Clinical Policy Title:	paricalcitol
Policy Number:	RxA.575
Drug(s) Applied:	Zemplar®
Original Policy Date:	03/06/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

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 an 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
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 member has previously met initial approval criteria listed in this policy; in
2. Member is responding positively to therapy as evidenced by a decrease 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

References

1. 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: https://kdigo.org/wp-content/uploads/2017/02/2017-KDIGO-CKD-MBD-GL-Update.pdf. Accessed July 28, 2022.

2. 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. Available at: https://www.kidney.org/sites/default/files/docs/ckd_evaluation_classification_stratification.pdf. Accessed July 28, 2022.

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. Continued therapy criteria II.A.1. was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance…". 4. References were reviewed and updated.	10/05/2020	12/07/2020
Policy was reviewed: 1. References were reviewed and updated.	10/10/2021	12/07/2021
PA policy was reviewed: 1. References were reviewed and updated.	07/28/2022	10/19/2022
Policy was reviewed.	10/19/2023	10/19/2023