Request to Share Care and Agreement Form

Use of oral sevelamer carbonate for hyperphosphataemia in adult patients with chronic kidney disease: shared care protocol: guideline no 1; version 2

This Request to Share Care provides Key Primary Care Information on responsibilities and monitoring. The aim is to support the GP to agree to share care arrangements. Refer to Full Shared Care Protocol for further information (page 4 onwards).
GP to review and must respond to provider Trust request to share care within 2 weeks using form provided on page 3.

For Completion by Specialist (with page 3 Shared Care Agreement Form)

Patient name……

DOB…… OR

NHS number……..

Addressograph label

Dose and formulation:
……..

Date of first prescription by specialist: ……..

Estimated date for prescribing to be continued by the GP: ……..…..

Next monitoring tests due and dates if not at 12 weekly monitoring: ……
.....

Specialist additional comments/advice: ……
……

Key Primary Care Information (refer to Full Shared Care Protocol for further information)

GP RESPONSIBILITIES

- Consider request to shared care arrangements and prompt completion and emailed return of signed response to the Specialist using the Shared Care Agreement Form within 14 days of its receipt.
- If shared care accepted prescribe sevelamer carbonate once the patient is clinically stable. This is usually within 8-12weeks after initiation of therapy.
- Prescribe as per recommendation from specialist. Ensure ongoing monitoring undertaken by specialist.
- There should be reciprocal sharing of blood tests between the GP and specialist.
- Re-iterating with the patient that non-attendance for blood testing may lead to withdrawal of the medication. Further help and advice can be sought from the hospital specialist team.
- Appropriately prompt notification to the hospital Specialist of any significant and relevant changes in the patient's condition or of an adverse reaction, referring to Specialist should any serious side effects occur. Stop treatment on advice of the Specialist or immediately if an urgent need to stop treatment arises such as bowel obstruction.
- Ensure no drug interactions with other medicines.
- Change dose or stop treatment as advised by Specialist.
- Report adverse events to the Specialist and MHRA/CHM.
- Generic sevelamer carbonate tablets are the product usually prescribed. (See further information on page 4)

MONITORING AND ACTIONS TO BE TAKEN

Monitoring Table – see GP monitoring highlighted in grey

Monitoring table		**Hospital specialist**	**Hospital specialist**	**Hospital specialist**	**GP**	**Hospital specialist**
Test	**Indication**	Pre-treatment baseline	During Treatment Initiation	Following Treatment Initiation	Ongoing	Annual review
Serum phosphorus	Baseline and ongoing assessment for disease and drug dose assessment	√	Monthly	*Monthly – 2 to 3 monthly	Not required by GP	√
Serum calcium		√	Monthly	*Monthly – 2 to 3 monthly	Not required by GP	√
Parathyroid hormone		√	3 monthly	3 monthly	Not required by GP	√

*Dialysis patients are monitored routinely monthly, non-dialysis patients are routinely monitored every 2-3months (see also page 4)

Action to be taken if Abnormal Result

GP will be informed by specialist via letter.

(Normal reference range may vary slightly between labs. Results should be recorded in the patient's shared care monitoring record booklet (where in use). Please note an unusual fall or rise or a consistent downward or upward trend in any value should prompt review of the patient and extra vigilance. Some patients may have abnormal baseline values, Specialist will advise)

- The expectation is that this information along with the full protocol provides sufficient information to enable GPs to be confident to take on the clinical & legal responsibility for prescribing.
- Prescribing and monitoring responsibility will only be transferred under this shared care protocol when:
  - Specialist has initiated treatment and prescribed/monitored treatment for initial stabilisation period.
  - Specialist has provided pre-treatment counselling and discussed patient responsibilities, preferences and obtained consent to shared care arrangements.
  - Specialist and patient have completed and signed the shared care agreement form (page 3).

Shared Care Agreement Form

This form is used to agree shared care between the Specialist, patient and primary care prescribers.

