Shared Care Guideline for Severe Adult Psoriasis, Atopic Dermatitis and Eczema

Methotrexate Tablets and Ciclosporin Capsules

Executive Summary/ Critical Information.

Indication	Route & Dose	Key aims of treatment in the long term	Monitoring undertaken by specialist before requesting shared care	On-going monitoring to be undertaken by GP	Duration of treatment	Stopping criteria	Follow up (weeks/months)
SEVERE PSORIASIS	**Methotrexate (MTX), initially 5 mg once a week as a single dose, increasing to a maximum dose of 25 mg once a week according to response. A low starting dose of 2.5mg is essential for the elderly or frail or those with renal impairment.**	**To induce and maintain remission, and relieve symptoms.**	**Prior to starting MTX or CIC:** **FBC, U+Es, LFTs** **Viral serology screen –** **Hepatitis B** **Hepatitis C** **HIV** **Varicella- Zoster virus (VZV)** **Baseline chest x-ray at discretion of clinician *(for methotrexate only).*** **Baseline Pc3P level *(for methotrexate only).***	**FBC** **U+Es** **LFTs** **Measured every 3 months to ensure safe use of medication.**	**MTX: duration will be continually reviewed by the hospital dermatology team.**	**Loss of response** **Toxicity / adverse effects** **Interactions with other drugs**	**<u>Hospital Dermatology Team</u>** **Bloods will be monitored by the hospital dermatology team every 2 weeks for the first 6 weeks (induction phase) and with any increased dose, and then monthly for 3 months.** **Prescription supplies will be managed by the hospital during the first 3 months induction period (i.e. for initial 6 weeks and during first 6 weeks of dose escalation or until the patient can be safely moved to Primary Care).**

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	Ciclosporin (CIC) 2.5 mg/kg daily in 2 divided doses, increased gradually to a maximum of 5 mg/kg/day if no improvement within 1 month.		**The following tests are monitored every 2 weeks for the first 6 weeks (induction phase) and with any increased dose, and then monthly for 3 months.** **FBC** **LFTs** **U+Es** **After 3 months patients can be switched to 3 monthly monitoring of FBC, LFTs and U+Es, and 4 monthly monitoring of PC3P levels.** **More frequent monitoring is required in patients at higher risk of toxicity.**		**CIC: usually up to 16 weeks, although longer course may be recommended by the hospital dermatology team.** **Hospital to assess outcome at 6 weeks and decide if treatment appropriate to stop / continue.** **It is recommended for a patient to use a single or intermittent short course of CIC up to 16 weeks.**		**Patient to be reviewed at least bi-annually by the dermatology clinician.** **<u>Primary Care (once patient stable)</u>** **<u>Bloods</u>: Monitor bloods according to recommended schedule.** **Issue on-going prescriptions.** **<u>Clinical Review</u>: Monitor the patient for loss of response or adverse effects.** **Loss of response is any deterioration in skin condition that is not responsive to additional topical treatment.** **In the event of abnormal bloods including leucopenia, neutropenia, anaemia, renal impairment, elevated ALP, AST or ALT, see section 10.**
SEVERE ATOPIC DERMATITIS	**Methotrexate (MTX), initially 5 mg once a week as a single dose, increasing to a maximum dose of 25 mg once a week according to response. A low starting dose of 2.5mg is essential for the**	**To induce and maintain remission, and relieve symptoms.**	**As above**	**As above**	**Usually up to 16 weeks, although longer courses may be recommended by the hospital dermatology team.** **Hospital to assess**		**Bloods will be monitored by the hospital dermatology team every 2 weeks for the first 6 weeks (induction phase) and with any increased dose, and then monthly for 3 months.** **Prescription supplies will be managed by the hospital during the first 3 months induction period (i.e. for initial 6 weeks and during first 6 weeks of dose escalation or until**

