NHS Somerset

Shared Care Protocol

For disease-modifying anti-rheumatic drugs (DMARDs) in rheumatology/ gastroenterology/ neurology and dermatology conditions:

- ***Azathioprine** in dermatology/ gastroenterology/ rheumatology/ neurology patients*
- ***Hydroxychloroquine** in dermatology/ rheumatology patients*
- ***Leflunomide** in rheumatology patients*
- ***Mercaptopurine** in gastroenterology patients*
- ***Methotrexate tablets and subcutaneous injection** in dermatology/ gastroenterology/ rheumatology/ neurology patients*
- ***Leflunomide & methotrexate** combination in rheumatology patients*
- ***Penicillamine** in rheumatology patients*
- ***Sulfasalazine** in gastroenterology/ rheumatology patients*

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*This shared care protocol (SCP) sets out details for the sharing of care for patients prescribed **azathioprine tablets, hydroxychloroquine tablets, leflunomide tablets, mercaptopurine tablets, methotrexate tablets, subcutaneous methotrexate injection, penicillamine tablets or sulfasalazine tablets.***

It should be read in conjunction with the latest Summary of Products Characteristics (SmPC) available at http://www.medicines.org.uk/emc as well as 'The 2025 British Society for Rheumatology guideline for the prescription and monitoring of conventional synthetic disease-modifying anti-rheumatic drugs'.

As outlined in NHS England Guidance 2018 (07573), 'Responsibility for Prescribing Between Primary & Secondary/Tertiary Care': When a specialist considers a patient's condition to be stable or predictable, they may seek the agreement of the GP concerned (and the patient) to share their care.

This document provides information on drug treatment for the shared commitment between the specialist and GP concerned. GPs are invited to participate. If the GP is not confident to undertake these roles, then they 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. The doctor who prescribes the medication has the clinical responsibility for the drug and the consequences of its use.

N.B. If the GP decides not to participate in shared care for a particular patient, they must inform the relevant specialist in writing, within 2 weeks of receipt of a request to share care.

Introduction:

This document covers the shared care guidelines for all the conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) which can be prescribed under shared care arrangements in Somerset for dermatology, gastroenterology, rheumatology and neurology conditions. The monitoring parameters set out are based on the 2025 BSR guideline for the prescription and monitoring of conventional synthetic disease-modifying anti-rheumatic drugs, although there are a few variations due to specialist recommendations.

There is a **drug information page for each csDMARD**, which should be read along with the **shared care responsibilities** and **monitoring section**.

NICE guideline 100 (NG100) 'Rheumatoid arthritis in adults: management' states: 1.2.1. Treat active RA in adults with the aim of achieving a target of remission or low disease activity if remission cannot be achieved (treat-to-target). Achieving the target may involve trying multiple conventional disease-modifying anti-rheumatic drugs (cDMARDs) and biological DMARDs with different mechanisms of action, one after the other.

Note: Conventional disease-modifying anti-rheumatic drugs (cDMARDs) are now widely referred to as conventional synthetic DMARDs (csDMARDs).

This shared care protocol is for adult patients aged 18 years and over.
This shared care protocol **does not** cover the use of these drugs in transplant or cancer care.

Off-label use:
Several drugs covered in this shared care protocol are not licensed for all the conditions they are used to treat, however, their use for the indications listed in this document are established and supported by various sources and bodies including the BNF, NICE, British Society for Rheumatology (BSR) and British Health Professionals in Rheumatology (BHPR), British Association of Dermatologists (BAD), Association of British Neurologists (ABN) and British Society of Gastroenterology (BSG).

MHRA/CHM advice: See individual drug information

Drug Information:

Azathioprine information
Azathioprine is an immunosuppressive pro-drug, which is cleaved rapidly in the liver to 6-mercaptopurine. The main toxic effect is myelosuppression, although hepatotoxicity is also well recognised. Azathioprine is metabolised by the enzyme thiopurine methyltransferase (TPMT). It has been established that approximately 89% of the population has a normal TPMT activity requiring normal doses of azathioprine (2.0-2.5 mg/kg/day in IBD), 11% have intermediate TPMT activity and are at a higher risk of adverse drug reaction on standard doses of azathioprine and 0.3% are deficient or have no detectable TPMT activity and are at risk of suffering life-threatening complications even when treated with low doses of azathioprine. TPMT activity can be measured phenotypically and genotypically.
Azathioprine - licensed indications relevant to shared care:
Adult patients in the treatment of: • Systemic lupus erythematosus; • Dermatomyositis and polymyositis; • Polyarteritis nodosa; • Generalised myasthenia gravis • Pemphigus vulgaris; • Auto-immune chronic active hepatitis; • Severe or moderately severe inflammatory bowel diseases (IBD; Crohn's disease or ulcerative colitis), in patients who are intolerant to steroids or who are dependent on steroids and in whom the therapeutic response is inadequate despite treatment with high doses of steroids.
Azathioprine - unlicensed indications relevant to shared care:
• Maintenance of remission of Crohn's disease or ulcerative colitis
Azathioprine dose (posology & method of administration) (see BNF & SPC for details)
• Lower doses if there is significant renal or hepatic impairment. • If allopurinol is prescribed concomitantly, the dose of azathioprine must be reduced to 25% of the original dose or avoided; Concomitant administration of other xanthine oxidase inhibitors, such as febuxostat, should be avoided.
Azathioprine dose in rheumatology indications:
• **A typical dose regimen may be:** 1mg/kg/day increasing after 4 to 6 weeks to 2-3mg/kg/day • It may take up to 3 months to see a clinical response.
Azathioprine dose in inflammatory bowel disease:
• The target dose is **2–2.5 mg/kg daily** for IBD, but lower doses are used in hepatology**;** • Typically starting at 50 mg once daily (adults) and increased to achieve target dose within 4-6 weeks especially if there are concerns about side-effects/TPMT results. • As clinical response is not usually expected for 12-16 weeks, azathioprine is often commenced with oral steroids for more immediate relief of symptoms with the steroid dose being tapered as the immunosuppressant begins to be effective.