Specialist and patient agreement

By signing below we accept:

- the Herts and West Essex Area Prescribing Committee shared care principles (HWE APC) and
- the requirements and responsibilities defined in this drug specific shared care protocol

Specialist name:	**Patient name or addressograph label:**
Designation:	
Provider Trust:	
Direct telephone number:	
Email: **Email (for use by GP to respond to request to share care):**	**Send to pharmacy when completed:-** **Via E-Mail: Sharedcare.enh-tr@nhs.net** **Via Post: Lister Pharmacy L83**
Date:	**Specialist Signature:**

Date:	**Patient Signature:**

GP response to shared care

Please return to specialist within two weeks of receipt of request to share care.

This form is to be completed by the GP who is requested to share care.

I agree to accept shared care for this patient as set out in this shared care protocol and HWE APC shared care principles ☐

I do not accept shared care for this patient ☐

My reason(s) for not prescribing are given below:

_____

_____

Please note that GP agreement is voluntary, with the right to decline to share care if for any reason you do not feel confident in accepting clinical responsibility. Refusal should not be for financial reasons.

GP name:	**Practice address /stamp:**
Direct telephone number:	
Email:	
Date:	**GP Signature:**

Please return a copy of the completed form to the requesting specialist within two weeks of receipt of request to share care (preferably by email). Sharedcare.enh-tr@nhs.net

1. Specialist to retain copy in patient's hospital records.
2. Copy to be given to patient.
3. GP to retain copy in patient's notes.

Full Shared Care Protocol

Use of oral sevelamer carbonate for hyperphosphataemia in adult patients with chronic kidney disease: shared care protocol: guideline no 1; version 2

This full protocol provides prescribing and monitoring guidance. It should be read in conjunction with HWE APC shared care principles, Summary of Product Characteristics (SPC) and the BNF.

BACKGROUND AND INDICATION(S) FOR USE

Disturbance of mineral metabolism is a common complication associated with chronic kidney disease (CKD). As renal function declines parathyroid hormone levels start to rise, this is driven by a fall in calcitriol production, hypocalcaemia and hyperphosphataemia.

The management of hyperphosphataemia is crucial and is one of the most important factors in the development of secondary hyperparathyroidism (SHPT). SHPT contributes significantly to the high incidence of morbidity and mortality seen in people with CKD. The management of hyperphosphataemia involves dietary restriction of phosphate, the use of oral phosphate binders and adequate dialysis (CKD stage 5). Available data and opinion suggests that dietary phosphate restriction should be initiated when parathyroid hormone levels start to rise, and/or when serum phosphate levels are elevated. As dietary restriction alone is unlikely to control serum phosphate levels in CKD stage 4 and 5, phosphate binders will be required.

Phosphate binders are indicated for the control of hyperphosphataemia in adult patients with chronic kidney disease. A number of phosphate binders are available which may be used in the context of a multiple therapeutic approach, and these include calcium carbonate (Calcichew®), calcium acetate (Renacet®), sevelamer hydrochloride (Renagel®), **sevelamer carbonate (Renvela®),** sucroferric oxyhydroxide (Velphoro®) and lanthanum (Fosrenol®). These products may be used in combination with 1α-hydroxycholecalciferol (alfacalcidol) or one of its analogues, or cinacalcet to control the development of renal bone disease.

NICE guideline NG203 (August 2021) recommends:

- the use of the calcium-based phosphate binder calcium acetate as the initial binder therapy for patients with chronic kidney disease, in conjunction with dietary phosphorous restriction, to control phosphorus and parathyroid levels. (Consider patient preference and use calcium carbonate if calcium acetate not suitable).
- offer sevelamer carbonate if calcium acetate is not indicated (for example, because of hypercalcaemia or low serum parathyroid hormone levels) or not tolerated. If hypercalcaemia develops with the use of calcium-based binders, it may be necessary to convert to a non-calcium containing phosphate binder, or to use a combination of both.
- If calcium acetate and sevelamer carbonate cannot be used, consider using sucroferric oxyhydroxide for patients on dialysis.
- Consider lanthanum only if other phosphate binders cannot be used.
- Consider patient preference utilising other formulations such as sachets where available when the patient is unable to swallow tablets.

