CRITERIA FOR THE USE OF LANTHANUM CARBONATE (FOSRENOL®) OR SEVELAMER HCL (RENAGEL®)
April 2017

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 APPLICATION

All of the following must be documented on the 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 PO_4
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 application form completely (attaching medications list and lab print out is acceptable).
2. Ensure nephrologists OR renal pharmacist AND renal dietitian have signed the application.
3. Send the applicationwith prescription to community contract pharmacy.
4. Community contract pharmacy will fax prescription and application to BCPRA (for records).

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

Mechanism to provide initial supply of sevelamer or lanthanum

- Once the 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 $14.95 per day based on usual laboratory monitoring and nephrologist's judgment.
- Sevelamer: Dose may be titrated to a maximum of 4 tablets PO TID ($21.288 per day) based on usual laboratory monitoring and nephrologist's judgment.
- Community pharmacist will refill lanthanum or sevelamer prescription according to the trial prescription amount protocol in maximum 60-day quantities as required over the initial 6-month titration period.

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.

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