Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Rayaldee (calcifediol)

Effective: July 14, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Rayaldee (calcifediol) ER oral capsule is a vitamin D_3 analog 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.

Limitations: Rayaldee is not indicated in patients with stage 5 chronic kidney disease or end-stage renal disease on dialysis.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Rayaldee (calcifediol) when **ALL** the following criteria are met:

1. Documented diagnosis of secondary hyperparathyroidism

AND

2. Patient is at least 18 years of age or older

AND

3. Patient has stage 3 or 4 chronic kidney disease

AND

4. Patient is not on dialysis

AND

5. Both of the following lab values, prior to initiating therapy:
    a. Total serum 25-hydroxyvitamin D level less than 30ng/mL
    b. Serum calcium level less than 9.8mg/dL

AND

6. Patient has tried and failed therapy with or there is clinical rationale to avoid use with TWO alternative vitamin D products*, such as:
    a. Nutritional Vitamin D supplements (e.g. cholecalciferol or ergocalciferol); AND/OR
    b. Vitamin D analogs (e.g. calcitriol [Rocaltrol], doxercalciferol [Hectorol], or paricalcitol [Zemplar])

***Note:** Does not have to be two products from each category; patient may try two nutritional vitamin D supplements or two vitamin D analogs.

Limitations

1. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. Rayaldee (calcifediol) [prescribing information]. Miami, FL: OPKO Pharmaceuticals, LLC; January 2024.
2. National Kidney Foundation. K/DOQI clinical practice guidelines for chronic kidney disease: evaluation, classification, and stratification. Am J Kidney Dis 2002;39:S1.
3. Quarles LD, Kendrick J. Management of secondary hyperparathyroidism in adult nondialysis patients with chronic kidney disease. In: UpToDate, Taylor EN (ed), Waltham, MA, 2025.
4. KDIGO 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease–Mineral and Bone Disorder (CKD-MBD). Kidney Int Suppl. 2017; 7:1-59.

Approval And Revision History

September 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- July 11, 2023: No changes.
- July 9, 2024: No changes.
- July 8, 2025: No changes.
- July 14, 2026: Administrative update to remove CareLink from the Medical Necessity Guideline template.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.