Kidney Disease Improving Global Outcomes (KDIGO) guidelines suggest lowering elevated phosphate levels towards the normal range and avoiding hypercalcaemia.
*For patients on haemodialysis corrected calcium and phosphate are monitored monthly. For non-haemodialysis patients, corrected calcium and phosphate are monitored at each clinic visit and more frequently if there are concerns.

DOSAGE, ROUTE OF ADMINISTRATION AND DURATION OF TREATMENT

Adult dosage and administration

Sevelamer carbonate is available as 800mg tablets and 800mg & 2.4g powder for oral suspension. For patients who are not on phosphate binders, dosage is determined individually based on serum phosphate concentrations (refer to the Summary of Product Characteristics for further details).
The dose range may vary between 1 and 5 tablets (of 800 mg each) per meal. The average actual daily dose used in the chronic phase of a one-year clinical study was 7 grams of sevelamer.

Patients should take sevelamer carbonate with meals and adhere to their dietary advice. Tablets should be swallowed whole not chewed. (Sachets will only be used where patient cannot swallow or tolerate tablets)

SPECIALIST RESPONSIBILITIES INCLUDING PRE-TREATMENT ASSESSMENT

- Diagnose and assess if patient is suitable for treatment with sevelamer carbonate and initiate treatment.
- Undertake pre-treatment counselling and document discussion in patient's records. Provide patient/carer with relevant (preferably written) information on use, side effects, need for monitoring of medication and precautions including that no new medicines are started (including over the counter preparations) unless this has been discussed with the GP, specialist or pharmacist.
- Obtain agreement and consent to share care. Complete and sign Specialist and patient agreement section of Shared Care Agreement form. Document in patient's notes and transfer once patient stabilised.
- Request for GP confirmation of acceptance of shared care by secure emailing of request to share care, protocol and completed agreement form, allowing 2 weeks for response.
- Receipt and recording in patient records/notes that GP has / has not accepted shared care and ensuring appropriate action if not (specialist to continue to prescribe/monitor).
- Prescribe for initial stabilisation period. This is usually 8-12 weeks.
- Undertake baseline and ongoing tests as indicated in the monitoring table. Review results of safety monitoring and request additional tests as required.
- Continue to review the patient at agreed specified intervals, sending a written summary to the GP whenever the patient is reviewed.
- Monitor response and adverse effects to treatment and need to continue therapy. Notify the GP of any changes to dose or cessation of therapy.
- Advise the GP on when to adjust the dose or to stop treatment.
- Notify GP if patient does not attend clinic repeatedly and advise on action to take.
- Specify formulation prescribed in correspondence.
- Provide any other advice, information or support for the GP if required. Communicate any clinically important issues and action to be taken and ensure clear back-up arrangements exist for GPs to obtain advice and support.
- Report any adverse events to MHRA/CHM and the GP.
- Support any training arrangements to ensure that GPs have the skills to ensure safe practice.

GP RESPONSIBILITIES

Refer to page 1 and GP Considerations for Shared Care page 8.

PATIENT RESPONSIBILITIES IN COOPERATION WITH SPECIALIST AND GP

- Confirm their agreement with the decision to move to a shared care model for their ongoing care and their understanding of the shared care agreement.
- Consent to share care and complete/sign Specialist and patient agreement section of Shared Care Agreement form.
- Take the sevelamer carbonate as prescribed.
- Attending for blood monitoring and follow up hospital or GP appointments.
- Report to the Specialist or GP if they subsequently do not have a clear understanding of the treatment.
- Ensuring a list of all medications is brought to all GP surgery, outpatient and A&E consultations.

