Effective Shared Care Agreement (ESCA)

Methotrexate

ESCA: For the treatment of active Crohn's disease despite repeated attempts to treat with steroids, 5 ASAs and Azathioprine or 6-Mercaptopurine

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of methotrexate in active Crohn's disease despite repeated attempts to treat with steroids, 5 ASAs and azathioprine or 6-mercaptopurine can be shared between the specialist and general practitioner (GP). You are **invited** to participate however, if you do not feel competent to undertake this role, then you are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care will be explained to the patient by the specialist initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. Patients with active Crohn's disease are usually under regular specialist follow-up, which provides an opportunity to discuss drug therapy.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

RESPONSIBILITIES and ROLES

Specialist responsibilities
1. Confirm the diagnosis of active Crohn's disease.
2. Discuss the potential benefits, treatment side effects, and possible drug interactions with the patient.
3. Ask the GP whether he or she is willing to participate in shared care before initiating therapy so that appropriate follow on prescribing arrangements can be made.
4. Do baseline monitoring prior to initiation of methotrexate.
5. Initiate treatment and stabilise dose of methotrexate **using 2.5 mg increments and only as a once weekly dose.** **Please note: Oral methotrexate 10 mg tablets are not recommended for use in the BSSE health economy.** **Please note: Parenteral methotrexate – ensure that the patient** • **has had the appropriate training to self-administer methotrexate** • **has been advised about safe disposal using a purple lidded sharps bin** • **has been advised about steps to take to in an event of a spillage (leaflet or the provision of a spillage kit)**
6. Ensure all patients receive a methotrexate patient information leaflet & dosage record booklet – as per NPSA alert.
7. Review the patient's condition and monitor response to treatment regularly.
8. A written summary to be sent promptly to the GP i.e. within 10 working days of a hospital outpatient review or inpatient stay.
9. Report serious adverse events to the MHRA.
10. Ensure clear backup arrangements exist for GPs, for advice and support (please complete details below).
General Practitioner responsibilities
1. Reply to the request for shared care as soon as practicable i.e. within 10 working days.
2. Prescribe methotrexate at the dose recommended **using 2.5 mg increments and only as a once weekly dose.** **Please note: Oral methotrexate 10 mg tablets are not recommended for use in the BSSE health economy.** **Please note: Parenteral methotrexate – ensure that the patient** • **has had the appropriate training to self-administer methotrexate** • **has been advised about safe disposal using a purple lidded sharps bin. Prescribe a Sharpsafe purple lidded sharps bin or a Sharpsguard purple lidded sharps bin or follow locally agreed process** • **has been advised about steps to take to in an event of a spillage (leaflet or the provision of a spillage kit) or follow locally agreed process**
3. Adjust the dose as advised by the specialist and update the methotrexate patient information leaflet & dosage record booklet – as per NPSA alert.
4. In the patient's notes, using the appropriate Read Code listed below, denote that the patient is receiving treatment under a shared care agreement.

GP Prescribing System	Read Code	Description		GP Prescribing System	Read Code	Description
EMIS and Vision	8BM5.00	Shared care prescribing		SystmOne	XaB58	Shared care

5. Monitor patient's response to treatment; make dosage adjustments if agreed with specialist
6. Report to and seek advice from the specialist or clinical nurse specialist on any aspect of patient care that is of concern to the GP, patient or carer and may affect treatment.
7. Refer back to specialist if condition deteriorates.
8. Report serious adverse events to specialist and MHRA.
9. Stop treatment on advice of specialist.
Patient's role
1. Take/administer the methotrexate on the same day each week. If using methotrexate injection, ensure that the used injection is disposed of in the purple lidded sharps bin. If there is a methotrexate spillage, please follow the instructions issued to you by the specialist.
2. Report to the specialist, clinical nurse specialist or GP if he or she does not have a clear understanding of the treatment.
3. Share any concerns in relation to treatment with methotrexate with the specialist, clinical nurse specialist or GP.
4. Ensure that the methotrexate patient information leaflet & dosage record booklet is presented to the consultant, GP and community pharmacists.
5. Report any adverse effects to the specialist or GP whilst taking methotrexate.
6. Attend regular outpatient appointments with the specialist.

