NHS Dorset

SHARED CARE PROTOCOL FOR THE USE OF PENICILLAMINE FOR PATIENTS WITHIN ADULT SERVICES

As well as this protocol, please ensure that summaries of product characteristics (SPCs), British national formulary (BNF) or the Medicines and Healthcare products Regulatory Agency (MHRA) or NICE websites are reviewed for up-to-date information on any medicine.

Specialist responsibilities

- Assess the patient and provide diagnosis; ensure that this diagnosis is within scope of this shared care protocol (section 2) and communicated to primary care.
- Use a shared decision-making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see section 11) to enable the patient to reach an informed decision. Obtain and document patient consent. Provide an appropriate patient information leaflet.
- Explain where drugs are used outside their license.
- Assess for contraindications and cautions (see section 4) and interactions (see section 7).
- Conduct required baseline investigations, arrange, and review the results of any blood or urine tests for the first 12 weeks of treatment (see section 8).
- Initiate, assess response and optimise treatment as outlined in section 5. Transfer to primary care is normally after the patient has been treated for 3 months and with satisfactory investigation results for at least 4 weeks.
- Explain the intention to share care for drug prescribing and monitoring to the patient. Explain the process and the potential timescales for this.
- Prescribe sufficient medication taking into account any delays in communication to general practice to enable transfer to primary care, including where there are unforeseen delays to transfer of care.

- Once treatment is established and stabilised, request shared care from the primary care provider either using the documentation in Appendix 1 or by clinic letter detailing the diagnosis, current and ongoing dose, baseline, and most recent test results, confirm the monitoring schedule and when the next monitoring is required. Include contact information (section 13).

- Conduct the required reviews and monitoring in section 8 and communicate the results to primary care. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate.
- Ensure there is a mechanism to receive rapid referral of a patient from primary care in the event of deteriorating clinical condition, non-adherence to monitoring requirements or need for further advice and support.
- Give advice to primary care on continuing treatment if a woman becomes or wishes to become pregnant.
- Provide advice to primary care on the management of adverse effects if required.
- Patients should be regularly reviewed, and the risk benefit re-assessed as patients get significantly older and frail with increasing co-morbidities and polypharmacy. Dose optimisation and/or dose tapering should be considered if clinically appropriate aiming for the lowest effective dose.
- Advise primary care if treatment should be discontinued

Primary care responsibilities

- Respond to the request from the specialist for shared care if further clarification or a refusal is intended. Acceptance of shared care is implied by nil response. It is asked that this be undertaken within 14 days of the request being received, where possible.
- If accepted, prescribe ongoing treatment as detailed in the specialist's request and as per section 5, considering any potential drug interactions in section 7.
- Assess for interactions with penicillamine when starting any new medicines see section 7
- Adjust the dose of penicillamine prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in section 9. Communicate any abnormal results to the specialist.
- Manage adverse effects as detailed in section 10 and discuss with specialist team when required.

- Stop penicillamine and make an urgent referral to the specialist if signs of myelosuppression, hepatic or renal dysfunction develop, or a serious skin reaction or oral ulceration is observed.
- Seek advice from the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist. If the decision to stop treatment is made in primary care e.g. due to increased frailty index, to let the specialist team know so they can arrange a review as needed.

Patient and/or carer responsibilities

- Take penicillamine as prescribed and avoid abrupt withdrawal unless advised by the primary care prescriber or specialist.
- Maintain engagement with specialist and primary care; attending regularly for monitoring and review appointments as requested, keeping their contact details up to date with both teams. To be aware that medicines may be stopped if they do not attend for the required blood monitoring or the review appointments
- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in section 11.
- Report the use of any over the counter medications to their primary care prescriber and be aware they should discuss the use of penicillamine with their pharmacist before purchasing any OTC medicines.
- Tell anyone who prescribes them a medicine that they are taking penicillamine.
- 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. Background

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Penicillamine is used to treat severe active rheumatoid arthritis not adequately controlled by NSAID therapy. In the treatment of rheumatoid arthritis, response to Penicillamine is often slow and improvement may not occur for 3-6months. It is now rarely used for this indication as other agents are likely to be more effective.

Penicillamine is a chelating agent which aids the elimination from the body of certain heavy metal ions, including copper, lead, and mercury, by forming stable soluble complexes with them that are readily excreted by the kidney. For this reason, it is used in the treatment of Wilson's disease (hepatolenticular degeneration), in conjunction with a low copper diet, to promote the excretion of copper. It may also be used to treat asymptomatic lead intoxication.

