Classification: Official

Publication approval reference: PAR1621_x

National shared care protocol:

Sulfasalazine for patients within adult services

4 July 2022, Version 1

Review date – January 2025

The content of this shared care protocol was correct as of January 2022. As well these protocols, 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.
- Assess for contraindications and cautions (see section 4) and interactions (see section 7).
- Conduct required baseline investigations and initial monitoring (see section 8).
- Initiate 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. Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Once treatment is optimised, complete the shared care documentation and send to patient's GP practice 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 annual 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.
- 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.

Primary care responsibilities

- Respond to the request from the specialist for shared care in writing. It is asked that this be undertaken within 14 days of the request being made, where possible.
- If accepted, prescribe ongoing treatment as detailed in the specialists request and as per section 5, taking into account any potential drug interactions in 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.
- Stop treatment as advised by the specialist.

Patient and/or carer responsibilities

- Take sulfasalazine 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 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.

- 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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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

3. Locally agreed off-label use

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To be agreed and completed locally (include supporting information)

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.

- Transfer of monitoring and prescribing to primary care is normally after the patient has been treated for 3 months, the 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.

5. Initiation and ongoing dose regimen

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- Transfer of monitoring and prescribing to primary care is normally after the patient has been treated for 3 months, the 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):

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:

In patients with GFR <10 mL/min, start at very low dose and monitor.

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) 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 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. 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) and/or aspartate aminotransferase (AST), & albumin
- Full blood count (FBC)
- Weight
- Height and blood pressure
- Assess for co-morbidities which may influence DMARD choice
- Screening for HIV and hepatitis B and C
- 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, but may be sooner in some indications.

- BP
- FBC
- U&Es, including creatinine and CrCl
- AST and/or ALT, albumin, and bilirubin
- Rheumatology patients: C-reactive protein (CRP) &/or erythrocyte sedimentation rate (ESR)

Following a dose change repeat every 2 weeks until the dose has been stable for 6 weeks, then revert to previous schedule.

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.

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 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/or AST and albumin • Rheumatology patients: CRP &/or ESR (both are not routinely required)	Monthly After 12 months no routine monitoring is required for the majority of patients. 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 • Unexplained fall in albumin; less than 30g/L	• Withhold treatment and discuss with specialist.
MCV >105 fL	Consider interruption in treatment. 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.

Acute infection	During serious infections (e.g. requiring intravenous antibiotics or hospitalisation) temporarily withhold sulfasalazine until the patient has recovered. Consider additional investigations (e.g. FBC), if clinically appropriate.
Liver function tests: ALT and/or AST greater than 100units/L And/or a sudden increase (e.g. doubling of baseline) 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 increase 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 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. 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	Consider withholding treatment and discussing with specialist.

• Peripheral neuropathy	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 with regard to 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 should be advised:

- 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 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 BSR and BHPR guideline on prescribing DMARDs in pregnancy and breastfeeding advises the following:

Pregnancy:

Sulfasalazine, with folate supplementation (5 mg/day), 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.

13. Specialist contact information

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Speciality	Contact name	Contact Details
Neurology	**ESNEFT Ipswich Site**	
	Dr Simon Kerrigan Dr Petr Pokorny Dr Mortada Elyas Dr Clare Galton Dr Andrew Graham	Email Secretaries: neurologyipswich@esneft.nhs.uk Tel: 01473 704044 / 01473 704041
	ESNEFT Colchester Site	
	Dr Imtiaz Ahmed Dr Dr Natalia Salari Dr Mohammed Sharief Epilepsy Nurse Specialist	Telephone Secretaries: 01206 742243 Email Secretaries: ch.neurology@esneft.nhs.uk Tel Epilepsy Nurse Specialist: 01206 746472
Gastroenterology	**ESNEFT Ipswich Site**	
	Dr Simon Williams Dr Louise Scovell Dr Yin Miao Dr Abdul Mohsen Dr Hermant Laxaman Dr Adnan Rislan IBD Nurse Specialist	Tel: 01473 703519 Tel: 01473 702535 Tel: 01473 703188 Tel: 01473 703505 Tel: 01473 702114 Tel: 01473 702865 Email: gastrosecs@esneft.nhs.uk Advice and guidance on NHS e-referrals
	ESNEFT Colchester Site	
	Dr Ian Gooding Dr Donagh O'Riordan Dr Mary McStay Dr Achuth Shenoy Dr Simon Ralphs IBD Nurse Specialist	Email secretaries: chu-ftr.gastroenterologysecretaries@esneft.nhs.uk 01206 744231 Email: colchesteribdadviceline@esneft.nhs.uk
Rheumatology	**ESNEFT Ipswich Site**	
	Dr Lane / Dr Watts: Dr Weerakoon / Dr Shand Dr Abdulkader/Dr Ntatsaki	Tel: 01473 702362 Tel: 01473 702039 Tel: 01473 707324 Email: ihn-tr.rheum-sharedcare@nhs.net Advice and guidance on NHS e-referrals
	ESNEFT Colchester Site	
	Dr Paul Byrne Dr Tom Walton Dr Rachel Davies Dr Lauren Steel Clinical Nurse Specialist May Clark Clinical Nurse Specialist Lucy Mascurine	Tel Department: (01206) 742165/742279 Email Nurses: rheumatology.nurseadvice@esneft.nhs.uk

14. Additional information

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Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient's GP or their contact details.

15. References

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- Salazopyrin En tabs. Date of revision of the text 10/2019. Accessed via https://www.medicines.org.uk/emc/product/6686/smpc on 19.08.21
- Salazopyrin tablets. Date of revision of the text 10/2019. Accessed via https://www.medicines.org.uk/emc/product/3838/smpc on 19.08.21
- Sulfasalazine 250mg/5mL oral suspension. Date of revision of the text 21.11.20. Accessed via https://www.medicines.org.uk/emc/product/413/smpc on 19.08.21
- 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 of Rheumatology and British Health Professionals in Rheumatology. 2016. Guideline on prescribing drugs in pregnancy and breastfeeding – Part I: standard and biologic disease modifying anti-rheumatic drugs and corticosteroids. Accessed via https://academic.oup.com/rheumatology/article/55/9/1693/1744535.
- eBNF – accessed via https://bnf.nice.org.uk/on 19.08.21
- UK Teratology Information Service. Use of sulfasalazine in pregnancy. Version 3 October 2020. Accessed via https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-SULFASALAZINE-IN-PREGNANCY/ on 19.08.21
- Best Use of Medicines in Pregnancy. Last updated September 2020, accessed via https://www.medicinesinpregnancy.org/Medicine--pregnancy/Sulfasalazine/ on 18.08.21
- NICE Clinical Knowledge Summaries - DMARD management. Last revised May 2021. Accessed via https://cks.nice.org.uk/topics/dmards/management/ on 17.08.21
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- Briggs G. Drugs in Pregnancy and Lactation, Ninth Edition. Sulfasalazine Monograph.

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.

To be agreed and completed locally

- Please note that ESNEFT-Gastroenterology teams on both sites will transfer patients between week 8 to 12 in line with the locally commissioned pathway and monitoring required in the service.

SNEE Integrated Medicines Optimisation Committee approved 13/02/2024 ESNEFT MGG approved 13/02/2024

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]* for 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 with regard to 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 are in agreement, 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 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