Clinical Policy: Calcifediol (Rayaldee™)

Reference Number: PA.CP.PMN.76
Effective Date: 01/18
Last Review Date: 07/17/19

Coding Implications
Revision Log

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

FDA approved indication
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 chronic kidney disease or end-stage renal disease on dialysis.

Policy/Criteria
** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria**

It is the policy of Pennsylvania Health and Wellness ® that Rayaldee is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of secondary hyperparathyroidism;
2. Member has stage 3 or 4 chronic kidney disease defined by eGFR of: 15-59ml/min;
3. Current (within the last 30 days) serum total 25-hydroxyvitamin D level is less than 30 ng/mL;
4. Failure, clinically significant adverse effects or contraindication to ergocalciferol or cholecalciferol;
5. Lab results over the previous 3-6 months show trending increase in iPTH level or current (within the last 30 days) lab show iPTH above the normal levels;
6. Requested dose does not exceed 60mcg/day and health plan approved daily quantity limit.

Approval duration: 12 months

Other diagnoses/indications: Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;

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: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

Approval duration: duration of request or 12 months *(whichever is less)*

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – PA.CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation key
ESRD: end stage renal disease
eGFR: estimated glomerular filtration rate
iPTH: intact parathyroid hormone

Appendix B: General Information
The stages of CKD are as follows:

- Stage 1: GFR at least 90 mL/min/1.73 m^2
- Stage 2: GFR between 60-89 mL/min/1.73 m^2
- Stage 3: GFR between 30-59 mL/min/1.73 m^2
- Stage 4: GFR between 15-29 mL/min/1.73 m^2
- Stage 5: GFR less than 15 mL/min/1.73 m^2 (or dialysis)

V. Dosage and administration

- The initial dose of Rayaldee is 30 mcg orally once daily at bedtime.
- Increase the dose to 60 mcg orally once daily at bedtime after approximately 3 months, if intact PTH remains above the desired therapeutic range.
- Rayaldee capsules should be swallowed whole.

VI. Product Availability

Extended release soft capsules: 30 mcg

VII. References

1. Rayaldee Prescribing Information. Miami, FL: Opko Pharmaceuticals, LLC. June 2016. http://www.rayaldee.com/. Accessed May 21, 2018.

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-Guideline-English.pdf. Accessed May 21, 2018.
5. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed May 21, 2018.

Reviews, Revisions, and Approvals	Date	Approval Date
Added iPTH lab requirement for initial approval and iPTH, calcium/vitamin D level monitoring for continued approval to Commercial policy; references reviewed and updated.	03.18	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	