

**Protocol for the Prevention and Management of Renal Osteodystrophy in the Adult Dialysis Patient using Oral Calcitriol (Rocaltrol®) 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 value 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 Rocaltrol 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. Select the initial dose (oral) of Rocaltrol:
  - a. For peritoneal dialysis patients, initial dose is 0.25 mcg of Rocaltrol 3 times per week.

- b. For hemodialysis patients, initial dose is based on severity of iPTH elevation:
    - iPTH 300-599            0.5-1.5 mcg Rocaltrol administered daily
    - iPTH >600              1.0-4.0 mcg Rocaltrol administered daily
  - c. Alternatively, hemodialysis patients may be given Rocaltrol as pulse dosing with each dialysis according to severity of iPTH elevation:
    - iPTH 300-599            0.5-1.0 mcg Rocaltrol with each dialysis
    - iPTH >600              1.0-4.0 mcg Rocaltrol with each dialysis
8. Monitoring Rocaltrol 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 Rocaltrol therapy
- a. Hypercalcemia: *Rocaltrol 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.
    - Consider alternate vitamin D product: doxercalciferol.
    - Rocaltrol 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: *Rocaltrol should be withheld if serum phosphorus >6.0 mg/dL.*
  - c. Elevated Ca x P: *Rocaltrol 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 or doxercalciferol.
    - Rocaltrol is then re-started at a dose reduced by 25-50%.
10. Titration of Rocaltrol
- The initial Rocaltrol 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 a dose reduced by 25-50% 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 Rocaltrol 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 Rocaltrol therapy

- a. Evaluate dietary phosphorus restriction and adherence to vitamin D prescription.
- b. Increase Rocaltrol dose to 4.0 -7.0 mcg daily (maximum recommended dose).
- c. Consider an alternate vitamin D product.
- d. Evaluate patient for parathyroidectomy.