Sevelamer for the treatment of hyperphosphatemia in haemodialysis patients – Ipswich and Suffolk

Specialist responsibilities

- Assess the patient and provide diagnosis; ensure that this diagnosis is within scope of this shared care protocol and communicated to primary care.
- Discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling to enable the patient to reach an informed decision. Obtain and document patient consent. Provide an appropriate patient information leaflet.
- Assess for contraindications and cautions and interactions.
- Conduct required baseline investigations and initial monitoring.
- Initiate and optimise treatment as outlined below. Prescribe the maintenance treatment for at least 4 weeks and until optimised.
- Once treatment is optimised, complete the shared care documentation and send to patient's GP practice detailing the diagnosis, current and ongoing dose, any relevant test results and when the next monitoring is required. Include contact information.
- Prescribe sufficient medication (minimum 1 month) to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Conduct the scheduled reviews and monitoring in and communicate the results to primary care. After a review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined below remains appropriate.
- Reassume prescribing responsibilities if a woman becomes or wishes to become pregnant.
- Provide advice to primary care on the management of adverse effects if required.

Primary care responsibilities

- Respond to the request from the specialist for shared care in writing within 14 days.
- If accepted, prescribe ongoing treatment as detailed in the specialist's request , taking into any account potential drug interactions listed below.
- Adjust the dose prescribed as advised by the specialist.
- Manage adverse effects as detailed below and discuss with specialist team when required.
- Refer the management back to the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist.

Patient and/or carer responsibilities

- Take the medication as prescribed and avoid abrupt withdrawal unless advised by the primary care prescriber or specialist.
- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed below.
- Report the use of any over the counter medications to their primary care prescriber and be aware they should discuss the use of the medication with their pharmacist before purchasing any OTC medicines.
- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant, and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.

1. Indications

• Hyperphosphatemia in haemodialysis patients.

2. Contraindications and cautions

Please see BNF & SPC for comprehensive information.

3. Initiation and ongoing dose regime

- Transfer of monitoring and prescribing to primary care is normally after the patient's dose has been optimised and with satisfactory investigation results for at least 4 weeks
- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician
- Termination of treatment will be the responsibility of the specialist.

The recommended starting dose of sevelamer carbonate (Renvela®) is based on serum phosphorous levels and is between 2.4g to 4.8g total daily dose based on individual clinical assessment.

Sevelamer must be taken 3 times a day in divided doses with meals.

The dose will then be titrated to effect based on serum phosphate/calcium levels as directed by the renal team. The usual dose varies between 800mg-4g three times a day.

4. Baseline investigations, initial monitoring and ongoing monitoring

Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to primary care.

Serum phosphate and serum calcium levels should be checked every 2-3 weeks until stable serum phosphate concentration is reached. Levels should then be checked regularly, the frequency of monitoring depends on the degree of chronic kidney disease and the patient's dialysis status

Monitoring of levels and adjustment of sevelamer dose is the responsibility of the renal team.

5. Adverse effects and other management

Result	Action for primary care
As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance	
Gastrointestinal disorders: diarrhoea, nausea, constipation (most common), abdominal pain	Rule out other causes. If patient remains intolerant seek advice from specialist as treatment may need to be changed or stopped.
Nervous system disorders: Headache, leg cramps, dizziness	Rule out other causes. If patient remains intolerant seek advice from specialist as treatment may need to be changed or stopped.

6. Significant medicine interactions

The following list is not exhaustive. Please see BNF or SPC for comprehensive information and recommended management.

Drugs for which a reduction in bioavailability could be clinically important should be administered at least 1 hour before, or 3 hours after, sevelamer; alternatively consider monitoring blood concentrations.

Examples of these drugs are:

- Ciprofloxacin
- Ciclosporin
- Mycophenolate
- Tacrolimus

Levothyroxine:

Very rare cases of hypothyroidism have been reported in patients co-administered with sevelamer Closer monitoring of thyroid stimulating hormone (TSH) levels is therefore recommended in patients receiving sevelamer carbonate and levothyroxine.

7. Pregnancy, paternal exposure and breast feeding

It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.

Pregnancy

There are no or limited amount of data from the use of sevelamer in pregnant women. Animal studies have shown some reproductive toxicity when sevelamer was administered to rats at high doses. Sevelamer has also been shown to reduce the absorption of several vitamins including folic acid. The potential risk to humans is unknown. Sevelamer carbonate should only be given to pregnant women if clearly needed and after a careful risk/benefit analysis has been conducted for both the mother and the foetus.

Breast-feeding

It is unknown whether sevelamer/metabolites are excreted in human milk. The non-absorbed nature of sevelamer indicates that excretion of sevelamer in breast milk is unlikely. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with sevelamer carbonate should be made taking into account the benefit of breast-feeding to the child and the benefit of sevelamer carbonate therapy to the woman.

