



## Commercial/Healthcare Exchange PA Criteria

*Effective: February 2017*

**Prior Authorization:** Rayaldee

**Products Affected:** Rayaldee (calcifediol) 30 mcg extended release oral capsules

**Medication Description:** Rayaldee is a prohormone of the active form of vitamin D3, calcitriol (1,25-dihydroxyvitamin D3). Rayaldee is converted to calcitriol by cytochrome P450 27B1 (CYP27B1), also called 1-alpha hydroxylase, primarily in the kidney. Calcitriol binds to the vitamin D receptor in target tissues and activates vitamin D responsive pathways that result in increased intestinal absorption of calcium and phosphorus and reduced parathyroid hormone synthesis.

**Covered Uses:** Treatment of secondary hyperparathyroidism in adults with stage 3 or 4 chronic kidney disease and serum total 25-hydroxyvitamin D levels less than 30 ng/mL.

**Exclusion Criteria:** Treatment of patients with secondary hyperparathyroidism with stage 5 chronic kidney disease or end-stage renal disease on dialysis.

**Required Medical Information:**

1. Diagnosis
2. Lab results

**Age Restrictions:** 18 years of age or older

**Prescriber Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:**

- A. Patient has a diagnosis of secondary hyperparathyroidism; AND
- B. Patient has stage 3 or 4 chronic kidney disease; AND
- C. Patient has a serum total 25-hydroxyvitamin D level less than 30 ng/mL; AND
- D. Patient has had previous treatment, intolerance, or contraindication to a generic vitamin D analog (i.e., ergocalciferol, cholecalciferol, or calcitriol)

**References:**

- 1) Product Information: RAYALDEE<sup>(R)</sup> oral extended-release capsules, calcifediol oral extended-release capsules. OPKO Pharmaceuticals LLC (per FDA), Miami, FL, 2016.



*Policy Revision history*

<b>Rev #</b>	<b>Type of Change</b>	<b>Summary of Change</b>	<b>Sections Affected</b>	<b>Date</b>
1	Policy Update	Updated EH Template and Criteria; CCI P&T Review History: 2/17, 5/18, 5/19 CCI Revision Record: 5/18	All	2/2017