NHS LINCOLNSHIRE in association with
UNITED LINCOLNSHIRE HOSPITALS TRUST

SHARED CARE GUIDELINE: SEVELAMER in the management of Hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis and for controlling hyperphosphataemia associated with chronic kidney disease (CKD).

General Principles

Shared Care Responsibilities:
In its guidelines on responsibility for prescribing (circular EL (91) 127) between hospitals and general practitioners, the Department of Health has advised that legal responsibility for prescribing lies with the doctor who signs the prescription. (*BNF* 63, March 2012, pg.1)

Aims:
(1) The aim of shared care guidelines is to provide information and/or guidance to GPs and hospital staff relating to the potentially complex implications of sharing patient care for a specific drug between primary and secondary/tertiary care.

(2) Specific shared care guidance should be available for any high cost drug, high-risk drug therapy or device that may be prescribed for a patient following specialist referral. Such guidance will only be produced where shared care is considered an appropriate option.

(3) Each guideline will include a clear statement of the responsibilities of both the GP and the specialist unit within the overall provision of the treatment to the patient.

(4) Shared care guidelines will ensure that the GP has sufficient information available to undertake to prescribe a specialist treatment if s/he so wishes. It is not the intention of these guidelines to insist that GPs prescribe such treatment and any doctor who does not wish to accept clinical or legal responsibility to prescribe such a drug is under no obligation to do so. Nonetheless the development of a shared care guideline will only be undertaken within the context of a broad acceptance between the Lincolnshire Prescribing and Clinical Effectiveness Forum (PACEF) and secondary/tertiary care that GP prescribing of such a treatment is appropriate within the constraints of formal shared care. Any drug approved for the development of a shared care guideline will automatically be classified as amber on the Lincolnshire Traffic Lights List and, if high-cost, will be supported financially through the High Cost Drugs Reserve. Thus there should be no financial reason why a GP should be deterred from prescribing a high cost drug under a shared care guideline.

Further copies

. Further copies of any guidelines in this series are available from NHS Lincolnshire Prescribing Advisers.

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Drug Details

Approved Name: **Sevelamer Hydrochloride and Sevelamer Carbonate**
Brand Name: Renagel (sevelamer hydrochloride), Renvela (sevelamer carbonate)
Form and Strength: Tablets 800mg (hydrochloride and carbonate),
Powder sachets 2.4g (carbonate)

Specialist Responsibilities

The specialist secondary/tertiary care service will:

1. Send a letter to the GP suggesting that shared care is agreed for this patient.
2. Carry out baseline measurements of U&Es, calcium, phosphate and parathyroid hormone levels and before commencing therapy will communicate these to the GP.
3. Provide patient with pre-treatment information leaflet and patient held record booklet.
4. Provide the GP with clear instructions as to the initial dose of sevelamar including details of any dose titration that might be required and when the patient will next be reviewed in clinic.
5. Periodically (at one to six monthly intervals in clinic) review the patient's clinical condition.
6. Communicate promptly any changes in biochemistry monitoring and modification of sevelamer dose to the GP.
7. Have a mechanism in place to receive rapid referral of a patient from the GP in the event of deteriorating clinical condition.
8. Follow up any adverse drug reactions reported by the GP and report back to the GP.
9. Advise the GP in stopping treatment.

GP Responsibilities

The GP will:

1. Notify the consultant in writing, within two weeks, if they agree to share care.
2. Initiate treatment with sevelamer according to instructions provided by the specialist service.
3. Provide repeat prescriptions according to recommendations on dosage by the renal unit, Lincoln County Hospital.
4. Monitor the patients overall health and wellbeing.
5. Monitor the patient for adverse drug reactions and remain vigilant to the risk of potential drug interaction.
6. Carry out investigations that are communicated and deemed appropriate.

Referral Criteria

1. Patients will have been stabilised on their Vitamin D analogues and other phosphate binders.
2. The specialist will have carried out an assessment of efficacy.

Licensed Indications

Renagel is licensed for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis. Renvela is also licensed for the control of hyperphosphataemia in patients with Chronic Kidney Disease not on dialysis who have a serum-phosphate concentration of 1.78mmol/litre or more.

Recommended Dosage and Administration

Serum phosphate level in patients not on phosphate binders

1.78-2.42 mmol/l	Renagel 800mg three times a day Renvela 800mg three times a day
>2.42mmol/l	Renagel 1600mg three times a day Renvela 1600mg three times a day

If Renagel or Renvela are prescribed as an alternative phosphate binder they should be given on a gram for gram basis with monitoring of serum phosphorus levels to ensure optimal daily doses.

