Step Therapy rule is not met for a Step 2 drug at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a history of one Step 1 drug within the 130-day look-back period is excluded from step therapy.

Step 1: calcitriol capsules, calcitriol oral solution

Step 2: Hectorol capsules (brand and generic), Rayaldee capsules, Rocaltrol capsules (brand), Rocaltrol oral solution (brand), Zemplar capsules (brand and generic)

CRITERIA

1. If the patient has tried one Step 1 product, authorization for a Step 2 product may be given.
2. If the patient has tried intravenous (IV) calcitriol injection, authorization for a Step 2 product may be given.
3. No other exceptions are recommended.

REFERENCES

1. Andress DL. Vitamin D treatment in chronic kidney disease. *Semin Dial.* 2005;18(4):315-321.
2. Kidney Disease Improving Global Outcomes (KDIGO). KDIGO 2017 clinical practice guideline update for the diagnosis, evaluation, prevention, and treatment of chronic kidney disease – mineral and bone disorder (CKD-MBD). *Kid Int Supp.* 2017;7:1-59.
3. Kidney disease statistics for the United States. National Institute of Diabetes and Digestive and Kidney Diseases Website. Available at: <https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease>. Created December 2016. Accessed on August 20, 2020.
4. Rocaltrol® capsules and oral solution [prescribing information]. Parsippany, NJ: Validus Pharmaceuticals, LLC; May 2018.
5. Hectorol® capsules [prescribing information]. Cambridge, MA: Genzyme Corporation; November 2018.
6. Zemplar® capsules [prescribing information]. North Chicago, IL: Abbvie Inc.; October 2019.
7. Rayaldee® extended-release capsules [prescribing information]. Miami, FL: OPKO Pharmaceuticals LLC; December 2019.