Zemplar (paricalcitol)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Zemplar (paricalcitol) oral capsules
Zemplar (paricalcitol) intravenous solution

APPROVAL CRITERIA

Requests for oral Zemplar (paricalcitol) may be approved when the following criteria are met:

  I.   Individual is 10 years of age or older; **AND**
  II.   Individual is using for prevention or treatment of secondary hyperparathyroidism associated with one of the following diagnoses:
      A. Stage 3 or 4 chronic kidney disease not yet requiring dialysis (pre-dialysis);

      OR
      B. Stage 5 chronic kidney disease requiring dialysis; **AND**
      C. Individual has a baseline corrected serum calcium level of less than or equal to 9.5 mg/dL; **AND**
      D. Individual has a serum intact parathyroid hormone (iPTH) level greater than 150 pg/mL.

Requests for Zemplar (paricalcitol) injection may be approved when the following criteria are met:

  I.   Individual is 5 years of age or older; **AND**
  II.   Individual is using to prevent or treat secondary hyperparathyroidism; **AND**
  III. Individual has a diagnosis of Stage 5 chronic kidney disease requiring dialysis; **AND**
  IV. Individual has a serum iPTH level greater than 150 pg/mL.

Zemplar (paricalcitol) agents may not be approved for the following:

  I.   Individual has hypercalcemia, defined as a serum corrected total calcium level of greater than 10.2 mg/dL or as determined by the reference laboratory assay (NKF 2003, 2010); **OR**
  II.   Using in conjunction with prescription-based doses of vitamin D or its derivatives or current evidence of vitamin D toxicity.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

<u>Key References</u>:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2016. URL: http://www.clinicalpharmacology.com. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2016; Updated periodically.