(cont. page 6/9)

- Reporting any change in symptoms and adverse effects promptly to the clinician who is currently prescribing.
- Confirm that no new medicines are started (including over the counter preparations) unless this has been discussed with the GP, specialist or pharmacist.
- Share any concerns in relation to treatment with sevelamer with the Specialist or GP.
- Inform Specialist, or GP, of any other medication being taken, including over-the-counter products.
- Alert GP/specialist of any changes of circumstance which could affect management of disease e.g. plans for pregnancy, plans to move/change GP practice

DISPENSING PHARMACIST RESPONSIBILITIES

- Confirming that the patient has received verbal and written patient counselling / information and provide additional counselling should this be required. · Check the patient is being monitored regularly to ensure that it is safe before issuing or dispensing prescriptions.
- Confirming that the patient has received verbal and written patient counselling / information and provide additional counselling should this be required.

MONITORING AND ACTIONS TO BE TAKEN

- Refer to page 2

SIDE EFFECTS AND ACTIONS TO BE TAKEN (REFER TO BNF AND SPC for full details)

- GP to liaise with Specialist if any side effects are a cause for concern

SIDE EFFECTS	Action to be taken by GP
Gastro-intestinal e.g. nausea, vomiting, upper abdominal pain and constipation.	**Very Common - Monitor and inform specialist if symptoms become significant.** **Intestinal obstruction -Stop treatment and inform specialist**
Flatulence, diarrhoea, dyspepsia, abdominal pain	**Common - Monitor and inform specialist if symptoms become significant**
Rash, Pruritis	**Frequency unknown - Inform specialist**

CONTRAINDICATIONS AND PRECAUTIONS (REFER TO BNF AND SPC for full details)

Hypophosphataemia: sevelamer should be avoided in patients with low phosphate levels.

Bowel obstruction: Sevelamer can crystallise leading to the formation of concretions. Sevelamer crystals have been associated with gastrointestinal mucosal injury therefore sevelamer is not recommended for use in patients with a history of bowel obstruction. Its use is cautioned for use in patients with swallowing difficulties, severe gastrointestinal motility disorders, major gastrointestinal tract surgery or acute inflammatory bowel disease.

Hypersensitivity to the active substance or to any of the excipients

Sevelamer carbonate should only be given to **pregnant or breastfeeding** women after a careful risk/benefit analysis has been conducted for both the mother and the foetus/child.

NOTABLE DRUG INTERACTIONS (REFER TO BNF AND SPC for full details)

Common drug interactions

Ciprofloxacin: sevelamer reduces the bioavailability of ciprofloxacin by up to 50% therefore should not be taken concurrently.

Mycophenolate: sevelamer possibly reduces the plasma concentration of mycophenolate, ciclosporin and tacrolimus, a close monitoring of blood concentrations of ciclosporin, mycophenolate mofetil and tacrolimus should be considered during the use of combination and after its withdrawal.

Very rare cases of hypothyroidism have been reported in patients co-administered with sevelamer hydrochloride, which contains the same active moiety as sevelamer carbonate, and levothyroxine. Closer monitoring of thyroid stimulating hormone levels is therefore recommended in patients receiving sevelamer carbonate and levothyroxine.

Anti-arrhythmic medical product should be taken at least one hour before or three hours after sevelamer carbonate, and blood monitoring can be considered. Possible reduction in absorption cannot be excluded.

CONTACT DETAILS for BACK-UP INFORMATION / ADVICE

East and North Hertfordshire NHS Trust

Department	Contact number	Specialist Team designated nhs.net email	Pharmacy Team shared care admin contact	Out of hours contact / switchboard
Consultant nephrologists	via switchboard	nephadmin.enh-tr@nhs.net	sharedcare.enh-tr@nhs.net 01438 284032	01438 314333
Clare Morlidge/ Charlotte Mallindine Renal pharmacists	01438 284677	renalpharmacists.enh-tr@nhs.net		
Renal dieticians	01438 284947	renaldieticians.enh-tr@nhs.net		

Outside normal working hours there is access to a Consultant Nephrologist via the hospital switchboard.

