Clinical Policy Title: **Calcifediol (Rayaldee)**

Policy Number: **RxA.273**

Drug(s) Applied: **Calcifediol (Rayaldee™)**

Last Review Date: **05/2020**

Line of Business: **Medicaid, Commercial**

Background

Calcifediol (Rayaldee™) is a prohormone of the active form of vitamin D3 (calcitriol).

Rayaldee is indicated for the treatment of secondary hyperparathyroidism in adult patients with stage 3 or 4 chronic kidney disease (CKD) and serum total 25-hydroxyvitamin D levels less than 30 ng/mL.

Limitation(s) of use: Rayaldee is not indicated in patients with stage 5 CKD or end-stage renal disease on dialysis.

Indication	Dosing Regimen	Maximum Dose
Secondary hyperparathyroidism	30 mcg PO once daily at bedtime. Increase the dose to 60 mcg once daily after 3 months if intact PTH is above the treatment goal. Additionally, ensure serum calcium is below 9.8 mg/dL, phosphorus is below 5.5 mg/dL and 25-hydroxyvitamin D is below 100 ng/mL before increasing the dose.	60 mcg per day

Extended-release capsules: 30 mcg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Secondary Hyperparathyroidism (must meet all)**:**

1. Diagnosis of secondary hyperparathyroidism;
2. Age ≥ 18 years;
3. Member has stage 3 or 4 CKD defined by eGFR of 15-59 mL/min;
4. Current (within the last 30 days) serum total 25-hydroxyvitamin D level is less than 30 ng/mL;

5. Failure of ergocalciferol or cholecalciferol, at up to maximally indicated doses, unless both are contraindicated or clinically significant adverse effects are experienced;
6. Lab results over the previous 3-6 months show trending increase in iPTH level or current (within the last 30 days) labs show iPTH above the normal levels;
7. Dose does not exceed 60 mcg per day (2 capsules per day).

Approval duration:
Medicaid – 12 months
Commercial – Length of Benefit

II. Continued Therapy

A. Secondary Hyperparathyroidism (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy (suspend dosing if intact PTH is persistently abnormally low, serum calcium is consistently above the normal range or serum 25-hydroxyvitamin D is consistently above 100 ng/mL);
3. If request is for a dose increase, new dose does not 60 mcg per day (2 capsules per day).

Approval duration:
Medicaid – 12 months
Commercial – Length of Benefit

III. Appendices

Appendix A: Abbreviation/Acronym Key

CKD: chronic kidney disease
eGFR: estimated glomerular filtration rate
FDA: Food and Drug Administration
iPTH: intact parathyroid hormone

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
cholecalciferol (Vitamin D3)	1,000 international units (IU) PO daily	1,000 IU/day
ergocalciferol (Calcidol®, Drisdol®)	50,000 IU PO once weekly for 8 weeks; repeat for another 8 weeks if 25-hydroxy vitamin D levels are less than 30 nanograms/mL	50,000 IU/week

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

None reported

Appendix D: General Information The

stages of CKD are as follows:

- Stage 1: eGFR at least 90 mL/min/1.73 m^2
- Stage 2: eGFR between 60-89 mL/min/1.73 m^2

- Stage 3: eGFR between 30-59 mL/min/1.73 m^2
- Stage 4: eGFR between 15-29 mL/min/1.73 m^2
- Stage 5: eGFR less than 15 mL/min/1.73 m^2 (or dialysis)

References

1. Rayaldee Prescribing Information. Miami, FL: Opko Pharmaceuticals, LLC. June 2016. http://www.rayaldee.com/. Accessed April 25, 2020
2. Levey AS, Eckardt KU, Tsukamoto Y, et al. Definition and classification of chronic kidney disease: a position statement from Kidney Disease: Improving Global Outcomes (KDIGO). Kidney Int 2005; 67:2089.
3. National Kidney Foundation. K/DOQI clinical practice guidelines for chronic kidney disease: evaluation, classification, and stratification. Am J Kidney Dis 2002; 39:S1.
4. Kidney Disease: Improving Global Outcomes (KDIGO) CKD–MBD Update Work Group. KDIGO 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease—Mineral and Bone Disorder (CKD–MBD). http://kdigo.org/wp-content/uploads/2017/03/KDIGO-2017-CKD-MBD-GuidelineEnglish.pdf. Accessed April 25, 2020
5. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed April 25, 2020

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
Updated references	04/29/2020	05/20/2020
Updated Criteria II, A, i to: Currently receiving medication that has been authorized by Rxadvance or member has previously met initial approval criteria listed in this policy;	05/08/2020	05/21/2020