Azathioprine - Contraindications (see BNF & SPC for details)

Azathioprine - Special warnings & precautions for use (see BNF & SPC for details)

- Exposure to sunlight and UV light should be limited and patients should wear protective clothing and use a sunscreen with a high protection factor to minimize the risk of skin cancer and photosensitivity.
- Live vaccines including oral polio, oral typhoid, intranasal influenza, varicella zoster, yellow fever, BCG and rubella (including MMR) should be administered with caution in patients taking azathioprine. The Green Book states that many adults with chronic inflammatory diseases (e.g. rheumatoid arthritis, inflammatory bowel disease, psoriasis, glomerulonephritis) will be on stable long term low dose corticosteroid therapy (defined as up to 20mg prednisolone per day for more than 14 days in adults or 1mg/kg/day in children under 20kg) either alone or in combination with other immunosuppressive drugs. Long term stable low dose corticosteroid therapy, either alone or in combination with low dose **non-biological** oral immune modulating drugs (e.g. azathioprine 3.0mg/kg/day), are **not** considered sufficiently immunosuppressive and these patients **can** receive live vaccines. **N.B. Green Book advice is new, from 2017 some literature and patient information leaflets and websites still state that patients on Azathioprine should not receive live vaccines - this could cause confusion**

Please refer to the Green Book Chapter 6 for current advice regarding the use of live vaccines in patients taking immune modulators.

Azathioprine - Interactions (see BNF & SPC for details)

Azathioprine - Pregnancy, breastfeeding & paternal exposure

- Careful assessment of risk versus benefit should be carried out pre-conception by the specialist clinician or IBD nurse. Risks of continuing azathioprine are usually outweighed by the benefits.

2022 BSR Guideline on prescribing drugs in pregnancy & breastfeeding states:

- Azathioprine is compatible throughout pregnancy.
- Azathioprine is compatible with breastfeeding.
- Azathioprine is compatible with paternal exposure.

The 2025 Global Consensus Statement on the Management of Pregnancy in Inflammatory Bowel Disease states that thiopurines remain safe and appropriate for maintenance of remission during pregnancy and provides information on shunting of metabolites in pregnancy, risk of intrahepatic cholestasis in pregnancy, suggested monitoring and management (see link for further information).

The UK Teratology Information Service (UKTIS) recommends regular monitoring of liver function and serum bile acid concentrations for women who are receiving azathioprine or other thiopurines during pregnancy (see link for further information).

- **MHRA Alert May 2025 Thiopurines and intrahepatic cholestasis of pregnancy - GOV.UK Intrahepatic cholestasis of pregnancy (ICP) has been rarely reported in patients treated with azathioprine products**

Refer to Green Book Chapter 6 for information on vaccination of babies/children who are exposed to immunosuppressive therapy in pregnancy, pregnancy and breastfeeding, or breastfeeding alone.

Azathioprine - Adverse effects (see BNF & SPC for details)

Hydroxychloroquine information

Hydroxychloroquine is an antimalarial and a disease-modifying anti-rheumatic drug used in the treatment of rheumatoid arthritis and systemic and discoid lupus erythematosus.

Hydroxychloroquine - licensed indications relevant to shared care:

Adult patients in the treatment of:

- Active rheumatoid arthritis
- Systemic and discoid lupus erythematosus
- Dermatological conditions caused or aggravated by sunlight

Hydroxychloroquine - dose (posology & method of administration) (see BNF & SPC for details)

Adults (including the elderly):

- The minimum effective dose should be employed; dose should not exceed 5mg/kg/day (calculated from ideal body weight, **NOT** actual body weight) and will be either 200mg or 400mg/ day.
- **In patients able to receive 400mg daily:** Initially, 400mg daily in divided doses, reducing to 200mg when no further improvement is evident. The maintenance dose should be increased to 400mg daily if the response lessens.
- No dose adjustment is required in patients above 65 years of age.
- In patients with hepatic or renal disease, and in those taking drugs known to affect those organs, estimation of plasma hydroxychloroquine levels should be undertaken in patients with severely compromised renal or hepatic function and dosage adjusted accordingly.

