

Protocol for the Prevention and Management of Renal Osteodystrophy in the Adult Dialysis Patient using Oral Doxercalciferol (Hectorol®) Therapy

1. Obtain baseline serum iPTH, calcium, phosphorus, albumin, aluminum, alkaline phosphatase, and magnesium concentrations.
2. Determine “corrected” serum calcium concentration:
 - Step 1: Normal serum albumin (4.0 gm/dL) minus the most recent serum albumin measurement = X
 - Step 2: X times 0.8 = Y
 - Step 3: Measured serum calcium concentration + Y = “corrected” serum calcium
3. Determine corrected calcium x phosphorus product (Ca x P).

Note: Corrected serum calcium and Ca x P results should be used in evaluating patients and in making decisions regarding drug therapy.

4. Obtain baseline dietary history and evaluation of phosphorus intake. Patients should be instructed in a renal diet that includes restriction of dietary phosphorus to 800-1000 mg/day.
5. Initiate pharmacologic treatment of hyperphosphatemia with either:
 - a. calcium-based phosphate binder (calcium carbonate or calcium acetate)
 - b. sevelamer (Renagel®)

Phosphate binding drugs should be adjusted to maintain the serum phosphorus between 3.5-5.5 mg/dL. *Note: For those patients receiving vitamin D therapy, the upper level of normal should be altered to 6.0 mg/dl. For those NOT receiving vitamin D it should be maintained between 3.5 and 5.5 mg/dl.*

Target Values	
Parameter	Target Range
Calcium*	8.4 to 10.2 mg/dL ***
Phosphorus	3.5-6.0 mg/dL ***
Ca x P*	<55
iPTH**	150-300 pg.mL

*corrected value

** Normal range: 10-65 pg/mL

*** Upper limit value differs for patients on vitamin D therapy

6. Initiate Hectorol therapy if the following criteria are met:
 - a. iPTH >300 pg/mL (>4 times the upper limit of normal)
 - b. Corrected serum calcium <10.2 mg/dL
 - c. Serum phosphorus < 6.0 mg/dL
 - d. Corrected Ca x P <55
 - e. Serum aluminum <60 mcg/L
7. The initial dose of Hectorol is 5.0 mcg orally three times weekly at dialysis.

Monitoring Hecetrol therapy

- a. Monitor corrected serum calcium, phosphorus, Ca x P at least two times per month upon initiating therapy and during titration.
- b. Monitor iPTH within one month of initiation of treatment and during titration.
- c. Evaluate patient dietary and phosphate binder consumption monthly or more often based upon the above laboratory parameters.

9. Evaluation of Hecetrol therapy

- a. Hypercalcemia: *Hecetrol should be withheld if corrected serum calcium concentration is >10.2 mg/dL.*
 - Serum calcium is monitored at least weekly until patient becomes normocalcemic.
 - Withdraw or decrease all calcium-based binders or supplements.
 - Consider a change to sevelamer if hypercalcemia persists.
 - Institute a low calcium diet.
 - Instruct patient on dietary and phosphate binder changes and importance of adherence to the prescription.
 - Consider low dialysate calcium concentration.
 - Hecetrol is then re-started at a dose reduced by 25-50%, only if all above measures fail to decrease calcium to less than 10.2 mg/dl.
- b. Hyperphosphatemia: *Hecetrol should be withheld if serum phosphorus >6.0 mg/dL.*
- c. Elevated Ca x P: *Hecetrol should be withheld if corrected serum Ca x P >55.*
 - Serum calcium and phosphorus is monitored weekly until Ca x P <55.
 - Evaluate patient adherence to diet and phosphate binder prescription.
 - Increase phosphate binder dosage.
 - Initiate sevelamer therapy or short-term treatment with an aluminum-based phosphate binder (e.g. aluminum hydroxide) if corrected Ca x P >55.
 - Consider alternate vitamin D product: paricalcitol.
 - Hecetrol is then re-started at a dose reduced by 25-50%, only if all above measures fail to reduce calcium to less than 10.2 mg/dl.

10. Titration of Hecetrol

The initial Hecetrol dose should be adjusted after 2-8 weeks of treatment based on patient response according to the table below:

iPTH response	iPTH decreased but above target range	iPTH decreased and in target range	iPTH unchanged and above target range	iPTH increased from baseline	PTH below 150 pg/mL
Vitamin D dosing	Maintain or increase by 25-50% after 2 to 8 weeks of therapy	Maintain dose	Increase dose by 25-50%	Increase dose by 25-50%	Withhold dose, restart at reduced dose when iPTH>200 pg/mL

11. Maintenance therapy
 - a. Optimal iPTH range is 150-300 pg/mL.
 - b. iPTH should be monitored quarterly once iPTH concentrations are within this range and the Hectorol dose has been stable for 8 weeks.
 - c. Serum calcium, phosphorus, albumin, alkaline phosphatase and magnesium should be monitored monthly if within normal limits.

12. Non-response to Hectorol therapy
 - a. Evaluate dietary phosphorus restriction and adherence to vitamin D prescription.
 - b. Increase Hectorol dose to 20 mcg three times weekly (maximum recommended dose of 60 mcg/week).
 - c. Consider an alternate vitamin D product.
 - d. Evaluate patient for parathyroidectomy.