

**Pharmacy Policy**

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**Royaldee**

**Policy Number:** 9.314

**Version Number:** 2.0

**Version Effective Date:** 9/1/2021

Product Applicability <input type="checkbox"/> <b>All Plan<sup>+</sup> Products</b>	
<b>Well Sense Health Plan</b>	<b>Boston Medical Center HealthNet Plan</b>
<input type="checkbox"/> New Hampshire Medicaid	<input type="checkbox"/> MassHealth - MCO
	<input type="checkbox"/> MassHealth - ACO
	<input checked="" type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct
	<input type="checkbox"/> Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

**Prior Authorization Policy**

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**Products Affected:**

- Royaldee(calcifediol)

The Plan may authorize coverage of the above products for members meeting the following criteria:

<b>Covered Use</b>	All FDA approved indications not otherwise excluded
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	1. Diagnosis of secondary hyperparathyroidism associated with a diagnosis of stage 3 or 4 chronic kidney disease ; <b>AND</b> 2. Serum total 25-hydroxyvitamin D level is less than 30 ng/ml; <b>AND</b>

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	<p>3. Corrected serum total calcium is below 9.8 mg/dL prior to initiating therapy; <b>AND</b></p> <p>4. Intolerance, inadequate response, or contraindication to max doses of Ergocalciferol (Vitamin D2), and Cholecalciferol (Vitamin D3); <b>AND</b></p> <p>5. Member will be starting on 30mcg once daily dosing</p>
<b>Age Restriction</b>	18 years or older
<b>Prescriber Restriction</b>	None
<b>Coverage Duration</b>	Initial : 6 months Reauthorization: 12 months
<b>Other criteria</b>	<p>Reauthorization:</p> <ol style="list-style-type: none"> <li>1. Serum total 25-hydroxyvitamin D level between 30 and 100 ng/mL, <b>AND</b></li> <li>2. A serum corrected total calcium below 9.8 mg/dL, <b>AND</b></li> <li>3. Serum phosphorus below 5.5 mg/dL.</li> </ol>

### Clinical Background Information and References

Royaldee® (calcifediol) [prescribing information]. Miami, FL: OPKO Pharmaceuticals, LLC; March 2016.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	9.073 Royaldee Policy retired, new policy created	1/1/2021	Pharmacy & Therapeutics (P&T) Committee
5/13/2021	P&T Annual review: No changes	9/1/2021	P&T Committee

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**Next Review Date**

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5/2022

**Other Applicable Policies**

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**Reference to Applicable Laws and Regulations, If Any**

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**Disclaimer Information**

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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