Hydroxychloroquine - Contraindications (see BNF & SPC for details)

Hydroxychloroquine - Special warnings & precautions (see BNF & SPC for details)
Annual retinopathy monitoring should be carried out after 5 years of hydroxychloroquine use (1 year in patients at high risk).
High risk factors include: tamoxifen use, hydroxychloroquine doses >5 mg/kg actual body weight, renal impairment e.g. eGFR <60 mL/min/1.73 m^2, prior chloroquine use

MHRA Alert Feb 2022 Hydroxychloroquine, chloroquine: increased risk of cardiovascular events when used with macrolide antibiotics; reminder of psychiatric reactions - GOV.UK

Hydroxychloroquine - Interactions (see BNF & SPC for details)
See also MHRA Alert above

Hydroxychloroquine - Pregnancy, breastfeeding & paternal exposure

2022 BSR Guideline on prescribing drugs in pregnancy & breastfeeding states:

- Hydroxychloroquine remains the antimalarial of choice in women planning a pregnancy with rheumatic disease in need of treatment and should be continued during pregnancy.
- Hydroxychloroquine is compatible with breastfeeding.
- Men should not be discouraged from taking hydroxychloroquine while trying to conceive

Refer to Green Book Chapter 6 for information on vaccination of babies/children exposed to immunosuppressive therapy in pregnancy, pregnancy & breastfeeding, or breastfeeding alone.

Hydroxychloroquine - Adverse effects (see BNF & SPC for details)

Leflunomide information

Leflunomide is a disease-modifying anti-rheumatic drug (normally used after Methotrexate/Sulfasalazine treatment is contra-indicated, not tolerated or ineffective). The therapeutic effect usually starts after 4 to 6 weeks and may further improve up to 4 to 6 months.

Leflunomide - licensed indications relevant to shared care:

Adult patients in the treatment of:
- active rheumatoid arthritis
- active psoriatic arthritis

Leflunomide - dose (posology & method of administration)(see BNF & SPC for details)

Adults:
- **Rheumatoid Arthritis:** The recommended maintenance dose of leflunomide is 10 mg to 20 mg once daily. Patients may be started on leflunomide 10 mg or 20 mg depending on the severity (activity) of the disease.
- **Active psoriatic arthritis:** The recommended maintenance dose for psoriatic arthritis is leflunomide 20 mg once daily.
- There is no dose adjustment recommended in patients with mild renal insufficiency.
- No dosage adjustment is required in patients above 65 years of age.

Leflunomide - Contraindications (see BNF & SPC for details)

Leflunomide- Special warnings & precautions for use (see BNF & SPC for details)

Leflunomide – Interactions (see BNF & SPC for details)

Leflunomide – Pregnancy, breastfeeding & paternal exposure

- Patients of child-bearing potential should use highly effective contraception during and for up to 2 years after treatment with leflunomide, unless a washout procedure is followed.
- Women on leflunomide considering pregnancy should stop and undergo cholestyramine washout before switching to alternative medication compatible with pregnancy.
- There is no human evidence of increased congenital abnormalities on leflunomide if washout is given. Therefore, if accidental conception occurs on leflunomide the drug should be stopped immediately and cholestyramine washout given until plasma levels are undetectable. Contact the rheumatology department urgently for advice about wash out.
- Breastfeeding is contraindicated when taking leflunomide due to potentially serious side effects. https://www.e-lactancia.org/breastfeeding/leflunomide/product/
- As there is a possible male-mediated foetal toxicity, reliable contraception during treatment should be guaranteed. For men to father a child, the same wash-out procedure as recommended for women should be considered.

Leflunomide Risk Minimisation Materials:
https://www.medicines.org.uk/emc/search?q=leflunomide

Refer to Green Book Chapter 6 for information on vaccination of babies/children who are exposed to immunosuppressive therapy in pregnancy, pregnancy and breastfeeding or breastfeeding alone.

Leflunomide - Adverse effects (see BNF & SPC for details)

Mercaptopurine information

Mercaptopurine is a cytotoxic purine analogue which interferes with nucleic acid synthesis. The drugs mercaptopurine and azathioprine (a prodrug of mercaptopurine) are commonly used unlicensed at low doses to treat inflammatory bowel disease (IBD). Mercaptopurine is an option where azathioprine has been beneficial, but side effects are affecting tolerability. The decision as to whether the patient is initiated on either Azathioprine or Mercaptopurine lies with the consultant.

Mercaptopurine - licensed indications relevant to shared care:

- N/A

Mercaptopurine - unlicensed indications relevant to shared care:

- Adults in the treatment of severe acute Crohn's disease or ulcerative colitis, maintenance of remission of Crohn's disease or ulcerative colitis

Mercaptopurine - Dose (posology & method of administration) (see BNF & SPC for details)

Adults over 18 years:

- Mercaptopurine is usually commenced at 25mg per day (half a 50mg tablet); dose is gradually increased to achieve the target dose, if tolerated.
- Responsible consultants will give instructions to individual patients and inform GPs regarding the target dose and rate of increase.
- Typically, target dose is 1–1.5 mg/kg daily; some patients may respond to lower doses. Tablets are scored to facilitate division of tablets into two halves, if required. A tablet cutter may be useful.
- If allopurinol is prescribed concomitantly, the dose of mercaptopurine must be reduced to 25% of the original dose or avoided; Concomitant administration of other xanthine oxidase inhibitors, such as febuxostat, should be avoided.
- As a clinical response is not usually expected for up to 12 weeks, mercaptopurine is often commenced with oral steroids for more immediate relief of symptoms, with the steroid dose being tapered as the mercaptopurine begins to take effect.
- Mercaptopurine should be administered at least 1 hour before or 3 hours after food or milk.