Penicillamine is also used as an adjunct to diet and urinary alkalinisation in the management of cystinuria. By reducing urinary concentrations of cystine, penicillamine prevents the formation of calculi and promotes the gradual dissolution of existing calculi.

This shared care protocol does not cover treatment of people less than 18 years old.

2. Indications

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The licensed indications for penicillamine are:

- Severe active rheumatoid arthritis including juvenile forms
- Wilson's disease (hepatolenticular degeneration)
- Cystinuria – dissolution and prevention of cystine stones
- Lead poisoning
- Chronic active hepatitis in adults.

3. Locally agreed off-label use

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Nil further identified

4. Contraindications and cautions

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This information does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it. Please see BNF & SPC for comprehensive information.

Contraindications:

- Known hypersensitivity to penicillamine or any of the excipients
- Agranulocytosis, aplastic anaemia, or severe thrombocytopenia due to penicillamine.
- Lupus erythematosus.
- Moderate or severe renal impairment

Cautions:

- Penicillamine should be used with caution in patients who have had adverse reactions to gold. Concomitant or previous treatment with gold may increase the risk of side effects with penicillamine treatment. Penicillamine therefore should be used with caution in patients who have previously had adverse reactions to gold and concomitant treatment with gold should be avoided.
- Renal impairment- care should be taken and dosage modified.
- Concomitant use of NSAIDs and other nephrotoxic drugs may increase the risk of renal damage- to monitor carefully.
- Careful monitoring is necessary in older people since increased toxicity has been observed in this patient population regardless of renal function.

- Patients with hypersensitivity to penicillin very rarely exhibit hypersensitivity to penicillamine
- The tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.
- Pregnancy: men and women of child-bearing age must use a reliable method of contraception. When planning a pregnancy, it is important that both men and women on this drug discuss medication with their specialist team

5. Initiation and ongoing dose regimen

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- Transfer of monitoring and prescribing to primary care is normally after at least 12 weeks, and when 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 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.

Initial stabilisation:

Rheumatoid Arthritis:

A daily dose of 125 - 250 mg per day is recommended for the first month, increasing by the same amount every four to twelve weeks until remission occurs.

Wilson's Disease:

1.5 – 2 g daily in divided doses, adjusted according to response, to be taken before food

Cystinuria:

Dissolution of cystine stones

1000 mg to 3000 mg daily, in divided doses.

Prevention of cystine stones

500 mg to 1000 mg at bedtime.

Lead Poisoning:

1000 mg to 1500 mg daily, in divided doses until urinary lead is stabilised at less than 0.5 mg per day. In the elderly

Chronic Active Hepatitis:
500 mg daily in divided doses, increased gradually over three months to a maintenance dose of 1250 mg daily. During this period, the dose of corticosteroids should be phased out. Not recommended in the elderly

The initial stabilisation period must be prescribed by the initiating specialist.

Maintenance dose (following initial stabilisation):

Rheumatoid arthritis
The minimum maintenance dose to achieve suppression of symptoms should be used and treatment should be discontinued if no improvement occurs within 12 months. Improvement may not occur for some months. The usual maintenance dose is 500 mg to 750 mg daily. However, up to 1500 mg daily may be required. Daily dosage in the elderly should not exceed 1000 mg. Reduction in maintenance dosage by 125 mg to 250 mg every 12 weeks may be attempted after a period of 6 months continuous remission.

Wilson's Disease
Patients must be maintained in negative copper balance and the minimum dose of Penicillamine required to achieve this should be given. Dose reduction may be attempted when remission occurs, decreasing to 750 mg to 1000 mg per day. It is advisable that a dose of 2000 mg per day should not be continued for more than 12 months. In the elderly 20 mg/kg/day in divided doses adjusting the dose minimal level necessary to control disease.

Cystinuria
Maintenance of adequate fluid intake (not less than 3 litres/day is important). The lowest effective dose should be used, and this is determined by quantitative amino acid chromatography of urine. Cystine levels in the urine should not exceed 300 mg/litre. In the elderly use the minimum dose to maintain urinary cystine levels below 200 mg/litre.

Lead Poisoning
1000 mg to 1500 mg daily, in divided doses until urinary lead is stabilised at less than 0.5 mg per day. In the elderly use 20 mg/kg/day in divided doses until lead levels in the urine is stabilised at less than 0.5 mg per day.

