

NOTTINGHAMSHIRE AREA PRESCRIBING COMMITTEE SHARED CARE PROTOCOL AGREEMENT

Management of Inflammatory Bowel Disease in ADULTS with AZATHIOPRINE, 6-MERCAPTOPYRINE or METHOTREXATE

OBJECTIVES

- Define the referral procedure from hospital to GP and vice versa.
- Define the back up care available from the Gastroenterology departments.
- Provide a summary of information on azathioprine, 6-mercaptopurine and methotrexate therapy to GPs.

REFERRAL CRITERIA

- Prescribing responsibility will only be transferred when it is agreed by the specialist and the patient's primary care prescriber that the patient's condition is stable.
- Prescribing responsibility will only be transferred to the patient's primary care prescriber once the prescriber has agreed to each individual case.

REFERRAL PROCESS

- The request for shared care should be accompanied by individual patient information, outlining all relevant aspects of the patients' care including:
 - Diagnosis of the patient's condition with the relevant clinical details.
 - Details of treatment to be undertaken by GP*.
**Including reasons for choice of treatment, drug or drug combination, frequency of treatment (including the day of the week if weekly treatment), number of months of treatment to be given before review by the consultant.*
 - Details of the patient's treatment to date (if relevant).
 - Date that treatment was started for each drug being transferred to shared care
 - Details of any recent dose changes (in the past 6 months).
 - Details of all other treatment that is not included in shared care being received by the patient – e.g. analgesics, anti-TNFs etc.
 - Details of current contraception if relevant
 - Details of monitoring arrangements.
 - Allergies.
 - Identified interactions and any action taken.
 - Details of medication supplied and when the patient is due to need a new supply.
 - Details of influenza and/or pneumococcal vaccines are given (to ensure that vaccinations are not duplicated).
 - Direction to the information sheets at www.nottsapc.nhs.uk.
- If the GP does not agree to share care for the patient then he/she will inform the Specialist of this decision in writing within 14 days.
- In the interim, the clinical responsibility and supply of the medicine under issue to the patient will be retained by the prescriber who initiated the treatment.
- In cases where shared care arrangements are not in place or where problems have arisen within the agreement and patient care may suffer, the responsibility for the patients' management including prescribing reverts back to the specialist.
- If an updated version of this shared care protocol is not received by the review date listed the medicine automatically reverts back to RED classification and this shared care guideline is no longer valid.

BACKGROUND INFORMATION AND SCOPE

The imidazole purine analogues azathioprine and mercaptopurine are the most widely used immunosuppressive agents in Inflammatory Bowel Disease and have been in use since the 1960s. Mercaptopurine is the active metabolite of azathioprine. Azathioprine and mercaptopurine appear identical in their pharmacologic and biologic effects, but their exact mode of action is unknown. In Inflammatory Bowel Disease, they are used in patients with steroid-dependent, frequently relapsing disease. Both agents can cause serious adverse reactions including leucopenia and thus require regular monitoring, cautious dose titration and awareness of drug interactions.

Methotrexate acts in an anti-inflammatory manner, probably through inhibition of cytokine and eicosanoid synthesis. Currently, methotrexate is positioned as a second-line immunosuppressive agent in a patient resistant or intolerant of azathioprine or mercaptopurine.

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

CONDITION TO BE TREATED

Inflammatory Bowel Disease.

AREAS OF RESPONSIBILITY

Specialists Roles and Responsibilities

The specialist will:

1. Confirm the working diagnosis.
2. Recommend and initiate the treatment.
3. Suggest that shared care may be appropriate for the patient's condition.
4. Ensure that the patient has an adequate supply of medication (usually 28 days) until shared care arrangements are in place. Further prescriptions will be issued if, for unseen reasons, arrangements for shared care are not in place at the end of 28 days. Patients should not be put in a position where they are unsure where to obtain supplies of their medication.
5. If shared care is considered appropriate for the patient, and the patient's treatment and condition are stable, the specialist will contact the GP.
6. Provide the patient's GP with relevant patient information as described in the referral process above.
7. Review patients annually and send a written summary within 14 days to the patient's GP.
8. Provide training for primary care prescribers if necessary to support the shared care agreement.
9. Make contact details for the specialist team available to primary care prescribers (working and non-working hours).
10. Supply details for fast track referral.
11. Provide the patient with details of their treatment, follow up appointments, monitoring requirements and nurse specialist contact details.
12. Counsel the patient particularly on contraception if appropriate (please see individual medication information sheet).