8. Specialist contact information

Ipswich Renal Team: renal.nurses@esneft.nhs.uk 01473 704732

West Suffolk Hospital Renal Team: Dr William Petchey, Dr Vivian Yiu, Dr Hsu Pheen Chong Tel: 01284 713148

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Templates for response to shared care guidelines are available in SNEE on DXS and Ardens. The listings are:

For Suffolk practices (DXS)

Form Name - Appendix 2 Accepting Shared Care

Form Reference - SUF2133

Folder Location - Medicines Management – Care Pathway

Form Name – SNEE Cannot Prescribe Form

Form Reference - SUF2132

Folder Location - Medicines Management – Care Pathway

For North East Essex practices (Ardens)

SystmOne

Form Name - Accepting Shared Care Appendix 2 (Primary Care Prescriber to Specialist)

Form Reference - SUF2133

Folder Location - Secondary Care Referrals P – Prescribing

Form Name –Unable to Prescribe Form – North East Essex

Form Reference – NEE2129

Folder Location – Secondary Care Referrals P – Prescribing

EMIS

Form Name - Accepting Shared Care Appendix 2 (Primary Care Prescriber to Specialist)

Form Reference - NEE2133

Folder Location - Prescribing

Form Name – Unable to Prescribe Form – North East Essex

Form Reference – NEE2129

Folder Location – Prescribing

The documents are also copied below for reference

Appendix 2: Shared Care Agreement Letter (Primary Care Prescriber to Specialist)

Primary Care Prescriber Response

Dear	*[insert Doctor's name]*
Patient	*[insert Patient's name]*
NHS Number	*[insert NHS Number]*
Identifier	*[insert patient's date of birth and/oraddress]*

Thank you for your request for me to accept prescribing responsibility for this patient under a shared care agreement and to provide the following treatment

Medicine	Route	Dose & frequency

I can confirm that I am willing to take on this responsibility from *[insert date]* and will complete the monitoring as set out in the shared care protocol for this medicine/condition.

Primary Care Prescriber signature:

Da

te:

Primary Care Prescriber address/practice stamp

Appendix 3: Shared Care Refusal Letter (Primary Care Prescriber to Specialist)

Re:

Patient	*[insert Patient's name]*
NHS Number	*[insert NHS Number]*
Identifier	*[insert patient's date of birth and/oraddress]*

Thank you for your request for me to accept prescribing responsibility for this patient.

In the interest of patient safety NHS *[insert CCG name]***,** in conjunction with local acute trusts have classified *[insert medicine name]*as a Shared Care drug, and requires a number of conditions to be met before transfer can be made to primary care.

I regret to inform you that in this instance I am unable to take on responsibility due to the following:

		Tick which apply
1.	**The prescriber does not feel clinically confident in managing this individual**	

	patient's condition, and there is a sound clinical basis for refusing to accept shared care As the patients primary care prescriber I do not feel clinically confident to manage this patient's condition because *[insert reason]*. I have consulted with other primary care prescribers in my practice who support my decision. This is not an issue which would be resolved through adequate and appropriate training of prescribers within my practice. **I have discussed my decision with the patient and request that prescribing for this individual remain with you as the specialist, due to the sound clinical basis given above.**	
2.	**The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement** As the medicine requested to be prescribed is not included on the national list of shared care drugs as identified by RMOC or is not a locally agreed shared care medicine I am unable to accept clinical responsibility for prescribing this medication at this time. **Until this medicine is identified either nationally or locally as requiring shared care the responsibility for providing this patient with their medication remains with you**	
3.	**A minimum duration of supply by the initiating clinician** As the patient has not had the minimum supply of medication to be provided by the initiating specialist I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.***	
4.	**Initiation and optimisation by the initiating specialist** As the patient has not been optimised on this medication I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.***	
5.	**Shared Care Protocol not received** As legal responsibility for clinical care lies with the clinician who signs the prescription, I need to ensure that I am in possession of sufficient clinical information for me to be confident to prescribe this treatment for my patient and it is clear where each of our responsibilities lie to ensure the patient is safely managed**.** For this reason I am unable to take clinical responsibility for prescribing this medication at this time, therefore would you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.***	
6.	**Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)**	

I would be willing to consider prescribing for this patient once the

above criteria have been met for this treatment.

NHS England ‘Responsibility for prescribing between Primary & Secondary/Tertiary care’ guidance (2018) states that “when decisions are made to transfer clinical and prescribing responsibility for a patient between care settings, it is of the utmost importance that the GP feels clinically competent to prescribe the necessary medicines. It is therefore essential that a transfer involving medicines with which GPs would not normally be familiar should not take place without full local agreement, and the dissemination of sufficient, up-to-date information to individual GPs.” In this case we would also see the term GP being interchangeable with the term Primary Care Prescriber.

Please do not hesitate to contact me if you wish to discuss any aspect of my letter in more detail and I hope to receive more information regarding this shared care agreement as soon as possible

Yours sincerely

Primary Care Prescriber signature:

Date:

Primary Care Prescriber address/practice stamp