Mercaptopurine - Contraindications (see BNF & SPC for details)

Mercaptopurine - Interactions (see BNF & SPC for details)

Mercaptopurine - Special warnings & precautions for use (see BNF & SPC for details)

- Mercaptopurine is also known as 6-mercaptopurine (6-MP). This should not be used on prescriptions because historically it has been associated with an increased risk of prescribing and pharmacy dispensing errors.
- Exposure to sunlight and UV light should be limited and patients should wear protective clothing and use a sunscreen with a high protection factor to minimize the risk of skin cancer and photosensitivity.
- Live vaccines including oral polio, oral typhoid, intranasal influenza, varicella zoster, yellow fever, BCG and rubella (including MMR) should be administered with caution in patients taking mercaptopurine. The Green Book states that many adults with chronic

inflammatory diseases (e.g. rheumatoid arthritis, inflammatory bowel disease, psoriasis, glomerulonephritis) will be on stable long term low dose corticosteroid therapy (defined as up to 20mg prednisolone per day for more than 14 days in adult or 1mg/kg/day in children under 20kg) either alone or in combination with other immunosuppressive drugs. Long term stable low dose corticosteroid therapy, either alone or in combination with low dose **non-biological** oral immune modulating drugs (e.g. 6-mercaptopurine 1.5mg/kg/day), are **not** considered sufficiently immunosuppressive and these patients **can** receive live vaccines. **N.B. Green Book advice is new, from 2017 some literature and patient information leaflets and websites still state that patients on Mercaptopurine should not receive live vaccines- this could cause confusion**

Please refer to the Green Book Chapter 6 for current advice regarding the use of live vaccines in patients taking immune modulators

Mercaptopurine - Pregnancy, breastfeeding and paternal exposure

- Careful assessment of risk versus benefit should be carried out pre-conception by the specialist clinician or IBD nurse. Risks of continuing mercaptopurine are usually outweighed by the benefits.

Note: Mercaptopurine is the active metabolite of azathioprine and shares the evidence base with azathioprine

2022 BSR Guideline on prescribing drugs in pregnancy & breastfeeding states:

- Azathioprine is compatible throughout pregnancy.
- Azathioprine is compatible with breastfeeding.
- Azathioprine is compatible with paternal exposure.

The 2025 Global Consensus Statement on the Management of Pregnancy in Inflammatory Bowel Disease states that thiopurines remain safe and appropriate for maintenance of remission during pregnancy and provides information on shunting of metabolites in pregnancy, risk of intrahepatic cholestasis in pregnancy, suggested monitoring and management (see link for further information).

The UK Teratology Information Service (UKTIS) recommends regular monitoring of liver function and serum bile acid concentrations for women who are receiving azathioprine or other thiopurines during pregnancy (see link for further information).

- **MHRA Alert May 2025 Thiopurines and intrahepatic cholestasis of pregnancy - GOV.UK Intrahepatic cholestasis of pregnancy (ICP) has been rarely reported in patients treated with azathioprine products.**

Refer to Green Book Chapter 6 for information on vaccination of babies/children who are exposed to immunosuppressive therapy in pregnancy, pregnancy and breastfeeding or breastfeeding alone.

Mercaptopurine – Adverse effects (see BNF & SPC for details)

Methotrexate information

Methotrexate inhibits the enzyme dihydrofolate reductase, essential for the synthesis of purines and pyrimidines. It is used in low doses for the treatment of active rheumatoid arthritis in adult patients, severe recalcitrant disabling psoriasis, which is not adequately responsive to other forms of therapy such as phototherapy, Psoralen combined with Ultraviolet A (PUVA) treatment, and retinoids, and severe psoriatic arthritis in adult patients. It is also used in patients with inflammatory bowel disease (small bowel Crohn's).

Methotrexate - licensed indications relevant to shared care:

Methotrexate tablets

- treatment of severe cases of uncontrolled psoriasis, unresponsive to conventional therapy.
- treatment of adults with severe, active, classical or definite rheumatoid arthritis

Methotrexate subcutaneous injection

- treatment of active rheumatoid arthritis in adult patients
- treatment of severe recalcitrant disabling psoriasis, which is not adequately responsive to other forms of therapy such as phototherapy, psoralens and ultraviolet A (PUVA), and retinoids, and severe psoriatic arthritis in adult patients.
- mild to moderate Crohn's disease either alone or in combination with corticosteroids in adult patients refractory or intolerant to thiopurines (N.B. Some injectable preparations only)

Methotrexate - unlicensed indications relevant to shared care:

- treatment of severe Crohn's Disease
- generalised myasthenia gravis
- dermatomyositis; connective tissue disease (SLE, myositis and vasculitis); blistering conditions; sarcoidosis; lymphomatoid papulosis.

