Cover Instruction Sheet - Fillable

New Rayaldee® Patient with Vitamin D >30 ng/mL Letter of Medical Necessity Instructions

Please complete the attached form with the required patient, prescriber, and practice information. Use black ink if completed by hand and print clearly to avoid processing delays.

Before submitting, review the form for accuracy and completeness and attach supporting documents as appropriate, such as Rayaldee Prescribing Information, relevant treatment guidelines, or peer-reviewed literature.

Confirm that the prescriber signature and date are included before sending.

This instruction sheet is for reference only and should not be included with the submission.

Date: _____

Physician: _____

Practice:_____

Practice Address: _____

Practice Phone: _____

Patient Name: _____

Patient D.O.B: _____

RE: Letter of Medical Necessity for Rayaldee® (calcifediol) extended-release 30 mcg capsules.

Insurance Plan: _____

To Whom It May Concern:

I am requesting that Rayaldee be approved for my patient, named above, who has been diagnosed with chronic kidney disease (CKD) and Secondary Hyperparathyroidism (SHPT). Rayaldee is medically necessary in this instance because the patient continues to have persistent elevation of intact parathyroid hormone (iPTH) despite prior treatment with vitamin D [1], which has failed to adequately reduce the patient's iPTH level despite 25(OH)D levels >30 ng/mL, demonstrating that the currently utilized therapy is insufficient to control the underlying SHPT. The patient's persistent elevation of iPTH in the setting of CKD is clinically significant and places the patient at increased risk for CKD-mineral and bone disorder (CKD-MBD), abnormal bone turnover, and progressive bone disease, as well as associated cardiovascular complications. All currently covered Part D drugs could produce adverse effects potentially leading to cardiovascular risks and faster disease progression.

Rationale for Treatment

Given the complicated nature of managing this disease state and the published data supporting the use of Rayaldee, I believe that Rayaldee therapy for my patient is warranted, appropriate, and medically necessary.

In this case, the therapeutic objective is not merely to achieve a minimum 25(OH)D concentration, but to achieve adequate vitamin D repletion while controlling the patient's persistently elevated iPTH. Rayaldee is proven in multiple studies to safely and effectively lower iPTH in adult patients with stage 3 or 4 CKD, with effects on serum Ca, P, and FGF23 similar to placebo. Contrary to this, while current formulary options such as calcitriol and other activated vitamin D therapies effectively suppress elevated PTH, they have been shown in randomized CKD studies [1,2] to increase serum calcium resulting in clinically significant hypercalcemia, which may exacerbate

the significant cardiovascular risks already associated with both CKD and SHPT. Because of this, the 2017 CKD-MBD Guideline for SHPT clearly states that, due to the increased risk of hypercalcemia, activated vitamin D should not routinely be used in stage 3 or 4 CKD and should be reserved for severe, progressive SHPT.

Please contact my office if you require further information. Your time and consideration are greatly appreciated.

Sincerely,

_____ _____

Prescriber's signature Date

_____ _____

Prescriber's First & Last Name Prescriber NPI #

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.

For Full Prescribing Information, please visit Rayaldee.com.

References

1. Thadhani R, et al. Vitamin D Therapy and Cardiac Structure and Function in Patients with Chronic Kidney Disease: The PRIMO Randomized Controlled Trial. JAMA.2012;307(7):674-684.
2. Wang AYM, et al. Effect of Paricalcitol on Left Ventricular Mass and Function in CKD: The OPERA Trial. J Am Soc Nephrol. 2014;25(1):175-186.

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