BACK-UP ADVICE AND SUPPORT

Trust	Contact details	Telephone No.	Email address:
	Consultant:-		
	Specialist Nurse		

SUPPORTING INFORMATION

Indication	Oral, subcutaneous or intramuscular injection, unlicensed therapy for IBD. Crohn's disease	
Dosage and Administration British Society of Gastroenterology recommendation	**Important note regarding the preparation** Supply **only** 2.5 mg strength tablets, as it reduces the risk of accidental overdose (see NPSA Alert – Improving compliance with oral methotrexate guidelines). **Please note: Oral methotrexate 10 mg strength is not recommended for use in the BSSE health economy.**	
	Oral route	Initially 15 mg **once per week** as a single dose, increasing to 20 mg once per week after 2 weeks and up to a maximum of 25 mg once a week after a further 2 weeks as tolerated and according to response. A lower starting dose may be required for the elderly or frail or those with renal impairment. Clinical response is usually evident in 4-6 weeks.
	Parenteral Administration	25 mg **once per week** for up to 16 weeks, then reduced to 15 mg **once a week.**
Renal Impairment	Methotrexate is contra-indicated in the presence of severe/significant renal impairment	
Hepatic impairment	Methotrexate is contra-indicated in the presence of significant hepatic impairment.	
Contra-indications / Special precautions	**Refer to SPC**	
Side effects	**Refer to SPC**	
Monitoring British Society of Gastroenterology recommendation	**Pre- treatment assessment**	Avoid use in patients with known liver disease (including fatty liver), alcohol excess, obesity, diabetes or women trying to conceive (negative pregnancy test may be required.) FBC, U&E, LFTs Pre-treatment - pulmonary function tests and CXR may be considered for some patients
	Monitoring	FBC, U&E, LFTs **every 2 weeks** after the last dose change; thereafter monthly until stabilised. Monitoring frequency every 2 - 3 months if patients results remain stable

Action to be taken : British Society of Gastroenterology recommendation	
WBC < 3.5 x 10^9/l	Withhold treatment and recheck in 1 week Discuss with Specialist team
Neutrophils < 2.0 x 10^9/l	Withhold treatment and recheck in 1 week Discuss with Specialist team
Platelets < 150 x 10^9/l	Withhold treatment and recheck in 1 week Discuss with Specialist team
MCV > 105 fl	Check serum B12, folate & TFT and Discuss with Specialist team
AST, ALT > 2 fold rise (from the upper limit of the reference range)	Consider for liver biopsy when persistent elevation occurs. Discontinue treatment in patients with abnormal LFT's who decline liver biopsy - **as per BSG guidance**
Albumin – unexplained fall in the absence of active disease	Discontinue treatment Discuss with Specialist team Monitor closely and consider need for liver biopsy
Nausea Rashes or oral ulceration, vomiting & diarrhoea	Nausea occurs commonly & may be reduced by changing timing of dose (before bedtime), ensure adequate intake of folic acid, & consider antiemetic at time of weekly dose Withhold treatment and recheck for signs of rashes or oral ulceration, vomiting & diarrhoea have subsided after 1 week Discuss with Specialist team
Renal function – significant deterioration compared to baseline or upper limit of normal of reference range	Withhold treatment and recheck results Discuss with Specialist team
Severe sore throat, abnormal bruising	Immediate FBC and withhold until the result of FBC is available
New or increasing dyspnoea or dry cough	Withhold treatment; CXR & pulmonary function tests; Discuss with Specialist team
Important notes	• If patient is systemically unwell and requiring antibiotics- withhold treatment for a minimum of one week. Repeat FBC 1 week after recommencing methotrexate • Live vaccines should not be administered • Influenza and pneumovax vaccines are recommended • Patients without immunity who are exposed to chickenpox or shingles should be administered varicella zoster immunoglobulin • Contraception during treatment is recommended
Side effects	**Refer to SPC**

Please note the information included in this document is correct at the time of writing. The manufacturer's Summary of Product Characteristics (SPC) and the most current edition of the British National Formulary should be consulted for up to date and more detailed prescribing information.

References

- SmPC Maxtrex Tablets
- British Society of Gastroenterology - Guidelines for the management of inflammatory bowel disease in adults (2019)
- Archived NPSA Alert - Improving compliance with oral methotrexate guidelines 2006

I agree to participate in this shared care agreement for the treatment of the below named patient with methotrexate in active Crohn's disease despite repeated attempts to treat with steroids, 5 ASAs and azathioprine or 6-mercaptopurine.

General Practitioner
Name (please print)_____Signature_____Date_____

Hospital Specialist/Consultant
Name (please print)_____Signature_____Date_____

Patient's name	Date of birth	Sex	Home Address	Hospital Number
				NHS Number

Please keep a copy of this agreement for your own records and forward the original to the above named Consultant at: