Clinical Policy: Paricalcitol Injection
Reference Number: PA.CP.PHAR.270
Effective Date: 01/18
Last Review Date: 09/18

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

FDA Approved Indication(s)
Zemplar is indicated for the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease (CKD) Stages 3 and 4, and CKD Stage 5 in patients on hemodialysis or peritoneal dialysis.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness ® that paricalcitol injection and Zemplar are medically necessary when one of the following criteria is met:

I. Initial Approval Criteria
A. Secondary Hyperparathyroidism in Chronic Kidney Disease (must meet all):
   1. Diagnosis of chronic kidney disease (CKD) stage 3, 4 or 5 as defined by the glomerular filtration rates established by the National Kidney Foundation;
   2. Age ≥ 5 years;
   3. Prescribed by or in consultation with a nephrologist or endocrinologist;
   4. Failure of a trial of calcitriol (Rocaltrol®) injection at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
   5. Paricalcitol is not prescribed concurrently with other vitamin D derivatives/analogs (e.g., calcitriol, doxercalciferol, alfacalcidol);
   6. Dose does not exceed 0.24 mcg/kg every other day.

   Approval Duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval
A. Secondary Hyperparathyroidism in Chronic Kidney Disease (must meet all):
   1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
   2. Member is responding positively to therapy;
   3. Paricalcitol is not prescribed concurrently with other vitamin D derivatives/analogs (e.g., calcitriol, doxercalciferol, alfacalcidol);
4. If request is for a dose increase, new dose does not exceed 0.24 mcg/kg every other day.

**Approval Duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2):
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53

### III. Diagnoses/Indications for which coverage is NOT authorized:
A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53

### IV. Appendices/General Information

**Appendix A: Abbreviation/Acronym Key**
- CKD: chronic kidney disease
- FDA: Food and Drug Administration
- iPTH: intact parathyroid hormone

**Appendix B: Therapeutic Alternatives**

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.*

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
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<tbody>
<tr>
<td>calcitriol injection</td>
<td>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 response</td>
<td>4 mcg/day</td>
</tr>
</tbody>
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*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**
Not applicable

### V. Dosage and Administration

**Indication**

| Secondary Hyperparathyroidism in CKD
|**Dosing Regimen**
| 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
| Maximum Dose
| 0.24 mcg/kg

### VI. Product Availability
Injection: 2 mcg/mL and 5 mcg/mL

References

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>J2501</td>
<td>Injection, paricalcitol, 1 mcg</td>
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<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
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<tr>
<td>2Q 2018 annual review: Removed requirement for oral calcitriol use prior to Zemplar due to lack of evidence to support that both agents are of clinical parity; Added limitation regarding concurrent administration with other vitamin D derivatives/analogs references reviewed and updated.</td>
<td>01.23.18</td>
</tr>
<tr>
<td>Added specialist requirement; added requirement for failure of trial of calcitriol injection; added requirement for positive response and max dose to re-auth; references reviewed and updated.</td>
<td>09/18</td>
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