SPECIALTY PHARMACY OPTIONS FOR Rayaldee® calcifediol ER capsules 30 mcg

PHARMACY NAME	PHONE	FAX	ADDRESS

NOTE: Patient has the right to choose the pharmacy of their choice.

KEEP THESE IN MIND WHEN SUBMITTING PRESCRIPTIONS

KEY PARAMETERS [1,2]

- ☐ eGFR 30-59 (CKD Stage 3)
- ☐ eGFR 15-29 (CKD Stage 4)
- ☐ Serum 25D <30 ng/mL
- ☐ Serum calcium <9.8 mg/dL
- ☐ iPTH progressively rising or persistently above the upper limit of normal

ICD-10 DIAGNOSIS CODES [3]

- ☐ N18.3 Chronic kidney disease (CKD) stage 3
- ☐ N18.4 Chronic kidney disease (CKD) stage 4
- ☐ N25.81 Secondary hyperparathyroidism (SHPT)
- ☐ E55.9 Vitamin D deficiency

Indication and Limitations of Use:

Rayaldee® (calcifediol) extended-release 30 mcg capsules is indicated for the 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. Rayaldee® is not indicated in patients with stage 5 chronic kidney disease or end-stage renal disease on dialysis.

Important Safety Information:

• ***Hypercalcemia:*** Excessive administration of vitamin D compounds, including Rayaldee, can cause hypercalcemia and hypercalciuria. Severe hypercalcemia due to substantial overdosage of vitamin D and its metabolites may require emergency attention. Patients should be informed about the symptoms of elevated calcium. • ***Digitalis toxicity:*** Potentiated by hypercalcemia of any cause. Monitor serum calcium and signs and symptoms of digitalis toxicity more frequently when initiating or adjusting the dose of Rayaldee. • ***Adynamic Bone Disease:*** Monitor for abnormally low levels of intact parathyroid hormone (iPTH) levels when using Rayaldee, and adjust dose if needed. • The most common adverse reactions (⩾3% and more frequent than placebo) were anemia, nasopharyngitis, increased blood creatinine, dyspnea, cough, congestive heart failure and constipation. • Care should be taken while dosing Rayaldee with cytochrome P450 inhibitors, thiazides, cholestyramine or drugs stimulating microsomal hydroxylation due to the potential for drug interactions. • Serum calcium should be below 9.8 mg/dL before initiating treatment. • Monitor serum calcium, phosphorus, 25-hydroxyvitamin D and iPTH 3 months after starting therapy or changing dose.

Please see Important Safety Information (ISI) and Full Prescribing Information available at www.Rayaldee.com.

REFERENCES: **1.** Rayaldee [prescribing information]. Miami, FL: OPKO Pharmaceuticals, LLC; January 2024. **2.** Uhlig K, Berns JS, Kesten-baum B, et al. KDOQI US Commentary on the 2009 KDIGO Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of CKD-Mineral and Bone Disorder (CKD-MBD). Am J Kidney Dis. 2010;55(5):773-799. **3**. https://www.cms.gov/medicare/icd-10/2023-icd-10-cm

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