For any queries relating to a patient's treatment sevelamer please contact the Specialist as documented at the top of this document. Read in conjunction with HWE APC shared care principles document.

For advice if you have any concerns contact the specialist team. If unable to contact specialist team or out of hours, contact medical registrar on call.

REFERENCES

- Genzyme therapeutics. Renvela 800mg film-coated tablets and 2.4g powder for oral suspension. Summary of Product Characteristics 2021 www.medicines.org.uk (accessed September 2023)
- Chronic kidney disease: assessment and management; NICE guideline 203 https://www.nice.org.uk/guidance/ng203 (accessed October 2023)
- KDIGO 2017. Clinical Practice Guideline for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD). Official journal of the international society of nephrology. Volume 7, Issue 1: July 2017

GP Considerations for Shared Care

This shared care agreement outlines suggested management for the prescribing of the specified drug(s) and indication(s) when the responsibility is shared between the specialist and general practitioner (GP). Sharing of care assumes communication between the specialist, GP and patient. It is important that patients are consulted about treatment and are in agreement with it. The intention to share care should be explained to the patient by the doctor initiating treatment and consent obtained.

Prescribing is to be initiated in secondary care by a provider Trust specialist and will usually be prescribed for 12 weeks unless otherwise stated within the agreed individual shared care protocol**. The expectation is that these shared care guidelines should provide sufficient information to enable GPs to be confident to take on the clinical and legal responsibility for the prescribing and the monitoring of this / these drug(s) in stable patients.** The questions below will help you confirm this:

- Is the patient's condition predictable or stable?
- Do you have the relevant knowledge, skills and access to equipment to allow you to monitor treatment as indicated in this shared care document?
- Have you been provided with relevant clinical details including monitoring data?
- Have this document and BNF/SPC provided sufficient information for you to feel confident in accepting clinical and legal responsibility for prescribing?

If you can answer YES to all of these questions (after reading this shared care guideline), then it is appropriate for you to accept the prescribing responsibility. GPs need to formally accept shared care by completing and returning the form provided within this protocol to the specialist within two weeks of receipt of request to share care.

If the answer is NO to any of these questions, you should not accept prescribing responsibility. You should respond back to the consultant outlining your reasons for NOT prescribing on the agreement form within two weeks of receiving the request to share care. If you do not have the confidence to prescribe, you still have the right to decline. In such an event, the total clinical responsibility for prescribing the medication and any monitoring required remains with the specialist. Please note that medication cost is not an acceptable reason for refusal to take on shared care.

The prescribing doctor legally assumes clinical responsibility for the drug and the consequences of its use as well as responsibility of monitoring (securing and reviewing blood test results).

Prescribing and monitoring responsibility will only be transferred when the consultant and the GP agree that the patient's condition is stable or predictable. This will usually be 12 weeks of treatment unless otherwise stated within the agreed individual shared care protocol.

Approval Information

Title of Guideline	Use of Oral Sevelamer Carbonate for hyperphosphataemia in Adult Patients with chronic kidney disease: Shared Care Protocol
Guideline Number	1
Version	2
Review Date	This shared care guidance will be reviewed upon request in the light of new evidence becoming available
Original Version Produced	guideline no 1; version 1 - East and North Hertfordshire NHS Trust Therapeutics Policy Committee, 2021
Approvals:	
Provider Trust Drug / Formulary Management Group (e.g. MUSP, TPC)	To be noted at East and North Hertfordshire NHS Trust Therapeutics Policy Committee
Hertfordshire and West Essex area prescribing committee	November 2023
Author/s	East and North Hertfordshire NHS Trust Pharmacy department and relevant specialisms supported by HWE ICB Pharmacy and Medicines Optimisation Team
Department(s) responsible for updating the guideline	East and North Hertfordshire NHS Trust Pharmacy department and relevant specialisms supported by HWE ICB Pharmacy and Medicines Optimisation Team