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(R) oral extended-release capsules, calcifediol oral extended-release capsules. OPKO Pharmaceuticals LLC (per FDA), Miami, FL, 2016.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
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