Dose adjusted according to serum phosphate levels.

Initial starting dose 2.4-4.8grams daily in 3 divided doses with meals.

Renagel – usual dosage range 2.4-12g daily in 3 divided doses.

Renvela - usual dose approximately 6 gram daily in 3 divided doses.

Patients should take Renagel/Renvela with meals and adhere to their prescribed diets.

The tablets must be swallowed whole

The powder should be dispersed in 60 ml of water per sachet prior to administration.

Background Pharmacology

Sevelamer is a non-absorbed phosphate binding polymer, free from calcium and aluminium which is effective in controlling hyperphosphataemia by binding to phosphate in the gastrointestinal tract reducing absorption which reduces plasma. Hyperphosphataemia can contribute to secondary hyperparathyroidism causing calcium phosphate precipitation in blood vessels and soft tissues resulting in widespread vascular disease.

Calcium containing phosphate binders are first line agents but high doses of these can lead to hypercalcaemia and contribute to calcification of blood vessels.

Preparations Available

800mg, film coated tablets sevelamer hydrochloride and sevelamer carbonate, 2.4g powder sachets sevelamer carbonate.

Adverse Effects

Gastrointestinal disturbances including nausea, vomiting, abdominal pain, constipation, diarrhoea and dyspepsia. Other adverse effects including hypotension, hypertension, headache, pruritus, rash, pain, infection and pharyngitis. In very rare cases intestinal obstruction and ileus/subileus.

Constipation may be a preceding symptom and patients who are constipated should be carefully monitored whilst receiving sevelamer.

Also reported intestinal perforation.

Drug Interactions

Sevelamer may reduce plasma concentration of mycophenolate mofetil, ciclosporin and tacrolimus. Advise to monitor immunosuppressant drug levels during concomitant administration.

Manufacturer recommends caution if sevelamer co-prescribed in patients currently taking anti-arrhythmic and anti-seizure medication.

Sevelamer reduces bioavailability of ciprofloxacin. Manufacturer advises against being administered simultaneously.

Close monitoring of TSH levels is recommended in patients receiving concomitant levothyroxine as sevelamer possibly reduces absorption.

Precautions and Contraindications

Precautions

Pregnancy, breast feeding

Gastrointestinal disorders – untreated or severe gastroparesis, diverticulosis gastric retention, active inflammatory bowel disease, gastric motility disorders, history of major GI surgery and abnormal or irregular bowel movement.

Dysphagia

Swallowing disorders

Use not studied in children below 18 years of age.

Contraindications

Hypophosphataemia

Bowel obstruction

Hypersensitivity to sevelamer or any of the excipients in the product.

Monitoring

Baseline

Blood levels of U&Es, calcium and phosphate at each clinic visit, parathyroid hormone levels every 3 months.

All monitoring is the responsibility of the renal services (see specialist responsibilities on page 2).

Treatment should be reviewed and advice from the supervising specialist sought if:

- there is deterioration in the clinical condition and/or the patient experiences major side-effects.
- serum calcium levels fall outside the range of 2.2 and 2.6mmol/l.

Indication of Likely Cost of Therapy in Primary Care

Sevelamer hydrochloride (Renagel)	800mg	180 tablets	£141.56
Sevelamer carbonate (Renvela)	800mg	180 tablets	£141.56
Sevelamer carbonate (Renvela)	2.4g	60 sachets	£141.56

At a dose of 800mg three times daily, the monthly cost is currently £66.85. At the normal maximum dose of 5 x 800mg three times daily the monthly cost is £110.10.

Information Given to the Patient

Patient information leaflet available with each container of sevelamer.

Contact Details

Consultant Nephrologists

Dr Little's Secretary: 01522 573961

Dr Malik's Secretary: 01522 572335

Dr Williams' Secretary: 01522 572335

Renal Pharmacist

Caroline Taylor: 01522 573598

Renal Pharmacist

County Hospital

References
1. BNF 63 March 2012
2. East and North Hertfordshire NHS Trust Sevelamer Shared Care Guidelines March 2006
3. SPC Renagel Genzyme Therapeutics. Limited. Last updated 31st January 2012. Accessed from eMC website June 19th 2012.
4. SPC Renvela, Genzyme Therapeutics. Last updated 30th January 2012. Accessed from eMC website June 19th 2012.
5. Prices from MIMS May 2012

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