Clinical Policy: Paricalcitol Injection (Zemplar)
Reference Number: CP.PHAR.270
Effective Date: 08.01.16
Last Review Date: 08.20
Line of Business: Commercial, HIM, Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Paricalcitol (Zemplar®) is a synthetically manufactured active vitamin D$_2$ analog.

FDA Approved Indication(s)
Paricalcitol injection (Zemplar) is indicated for the prevention and treatment of secondary hyperparathyroidism (HPT) in patients 5 years of age and older with chronic kidney disease (CKD) on 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.

It is the policy of health plans affiliated with Centene Corporation® that Zemplar injection is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Secondary Hyperparathyroidism in Chronic Kidney Disease (must meet all):
      1. Diagnosis of secondary HPT due to CKD;
      2. Prescribed by or in consultation with a nephrologist or endocrinologist;
      3. Age ≥ 5 years;
      4. Member is on dialysis;
      5. 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;
      6. Failure of calcitriol (Rocaltrol®) injection at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
      7. Paricalcitol is not prescribed concurrently with other vitamin D derivatives/analogs (e.g., calcitriol, doxercalciferol);
      8. Dose does not exceed 0.24 mcg/kg every other day.
   Approval duration: 6 months

   B. Other diagnoses/indications:
      1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Approval
   A. Secondary Hyperparathyroidism in Chronic Kidney Disease (must meet all):
1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member is responding positively to therapy as evidenced by a decrease in 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: 12 months**

**B. Other diagnoses/indications (1 or 2):**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   
   **Approval duration: Duration of request or 6 months (whichever is less); or**
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**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 – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.**

**IV. Appendices/General Information**

**Appendix A: Abbreviation/Acronym Key**

CKD: chronic kidney disease
FDA: Food and Drug Administration
HPT: hyperparathyroidism
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>
</tr>
</thead>
<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>
<tr>
<td>(Rocaltrol®)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*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/Boxed Warnings**

- Contraindication(s): hypercalcemia, vitamin D toxicity, hypersensitivity
- Boxed warning(s): none reported

**V. Dosage and Administration**
Indication | Dosing Regimen | Maximum Dose
---|---|---
Secondary HPT in CKD | Adults: 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. Pediatric age ≥ 5 years: Initial: 0.04 mcg/kg if baseline intact PTH is < 500 pg/mL, or 0.08 mcg/kg if baseline intact PTH is ≥ 500 pg/mL administered no more frequently than every other day at any time during dialysis. The dose may be increased by 0.04 mcg/kg at 2- to 4- week intervals. | Adults: 0.24 mcg/kg Pediatric: see dosing regimen

VI. Product Availability
Single-dose vial for injection: 2 mcg/mL, 5 mcg/mL
Multiple-dose vial for injection: 10 mcg/2mL

VII. 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>
</tr>
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<tbody>
<tr>
<td>J2501</td>
<td>Injection, paricalcitol, 1 mcg</td>
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</tbody>
</table>
Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Change Description</th>
<th>Date</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy developed.</td>
<td>08.16</td>
<td>08.16</td>
</tr>
<tr>
<td>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.</td>
<td>02.17</td>
<td>02.17</td>
</tr>
<tr>
<td>Safety criteria was applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs.</td>
<td>08.17</td>
<td>08.17</td>
</tr>
<tr>
<td>3Q 2018 annual review: converted to new template; HIM Medical added; added specialist requirement; added requirement for positive response and max dose to re-auth; references reviewed and updated.</td>
<td>06.11.18</td>
<td>08.18</td>
</tr>
<tr>
<td>3Q 2019 annual review: added requirement for baseline iPTH levels for initial approval, and for documentation of improvement in iPTH levels for reauthorization, in line with the previously approved approach for other therapies for secondary hyperparathyroidism in CKD on dialysis; references reviewed and updated.</td>
<td>05.10.19</td>
<td>08.19</td>
</tr>
<tr>
<td>3Q 2020 annual review: added Commercial line of business, modified HIM-Medical Benefit to HIM line of business; references reviewed and updated.</td>
<td>05.04.20</td>
<td>08.20</td>
</tr>
</tbody>
</table>

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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