Methotrexate - Dose (posology & method of administration) (see BNF & SPC for details)

Adults over 18 years:

- Methotrexate dose is usually titrated at regular intervals until target dose / response is achieved.
- Maximum weekly dose of methotrexate tablets should not exceed 25mg unless there has been prior agreement between consultant and GP.
- Methotrexate must be used with caution in renal failure or hepatic impairment; elderly patients should be given a smaller test dose and titrated at a slower rate.
  Dose adjustment needed in renal impairment. If CrCl is less than 30mL/min discontinuation may be indicated.
- To reduce dosing errors **only the 2.5 mg tablets should be prescribed**.
- The dose should be taken **ONCE WEEKLY on the same day each week,** and that day should be clearly communicated to the patient.
- Folic acid tablets 5mg to be taken once EACH WEEK on the day before or the day after methotrexate to limit side effects, e.g. gastrointestinal and haematological toxicity.

- **Folic acid alongside methotrexate -** minimum 5mg once weekly, but this can be increased to 5mg daily, except for methotrexate day, to resolve some side effects.

Methotrexate – Contraindications (see BNF & SPC for details)

Methotrexate – Special warnings and precautions for use (see BNF & SPC for details)

- Live vaccines including oral polio, oral typhoid, intranasal influenza, varicella zoster, yellow fever, BCG and rubella (including MMR) should be administered with caution in patients taking methotrexate. The Green Book states that many adults with chronic inflammatory diseases (e.g. rheumatoid arthritis, inflammatory bowel disease, psoriasis, glomerulonephritis) will be on stable long term low dose corticosteroid therapy (defined as up to 20mg prednisolone per day for more than 14 days in adult or 1mg/kg/day in children under 20kg) either alone or in combination with other immunosuppressive drugs. Long term stable low dose corticosteroid therapy, either alone or in combination with low dose **non-biological** oral immune modulating drugs (e.g. methotrexate 25mg per week in adults or up to 15mg/m2 in children), are **not** considered sufficiently immunosuppressive and these patients **can** receive live vaccines. **N.B. Green Book advice is new, from 2017 some literature and patient information leaflets and websites still state that patients on Methotrexate should not receive live vaccines - this could cause confusion.**

Please refer to the Green Book Chapter 6 for current advice regarding the use of live vaccines in patients taking immune modulators

- Following influenza or COVID-19 vaccination in adults, methotrexate should be withheld for up to two weeks, if disease activity/risk of flare allows.

Note that the dose is a **weekly** dose. To avoid error with low-dose methotrexate, it is recommended that:

- Before prescribing methotrexate, make sure that the patient is able to understand and comply with **once-weekly dosing**
- The patient is carefully advised of the **dose** and **frequency** and the reason for taking methotrexate and any other prescribed medicine (e.g. folic acid);
- All patients on methotrexate should have an **agreed day of the week** for dosing and be co-prescribed folic acid supplementation at a minimum dose of 5mg once weekly, not on the day of methotrexate
- **Only the 2.5mg strength** methotrexate tablets should be prescribed and dispensed;
- The prescription and the dispensing label clearly show the dose and frequency of methotrexate administration, including the **day of the week** they will take their methotrexate

MHRA Alert September 2020 Methotrexate once-weekly for autoimmune diseases: new measures to reduce risk of fatal overdose due to inadvertent daily instead of weekly dosing - GOV.UK

- The patient is warned to report immediately the onset of any feature of blood disorders (e.g. sore throat, bruising, and mouth ulcers), liver toxicity (e.g. nausea, vomiting, abdominal discomfort, and dark urine), respiratory effects (e.g. shortness of breath).
- In most patients, subcutaneous methotrexate will replace current oral methotrexate and monitoring should be continued as already being done by the GP without any change. The monitoring for subcutaneous and oral methotrexate is the same (i.e. a straight switch from the current monitoring

- Photosensitivity reactions are known side effects of methotrexate treatment and can be severe. Patients should be advised to take precautions to protect their skin in the sun.

MHRA Alert August 2023 **Methotrexate: advise patients to take precautions in the sun to avoid photosensitivity reactions - GOV.UK**

Methotrexate – Interactions (see BNF & SPC for details)

Methotrexate - Pregnancy, breastfeeding and paternal exposure

2022 BSR Guideline on prescribing drugs in pregnancy & breastfeeding states:

- Methotrexate at any dose should be avoided in pregnancy and stopped at least one month in advance of planned conception, when it should be switched to another pregnancy-compatible drug to ensure maintenance of maternal disease suppression.
- In women treated with low-dose methotrexate (≤ 25mg / week) within one month prior to conception, folate supplementation (5 mg/day) should be continued prior to and up to 12 weeks of pregnancy.
- In the case of accidental pregnancy on low-dose methotrexate, the drug should be stopped immediately, folate supplementation (5 mg/day) continued and a careful evaluation of foetal risk carried out by local experts.
- Methotrexate cannot be recommended in breastfeeding because of theoretical risks and insufficient outcome data.
  The UK Drugs in Lactation Advisory Service (UKDILAS) advises caution in breastfeeding and can be contacted for further information. Alternatives are preferred.

