Clinical Policy: Paricalcitol Injection (Zemplar)

Reference Number: CP.PHAR.270
Effective Date: 08.01.16
Last Review Date: 08.22
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Paricalcitol (Zemplar®) is a synthetically manufactured active vitamin D_2 analog.

FDA Approved Indication(s)
Paricalcitol injection (Zemplar) is indicated for the prevention and treatment of secondary hyperparathyroidism (HPT) in patients 5 years of age and older with chronic kidney disease (CKD) on dialysis.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Zemplar injection is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Secondary Hyperparathyroidism in Chronic Kidney Disease (must meet all)**:**

1. Diagnosis of secondary HPT due to CKD;
2. Prescribed by or in consultation with a nephrologist or endocrinologist;
3. Age ≥ 5 years;
4. Member is on dialysis;
5. Lab results over the previous 3-6 months show trending increase in iPTH level or current (within the last 30 days) labs show iPTH above the normal levels;
6. For brand Zemplar requests, member must use generic paricalcitol, unless contraindicated or clinically significant adverse effects are experienced;
7. Failure of calcitriol (Rocaltrol®) injection at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
8. Paricalcitol is not prescribed concurrently with other vitamin D derivatives/analogs (e.g., calcitriol, doxercalciferol);
9. Dose does not exceed 0.24 mcg/kg every other day.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business:

CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Approval

A. Secondary Hyperparathyroidism in Chronic Kidney Disease (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
2. Member is responding positively to therapy as evidenced by a decrease in iPTH;
3. Paricalcitol is not prescribed concurrently with other vitamin D derivatives/analogs (e.g., calcitriol, doxercalciferol);
4. For brand Zemplar requests, member must use generic paricalcitol, unless contraindicated or clinically significant adverse effects are experienced;
5. If request is for a dose increase, new dose does not exceed 0.24 mcg/kg every other day.

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CKD: chronic kidney disease
FDA: Food and Drug Administration
HPT: hyperparathyroidism
iPTH: intact parathyroid hormone

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
calcitriol injection (Rocaltrol®)	1 to 2 mcg/day IV 3 times weekly on approximately every other day; may increase by 0.5 to 1 mcg/dose at 2 to 4 week intervals to optimal response	4 mcg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypercalcemia, vitamin D toxicity, hypersensitivity to paricalcitol or any of the inactive ingredients in Zemplar
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Secondary HPT in CKD	Adults: Initial: 0.04 mcg/kg to 0.1 mcg/kg (2.8 – 7 mcg) administered as a bolus dose no more frequently than every other day at any time during dialysis. The dose may be increased by 2 to 4 mcg at 2- to 4- week intervals Pediatric age ≥ 5 years: Initial: 0.04 mcg/kg if baseline intact PTH is < 500 pg/mL, or 0.08 mcg/kg if baseline intact PTH is ≥ 500 pg/mL administered three times per week, no more frequently than every other day, at any time during dialysis. The dose may be increased by 0.04 mcg/kg at 2- to 4- week intervals.	Adults: 0.24 mcg/kg Pediatric: see dosing regimen

VI. Product Availability

Single-dose vial for injection: 2 mcg/mL, 5 mcg/mL
Multiple-dose vial for injection: 10 mcg/2 mL

VII. References

1. Zemplar Injection Prescribing Information. North Chicago, IL: AbbVie Inc.; May 2021. Available at www.zemplar.com. Accessed May 17, 2022.
2. Kidney Disease: Improving Global Outcomes (KDIGO) CKD–MBD Work Group. KDIGO 2017 clinical practice guideline update for the diagnosis, evaluation, prevention, and treatment of chronic kidney disease–mineral and bone disorder (CKD–MBD). Kidney International Supplements 2017; 7:1–59. Available at: http://kdigo.org/wp-content/uploads/2017/02/2017-KDIGO-CKD-MBD-GL-Update.pdf.
3. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Truven Health Analytics. Updated periodically. Accessed May 17, 2022.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J2501	Injection, paricalcitol, 1 mcg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2018 annual review: converted to new template; HIM Medical added; added specialist requirement; added requirement for positive response and max dose to re-auth; references reviewed and updated.	06.11.18	08.18
3Q 2019 annual review: added requirement for baseline iPTH levels for initial approval, and for documentation of improvement in iPTH levels for reauthorization, in line with the previously approved approach for other therapies for secondary hyperparathyroidism in CKD on dialysis; references reviewed and updated.	05.10.19	08.19
3Q 2020 annual review: added Commercial line of business, modified HIM-Medical Benefit to HIM line of business; references reviewed and updated.	05.04.20	08.20
3Q 2021 annual review: no significant changes; added redirection for brand Zemplar requests to generic paricalcitol to both initial and continued therapy sections; references reviewed and updated.	05.10.21	08.21
3Q 2022 annual review: no significant changes; references reviewed and updated.	05.17.22	08.22
Template changes applied to other diagnoses/indications and continued therapy section.	09.20.22	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members

and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.