Clinical Policy: Paricalcitol Injection (Zemplar)

Reference Number: LA.PHAR.270
Effective Date: 02.22.24
Last Review Date: 05.07.24
Line of Business: Medicaid

Coding Implications
Revision Log

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

Please note: This policy is for medical benefit

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 Louisiana Healthcare Connections 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 generic doxercalciferol 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., 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 LA.PMN.255

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: LA.PMN.53 for Medicaid.

II. Continued Approval

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

1. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;
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., 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 LA.PMN.255
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: LA.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 – LA.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
doxercalciferol (Hectorol®) injection	4 mcg/day IV 3 times weekly; may increase at 8-week intervals by 1 mcg to 2 mcg if intact PTH is not lowered by 50% and fails to reach the target range	18 mcg/week

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 vials 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 September 15, 2023.
2. Hectorol Prescribing Information. Cambridge, MA: Genzyme Corporation; April 2023. Available at https://products.sanofi.us/hectorol_injection/hectorol_injection.pdf. Accessed September 15, 2023.
3. 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.
4. Shroff R, Wan M, Nagler EV, et al. Clinical practice recommendations for treatment with active vitamin D analogues in children with chronic kidney disease stages 2-5 and on dialysis. Nephrol Dial Transplant 2017;32:1114-27. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5837664/pdf/gfx080.pdf.
5. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Truven Health Analytics. Updated periodically. Accessed September 15, 2023.

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	LDH Approval Date
Converted corporate to local policy.	06.15.23	01.23.24
Annual review; Replaced redirection to IV calcitriol with redirection to IV doxercalciferol since IV calcitriol is no longer commercially available; references reviewed and updated.	05.07.24	

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. LHCC 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.

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 LHCC-level administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. 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. LHCC 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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