HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES

CALCIFEDIOL (RAYALDEE)

Generic	Brand	HICL	GCN	Exception/Other
CALCIFEDIOL	RAYALDEE	00998		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of secondary hyperparathyroidism and meet **ALL** of the following conditions?
   - Patient is at least 18 years of age
   - Patient has stage 3 or 4 chronic kidney disease
   - Patient is not on dialysis

   If yes, continue to #2.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Rayaldee guideline, Rayaldee is only covered for the treatment of secondary hyperparathyroidism in a patient at least 18 years of age with stage 3 or 4 chronic kidney disease who is not on dialysis. Your provider did not indicate that you meet the above criteria and therefore your request was not approved.

2. Does the patient meet **ALL** of the following lab values, prior to initiating therapy?
   - Total serum 25-hydroxyvitamin D level less than 30ng/mL
   - Serum calcium level less than 9.8mg/dL

   If yes, continue to #3.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Rayaldee guideline, Rayaldee is only covered when your laboratory values prior to initiating therapy show a total serum 25-hydroxyvitamin D level less than 30ng/mL and a calcium level less than 9.8mg/dL. Your provider did not submit lab values as described above and therefore your request was not approved.

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CALCIFEDIOL (RAYALDEE)

INITIAL CRITERIA (CONTINUED)

3. Has the patient tried and failed therapy with **AT LEAST TWO** alternative Vitamin D products, **OR** is there clinical rationale to avoid use with at least two alternative vitamin D products, such as:
   - Nutritional Vitamin D supplements (e.g. cholecalciferol or ergocalciferol)
   - Vitamin D analogs (e.g. calcitriol (Rocaltrol), doxercalciferol (Hectorol), or paricalcitol (Zemplar)

   If yes, **approve for 12 months by HICL.** (The quantity limit is hard-coded for two capsules per day.) Please use status code #056.

   Requests for products on formulary with a restriction, please use the approval text provided.
   APPROVAL TEXT: Your request for Rayaldee (calcifediol) has been approved with a quantity limit of 60 capsules per 30 days for a 12-month period.

   Requests for products not on formulary, please use the approval text provided.
   APPROVAL TEXT: Your request for Rayaldee (calcifediol) has been approved with a quantity limit of 60 capsules per 30 days at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Rayaldee guideline, a previous trial with at least two alternative Vitamin D medications OR there is clinical rationale to avoid use with at least two alternative vitamin D products, such as: Nutritional Vitamin D supplements (e.g. cholecalciferol or ergocalciferol), Vitamin D analogs (e.g. calcitriol (Rocaltrol), doxercalciferol (Hectorol), or paricalcitol (Zemplar) is required prior to approval of Rayaldee. Your provider did not indicate that you previously tried at least two alternative medications and therefore your request was not approved.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of secondary hyperparathyroidism and meet **ALL** of the following conditions?
   - Patient with stage 3 or 4 chronic kidney disease
   - Patient is not on dialysis

   If yes, continue to #2.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Rayaldee guideline, Rayaldee is only covered for the treatment of secondary hyperparathyroidism in a patient with stage 3 or 4 chronic kidney disease who is not on dialysis. Your provider did not indicate that you meet the above criteria and therefore your request was not approved.

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CALCIFEDIOL (RAYALDEE)

RENEWAL CRITERIA (CONTINUED)

2. Does the patient meet **ALL** of the following lab values, obtained within the last 6 months?
   - Total serum 25-hydroxyvitamin D level less than 100ng/mL
   - Serum calcium level less than 9.8mg/dL

   If yes, **approve for 12 months by HICL.** (The quantity limit is hard-coded for two capsules per day.) Please use status code #056.

   Requests for products on formulary with a restriction, please use the approval text provided.
   APPROVAL TEXT: Your request for Rayaldee (calcifediol) has been approved with a quantity limit of 60 capsules per 30 days for a 12-month period.

   Requests for products not on formulary, please use the approval text provided.
   APPROVAL TEXT: Your request for Rayaldee (calcifediol) has been approved with a quantity limit of 60 capsules per 30 days at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Rayaldee renewal guideline, Rayaldee is only covered when your laboratory values, obtained within the last 6 months, show a total serum 25-hydroxyvitamin D level less than100ng/mL and a calcium level less than 9.8mg/dL. Your provider did not submit lab values as described above and therefore your request was not approved.

RATIONALE
Promote appropriate utilization of Rayaldee based on FDA approved indication and dosing, and promote the first line use of nutritional vitamin D supplements or analogs when clinically appropriate.

FDA APPROVED INDICATIONS
Rayaldee is a vitamin D 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 of Use: Rayaldee is not indicated in patients with stage 5 chronic kidney disease or end-stage renal disease on dialysis.

Calcifediol ER (Rayaldee) has not been studied in patients on dialysis. The safety of calcifediol ER (Rayaldee) in this population is unknown.

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CALCIFEDIOL (RAYALDEE)

FDA APPROVED INDICATIONS (CONTINUED)

Chronic kidney disease (CKD) classification based upon glomerular filtration rate (GFR)

Stage 1	GFR ≥90 mL/min
Stage 2	GFR 60-89 mL/min
Stage 3a	GFR 45-59 mL/min
Stage 3b	GFR 30-44 mL/min
Stage 4	GFR 15-29 mL/min
Stage 5	GFR <15 mL/min

REFERENCES

- Rayaldee (calcifediol) [Prescribing Information]. Miami, FL: OPKO Pharmaceuticals, LLC; June 2016.
- National Kidney Foundation. K/DOQI clinical practice guidelines for chronic kidney disease: evaluation, classification, and stratification. Am J Kidney Dis 2002;39:S1.
- Quarles LD, Berkoben M. Management of secondary hyperparathyroidism and mineral metabolism abnormalities in adult predialysis patients with chronic kidney disease. In: UpToDate, Post, TW (ed), Waltham, MA, 2017.
- 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.

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