NHS Dorset

SHARED CARE PROTOCOL - SULFASALAZINE FOR PATIENTS WITHIN ADULT SERVICES

As well 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 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 and formulation, 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 sulfasalazine when starting any new medicines see section 7.
- Adjust the dose of sulfasalazine 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 sulfasalazine 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. See section 12
- 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 sulfasalazine 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 sulfasalazine with their pharmacist before purchasing any OTC medicines.
- Tell anyone who prescribes them a medicine that they are taking sulfasalazine.
- 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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This shared care guideline has been prepared to support the transfer of responsibility for prescribing from secondary to primary care. Shared Care is only appropriate if it provides the optimum solution for the patient.

Sulfasalazine is a disease modifying antirheumatic drug (DMARD) used to treat a number of rheumatological conditions, and to induce and maintain remission in certain inflammatory gastrointestinal diseases.

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

2. Indications

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The licensed indications for sulfasalazine are:

- Rheumatoid arthritis (EC tablets only)
- Ulcerative colitis
- Active Crohn's disease

Sulfasalazine is also used off-label for other chronic inflammatory disorders including:

- Seronegative spondyloarthropathies such as psoriatic arthritis
- Sarcoidosis
- Refractory urticaria

3. Locally agreed off-label use

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Nil further identified- see above

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 sulfasalazine, its metabolites or any of the excipients as well as sulfonamides or salicylates.
- Porphyria.

Cautions:

- Hepatic or renal impairment.
- Pre-existing blood dyscrasias.
- Severe allergy or bronchial asthma.
- Glucose-6-phosphate dehydrogenase (G6PD) deficiency due to risk of haemolytic anaemia.
- Folic acid deficiency.
- Adequate fluid intake should be maintained during treatment to avoid crystalluria and kidney stone formation.
- Slow acetylator status increases the risk of sulfapyridine-related adverse drug reactions (ADRs) which can present as a drug-induced lupus-like syndrome.

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 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.

Initial stabilisation:

Treatment of acute attacks of ulcerative colitis and Crohn's disease:

Oral: 1-2g four times daily until remission. The night-time interval between doses should not exceed 8 hours.

Rheumatoid arthritis (using enteric coated (EC) tablets where possible):

500mg daily, increasing by 500mg each week until 2-3g per day in divided doses is reached according to response. Only the enteric coated tablets are licensed in rheumatoid arthritis; use of other formulations is off label.

For other indications take specialist advice.

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

Maintenance dose (following initial stabilisation):

Ulcerative colitis and Crohn's disease:

Oral: Usual maintenance dose 500mg four times daily.

Rheumatoid arthritis and other indications (using EC tablets):

2-3g daily in 3-4 divided doses.

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

Conditions requiring dose adjustment:

- Renal impairment: in patients with CrCl less than 10 mL/min the dose should be started at very low dose and monitor. In patients with moderate to severe renal impairment, toxicity includes increased risk of crystalluria – ensure high fluid intake See section 11

6. Pharmaceutical aspects

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Route of administration:	Oral
Formulation:	500mg tablets 500mg enteric coated (EC) tablets 250mg/5mL oral suspension (contains ethanol, see below) – this is significantly more expensive than the tablets Licensed indications vary with formulation. See relevant summary of product characteristics for full details.
Administration details:	EC tablets should be swallowed whole and not crushed or broken.

Other important information:	Plain tablets and the oral suspension are only licensed for use in ulcerative colitis or active Crohn's disease. The oral suspension contains 4.7 mg of alcohol (ethanol) in each 5ml, equivalent to less than 1ml of beer or wine. The small amount of alcohol in this medicine will not have any noticeable effects. Once opened the contents have an expiry of one month EC tablets are licensed for use in rheumatoid arthritis as well as ulcerative colitis and active Crohn's disease. Their use in ulcerative colitis and Crohn's disease is usually recommended if the patient experiences gastro-intestinal intolerance with the plain tablets. Sulfasalazine may cause a yellow-orange discolouration of body fluids and skin. Certain types of extended wear soft-contact lenses may be permanently stained. Sulfasalazine or its metabolites may interfere with ultraviolet absorbance, particularly at 340 nm, and may cause interference with some laboratory assays that use NAD(H) or NADP(H) to measure ultraviolet absorbance around that wavelength. Examples of such assays may include urea, ammonia, LDH, α-HBDH and glucose. It is possible that alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatine kinase-muscle/brain (CK-MB), glutamate dehydrogenase (GLDH), or thyroxine may also show interference when sulfasalazine treatment is given at high doses. Consult with the testing laboratory regarding the methodology used. Caution should be exercised in the interpretation of these laboratory results in patients who are receiving sulfasalazine. Results should be interpreted in conjunction with clinical findings.