- Low dose methotrexate (≤ 25mg / week) is compatible with paternal exposure.

  The UK Teratology Information Service (UKTIS) recommends that where a couple wishes to attempt conception and the male partner's condition is well-controlled with methotrexate, an assessment and discussion of the potential benefits and risks of continuing paternal treatment vs. discontinuation should be undertaken. The risks to the foetus are theoretical and are not supported by the available human data.

Refer to Green Book Chapter 6 for information on vaccination of babies/children who are exposed to immunosuppressive therapy in pregnancy, pregnancy and breastfeeding or breastfeeding alone.

Methotrexate - Adverse effects (see BNF & SPC for details)

Penicillamine information

Penicillamine is an anti-rheumatic drug, mainly used in the treatment of rheumatoid arthritis.

Penicillamine – Licensed indications relevant to shared care:

- Severe active rheumatoid arthritis, including juvenile forms

Penicillamine - Dose (posology & method of administration) (see BNF & SPC for details)

Adults over 18 years, Rheumatoid Arthritis: 125mg to 250mg daily for the first month. Increase by the same amount every four to twelve weeks until remission occurs. The usual maintenance dose is 500 to 750mg daily.

The minimum maintenance dose to achieve suppression of symptoms should be used and treatment should be discontinued if no benefit is obtained within 12 months. Improvement may not occur for some months.

The elderly: 20mg/kg/day in divided doses adjusting the dose to minimal level necessary to control disease.

Penicillamine – Contraindications (see BNF & SPC for details)

Penicillamine – Specials warning & precautions for use (see BNF & SPC for details)

Renal insufficiency: Extra precautions should be taken to monitor for adverse effects in patients with Wilson's disease and renal insufficiency.

Tablets should be taken at least half an hour before meals. Indigestion remedies or products containing iron or zinc should not be taken within 2 hours of the penicillamine dose.

Penicillamine - Interactions (see BNF & SPC for details)

Penicillamine – Pregnancy, breastfeeding & paternal exposure

- Penicillamine is not usually used in pregnancy - safety data is conflicting. The manufacturer states that penicillamine should not be administered to patients with Rheumatoid Arthritis who are pregnant, and therapy should be stopped when pregnancy is confirmed or suspected, unless considered to be absolutely essential by the physician. If there are no suitable alternatives, the UK Teratology Information Service (UKTIS) can be consulted for further information and advice in order to make a risk/benefit analysis with the patient as part of a fully informed shared decision.
- LactMed and e-lactancia state for penicillamine in breastfeeding - low or undetectable levels in breastmilk, with poor oral bioavailability in the presence of food. Penicillamine is considered compatible with breastfeeding.

Penicillamine - Drugs and Lactation Database (LactMed®) - NCBI Bookshelf
Penicillamine and breastfeeding. Are they compatible? https://www.e-lactancia.org/breastfeeding/penicillamine/product/

- When planning a pregnancy, it is important that both men and women on this drug discuss with their specialist.

Penicillamine - Adverse effects (see BNF & SPC for details)

Sulfasalazine

Sulfasalazine is an effective second line drug for treatment of rheumatoid arthritis which has failed to respond to non-steroidal anti-inflammatory drugs (NSAIDs). It can also be used for the induction and maintenance of remission of ulcerative colitis and for treatment of active Crohn's Disease but is rarely indicated in IBD as the newer and generally better tolerated 5-aminosalicylate (5-ASA) medications are used instead.

Sulfasalazine – Licensed indications relevant to shared care

- Induction and maintenance of remission of ulcerative colitis; treatment of active Crohn's Disease.
- Treatment of rheumatoid arthritis which has failed to respond to non-steroidal anti-inflammatory drugs (NSAIDs).

Sulfasalazine - Dose (posology & method of administration) (see BNF & SPC for details)

Week 1: 500mg each evening
Week 2: 500mg twice daily
Week 3: 500mg in the morning and 1 gram in the evening

Week 4: 1 gram twice daily • The dose may be increased to 3 grams daily if no response. • Tablets should not be crushed or broken. It is recommended that tablets should be taken with water. • Only the enteric coated tablets are licensed in rheumatoid arthritis
Sulfasalazine – Contraindications (see BNF & SPC for details)
Sulfasalazine – Special warnings & precautions for use (see BNF & SPC for details)
Sulfasalazine – Interactions (see BNF & SPC for details)
Sulfasalazine - Pregnancy, breasfeeding & paternal exposure.
2022 BSR Guideline on prescribing drugs in pregnancy & breastfeeding states: • Sulfasalazine is compatible throughout pregnancy, with folic acid 5 mg/day recommended in the periconception period and during the first trimester. • Sulfasalazine is compatible with breastfeeding in healthy, full-term infants. • Men taking sulfasalazine may have reduced fertility. There is no evidence, however, that conception is enhanced by stopping sulfasalazine for 3 months prior to conception unless conception is delayed >12 months when other causes of infertility should also be considered. **The 2025 Global Consensus Statement on the Management of Pregnancy in Inflammatory Bowel Disease** states that sulfasalazine is considered low risk in pregnancy and compatible with breastfeeding in healthy, full term infants. There is no evidence that paternal sulfasalazine exposure increases congenital anomalies. It states that sulfasalazine may cause reversible reduction in male fertility (sperm count and motility). Stopping sulfasalazine 2-3 months preconception may help if conception is delayed but this should be balanced against the risk of disease flare and alternatives such as switching to a 5-ASA agent. See link above and British Society of Gastroenterology guidelines on inflammatory bowel disease in adults: 2025 for further information on management of IBD in pregnancy, considerations of switching medication, and recommendation on folic acid supplementation in IBD.
Sulfasalazine - Adverse effects (see BNF & SPC for details)

The drug information above is not exhaustive. The manufacturer's summary of product characteristics (SmPC) and the most current edition of the British National Formulary should be consulted for full information on contra-indications, warnings, side-effects and drug interactions.

