LINCOLNSHIRE CLINICAL COMMISSIONING GROUPS
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* 68, September 2014 - March 2015, pg.5)

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 guideline in this series are available from members of the Greater East Midlands Commissioning Support Unit (GEMS) Prescribing & Medicines Optimisation Team.

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Principles of shared care

The General Medical Council published their Good Practice In Prescribing And Managing Medicines which came into effect 25th February 2013. A section of the guidance provides recommendations for the sharing of care which applies to any instance when care is shared between different services.

Good practice recommendation 35.

- Decisions about who and who should take responsibility for continuing care or treatment after initial diagnosis or assessment should be based on patients best interest rather than on convenience or the cost of the medicine and associated monitoring or follow-up

Good practice recommendation 36.

- Shared care requires the agreement of all parties including the patient. Effective communication and continuing liaison between all parties to a shared care agreement is essential.

Good practice recommendation 37.

- If you prescribe at the recommendation of another doctor, nurse or other healthcare professional, you must satisfy yourself that the prescription is needed, appropriate for the patient and within the limits of your competence.

Good practice recommendation 38.

- If you delegate assessment of a patients' suitability for a medicine, you must be satisfied that the person to whom you delegate has the qualifications, experience, knowledge and skills to make the assessment. You must give them enough information about the patient to carry out the assessment required

Good practice recommendation 39.

- In both cases, you will be responsible for any prescription you sign.

Good practice recommendation 40.

- If you recommend that a colleague, for example a junior doctor or general practitioner, prescribes a particular medicine for a patient, you must consider their competence to do so. You must satisfy yourself that they have sufficient knowledge of the patient and the medicine, experience (especially in the case of junior doctors) and information to prescribe. You should be willing to answer their questions and otherwise assist them in caring for the patient, as required

Good practice recommendation 41

- If you share responsibility for a patient's care with a colleague, you must be competent to exercise your share of clinical responsibility.

You should:

a) Keep yourself informed about the medicines that are to be prescribed for the patient
b) Be able to recognise serious and frequently occurring adverse side effects
c) Make sure appropriate clinical monitoring arrangements are in place and that the patient and the healthcare professionals involved understand them
d) Keep up to date with relevance guidance on the use of the medicines and on the management of the patient's condition

Good practice recommendation 42

- In proposing a shared care arrangement, specialists may advise the patient's general practitioner which medicine to prescribe. If you are recommending a new or rarely prescribed medicine you should specify the dosage and means of administration and agree a protocol for treatment. You should explain the use of unlicensed medicines and departures from authoritative guidance or recommended treatments and provide both the general practitioner and the patient with sufficient information to permit the safe management of the patient's condition.

Good practice recommendation 43

- If you are uncertain about your competence to take responsibility for the patients continuing care you should seek further information or advice from the clinician with whom the patient's care is shared or from another experienced colleague. If you are still not satisfied you should explain this to the other clinician and to the patient and make appropriate arrangements for their continuing care.

Drug Details

Approved Name: **Sevelamer hydrochloride and Sevelamer carbonate**
Brand Name: Renagel (hydrochloride) , Renvela (carbonate) Sevalamer carbonate is also available as generic tablets.
All new patients will be initiated onto Sevalamer carbonate, generic or Renvela brand. Sevelamer hydrochloride (Renagel) is now listed as non-formulary and should only be used for existing patients.
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 requesting that the GP participates in shared care. As part of the communication the GP should be signposted to where they can find a copy of the shared care protocol e.g. the PACEF website http://lincolnshire-pacef.nhs.uk/lincolnshire-prescribing-and-clinical-effectiveness-forum-
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 sevelamer 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 (sevelamer hydrochloride), sevalamer carbonate (generic brands and Renvela) are licensed for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis.
Renvela (sevelamer carbonate) and the generic sevelamer carbonates are also licensed for the control of hyperphosphataemia in patients with Chronic Kidney Disease not on dialysis with serum phosphate ≥ 1.78mmol/litre

Recommended Dosage and Administration

Calcium based phosphate binders are normally used firstline. Sevalamer would be indicated if calcium levels rise to 2.5mmol/l or above. Sevalamer may also be used in combination with a calcium based phopshate binding agent if the calcium levels remain in range but the phosphate levels are not controlled with one binder alone.
Sevelamer may also be considered if patient has not tolerated previous treatment with phosphate binders.
Serum phosphate level in patients not on phosphate binders

1.76-2.42 mmol/l	Renagel 800mg three times a day sevalemr carbonate 800mg three times a day Renvela 800mg three times a day
>2.42mmol/l	Renagel 1600mg three times a day sevalemr carbonate 1600mg three times a day Renvela 1600mg three times a day

If Renagel (sevelamer hydrochloride) is prescribed as an alternative phosphate binder it should be given in equivalent doses on a mg weight basis compared to the patient's previous calcium based phosphate binder.
For patients previously on phosphate binders (sevelamer hydrochloride or calcium based binder),Sevelamer carbonate prescribed generically or as the brand Renvela, 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. Normal dosage range 1 – 5 x 800mg tablets per meal or an average of approximately 6 g per day for Renvela sachets.
Patients should take sevelamer carbonate/hydrochloride 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.

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- manufacturer advises use only if potential benefit outweighs risk.
breast feeding –unlikely to be present in milk (however manufacturer advises avoid) for the Renagel formulation manufacturer advises use only if potential benefit outweighs risk.
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.
Swallowing disorders

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	800mg (Renagel)	180 tablets	£167.04
Sevelamer carbonate	800mg (generic)	180 tablets	£135.81
Sevelamer carbonate	800mg (Renvela)	180 tablets	£167.04
Sevelamer carbonate	2.4g (Renvela)	60 sachets	£167.04

Cost of treatment

Generic sevelamer carbonate

At a dose of 800mg three times daily, the monthly cost is currently £63.00 . At the maximum dose of 5 x 800mg three times daily the monthly cost is £105.63

Renvela or Renagel

At a dose of 800mg three times daily, the monthly cost is currently £77.95. At the maximum dose of 5 x 800mg three times daily the monthly cost is £129.92

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 Hardy's Secretary: 01522 572335
Dr Williams' Secretary: 01522 573961

Renal Pharmacist

Caroline Taylor: 01522 573598
Renal Pharmacist
County Hospital

References

1. BNF 68 September 2014 – March 2015
2. East and North Hertfordshire NHS Trust Sevelamer Shared Care Guidelines March 2006
3. SPC Renagel /Renvela, Genzyme Therapeutics. Last updated 11th April 2014 on eMC website
4. Summary of Product Characteristics (SPC) sevelamer carbonate Genthon 800mg film coated tablets Consilient health. Last updated 16th February 2015.
5. Summary of Product Characteristics (SPC) sevelamer carbonate Zentiva 800mg film coated tablets Zentiva. Last updated 19th February 2015.
6. Prices from Drug Tariff October 2015

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