# calcifediol (Rayaldee®)

EOCCO POLICY

## Policy Type: PA  Pharmacy Coverage Policy: EOCCO088

### Description

Calcifediol (Rayaldee) is an orally administered prohormone of vitamin D3, calcitriol (1,25-dihydroxyvitamin D3).

### Length of Authorization

- Initial: 12 months
- Renewal: 12 months

### Quantity limits

| Product Name | Dosage Form | Indication | Quantity Limit | DDID |
|---|---|---|---|---|
| calcifediol (Rayaldee) | 30 mcg ER Capsule | Secondary hyperparathyroidism in Stage 3 or 4 CKD | 60 capsules/30 days | 195578 |

### Initial Evaluation

I. Calcifediol (Rayaldee) may be considered medically necessary when the following criteria below are met:
   A. Member has a diagnosis of stage 3 (GFR 30-59 mL/min) or stage 4 (GFR 15-29 mL/min) chronic kidney disease (CKD); **AND**
   B. Member has a diagnosis of secondary hyperparathyroidism (enlarged parathyroid glands due to excessive secretion of parathyroid hormone) ; **AND**
   C. Member is **not** on dialysis; **AND**
   D. Member has a 25-hydroxyvitamin D serum level of < 30 ng/mL; **AND**
   E. Medication is prescribed by, or in consultation with a nephrologist or endocrinologist; **AND**
   F. Treatment with ALL the following has been ineffective, contraindicated, or not tolerated:
      i. calcitriol (Rocaltrol)
      ii. paricalcitol (Zemplar).

II. Calcifediol (Rayaldee) is considered investigational when used for all other conditions, including but not limited to:
   A. Chronic Kidney Disease (CKD) stages 1, 2 and 5 with hyperparathyroidism
   B. End Stage Renal Disease (ESRD) on dialysis with hyperparathyroidism
   C. Secondary hyperparathyroidism without CKD stage 3 or 4 diagnosis

## Renewal Evaluation

I. Member has not been established on therapy by the use of free samples, manufacturer coupons, or otherwise; **AND**
II. Member has received a previous prior authorization approval for this agent; **AND**
III. Medication is prescribed by, or in consultation with a nephrologist or endocrinologist; **AND**
IV. Member has a diagnosis of stage 3 (GFR 30-59 mL/min) or stage 4 (GFR 15-29 mL/min) chronic kidney disease (CKD); **AND**
V. Member has a diagnosis of secondary hyperparathyroidism (enlarged parathyroid glands due to excessive secretion of parathyroid hormone); **AND**
VI. Member is **not** on dialysis; **AND**
VII. Member has exhibited improvement or stability of disease symptoms defined by the following:
   A. Intact parathyroid hormone (PTH) remains above the treatment goal; **AND**
   B. Total 25-hydroxyvitamin D serum level is between < 100 ng/mL; **AND**
   C. Serum calcium < 9.8 mg/dL; **AND**
   D. Serum phosphorous < 5.5 mg/dL

## Supporting Evidence

I. Calcifediol (Rayaldee) was studied in two identical multicenter, randomized, placebo-controlled, double-blind trials in 429 patients with secondary hyperparathyroidism with stage 3 or 4 CKD and serum concentration of 25-hydroxyvitamin D levels between 10 and 30 ng/mL.
II. The primary efficacy outcome was the reduction in plasma PTH from baseline when comparing calcifediol (Rayaldee) to placebo which were 33% versus 8% in trial one and 34% versus 7% in trial two by 26 weeks.
III. There is currently insufficient evidence to suggest that there is a difference between calcifediol ER (Rayaldee) from other vitamin D analogs.
IV. The treatment goal for intact PTH is patient dependent, and will be defined by the provider. In clinical trials the patient's Rayaldee dose was increased to 60 mcg per day when the intact PTH level was greater than 70 pg/mL, the serum 25-hydroxyvitamin D level was less than 65 ng/mL, and the serum calcium level was less than 9.8 mg/dL.
V. Stages of CKD

| Stage | GFR (mL/min/1.73 $m^2$ | |
|---|---|---|
| 1 | ≥ 90 | Normal kidney or high |
| 2 | 60-89 | Mildly reduced kidney function |

| | | |
|---|---|---|
| 3 A | 45-59 | Mild to moderately reduced kidney function |
| 3 B | 30-44 | Moderate to severely reduced kidney function |
| 4 | 15-29 | Severely reduced kidney function |
| 5 | <15 or on dialysis | End stage kidney failure (sometimes called established renal failure) |
| Stage 1 or Stage 2 are not considered CKD in the absence of kidney damage | | |

## Investigational or Not Medically Necessary Uses

I. There is currently limited evidence to suggest safety and/or efficacy with calcifediol (Rayaldee), when used for the treatment of CKD stage 1, 2, and 5, ESRD on dialysis, and secondary hyperarathyoroidism without CKD stage 3 or 4.

## References

1. Rayaldee [Prescribing Information]. OPKO Pharmaceuticals, LLC. Miami, FL. March 2016.

## Policy Implementation/Update:

| | |
|---|---|
| Date Created | January 2017 |
| Date Effective | February 2017 |
| Last Updated | October 2019 |
| Last Reviewed | 01/2017, 02/2017, 10/2019 |

| Action and Summary of Changes | Date |
|---|---|
| Criteria was transitioned into policy format with the addition of renewal criteria, investigational section, and supporting evidence. | 10/2019 |