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

- **Digoxin:** Reduced absorption may be seen when used concomitantly with sulfasalazine.
- Sulfonamides are chemically similar to some **oral hypoglycaemic agents** and may cause hypoglycaemia. Patients receiving sulfasalazine and hypoglycaemic drugs should closely monitor blood glucose.
- **Azathioprine and 6-mercaptopurine:** Possible risk of bone marrow suppression and leucopenia
- **Folate** absorption and metabolism may be reduced by sulfasalazine**.**
- **Darolutamide and voxilaprevir** may increase exposure to sulfasalazine, manufacturer advises avoid.

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

- Urea and electrolytes (U&Es) including creatinine and creatinine clearance (CrCl)
- Alanine aminotransferase (ALT) & albumin
- Full blood count (FBC)
- Weight
- Height and blood pressure
- Assess for co-morbidities which may influence DMARD choice.
- Screening for viral infections as per local policy, e.g. HIV, hepatitis B and C, varicella zoster, Epstein Barr virus, cytomegalovirus
- Screening for lung disease, including tuberculosis, should be undertaken at clinician discretion on a case-by-case basis.
- Provide or request appropriate vaccination prior to treatment initiation, according to local arrangements (e.g. pneumococcal, influenza, COVID-19)

Initial monitoring and at dose change:

To be repeated every 2 weeks until the dose has been stable for 6 weeks, then monthly for three months. 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.

- BP
- FBC
- U&Es, including creatinine and CrCl
- ALT and albumin (LFTs)
- 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 every 2 weeks until the dose has been stable for 6 weeks, then revert to previous schedule. More frequent monitoring is appropriate in patients at higher risk of toxicity, e.g. concurrent use of more than one DMARD.

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 should usually be undertaken annually unless the patient has been stabilised on treatment for a long time and considered suitable for patient initiated follow up (PIFU). Access to the specialist team for advice and guidance should still be available if the patient is enrolled with PIFU.

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)	In first year of treatment standard monitoring is required (every 12 weeks). Patients who have been stable for 12 months no routine monitoring is required for most patients. Where necessary seek advice on increased frequency of monitoring on a case-by-case basis. Annual serum creatinine or eGFR may be considered. **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.
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	Temporarily withhold sulfasalazine until the patient has recovered. Consider additional investigations (e.g. FBC), if clinically appropriate. 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 if CrCl reduces to <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 team. In patients with moderate to severe renal impairment, toxicity includes increased risk of crystalluria – ensure high fluid intake
Gastrointestinal disorders Nausea, vomiting, diarrhoea, or unintentional weight loss	Review for reversible causes and treat as appropriate. Advise patient to take with food. If no improvement contact specialist team.
Other symptoms • Skin/mucosal reaction, e.g. serious rash • Diffuse alopecia • Breathlessness or cough • Peripheral neuropathy	Consider withholding treatment and discussing with specialist. For widespread rash, discontinue and discuss with specialist urgently.

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 – see below
- Nausea, vomiting, diarrhoea, jaundice, dark urine, and unintentional weight loss.
- Hair loss
- Breathlessness, infection, or cough
- Symptoms of peripheral neuropathy e.g. pins and needles, numbness or burning pain in extremities

The patient and/or carer should be advised:

- What shared care means for their treatment, what to expect, and their responsibilities under shared care.
- Life-threatening skin reactions Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported with the use of sulfasalazine. The highest risk for occurrence is within the first weeks of treatment. Patients should be advised to report a progressive skin rash often with blisters or mucosal lesions, or any other sign of hypersensitivity.
- During a serious systemic infection, sulfasalazine should be temporarily discontinued until the patient has recovered from the infection.
- Tell anyone who prescribes them a medicine that they are taking sulfasalazine. 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.
- Sulfasalazine may cause a harmless yellow-orange discolouration of body fluids and skin. Certain types of extended wear soft-contact lenses may be permanently stained.
- To maintain adequate fluid intake during treatment to reduce the risk of crystalluria and kidney stones.