	elderly or frail or those with renal impairment. **Ciclosporin 2.5 mg/kg daily in 2 divided doses, increased gradually to a maximum of 5 mg/kg/day if no improvement within 2 weeks.**				**outcome at 8 weeks and decide if treatment appropriate to stop / continue.** **It is unusual for a patient to require a course longer than 6 months.**		**the patient can be safely moved to Primary Care).** **Patient to be reviewed at least bi-annually by the dermatology clinician.** **<u>Primary Care (once patient stable)</u>** **<u>Bloods</u>: Monitor bloods according to recommended schedule** **Issue on-going prescriptions.** **<u>Clinical Review</u>: Monitor the patient for loss of response or adverse effects.** **Loss of response is any deterioration in skin condition that is not responsive to additional topical treatment.** **In the event of abnormal bloods including leucopenia, neutropenia, anaemia, renal impairment, elevated ALP, AST or ALT, see section 10.**
SEVERE ECZEMA	**Methotrexate (MTX), initially 5 mg once a week as a single dose, increasing to a maximum dose of 25 mg once a week according to response. A low starting dose of 2.5mg is essential for the elderly or frail or**	**To induce and maintain remission, and relieve symptoms.**	**As above**	**As above**	**Usually up to 16 weeks, although longer courses may be recommended by the hospital dermatology team.** **Hospital to assess outcome at 8**		**Bloods will be monitored by the hospital dermatology team every 2 weeks for the first 6 weeks (induction phase) and with any increased dose, and then monthly for 3 months.** **Prescription supplies will be managed by the hospital during the first 3 months induction period (i.e. for initial 6 weeks and during first 6 weeks of dose escalation or until**

	those with renal impairment.				**weeks and decide if treatment appropriate to stop / continue.** **It is unusual for a patient to require a course longer than 6 months.**		**the patient can be safely moved to Primary Care).** **Patient to be reviewed at least bi-annually by the dermatology clinician.** **<u>Primary Care (once patient stable)</u>** **<u>Bloods</u>: Monitor bloods according to recommended schedule** **Issue on-going prescriptions.** **<u>Clinical Review</u>: Monitor the patient for loss of response or adverse effects.** **Loss of response is any deterioration in skin condition that is not responsive to additional topical treatment.** **In the event of abnormal bloods including leucopenia, neutropenia, anaemia, renal impairment, elevated ALP, AST or ALT, see section 10.**

Key Safety Notice (for instance: notification if prescribing must be brand specific or BNF cautionary and advisory warnings).

Methotrexate – ONCE WEEKLY dosing and always prescribe and dispense as **2.5mg tablets**. Folic acid – prescribe 5mg to be taken DAILY except on methotrexate days. Metoclopramide may be used to prevent nausea; 10mg, 30 minutes before methotrexate. Ongoing use of metoclopramide should be reviewed by the dermatology clinician during routine appointments AND by the GP prior to issuing repeat prescriptions.

Ciclosporin – Patients should be stabilised on a particular brand of oral ciclosporin. Prescribing and dispensing of ciclosporin should be by brand name to avoid inadvertent switching, which may lead to clinically important changes in blood-ciclosporin levels. (MHRA/CHM 2009).

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For all medications - patients should be warned to report immediately the onset of sore throat, bruising and mouth ulcers, liver toxicity (nausea, vomiting, dark urine and abdominal discomfort) and respiratory effects (cough or shortness of breath for those taking methotrexate).
Other
It is important that patients do not have a break in treatment unless recommended by a healthcare professional. In the event of an interruption in supply due to drug shortages, inform the hospital via email: bartshealth.med-dermadmin@nhs.net

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1. Background

Methotrexate is used as a disease-modifying agent to induce and maintain remission in severe psoriasis, atopic dermatitis and eczema unresponsive to conventional therapy. Methotrexate inhibits the enzyme dihydrofolate reductase, essential for the synthesis of purines and pyrimidines. The predominant toxic effects are myelosuppression and rarely pneumonitis. Methotrexate is excreted by the kidney and is therefore contraindicated in patients with significant renal impairment.

Ciclosporin is used as a disease-modifying agent to induce and maintain remission in severe psoriasis and atopic dermatitis unresponsive to conventional therapy. Ciclosporin, a calcineurin inhibitor, is a potent immunosuppressant that is virtually non-myelotoxic but markedly nephrotoxic.

This guideline sets out prescribing and monitoring responsibilities to facilitate shared care of these medications.

