



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: Paricalcitol Capsules

Brand Name: Zemplar

Medication Class: Vitamin D

FDA Approved Uses: Prevention and treatment of secondary hyperparathyroidism associated with stage 3 or 4 chronic kidney disease.

Available Dosage Forms: Capsules available as 1mcg, 2mcg, and 4mcg.

Usual Dose: May be administered daily or 3 times a week (administered at least every other day).

Average weekly dose is the same whether administered once a day or 3 times a week.

Initial dose based on pretreatment iPTH levels:

	iPTH ≤ 500pg/ml	iPTH > 500 pg/ml
Daily	1 mcg	2 mcg
3 times a week	2 mcg	4 mcg

Dose titration based on serum or plasma iPTH levels:

iPTH Relative to Baseline	Oral Paricalcitol Dose	Dosage Adjustment at 2 to 4 week intervals	
		Daily Dosage	3 times weekly dosage
Same or increased	Increase	1 mcg	2 mcg
Decreased by < 30%			
Decreased by ≥ 30%, ≤ 60%	Maintain	---	---
Decreased by > 60%	Decrease	1 mcg	2 mcg
iPTH < 60 pg/ml			

Duration of Therapy: indefinite

Criteria for Use: (bullet points below are all inclusive unless otherwise noted)

- Must have clinically diagnosed stage 3 or 4 chronic kidney disease.
 - Stage 3
 - GFR 30-59 mL/min/1.73 m²
 - Target iPTH 35-70 pg/ml
 - Stage 4
 - GFR 15-29 mL/min/1.73 m²
 - Target iPTH 70-110 pg/ml
 - Clinically documented secondary hyperparathyroidism.
- Or
- Patients requiring prevention of secondary hyperparathyroidism.



- Corrected total calcium <9.5 mg/dl
- Failed/intolerant to calcitriol.

Monitoring:

- The following should be monitored at least every 2 weeks for 3 months, then monthly for 3 months, and then every 3 months thereafter.
 - Calcium
 - Phosphorus
 - iPTH

Contraindications:

- Patients with evidence of vitamin D toxicity.
- Hypercalcemia.
- Hypersensitivity to any of the product ingredients.

Not Approved if:

- Patient has any contraindications to the use of paricalcitol.
- Patient does not meet the above stated criteria.

Special Considerations:

- Has been available as an injection
- Studies comparing oral paricalcitol with calcitriol or other vitamin D analogs are not available.
- Paricalcitol is the synthetic analog of calcitriol, the metabolically active form of vitamin D.

P&T Approval: _____ Date: _____