Shared Care Responsibilities

Specialist responsibilities:

1. Assess the patient, provide diagnosis and confirm the need for DMARD therapy.

2. Using a shared decision-making approach; discuss the benefits and risks of the treatment with the patient / carer and provide the appropriate counselling to enable the patient to reach an informed decision. This includes, where appropriate, the risks associated with pregnancy and the need for a reliable method of contraception and taking into consideration 'whole journey prescribing' when discussing future pregnancy planning (males and females) and breastfeeding.

3. Provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.

4. Obtain and document patient consent. Discuss any off-label use of the medication as part of the consent process.

5. Assess for contraindications and cautions, and check for interactions.

6. Prior to commencing a new DMARD, patients should be assessed for risk factors for toxicity

7. Check that the patient has been vaccinated against flu and pneumococcus (this is recommended). Consider vaccination timing for methotrexate: following flu or COVID-19 vaccination, withhold methotrexate for up to 2 weeks if disease activity allows

8. Consider NICE recommendations regarding screening for hepatitis B and C in patients at increased risk of infection. Baseline HIV status should also be established in those with risk factors. Test for latent tuberculosis (TB) in at risk patients.

9. Counsel the patient / carer on potential side effects, and the signs and symptoms of drug toxicity or intolerance.

10. Carry out baseline investigations (see **Table 2: 'Monitoring'**) and any additional responsibilities for specialist (see **Table 1: 'Additional specialist, GP and patient responsibilities listed by drug'**).

11. Initiate treatment and carry out any relevant ongoing monitoring (see **Table 3: Standard monitoring schedule**)

12. Prescribe medication for the length of time specified below and request GP to continue/commence monitoring:

DMARD	Speciality	Duration of treatment to be prescribed by consultant before requesting shared care
Azathioprine	Gastroenterology	Minimum of 3 months - at least until the patient is stable
Azathioprine	Dermatology/ Rheumatology/ Neurology	Issue the first prescription for 4 weeks supply and request GP to continue/commence monitoring. Check response to treatment after 4 weeks.
Hydroxychloroquine	Dermatology/ Rheumatology	Issue the first prescription for 4 weeks supply and request GP to continue/commence monitoring. Check response to treatment after 4 weeks.
Leflunomide	Rheumatology	Issue the first prescription for 4 weeks supply and request GP to continue/commence monitoring. Check response to treatment after 4 weeks.
Mercaptopurine	Gastroenterology	Minimum of 3 months - at least until the patient is stable
Methotrexate	Dermatology/ Gastroenterology/ Rheumatology/ Neurology	Issue the first prescription for 4 weeks supply and request GP to continue/commence monitoring. Check response to treatment after 4 weeks.
Penicillamine	Rheumatology	Issue the first prescription for 4 weeks supply and request GP to continue/commence monitoring. Check response to treatment after 4 weeks.
Sulfasalazine	Rheumatology/ Gastroenterology	Issue the first prescription for 4 weeks supply and request GP to continue/commence monitoring. Check response to treatment after 4 weeks.

13. Provide GP with diagnosis, current and ongoing dose, relevant test results and confirm the monitoring schedule and when the next monitoring is required.

14. Refer patient to specialist nurse service where appropriate (e.g. new patient) for further advice on taking the drug, its cautions, potential side effects associated with treatment, signs and symptoms of drug toxicity, monitoring requirements and the timing of re assessment and by whom.

15. Advise patients to contact the specialist team or GP should they have adverse effects or warning symptoms of toxicity and ensure patients are aware of who to contact out of hours if needed (NHS 111 or if symptoms are escalating, attend A&E).

16. Follow the patient's response to treatment at the out-patient clinic.

17. Prompt verbal communication followed up in writing to GP of changes in treatment or monitoring requirements, results of monitoring, assessment of

adverse events or when to stop. Urgent changes to treatment should be communicated by telephone to GP.

18. Request GP to monitor as required in the monitoring section of this protocol. Provide individual monitoring advice for patients with risk factors for DMARD toxicity.

19. Assess risk factors for DMARD toxicity at least annually, adjusting the frequency of monitoring according to the level of risk identified. Communicate changes in risk factors and monitoring frequency to primary care.