2. Important information

Monitoring by Secondary Care
As above

Monitoring by Primary Care

As above

3. Drug name, form, and licensed indications (unlicensed / off-label)

Methotrexate (available as 2.5mg tablets) is used to induce and maintain remission in in severe psoriasis, atopic dermatitis and eczema unresponsive to conventional therapy. This is a licensed indication for severe psoriasis and an unlicensed indication for severe atopic dermatitis and severe eczema.

Ciclosporin (available as 10mg, 25mg, 50mg and 100mg capsules) is used to induce and maintain remission in severe psoriasis and severe atopic dermatitis unresponsive to conventional therapy. These are unlicensed indications.

4. Dose and Administration

Methotrexate

Severe psoriasis, atopic dermatitis and eczema: starting dose of **5mg ONCE A WEEK as a single dose.**
A low starting dose of 2.5mg is often used for the elderly or those with renal impairment.
Folic acid is co-prescribed: 5mg once daily, except for methotrexate day, and is useful if nausea, abdominal discomfort, diarrhoea or anorexia associated with methotrexate is a problem.
Clinical response is usually evident in 4 - 6 weeks but may take up to 12 weeks.
Metoclopramide may be used to prevent nausea, 10mg taken, 30 minutes before methotrexate.
All dose titrations will be carried out by the specialists in secondary care.
Ciclosporin

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Severe psoriasis: 2.5 mg/kg daily in 2 divided doses, increased gradually to a maximum of 5 mg/kg/day if no improvement within 1 month. Therapy discontinued if response still insufficient or effective dose not tolerated after 6 weeks.

Initial treatment of 5 mg/kg/day justified if condition requires rapid improvement. Treatment is usually for up to 16 weeks but can be continued longer at the recommendation of a specialist.

Severe atopic dermatitis: 2.5 mg/kg daily in 2 divided doses, increased gradually to a maximum of 5 mg/kg/day if no improvement within 2 weeks. Therapy discontinued if response still insufficient after 8 weeks. Initial treatment of 5 mg/kg/day justified if condition requires rapid improvement. Treatment is usually for up to 16 weeks but can be continued longer at the recommendation of a specialist.

5. Contraindications / Cautions

Immunisation with LIVE vaccines	Patients on methotrexate or ciclosporin must NOT receive immunisation with LIVE vaccines, such as polio, MMR, BCG, Zostavax, or yellow fever Annual influenza vaccination (provided it is not a LIVE vaccine) is recommended and pneumococcal vaccination should be considered.
Chickenpox / Shingles	Patients should avoid contact with those who have ACTIVE chickenpox or shingles and should report any such contact immediately to the hospital specialist to allow a management plan to be made.
Pregnancy / Breastfeeding	Sexually active females should use at least two forms of contraception and have a pregnancy test prior to starting methotrexate, where applicable. Patients planning on becoming pregnant should consult their specialist so that optimal disease control and modification of medical strategy can be considered. Methotrexate causes embryotoxicity, abortion and foetal defects in humans. Therefore, the possible risks of effects on reproduction should be discussed with patients of child-bearing potential. Female and male patients should STOP methotrexate at least 6 months prior to conception due to proven teratogenic impact of this medication. There is less evidence that male patients should stop methotrexate should they want to father a child and careful discussion with the dermatology team is recommended. If a female becomes pregnant whilst on methotrexate this should be stopped immediately and urgent advice sought from the dermatology team and obstetric department. Methotrexate is contraindicated during breastfeeding. Methotrexate affects spermatogenesis and oogenesis and may therefore decrease fertility. This effect appears to be reversible after discontinuation of therapy. Patients and their partners should be advised to avoid pregnancy until 6 months after cessation of methotrexate therapy. Careful assessment of risk versus benefit to be considered before ciclosporin use during pregnancy and breastfeeding.

