

| Market Applicability | | | | | | | | | | | | | | |
|----------------------|----|----------|--------|--------|----|----|----|----|----|----|----|----|----|----|
| Market | DC | FL & FHK | FL MMA | FL LTC | GA | KS | KY | MD | NJ | NV | NY | TN | TX | WA |
| Applicable | X | X | NA | NA | X | NA | X | X | X | X | X | NA | NA | X |

*FHK- Florida Healthy Kids

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:

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

| Market Applicability | | | | | | | | | | | | | | |
|----------------------|----|----------|--------|--------|----|----|----|----|----|----|----|----|----|----|
| Market | DC | FL & FHK | FL MMA | FL LTC | GA | KS | KY | MD | NJ | NV | NY | TN | TX | WA |
| Applicable | X | X | NA | NA | X | NA | X | X | X | X | X | NA | NA | X |

*FHK- Florida Healthy Kids

- 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 |

Key References:

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.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.