Clinical Policy: Paricalcitol Injection

Reference Number: PA.CP.PHAR.270
Effective Date: 01/18
Last Review Date: 07/17/19

Coding Implications
Revision Log

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

FDA Approved Indication(s)
Zemplar is indicated for the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease (CKD) Stages 3 and 4, and CKD Stage 5 in patients on hemodialysis or peritoneal 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.

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness ® that paricalcitol injection and Zemplar are **medically necessary** when one of the following criteria is met:

I. Initial Approval Criteria

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

1. Diagnosis of chronic kidney disease (CKD) stage 3,4 or 5 as defined by the glomerular filtration rates established by the National Kidney Foundation;
2. Age ≥ 5 years;
3. Prescribed by or in consultation with a nephrologist or endocrinologist;
4. Failure of a trial of calcitriol (Rocaltrol®) injection at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
5. Paricalcitol is not prescribed concurrently with other vitamin D derivatives/analogs (e.g., calcitriol, doxercalciferol, alfacalcidol);
6. Dose does not exceed 0.24 mcg/kg every other day.

Approval Duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. Paricalcitol is not prescribed concurrently with other vitamin D derivatives/analogs (e.g., calcitriol, doxercalciferol, alfacalcidol);

4. 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 (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53

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 – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
CKD: chronic kidney disease
FDA: Food and Drug Administration
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
Not applicable

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Secondary Hyperparathyroidism in CKD	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	0.24 mcg/kg

VI. Product Availability

Injection: 2 mcg/mL and 5 mcg/mL

References

1. Paricalcitol Injection Prescribing Information. Lake Forest, IL: Hospira, Inc.; February 2018. Available at http://www.hospira.com/en/. Accessed May 21, 2018.
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. Accessed May 21, 2018.
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.
4. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Truven Health Analytics. Updated periodically. Accessed May 21, 2018

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
2Q 2018 annual review: 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/analogsreferences reviewed and updated.	01.23.18	
Added specialist requirement; added requirement for failure of trial of calcitriol injection; added requirement for positive response and max dose to re-auth; references reviewed and updated.	09/18	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	