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Obesity, Diabetes Mellitus or excessive alcohol intake	Increased risk of liver damage in patients on methotrexate
Renal / Hepatic impairment	Ciclosporin is contraindicated in moderate / severe renal or liver impairment
Uncontrolled infection	Methotrexate and ciclosporin are contraindicated
Uncontrolled hypertension	Ciclosporin is contraindicated
Malignancy	Ciclosporin is contraindicated
Digoxin	Reduced absorption of digoxin (MTX only)
Probenecid	Renal elimination of ciclosporin is reduced
Grapefruit juice	Concomitant intake of grapefruit juice increases the bioavailability of ciclosporin and should be avoided
Erythromycin, fluconazole, itraconazole, diltiazem	Increase ciclosporin levels via cytochrome p450
Carbamazepine, phenytoin, rifampicin, St. John's Wort	Decrease ciclosporin levels via cytochrome p450
Potassium sparing diuretics, angiotensin II receptor antagonists and potassium	Concomitant use with ciclosporin may increase risk of hyperkalemia

For a complete list of cautions / contraindications, please refer to the SPC:
https://www.medicines.org.uk/emc

6. Drug interactions

Concomitant use of nephrotoxic, hepatotoxic or myelotoxic drugs should be avoided.
For a complete list of cautions / contraindications and drug interactions, please refer to the SPC: https://www.medicines.org.uk/emc

7. Side effects which require managing

The frequencies of the adverse reactions are classified as follows: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100).

Adverse effects	**Drug**	
	Methotrexate	**Ciclosporin**
Infections	Common	Common
Opportunistic infections	Uncommon	Uncommon
Lymphoma	Uncommon	Uncommon

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Blood and lymphatic system disorders		
Leucopenia	Common	Common
Bone marrow suppression	Uncommon	-
Agranulocytosis	Uncommon	-
Thrombocytopaenia	Uncommon	Uncommon
Anaemia	Uncommon	Uncommon
Hematopoietic disorders	Uncommon	-
Anaphylactic type reaction	Uncommon	-
Nervous system disorders		
Tremor	-	Very common
Headache	Common	Very common
Drowsiness	Common	-
Dizziness	Common	-
Fatigue	Common	Common
Paraesthesia	-	Common
Convulsions	-	Common
Vertigo	Uncommon	-
Signs of encephalopathy	-	Uncommon
Nosebleed	Uncommon	
Hepatobiliary disorders		
Abnormal liver function tests (increased ALAT, ASAT, alkaline phosphatase and bilirubin)	Very common	Common
Decrease in serum albumin	Common	-
Fatty degeneration of the liver	Common	-
Renal and urinary disorders		
Renal insufficiency	Uncommon	Very common
Nephropathy	Uncommon	-
Inflammation and ulceration of the urinary bladder	Uncommon	-
Disturbed micturition	Uncommon	-
Dysuria	Uncommon	-
Gastrointestinal disorders		
Stomatitis	Very common	-
Dyspepsia	Very common	-

Anorexia	Very common	-
Nausea	Very common	Common
Vomiting	Very common	Common
Abdominal pain	Very common	Common
Oral ulcer	Common	-
Diarrhoea	Common	Common
Gingival hyperplasia	-	Common
Peptic ulcer	-	Common
Respiratory disorders		
Pneumonitis	Uncommon	-
Interstitial pneumonitis	Uncommon	-
Interstitial / pulmonary fibrosis	Uncommon	-
Vaginal inflammation and ulceration	Uncommon	-
Chills	Uncommon	-
Metabolism and nutrition disorders		
Hyperlipidaemia	-	Very common
Anorexia	-	Common
Hyperuricaemia	-	Common
Hyperkalaemia	-	Common
Hypomagnesaemia	-	Common
Hyperglycemia	-	Common
Vascular disorders		
Hypertension	-	Very common
Flushing	-	Common
Skin and subcutaneous tissue disorders		
Hirsutism	-	Very common
Erythematous rash	Common	-
Alopecia	Common	-
Exanthema	Common	-
Acne	-	Common
Hypertrichosis	-	Common
Pruritus	Uncommon	-
Stevens-Johnson´s syndrome	Uncommon	-
Toxic epidermal necrolysis	Uncommon	-
Herpetiform eruptions of the skin	Uncommon	-

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Increased skin pigmentation Allergic rashes	Uncommon -	- Uncommon
Musculoskeletal and connective tissue disorders		
Osteoporosis Arthralgia Increased rheumatic nodules Myalgia Muscle cramps	Uncommon Uncommon Uncommon Uncommon -	- - - Common Common
General disorders		
Pyrexia Oedema Weight increase	- - -	Common Uncommon Uncommon

Ciclosporin: Increases in serum creatinine and urea during first few weeks of therapy dose are generally dose-dependant and reversible, usually reversible on dose reduction.

