RXADVANCE
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Clinical Policy Title:	paricalcitol
Policy Number:	RxA.575
Drug(s) Applied:	Zemplar®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Paricalcitol (Zemplar®) is a synthetically manufactured active vitamin D2 analog. It 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
paricalcitol Injection (Zemplar®)	Secondary hyperparathyroidism 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 5 years of age: Initiate 0.04 mcg/kg if baseline intact PTH is less than 500 pg/mL, or 0.08 mcg/kg if baseline intact PTH is 500 pg/mL or greater administered as a bolus dose no more frequently than every other day at any time during dialysis. The dose may be Increased by 0.04 mcg/kg every 2 to 4 weeks	Adults: 0.24 mcg/kg Pediatric: See dosing regimen.

Dosage Forms

- 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 of age or older;
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
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
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
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
CKD: chronic kidney disease
FDA: Food and Drug Administration
iPTH: intact parathyroid hormone
HPT: hyperparathyroidism

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

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	4 mcg/day

	response	

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;
  - known hypersensitivity to paricalcitol or any inactive ingredient

- Boxed Warning(s):
  - None.

APPENDIX D: General Information

- Decreased renal conversion of vitamin D to its primary active metabolite (1,25-hydroxyvitamin D) in chronic renal failure leads to reduced activation of vitamin D receptor (VDR), which subsequently removes inhibitory suppression of parathyroid hormone (PTH) release; increased serum PTH (secondary hyperparathyroidism) reduces calcium excretion and enhances bone resorption.
- Paricalcitol is a synthetic vitamin D_2 analog which binds to and activates the VDR in kidney, parathyroid gland, intestine and bone, thus reducing PTH levels and improving calcium and phosphate homeostasis.

References

1. Paricalcitol Injection Prescribing Information. Lake Forest, IL: Hospira, Inc.; January 2020. Available at http://labeling.pfizer.com/ShowLabeling.aspx?id=4563 . Accessed October 05,2020.
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 October 05, 2020.
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. Accessed October 05, 2020.
4. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Truven Health Analytics. Updated periodically. Accessed October 05, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical policy title was updated as “paricalcitol”. 2. Lines of business policy applies to all lines of business. 3. Dosing information updated. 4. Continued therapy criteria II.A.1. was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance…”. 5. Updated Appendix C: added “known	10/05/2020	12/07/2020

hypersensitivity…" to contraindications. 6. Appendix D was added. 7. References were reviewed and updated.		