Chronic active hepatitis
1250 mg daily. The dose of corticosteroids should be phased out. Throughout therapy, liver function tests should be carried out periodically to assess the disease status.

The initial maintenance period must be prescribed by the initiating specialist. Specialist heavy metal ion blood or urinary tests to monitor outcomes remain under the responsibility of the specialist team

Conditions requiring dose adjustment: Renal Insufficiency: Penicillamine therapy should be initiated at a low dose with intervals between dose increases of at least 12 weeks. Ongoing fortnightly monitoring may be required in certain at-risk patients.

6. Pharmaceutical aspects

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Route of administration:	Oral
Formulation:	125mg film-coated tablets 250mg film-coated tablets
Administration details:	Penicillamine should be taken on an empty stomach at least half an hour before meals If concomitant oral iron, digoxin, or antacid therapy is indicated, this should not be given within two hours of taking penicillamine

Other important information:	Patients taking penicillamine for rheumatoid arthritis should be warned not to expect improvement for at least 6 to 12 weeks after treatment is initiated. Penicillamine should be discontinued if there is no improvement within 1 year. Monitoring of blood and platelet counts should be carried out at appropriate intervals, together with urinalysis for detection of haematuria and proteinuria Patients should be asked about the presence of rash or oral ulceration at each appointment Pyridoxine daily may be given to patients on long term therapy, especially if they are on a restricted diet, since penicillamine increases the requirement of this vitamin. This would be on specialist advice only

7. Significant medicine interactions

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

- Oral Antacids decrease the absorption of oral Penicillamine. Manufacturer advises separate administration by 2 hours
- Oral Iron is predicted to decrease the absorption of oral Penicillamine. Manufacturer advises separate administration by at least 2 hours.
- Penicillamine potentially decreases the concentration of Digoxin. Manufacturer advises separate administration by 2 hours.
- Concomitant use of NSAIDs and other nephrotoxic drugs may increase the risk of renal damage- for close monitoring
- Concomitant use of gold is not recommended
- Concomitant use of clozapine: penicillamine may potentiate the blood dyscrasias seen with clozapine
- Concomitant use of chloroquine or hydroxychloroquine: predicted to increase the risk of haematological toxicity when given with Penicillamine; manufacturer advises avoid
- Concomitant use of zinc: oral absorption of penicillamine may be reduced by concomitant administration of zinc; absorption of zinc may also be reduced by penicillamine.

8. Baseline investigations, initial monitoring, and ongoing monitoring to be undertaken by specialist

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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.

Baseline investigations

- Urinalysis (blood and protein)
- Urea and electrolytes (U&Es) including creatinine and creatinine clearance (CrCl)
- Alanine aminotransferase (ALT) and albumin
- Full blood count (FBC)
- Weight
- Assess for co-morbidities which may influence DMARD choice

Initial monitoring and at dose change:

During the first eight weeks of therapy full blood counts should be carried out fortnightly and urinalysis should be carried out weekly. If the dose is stable this can then be reduced to monthly. After which, the transfer of prescribing to primary care should normally only take place when the patient has received a stable dose for at least 4 weeks and their blood and physical tests results have been satisfactory. It is anticipated that this should be around 12 weeks after initiation of the medicine

- FBC
- Urea and electrolytes (U&Es) including creatinine and creatinine clearance (CrCl)
- ALT and albumin (LFTs)
- Urinalysis (blood and protein)
- Rheumatology patients: C-reactive protein (CRP) &/or erythrocyte sedimentation rate (ESR) (for monitoring disease activity/outcomes rather than for safety- this may continue to be monitored by the rheumatology team but will not be part of the primary care safety monitoring parameters)

Following a dose change repeat bloods one week after dose increase if stable revert to usual monitoring regime.

Ongoing monitoring:

The specialist will retain the responsibility for monitoring the patient's ongoing response to treatment and advise if a dose change or treatment cessation is appropriate. This includes the requirement for any heavy metal ion blood or urinary tests to monitor outcomes. This should usually be undertaken at least annually.

After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate.

9. Ongoing safety monitoring requirements to be undertaken by primary care

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See section 10 for further guidance on management of adverse effects/responding to monitoring results.

