RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title: **Paricalcitol Injection (Zemplar)**
Policy Number: **RxA.575**
Drug(s) Applied: **Paricalcitol (Zemplar®)**
Last Review Date: **01/2020**
Line of Business: **Commercial, Medicaid, HIM–Medical Benefit**

Background

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

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

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

Injection: 2 mcg/mL, 5 mcg/mL

Clinical Policy

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

I. Initial Approval Criteria

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

1. Diagnosis of secondary hyperparathyroidism associated with CKD on dialysis);
2. Prescribed by or in consultation with a nephrologist or endocrinologist;
3. Age ≥ 5 years;
4. 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;
5. Failure of calcitriol (Rocaltrol®) injection at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
6. Paricalcitol is not prescribed concurrently with other vitamin D derivatives/analogs (e.g., calcitriol, doxercalciferol);
7. Dose does not exceed 0.24 mcg/kg every other day.

Approval duration: 6 months

II. Continued Approval

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

1. Currently receiving medication via RxAdvance benefit or member has previously met all 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., calcitriol, doxercalciferol);
4. If request is for a dose increase, new dose does not exceed 0.24 mcg/kg every other day.

Approval duration: 12 months

III. Appendices

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/Boxed Warnings

- Contraindication(s): hypercalcemia, vitamin D toxicity
- Boxed warning(s): none reported

References

1. Paricalcitol Injection Prescribing Information. Lake Forest, IL: Hospira, Inc.; February 2018. Available at http://www.hospira.com/en/. Accessed May 10, 2019.
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 10, 2019.
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 10, 2019.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	03/06/2020