

STEP THERAPY POLICY

- POLICY:** Vitamin D Analog (Oral) Step Therapy Program
- Doxercalciferol capsules (generic only)
 - Rayaldee® (calcifediol extended-release capsule – OPKO)
 - Rocaltrol® (calcitriol capsules and oral solution – Validus, generic)
 - Zemplar® (paricalcitol capsules – Abbvie, generic)

REVIEW DATE: 09/14/2022

OVERVIEW

The oral vitamin D analogs are all indicated for the management of secondary hyperparathyroidism associated with chronic kidney disease (CKD) in patients not on dialysis.¹⁻⁴ All of the oral agents, with the exception of Rayaldee, are also indicated for secondary hyperparathyroidism in patients receiving dialysis. Additionally, calcitriol capsules and oral solution are indicated for the management of hypocalcemia in patients with certain hypoparathyroidism diagnoses.

Guidelines

The Kidney Disease: Improving Global Outcomes (KDIGO) clinical practice guidelines for the prevention, diagnosis, evaluation, and treatment of metabolic bone disease (2017) no longer recommend routine use of calcitriol and the vitamin D analogs in patients with CKD Stages 3a through 5 (not receiving dialysis).⁵ Calcitriol and vitamin D analogs may be used in patients with CKD G4 to G5 with severe and progressive hyperparathyroidism. In patients with CKD G5D requiring parathyroid hormone-lowering therapy, treatment with calcimimetics, calcitriol, or vitamin D analogs, or a combination of calcimimetics with calcitriol or vitamin D analogs are suggested. The guidelines do not note a preference for one product over another; all would be appropriate initial therapy choices.

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product 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 of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1: calcitriol capsules, calcitriol oral solution

Step 2: generic doxercalciferol capsules, generic paricalcitol capsules, Rayaldee capsules, Rocaltrol capsules (brand), Rocaltrol oral solution (brand), Zemplar capsules

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. If the patient has tried intravenous (IV) calcitriol injection, approve a Step 2 Product.

09/14/2022

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3. No other exceptions are recommended.

REFERENCES

1. Doxercalciferol capsules [prescribing information]. East Brunswick: Avet; September 2020.
2. Rayaldee® extended-release capsules [prescribing information]. Miami, FL: OPKO; April 2021.
3. Zemplar® capsules [prescribing information]. North Chicago, IL: Abbvie; April 2021.
4. Rocaltrol® capsules and oral solution [prescribing information]. Parsippany, NJ: Validus; May 2018.
5. 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.