Primary Care Prescribers Roles and Responsibilities

The GP will be responsible for:

1. Ensuring that he/she has the information and knowledge to understand the therapeutic issues relating to the patients' clinical condition.
2. Undergoing any additional training necessary in order to carry out a practice-based service.
3. Agreeing that in his / her opinion the patient should receive shared care for the diagnosed condition unless good reasons exist for the management to remain within secondary care.
4. Prescribing the maintenance therapy in accordance with the written instructions contained within the GP information sheets, and communicating any changes of dosage to the patient.
5. Administration of influenza, pneumococcal and any other vaccines recommended in the national schedules/advice as appropriate.
6. Reporting any adverse effect in the treatment of the patient to the consultant.
7. Ensuring that the patient is monitored according to the Nottinghamshire Area Prescribing Committee shared care agreement for inflammatory bowel disease and will take the advice of the referring consultant if there are any amendments to the suggested monitoring schedule.
8. Ensuring that the patient is given the appropriate appointments for follow up and monitoring, and those defaulting from follow up are contacted to arrange alternative appointments. It is the GPs responsibility to decide whether to continue treatment in a patient who does not attend appointments required for follow up and monitoring. As a guide, a telephone or written reminder should be sent to the patient if follow up is 1-2 weeks late. A telephone reminder is necessary if follow up is 3 weeks late. A written letter stating that medication will be stopped and consultant informed is necessary if follow up is 4 weeks late.
9. For methotrexate: Female patients must not become pregnant whilst taking this medication. Advice should be given to use two methods of contraception throughout this period.

Community Pharmacist Roles and Responsibilities

The community pharmacist will

1. Professionally check prescriptions to ensure they are safe for the patient and contact the GP if necessary to clarify their intentions.
2. Fulfil legal prescriptions for medication for the patient unless they are considered unsafe.
3. Counsel the patient on the proper use of their medication.
4. Advise patients suspected of experiencing an adverse reaction to their medicines to contact their GP.

Patient's Roles and Responsibilities

The patient will:

1. Take their medication as agreed, unless otherwise instructed by an appropriate healthcare professional.
2. Attend all follow-up appointments, regular blood tests, routine influenza and pneumococcal vaccinations with GP and specialist. If they are unable to attend any appointments they should inform the relevant practitioner as soon as possible and arrange an alternative appointment.
3. Inform all healthcare professionals of their current medication prior to receiving any new prescribed or over-the-counter medication.
4. Report all suspected adverse reactions to medicines to their GP.
5. Ensure not to run out of their medications, request a supply of maintenance therapy in a timely manner, and store their medication securely away from children.
6. Read the information supplied by their GP, specialist and pharmacist and contact the relevant practitioner if they do not understand any of the information given.

REFERENCES

Lamb CA, Kennedy NA, Raine T, *et al.* British Society of Gastroenterology consensus guidelines on the management of inflammatory bowel disease in adults. *British Society of Gastroenterology*. 2019, available at www.bsg.org.uk

Gastroenterology Support and Advice - Please contact the appropriate Inflammatory Bowel Disease Nurse Specialist or in their absence the patient's Gastroenterologist, if you require any advice about treatment or disease management within this client group

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Associate Specialist	
Dr J Iqbal	extension 5675

Out of hours

A Consultant, Specialist Registrar or Pharmacist may be contacted via the appropriate hospital switchboard.

Version Control- Management of Inflammatory Bowe Disease in Adults			
Version	Author(s)	Date	Changes
2.1	Shary Walker - Interface and Formulary Pharmacist	11/2020	- Statement on influenza & other vaccines - Information re: vaccination, ordering repeat prescription and blood tests added under patient's responsibilities - Contacts updated
2.2	Shary Walker	12/2021	Added counselling and contraception responsibilities for methotrexate