



STEP THERAPY POLICY

- POLICY:** Vitamin D Analog (Oral) Step Therapy Policy
- Doxercalciferol capsules (generic only)
 - Rayaldee® (calcifediol extended-release capsule – OPKO)
 - Rocaltrol® (calcitriol capsules and oral solution – Validus, generic)
 - Zemplar® (paricalcitol capsules – Abbvie, generic)

REVIEW DATE: 09/18/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

The **oral vitamin D analogs** are all **indicated for the management of secondary hyperparathyroidism associated with chronic kidney disease (CKD) in patients not on dialysis.**¹⁻⁴ All of the oral agents, with the exception of Rayaldee, are also indicated for secondary hyperparathyroidism in patients receiving dialysis. Additionally, calcitriol capsules and oral solution are indicated for the management of hypocalcemia in patients with certain hypoparathyroidism diagnoses.

Guidelines

The Kidney Disease: Improving Global Outcomes (KDIGO) clinical practice guidelines for the prevention, diagnosis, evaluation, and treatment of chronic kidney disease-metabolic bone disease (2017) no longer recommend routine use of calcitriol and the vitamin D analogs in patients with CKD Stages 3a through 5 (not receiving dialysis).⁵ Calcitriol and vitamin D analogs may be used in patients with CKD G4 to G5 with severe and progressive hyperparathyroidism. In patients with

CKD G5D requiring parathyroid hormone-lowering therapy, treatment with calcimimetics, calcitriol, or vitamin D analogs, or a combination of calcimimetics with calcitriol or vitamin D analogs are suggested. The guidelines do not note a preference for one product over another; all would be appropriate initial therapy choices.

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Step 1: generic calcitriol capsules, generic calcitriol oral solution

Step 2: generic doxercalciferol capsules, generic paricalcitol capsules, Rayaldee capsules, Rocaltrol capsules (brand), Rocaltrol oral solution (brand), Zemplar capsules

Vitamin D Analog (Oral) Step Therapy Policy product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. If the patient has tried intravenous (IV) calcitriol injection, approve a Step 2 Product.

REFERENCES

1. Doxercalciferol capsules [prescribing information]. Congers, NY: Chartwell Rx; January 2023.
2. Rayaldee® extended-release capsules [prescribing information]. Miami, FL: OPKO; January 2024
3. Zemplar® capsules [prescribing information]. North Chicago, IL: Abbvie; August 2024.
4. Rocaltrol® capsules and oral solution [prescribing information]. Parsippany, NJ: Validus; January 2021
5. Kidney Disease Improving Global Outcomes (KDIGO). KDIGO 2017 clinical practice guideline update for the diagnosis, evaluation, prevention, and treatment of chronic kidney disease – mineral and bone disorder (CKD-MBD). *Kid Int Supp.* 2017;7:1-59.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	09/13/2023

Annual Revision	No criteria changes.	09/18/2024
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