Cover Instruction Sheet - Fillable

Existing Rayaldee® Patient 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 reapproved 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 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 the continuation of Rayaldee therapy for my patient is warranted, appropriate, and medically necessary. 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. On Rayaldee, the patient continues to achieve clinically meaningful reduction in iPTH and experience very favorable tolerability without any observable adverse events. The patient's 25(OH)D level continues to measure within the FDA approved range (30-100 ng/mL) for subsequent Rayaldee dosing.

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. In contrast, current treatment options, such as calcitriol and other activated vitamin D therapies, effectively suppress elevated PTH but have been shown in randomized CKD studies[1,2] to increase serum calcium and the risk of clinically significant hypercalcemia. This is a clinically important concern in patients with CKD and SHPT, populations already at elevated cardiovascular risk. 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. Thank you for your time and consideration of this request.

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. 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.
2. 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.

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