

**CRITERIA FOR THE USE OF LANTHANUM CARBONATE (FOSRENOL®) OR
SEVELAMER HCL (RENAGEL®) October 2009**
Initial Application & Continued Use Forms

Preamble:

Due to the expense and available scientific evidence, the decision has been made to provide lanthanum or sevelamer to facilitate maximal vitamin D use that will potentially protect patients from parathyroidectomy.

Lanthanum and sevelamer have been approved by Health Canada for the control of hyperphosphatemia in patients with ESRD on hemodialysis or peritoneal dialysis. These drugs are not approved for use in predialysis patients.

While it is recognized that lanthanum and sevelamer are potentially useful agents in conjunction with other therapeutic modalities, including calcium based phosphate binders, at this time the BCPRA is only able to fund the use of lanthanum **or** sevelamer under the following criteria. Except when hypercalcemia exists, there is currently insufficient outcome evidence to support the cost utility of prescribing lanthanum or sevelamer over calcium-based phosphate binders for treatment of chronically elevated serum phosphate. Should physicians wish to prescribe lanthanum or sevelamer outside of these criteria, the BCPRA is unable to fund either agent. Lanthanum and sevelamer are extremely expensive (approximately \$2,000 to over \$9,000 per year depending on dosage). Further, BCPRA will not fund treatment with both lanthanum and sevelamer concomitantly, as there is no literature evidence to support this practice.

The maximum funded lanthanum regimen is 1000 mg PO TID (\$4849 per year)

The maximum funded sevelamer regimen is 5 x 800 mg tablets PO TID (\$9169 per year)

The typical sevelamer regimen is 3 x 800 mg tablets PO TID (\$5439 per year)

The WHO comparative dose of 2.25 g (4.5 x 500mg) lanthanum is 6.4 g (8x 800mg) sevelamer.

CRITERIA FOR INITIAL APPLICATION

All of the following must be documented on the initial application form:

1. Failure of conventional therapy to maintain acceptable serum levels of phosphate, calcium and parathyroid hormone.

- Hypercalcemia (Serum Ca > 2.6 mmol/L or iCa > 1.35 mmol/L) on at least two consecutive readings
- Diet and drug therapy must be reviewed by renal team to ensure that treatment failure is not resulting from these or other factors:
 - Lanthanum or sevelamer will be funded for patients with reasonable dietary adherence.
 - Correctable adverse effects (e.g. palatability), timing of drug dosage (e.g. calcium between vs. with meals/snacks)
 - Limit calcium load through trial of calcium acetate (with minimal effective Vitamin D analogue dose)
 - Potentially avoidable interactions (e.g. proton pump inhibitors) with prescribed diet and drug therapy.

2. Serum PO₄

3. Current dose of Vitamin D analogue

4. Current use and dose of calcium containing binding agent

5. iPTH

Mechanism for ordering lanthanum or sevelamer

1. Fill out the following order form completely (attaching medications list and lab print out is acceptable).
2. Ensure nephrologists OR renal pharmacist AND renal dietitian have signed the order form.
3. Send the form with prescription to community contract pharmacy.
4. Community contract pharmacy will fax prescription and order form to BCPRA (for records).

The community contract pharmacy will not be reimbursed by BCPRA for lanthanum or sevelamer unless a completed order form accompanies the prescription.

Mechanism to provide initial supply of sevelamer or lanthanum

- Once the initial application form and prescription are received by the community contract pharmacy, initial therapy will be approved for 6 months (titration & evaluation period).
- Lanthanum: Dosage may be titrated to a maximum of 1000 mg PO TID based on usual laboratory monitoring and nephrologist's judgment.
- Sevelamer: Dose may be titrated to a maximum of 4 g (5 x 800 mg) PO TID based on usual laboratory monitoring and nephrologist's judgment.
- Community pharmacist will refill lanthanum or sevelamer prescription in maximum 60-day quantities as required over the initial 6-month titration period.

CRITERIA FOR CONTINUED USE

All of the following must be documented on the continuation form:

1. Adherence to diet and drug therapy
2. Serum calcium reduction
3. Acceptable control of hyperphosphatemia
4. Parathyroid hormone reductions or stabilization

Mechanism to provide ongoing lanthanum or sevelamer therapy

- Ongoing therapy will be approved for one year if objective data shows improvement in biochemical parameters at the end of the initial 6-month titration phase and at yearly intervals thereafter.
- It is expected that use of calcium based phosphate binders (alone or in combination with non-calcium based phosphate binders) is reconsidered during the annual review.
- Once the continuation form and prescription is received by the regional contract pharmacy, the prescription may be refilled at 100-day intervals for two refills.