EVALUATE YOUR STAGE 3 AND 4 CKD PATIENTS FOR SHPT[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	CKD Stage 3
☐ N18.4	CKD Stage 4
☐ N 25.81	Secondary hyperparathyroidism (SHPT)
☐ E55.9	Vitamin D deficiency

Rayaldee® is the first and only FDA-approved SHPT treatment that provides a two-for-one benefit: raises 25D and lowers PTH[1,4]

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.

Please see Important Safety Information on back and Full Prescribing Information available at Rayaldee.com.

REFERENCES: 1. Rayaldee [prescribing information]. Miami, FL: OPKO Pharmaceuticals, LLC; April 2021. **2.** Uhlig K, Berns JS, Kestenbaum 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.** www.icd10data.com **4.** Sprague SM, Crawford PW, Melnick JZ, et al. Use of extended-release calcifediol to treat secondary hyperparathyroidism in stages 3 and 4 chronic kidney disease. Am J Nephrol 2016;44:316–25.

OPKO RENAL
A DIVISION OF OPKO HEALTH, INC.

Rayaldee®
calcifediol ER capsules
30 mcg

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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.

For Full Prescribing Information, please visit Rayaldee.com.