Ciclosporin: Lymphadenopathy - if the patient develops a single swollen lymph node that is NOT related to inflamed skin, stop the ciclosporin and refer the patient to the specialist for review.

For complete list of side effects, please refer to the SPC: https://www.medicines.org.uk/emc.

8. Process for Referral Back to Secondary Care

If a GP has taken blood tests for the general medical management of a patient and blood test results fall into any of the categories listed below or the patient reports one of the adverse events listed in section 7, the patient should be told to stop the immunosuppressant and the hospital dermatology team should be informed by email: bartshealth.med-dermadmin@nhs.net. Further assessment and or medication will be organised from secondary care.

Adverse effects	Action
<u>Blood test results</u> **WBC < 4.0 x 10^9/L** **Neutrophils < 2.0 x 10^9/L** **Significant increase in serum creatinine (>15%) or potassium** **Significant decrease in serum magnesium** **GFR <60 or creatinine rise >30% over 12 months** **ALT/AST >2x UL** **Platelets <150 x 10^9/L**	Consider withholding medication and contact dermatology specialist team.

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<u>Signs and symptoms</u> **Increase in blood pressure** **Paraesthesia** **Gum hypertrophy** **Hypertrichosis**	
MCV > 105 fl	Check B12, folate and thyroid function tests (TFTs). If low, start appropriate supplementation. Check alcohol status. If no cause found, discuss with specialist.
New or increasing dyspnoea or persistent cough (with no other obvious cause – suspected pneumonitis)	**Stop methotrexate** and discuss with specialist
Rash or oral ulceration	**RASH** - Withhold until symptoms clear. Consider re-challenging at a lower dose. If rash recurs, stop drug and discuss with specialist. **MOUTH ULCERS** – Check FBC for leucopenia. May respond to increasing folic acid if on MTX or by treating with an OTC mouth ulcer medication. If severe despite extra folic acid stop methotrexate and refer to a specialist for advice.
Hypersensitivity reactions	Fever, malaise, rash, vomiting, muscle / bone pain, dizziness. Stop drug and discuss with specialist.
Abnormal bruising, bleeding or sore throat	Withhold until FBC result available.
Nausea, vomiting, diarrhoea	Recommend taking methotrexate tablets after meals to reduce nausea. An anti-emetic or dose reduction may help (or splitting the dose in divided doses). If symptoms persist, stop drug and discuss with specialist. There is a possibility to switch to subcutaneous methotrexate to avoid nausea side effects.
Suspected infection requiring antibiotics	Check FBC for leucopenia. Withhold temporarily until infection clears.

9. Monitoring and Responsibilities

a. Hospital specialist:

- Initiate, stabilise and prescribe treatment during the *induction phase* (6 weeks) and until the GP formally agrees to share care (as a minimum, supply the first 3 months treatment or until the patient is stabilised). This will include monitoring safety, adverse events, and clinical response to therapy as well as drug levels where appropriate.
- Send a letter to the GP requesting shared care for this patient.

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- Laboratory supervision of the patient on a regular basis (every 2 weeks) for the 6 week induction phase and for 6 weeks following any dose increment. And then every 1 - 3 months for patients receiving continuation of the course.
- Send a letter to the GP after each clinic attendance ensuring current dose and most recent blood results are documented. Where monitoring is via virtual contact, a letter will be sent when to update the GP of any dose change.
- Evaluation of any reported adverse effects by GP or patient.
- Advise GP on review, duration or discontinuation of treatment where necessary.
- Inform GP of patients who do not attend clinic appointments.
- Inform GP, by letter, of clinic visits and action taken for management of patient.

Pre-treatment monitoring	Viral serology screen (HIV, Hepatitis B and C, VZV), urinalysis (MTX only) CRP, FBC, Renal profile, U+Es, LFTs (ALT and / or AST, ALP), blood pressure (CIC only), lipid profile (CIC only)
Monitoring during Induction	FBC – every 2 weeks for the first 6 weeks (induction phase) and with any increased dose, and then monthly for 3 months U+Es – every 2 weeks for the first 6 weeks (induction phase) and with any increased dose, and then monthly for 3 months ALT / AST / ALP – every 2 weeks for the first 6 weeks (induction phase) and with any increased dose, and then monthly for 3 months. Consider liver biopsy if persistently raised Blood pressure – every 1 –3 months Lipid profile – 6 monthly Chest x-ray and lung function tests if symptoms occur (MTX only) Procollagen 3 propeptide levels every 4 months (MTX only) – refer to hepatology if raised

b. General Practitioner / Primary Care:

