

Clinical Policy: Paricalcitol Injection (Zemplar)

Reference Number: CP.PHAR.270

Effective Date: 08/16

Last Review Date: 08/17

[Coding Implications](#)
[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for paricalcitol injection (Zemplar® Injection).

Policy/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. Hyperparathyroidism in Chronic Kidney Disease (must meet all):

1. Age \geq 5 years;
2. Diagnosis of chronic kidney disease (CKD) stage 5 defined as glomerular filtration rate <15 mL/min/1.73m² or dialysis;
3. Paricalcitol injection will be used for the prevention and treatment of secondary hyperparathyroidism associated with CKD Stage 5;
4. Paricalcitol is not prescribed concurrently with other vitamin D derivatives/analogs (e.g., calcitriol, doxercalciferol, alfacalcidol).

Approval Duration: 6 months

B. Other diagnoses/indications: Refer to CP.PHAR.57.

II. Continued Approval

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

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Paricalcitol is not prescribed concurrently with other vitamin D derivatives/analogs (e.g., calcitriol, doxercalciferol, alfacalcidol).

Approval Duration: 12 months

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy.

Background

Description/Mechanism of Action:

Paricalcitol is a synthetic, biologically active vitamin D analog of calcitriol with modifications to the side chain (D2) and the A (19-nor) ring. Preclinical and in vitro studies have demonstrated

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Paricalcitol

that paricalcitol's biological actions are mediated through binding of the vitamin D receptor, which results in the selective activation of vitamin D responsive pathways. Vitamin D and paricalcitol have been shown to reduce parathyroid hormone levels by inhibiting parathyroid hormone synthesis and secretion.

FDA Approved Indications:

Paricalcitol injection (generic) is a synthetically manufactured active vitamin D₂ analog/aqueous solution for intravenous injection indicated for:

- Prevention and treatment of secondary hyperparathyroidism associated with CKD Stage 5.

Zemplar is a synthetically manufactured analog of calcitriol, the metabolically active form of vitamin D/aqueous solution for intravenous injection indicated for:

- Prevention and treatment of secondary hyperparathyroidism associated with CKD Stage 5.

Appendices

Appendix A: Abbreviation Key

CKD: chronic kidney disease

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	Approval Date
Policy developed.	08/16	08/16
Removed requirement for oral calcitriol use prior to Zemplar due to lack of evidence to support that both agents are of clinical parity. Added limitation regarding concurrent administration with other vitamin D derivatives/analogs.	02/17	02/17
Safety criteria was applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs.	08/17	08/17

References

1. Paricalcitol Injection Prescribing Information. Lake Forest, IL: Hospira, Inc.; October 2014. Available at <http://www.hospira.com/en/>. Accessed August 2017.
2. Zemplar Injection Prescribing Information. North Chicago, IL: AbbVie, Inc.; January 2013. Available at www.rxabbvie.com/pdf/zemplarivpi.pdf. Accessed August 2017.
3. National Kidney Foundation. KDOQI clinical practice guidelines for chronic kidney disease: evaluation, classification, and stratification. *Am J Kidney Dis.* 2002; 39(suppl 1): S1-S266.

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.

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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.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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