Original Effective Date: 07/20/2014
Current Effective Date: 09/20/2023
Last P&T Approval/Version: 07/26/2023
Next Review Due By: 07/2024
Policy Number: C4967-C

Zemplar (paricalcitol)

PRODUCTS AFFECTED

Zemplar (paricalcitol), paricalcitol

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Prevention and treatment of secondary hyperparathyroidism

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review.

A. PREVENTION OR TREATMENT OF SECONDARY HYPERPARATHYROIDISM:
1. (a) Documented diagnosis of chronic kidney disease (CKD) stage 3 or stage 4 and member requires prevention or treatment of secondary hyperparathyroidism
   OR

(b) Documented diagnosis of chronic kidney disease (CKD) stage 5 AND member is currently receiving regular hemodialysis (HD) or peritoneal dialysis (PD) treatments and member requires prevention or treatment of secondary hyperparathyroidism
AND

2. FOR MEMBERS WITH CHRONIC KIDNEY DISEASE STAGE 5: Documentation that member's serum calcium level (calcium level corrected for albumin) is lower than 9.5 mg/dL [DOCUMENTATION REQUIRED]
   NOTE: Corrected calcium level = serum calcium + 0.8(4 - albumin level)
   AND
3. Documentation of member's baseline intact parathyroid hormone (iPTH) level [DOCUMENTATION REQUIRED]
   AND
4. Documentation the member has tried and failed or has serious side effects to calcitriol AND
5. FOR MEMBERS ON DIALYSIS: Prescriber attests that member is not a candidate for IV paricalcitol therapy administered at the time of dialysis due to medically acceptable contraindication
   AND
6. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review. [Contraindications to Zemplar (paricalcitol) include: evidence of hypercalcemia, evidence of vitamin D toxicity.]
   AND
7. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or intolerance to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

CONTINUATION OF THERAPY:

A. PREVENTION OF SECONDARY HYPERPARATHYROIDISM:

1. Documentation that member experienced normalization of intact parathyroid hormone (iPTH) from baseline [DOCUMENTATION REQUIRED]
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Prescriber attests or clinical reviewer has found prescriber is monitoring serum calcium and phosphate levels per labeled recommendations
   Note: If hypercalcemia is observed, the dose of Zemplar should be reduced or withheld until these parameters are normalized

DURATION OF APPROVAL:

Initial authorization: 12 month, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with an endocrinologist or nephrologist. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization request]

AGE RESTRICTIONS:

10 years of age and older

QUANTITY:

No Requirement

PLACE OF ADMINISTRATION:

The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and

patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Hyperparathyroid Treatment – Vitamin D Analogs

FDA-APPROVED USES:
Indicated in adults and pediatric patients 10 years and older for the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease (CKD) stages 3 and stage 4 or CKD stage 5 on hemodialysis or peritoneal dialysis.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Zemplar are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Zemplar (paricalcitol) include: evidence of hypercalcemia, evidence of vitamin D toxicity.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Paricalcitol CAPS 1MCG, 2MCG, 4MCG
Zemplar CAPS 1 MCG, 2 MCG

REFERENCES

1. Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Update 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 Int. 2017;7(suppl 1):1-59. doi: 10.1016/j.kisu.2017.04.001.
2. Shehab N, Lewis CL, Streetman DD, Donn SM. Exposure to the pharmaceutical excipients benzyl alcohol and propylene glycol among critically ill neonates. Pediatric Crit Care Med. 2009;10(2):256-259.
3. Zemplar (paricalcitol capsules) [prescribing information].North Chicago, IL; AbbVie Inc; April 2021.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Products Affected Diagnosis Required Medical Information Continuation of Therapy Prescriber Requirements Drug Class FDA-Approved Uses Contraindications/Exclusions/ Discontinuation Available Dosage Forms	Q3 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Contraindications/Exclusions/Discontinuation	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file