- Sulfasalazine oral suspension contains 4.7 mg of alcohol (ethanol) in each 5ml, equivalent to less than 1ml of beer or wine. The small amount of alcohol in this medicine will not have any noticeable effects.

Patient information:

General information: https://www.nhs.uk/medicines/sulfasalazine/

General information: https://patient.info/medicine/sulfasalazine-salazopyrin-sulazine

Rheumatology: https://www.versusarthritis.org/about-arthritis/treatments/drugs/sulfasalazine/

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.

The British Society for Rheumatology updated guideline on prescribing drugs in pregnancy and breastfeeding 2022 advises the following:

Pregnancy:

Sulfasalazine, with folate supplementation (5 mg/day), taken in the periconception period and during the first trimester is compatible throughout pregnancy.

Information for healthcare professionals: https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-SULFASALAZINE-IN-PREGNANCY/

Information for patients and carers: https://www.medicinesinpregnancy.org/Medicine--pregnancy/Sulfasalazine/

Breastfeeding:

Sulfasalazine is compatible with breastfeeding in healthy, full-term infants.

There have been reports of bloody stools or diarrhoea in infants who were breastfeeding from mothers on sulfasalazine. In cases where the outcome was reported, bloody stools or diarrhoea resolved in the infant after discontinuation of sulfasalazine in the mother.

Information for healthcare professionals: https://www.sps.nhs.uk/medicines/sulfasalazine/

Paternal exposure:

Men taking sulfasalazine may have reduced fertility, due to oligospermia and impaired mobility, which may take 2-3 months to return to normal following treatment cessation.

The British Society for Rheumatology updated guideline on prescribing drugs in pregnancy and breastfeeding 2022 advises 'there is little evidence to suggest that sulfasalazine should be stopped pre-conception, unless conception is delayed by more than 12 months when stopping sulfasalazine should be considered along with other causes of infertility'.

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:

Rheumatology

- Advice and Guidance.
- Consultant Connect
- UHD switchboard – on-call rheumatologist during office hours
- Rheumatology advice line: This is not a direct connection (answerphone service) and is not for emergency calls. It requires patients/clinicians to leave a message via the answerphone service. The messages will be logged, triaged and answered in order of need.

Gastroenterology

- Advice and Guidance
- Consultant Connect
- IBD advice line: This is not a direct connection (answerphone service) and is not for emergency calls. It requires patients/clinicians to leave a message via the answerphone service. The messages will be logged, triaged and answered in order of need.

Dermatology

- Via switchboard to the on-call dermatology doctor (do not use 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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- Salazopyrin tablets. Last updated 5th June 2024. Accessed via https://www.medicines.org.uk/emc/product/3838/smpc
- Sulfasalazine 250mg/5mL oral suspension. Last updated 20th February 2024. Accessed via https://www.medicines.org.uk/emc/product/413/smpc
- British Society of Rheumatology and British Health Professionals in Rheumatology. 2017. Guidelines for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs. Accessed via https://academic.oup.com/rheumatology/article/56/6/865/3053478.
- British Society for Rheumatology guideline on prescribing drugs in pregnancy and breastfeeding: immunomodulatory anti-rheumatic drugs and corticosteroids | Rheumatology | Oxford Academic 2022
- eBNF – accessed via Sulfasalazine | Drugs | BNF | NICE
- UK Teratology Information Service. Use of sulfasalazine in pregnancy. Version 4 November 2024. Accessed via https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-SULFASALAZINE-IN-PREGNANCY/
- Best Use of Medicines in Pregnancy. Last updated November 2024, accessed via https://www.medicinesinpregnancy.org/Medicine--pregnancy/Sulfasalazine/
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- Menter, MD et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 4. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. JAAD: 2009: 61: 3: 451-485. DOI: https://doi.org/10.1016/j.jaad.2009.03.027

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 of time:	
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) Not routinely used in the Dorset system; acceptance of shared care is implied by a nil return.

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 patient's 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