

Market Applicability/Effective Date														
Market	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

\*FHK- Florida Healthy Kids

## Rayaldee (calcifediol)

Override(s)	Approval Duration
Prior Authorization	Initial Requests: 3 months Maintenance Therapy Requests: 12 months

Medications	Quantity Limit
Rayaldee (calcifediol)	May be subject to quantity limit

### APPROVAL CRITERIA

Initial requests for Rayaldee (calcifediol) may be approved if the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Individual is using for treatment of secondary hyperparathyroidism (HPT) associated with a diagnosis of stage 3 or stage 4 chronic kidney disease (CKD); **AND**
- III. Individual has a serum total 25-hydroxyvitamin D level less than 30 ng/mL and a serum corrected total calcium below 9.8 mg/dL; **OR**
- IV. Individual is using for neonatal hypocalcemia (DrugDex B IIa).

Continuation of therapy requests for Rayaldee (calcifediol) may be approved if the following criteria are met:

- I. Individual is 18 years of age or older and using for treatment of secondary HPT associated with stage 3 or 4 CKD; **AND**
- II. Individual has a serum total 25-hydroxyvitamin D level between 30 and 100 ng/mL, a serum corrected total calcium below 9.8 mg/dL, and serum phosphorus below 5.5 mg/dL.

Rayaldee (calcifediol) may not be used for the following:

- I. Individual has a diagnosis of stage 5 chronic kidney disease or end-stage renal disease on dialysis.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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**Key References:**

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2016. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2016; Updated periodically.

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