Monitoring and advice	Frequency
• FBC • U&Es including creatinine and CrCl • ALT and albumin (LFTs) • Urinalysis (Blood and Protein)	Monthly for 12 months Patients who have been stable for 12 months can reduce to 3 monthly monitoring. Where necessary seek advice on increased frequency of monitoring on a case-by-case basis. **The decision to discontinue monitoring should be following advice from the specialist for the individual patient.**
Vaccines are safe and recommended for this patient group and should be offered in line with the standard schedule. Refer to Green Book Chapter 6 for further details. **Annual** influenza (The Green Book, Chapter 19) vaccinations are recommended.	• Shingles vaccination: one course. • Other vaccinations as per national schedule. • Influenza vaccination: annual. It is advisable to add the patient to the influenza vaccine list.

(If relevant) If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.

10. Adverse effects and other management

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Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard

For information on incidence of ADRs see relevant summaries of product characteristics

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	
Full blood count • WCC less than 3.5 x10^9/L • Lymphocytes less than 0.5 x10^9/L • Neutrophils less than 1.6 x10^9/L • Platelets less than 140 x10^9/L • Unexplained eosinophilia; greater than 0.5 x10^9/L	Withhold treatment and discuss with specialist team.
Urinalysis If proteinuria >2 on urinary dipstick	Check mid-stream sample of urine. If evidence of infection, treat appropriately. Proteinuria occurs in up to 30% of patients and is partially dose related. If sterile and persists, on two consecutive occasions discuss with specialist. Haematuria is rare, but if it occurs in the absence of renal stones or other known causes, treatment should be stopped immediately

MCV >105 fL	Consider interruption in treatment if there is a significant increase from baseline. Check serum folate, B12, alcohol history and TSH and treat any underlying abnormality. If results of these additional investigations are normal discuss with specialist team urgently.
Signs or symptoms of bone marrow suppression, e.g. unexplained bleeding or bruising with or without sore throat, purpura, mouth ulcers.	Check FBC immediately, withhold treatment while awaiting results, and discuss with the specialist team. See haematological monitoring above.
Systemic infection requiring antibiotics	It is recommended that Penicillamine should be stopped during active infection and restarted after the infection has resolved. Contact specialist for advice as needed.
Liver function tests: ALT >100units/L, or any sudden increases (e.g. doubling of baseline) OR Unexplained fall in albumin; less than 30g/L Jaundice	Withhold and discuss with specialist team. Check any other reason for risk of hepatic dysfunction such as alcohol history and drug interactions, including OTC or complementary medication.
Renal function Creatinine increases of greater than 30% from baseline in the last 12 months or CrCl reduces to less than 60mL/min	Use clinical judgement and repeat in 1 week. Rule out other causes. If still more than 30% from baseline, withhold and discuss with specialist.
Gastrointestinal disorders Nausea, vomiting, diarrhoea, or unintentional weight loss	Review for reversible causes. Taking the medicine before bed may reduce nausea. If no improvement contact specialist team.

Taste Disturbances	Taste loss or metallic taste may be transient for a few weeks - continue treatment, usually settles spontaneously
Rash	Rash occurs in up to 35% of patients. Unexplained acute widespread rash: Withhold and seek urgent specialist advice. Late rashes (may occur after several months or years of therapy) are more serious than early ones- Withhold until discussed with specialist team
Neurological symptoms	Deterioration of the neurological symptoms of Wilson's disease (dystonia, rigidity, tremor, dysarthria) have been reported following introduction of penicillamine in patients treated for this condition. This may be a consequence of mobilisation and redistribution of copper from the liver to the brain. Consider withholding treatment and discussing with specialist.

11. Advice to patients and carers

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The specialist will counsel the patient regarding the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.

The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:

- Sore throat, mouth ulcers, fever, malaise, swollen lymph nodes, or unexplained bleeding or bruising
- Progressive skin rash with blisters or oral ulcerations
- Nausea, vomiting, diarrhoea, jaundice, dark urine, and unintentional weight loss.

The patient and/or carer should be advised:

- What shared care means for their treatment, what to expect, and their responsibilities under shared care.

- To be aware that if hypersensitive to penicillin may react rarely to penicillamine.
- Alteration of taste may settle spontaneously.
- During a serious systemic infection, penicillamine should be temporarily discontinued until the patient has recovered from the infection.
- Tell anyone who prescribes them a medicine that they are taking penicillamine. Always ask a pharmacist before purchasing any medicines over the counter, including herbal remedies, and ask if they are safe.
- That vaccination in line with current national advice (e.g. for COVID-19, influenza) is safe and recommended.
- To use effective contraception, and to take a pregnancy test if they think they could be pregnant. Patients should inform the specialist or GP immediately if they become pregnant.