- Monitor patient's overall health and well-being.
- Ensure patient is up to date with cancer screening programmes.
- In times of disease activity / flare ups, inform the hospital specialist.
- After induction, monitor routine bloods (renal profile / liver function tests / FBC / CRP) every 3 months if patient is stable. Refer back to hospital specialist via contact details below if toxicity is suspected – refer to section 8 above.
- Provide on-going prescriptions every 3 months as appropriate.
- Report any adverse events to the consultant, where appropriate.
- Report any adverse events via the yellow card scheme, where appropriate.
- Discuss need for annual influenza immunisation and pneumococcal vaccination.
- Contact hospital dermatology team if concerned about toxicity or overdose.

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c. Patient or parent / carer:

- Ensure they have a clear understanding of their treatment and potential adverse effects.
- Report any adverse effects to their GP and / or hospital dermatology team.
- Report any changes in disease symptoms to GP and / or hospital dermatology team.
- Alert GP and / or specialist of any changes of circumstance which could affect management of disease e.g. plans for pregnancy.

10. Contact Information for Advice and Support

	Phone number / email address
Main switchboard	0207 377 7000
Consultant Dermatologists *Dr Anthony Bewley* *Dr Malvina Krupiczojc* *Dr Thiviyani Maruthappu* *Dr Rebeca Goiriz* *Dr Bryan McDonald* *Dr Richard Bull* *Dr Suchitra Chinthapalli* *Dr Portia Goldsmith* *Dr Catherine Harwood* *Dr Arucha Ekeowa-Anderson* *Dr Sarah Mehrtens*	bartshealth.med-dermadmin@nhs.net
Clinical Nurse Specialists *Angela Braeger* *Rosalyn Eldridge*	bartshealth.med-dermadmin@nhs.net
Registrar on–call out of hours	*Air call via switchboard*
Dermatology Pharmacist	0208 535 6404 (Whipps Cross)

11. References

BAD guidance
https://www.medicines.org.uk/emc

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12. Document Management

Document ratification and history	
Produced by:	Bart Health NHS Trust Usha Hawker (Lead Specialist Medicine Pharmacist) and Dr Malvina Krupiczojc (Dermatology Consultant)
Approved by:	Waltham Forest and East London Medicines Optimisation and Commissioning Committee (WELMOCC)
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Appendix 1

Shared Care Guideline: Prescribing Agreement	
Section A: To be completed by the hospital consultant initiating the treatment	
GP Practice Details: Name: Tel No: Email (nhs.net):	**Patient Details:** Name: DOB: NHS Number (10 digits):
Consultant Details: Consultant Name: Secretary Contact Details: Tel No: Email (nhs.net):	
Diagnosis:	**Drug Name (to be prescribed by GP):** **Dose:** **Frequency:**
I will review the patient in clinic in weeks / months (*Delete as appropriate)*.	

Dear

Your patient started treatment with the above drug for the above diagnosis on (insert date) and in my view; his/her condition is now stable.

The patient has given consent to treatment under a shared care prescribing agreement and has agreed to comply with instructions and follow up requirements.

I am requesting your agreement to sharing the care of this patient from (insert date) in accordance with the attached Shared Care Prescribing Guideline.

This patient was reviewed on (insert date). These are the results relevant for the drug and/or condition, as outlined in the shared care document:

Test	Baseline	Date

Please continue to monitor the patient as outlined in the shared care guidelines. Refer to the attached guidelines for monitoring criteria.

Other relevant information:

Consultant Signature:	Date:

Section B: To be completed by the GP and returned to the hospital consultant as detailed in Section A above [If returned via e-mail, use NHS.net email account ONLY]

Please sign and return your agreement to shared care within 14 days of receiving this request.

☐ Yes, I accept sharing care as per shared care prescribing guideline.

☐ No, I am not willing to undertake shared care for this patient for the following reason:

(Please give reason)

GP Name:	GP Signature:	Date:

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