

Policy Name:	Royaldee (calcifediol)	Policy #:	2522P
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Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Royaldee.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Royaldee under the specialty pharmacy benefit when the following criteria has been met.

Criteria

1. Coverage Criteria

- 1.1 Documented secondary hyperparathyroidism and stage 3 or 4 chronic kidney disease
- 1.2 Documented total blood vitamin D level less than 30ng/mL
- 1.3 Ordered by an endocrinologist (hormone doctor) or nephrologist (kidney doctor)
- 1.4 Documented failure, intolerance, or contraindication to cholecalciferol or ergocalciferol
- 1.5 Documented failure, intolerance, or contraindication to calcitriol or paricalcitol

2. Exclusion Criteria

- 2.1 Excluded in patients with Stage 5 Chronic Kidney Disease, or in patients with end-stage renal disease on dialysis

3. Approval Period

- 3.1 Initial: 12 Months
- 3.2 Reauthorization: 12 months with documented clinical benefit

CPT Codes

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HCPCS Codes

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References

1. Royaldee [Prescribing Information]. Miami, FL: OPKO Pharmaceuticals; April 2021.
2. Cozzolino M, Ketteler M. Evaluating extended-release calcifediol as a treatment option for chronic kidney disease-mineral and bone disorder (CKD-MBD). *Expert Opin Pharmacother*. 2019 Dec;20(17):2081-2093.
3. Kidney Disease: Improving Global Outcomes (KDIGO): Clinical practice guideline for the diagnosis, evaluation, prevention, and treatment of chronic kidney disease – Mineral and bone disorder (CDK-MBD), update (2017).

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.