Patient information:

General information: Penicillamine patient information

General Information: Penicillamine 250 mg film-coated tablets - Patient Information Leaflet (PIL)

12. Pregnancy, paternal exposure, and breast feeding

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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.

All patients should be informed of the risks and benefits of taking this medicine during pregnancy and breastfeeding. The specialist team should be contacted if a patient becomes pregnant or is planning to become pregnant or breastfeed.

Pregnancy/ Breastfeeding: The safety of penicillamine for use during pregnancy & lactation has not been established and the manufacturer advises to avoid. Men and women of child-bearing age must use a reliable method of contraception. When planning a pregnancy, it is important that both men and women on this drug discuss with their specialist

Information for healthcare professionals: Penicillamine SPS - Specialist Pharmacy Service

13. Specialist contact information

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Please approach the patient's named secondary care clinician via the usual method of communication, this may be via letter or if more urgent via advice and guidance

14. Additional information

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Where patient care is transferred from one specialist service or GP practice to another the GP is responsible for letting the specialist team know if they are unhappy with continuing the shared care. All involved healthcare professionals should ensure a prompt transfer of care that includes effective information sharing and continued access to the medicines by the patient during the transition.

15. References

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- Penicillamine 125 mg film-coated tablets - Summary of Product Characteristics (SmPC) - (emc) Last updated 8th Mar 2024
- Penicillamine 250 mg film-coated tablets - Summary of Product Characteristics (SmPC) - (emc) Last updated 11th Mar 2024
- NICE Clinical Knowledge Summaries (CKS). DMARDs – penicillamine.
- eBNF – accessed via Penicillamine | Drugs | BNF | NICE
- NICE Clinical Knowledge Summaries - DMARD management. Last revised December 2023. Accessed via https://cks.nice.org.uk/topics/dmards/management/

16. Other relevant national guidance

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- Shared Care for Medicines Guidance – A Standard Approach (RMOC). Available from https://www.sps.nhs.uk/articles/rmoc-shared-care-guidance/
- NHSE guidance – Responsibility for prescribing between primary & secondary/tertiary care. Available from https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/
- General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care
- NICE NG197: Shared decision making. Last updated June 2021. https://www.nice.org.uk/guidance/ng197/.

17. Local arrangements for referral

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Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.

Via the usual methods

Appendix 1: Shared Care Request letter (Specialist to Primary Care Prescriber)

Dear *[insert Primary Care Prescriber's name]*

Patient name: *[insert patient's name]*
Date of birth: *[insert date of birth]*
NHS Number*:* *[insert NHS Number]*
Diagnosis: *[insert diagnosis]*

As per the agreed *[insert APC name]*shared care protocol for *[insert medicine name]* the treatment of *[insert indication],* this patient is now suitable for prescribing to move to primary care.

The patient fulfils criteria for shared care, and I am therefore requesting your agreement to participate in shared care. Where baseline investigations are set out in the shared care protocol, I have carried these out.

I can confirm that the following has happened regarding this treatment:

	Specialist to complete
The patient has been initiated on this therapy and has been on an optimised dose for the following period:	
Baseline investigation and monitoring as set out in the shared care documents have been completed and were satisfactory	*Yes / No*
The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care	*Yes / No*
The risks and benefits of treatment have been explained to the patient	*Yes / No*
The roles of the specialist/specialist team/ Primary Care Prescriber / Patient and pharmacist have been explained and agreed	*Yes / No*
The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments	*Yes / No*
I have enclosed a copy of the shared care protocol which covers this treatment/the SCP can be found here (insert electronic/ web link)	*Yes / No*
I have included with the letter copies of the information the patient has received	*Yes / No*
I have provided the patient with sufficient medication to last until	
I have arranged a follow up with this patient in the following timescale	

Treatment was started on, *[insert date started]* and the current dose is *[insert dose and frequency]*.

If you agree, please undertake monitoring and treatment from *[insert date]* NB: date must be at least 1 month from initiation of treatment.

The next blood monitoring is due on *[insert date]* and should be continued in line with the shared care guideline.

Please respond to this request for shared care, in writing, within 14 days of the request being made where possible.

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: _____Date: _____

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 applies
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 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 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 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