20. Advise GP regarding any concerns about monitoring or, adverse effects, at any stage.

21. Report any serious adverse events to the MHRA via the yellow card system www.mhra.gov.uk/yellowcard

22. All patients will remain under the ongoing care of a named consultant/specialist.

23. Review treatment and reassume prescribing responsibilities if a patient becomes or wishes to become pregnant

24. The specialist will provide support if problems occur using the contact details provided.

General Practitioner responsibilities:

1. Accept request to take on prescribing & monitoring of DMARD once the specialist has fulfilled their specialist responsibilities above around initiation of treatment, baseline investigations and minimum duration of treatment before requesting shared care.

2. Repeat prescribing of the DMARD no sooner than specified in the table above after initiation.

3. Discuss any important test abnormality with the consultant/specialist before continuing treatment.

4. Ensure that the patient has received counselling in verbal and written form. Reinforce educational points provided by the hospital. See also **'Advice to patients & carers'**

5. Report any suspected adverse reactions to the consultant/specialist.

6. Be alert to the possibility of interactions when initiating new drugs.

7. Report any significant events relating to DMARD therapy to Somerset ICB via Datix / usual channels.

8. Liaise with the hospital consultant/specialist regarding any complications of treatment.

9. Undertake blood monitoring and monitor for specific side effects. See **Table 2: 'Monitoring'** and **Table 3: Standard monitoring schedule.** See also additional responsibilities for GP in **Table 1: 'Additional specialist, GP and patient responsibilities listed by drug'** and **Table 4: Parameters for concern, adverse effects & other management**

10. Report to and seek advice from specialist on any aspect of patient care of concern to GP which may affect treatment. Prompt referral to specialist if there is a change in patient's health status.

11. Stop treatment in case of severe adverse event or as per shared care guideline **(**see **Table 4: Parameters for concern, adverse effects & other management)**

12. Report any serious adverse reactions to the MHRA via the Yellow Card scheme www.mhra.gov.uk/yellowcard

Patient / carer responsibilities:

1. After counselling, be willing to take the medication as prescribed.

2. Report any concerns in relation to treatment to their specialist team or GP.

3. Inform any healthcare professionals treating them, that they are taking a DMARD medication.

4. Attend regularly for monitoring and review appointments with primary care and specialist. Be aware that medicines may be stopped if they do not attend appointments.

5. Use effective contraception, and to take a pregnancy test if they think they could be pregnant. Inform the specialist or GP as soon as possible if they become pregnant or wish to become pregnant.

6. Report the use of any over the counter (OTC) medications to their prescriber.

7. Be aware that they should discuss the use of the DMARD medication with their pharmacist before purchasing any OTC medicines, herbal remedies or accessing any community pharmacy services.

8. Report any adverse effects or warning symptoms whilst taking DMARD therapy to their specialist team or GP, such as mouth ulcers, sore throat, fever, epistaxis, rash, unexpected bruising or bleeding, and any unexplained illness/infection (this will vary depending on treatment).

Advice to patients & carers:

The patient should be advised to report any of the following signs or symptoms to their **specialist team or GP** without delay:

- Signs or symptoms of bone marrow suppression, such as sore throat, mouth ulcers, abnormal bleeding or bruising, or other signs of infection e.g. fever, skin rash, swollen glands.
- Unexplained bleeding or bruising, nosebleeds, black stools, or blood in the vomit or stools.
- Signs or symptoms of liver problems, such as yellow skin or eyes (jaundice), itching all over, nausea or vomiting.
- Skin rash with blisters or mucosal lesions, or any other sign of hypersensitivity
- Persistent cough, shortness of breath, or any other problems with breathing.
- Signs or symptoms of pancreatitis, e.g. abdominal pain, nausea, or vomiting
- Symptoms of peripheral neuropathy e.g. pins and needles, numbness, weakness or burning pain in extremities
- Signs of kidney problems e.g. swollen hands, ankles or feet, changes to frequency of urination or not urinating at all
- Skin rash with blisters or mucosal lesions, or any other sign of hypersensitivity
- Symptoms of chickenpox or contact with a person with chickenpox or shingles.
- For hydroxychloroquine:
  - Vision disturbances including blurred vision, changes in visual acuity or abnormal colour vision.
  - Muscle weakness

If **out of hours** and side effects are severe, patient should stop treatment and **call NHS 111**, or if symptoms are escalating, **attend A&E**

The patient / carer should be advised:

- Read and keep the Patient Information Leaflets provided by the specialist team about their medication.
- Tell anyone who prescribes them a medicine that they are taking a DMARD medication. Always tell the pharmacist that they are taking a DMARD medication before purchasing any OTC medicines, including herbal remedies, or accessing any community pharmacy services.
- Use effective contraception, and to take a pregnancy test if they think they could be pregnant. Patients should inform the specialist or GP immediately if they become pregnant. All patients, both men and women, should inform their specialist well in advance if they are planning a pregnancy.
- For Methotrexate, Azathioprine & Mercaptopurine: Photosensitivity reactions are known side effects - exposure to sunlight and UV light should be limited and patients should wear protective clothing and use a sunscreen with a high protection factor to minimize the risk of skin cancer and photosensitivity.

Table 1: Additional specialist, GP and patient responsibilities listed by drug

Drug		Other monitoring / responsibilities
AZATHIOPRINE	Specialist	• Ascertain immune status by enquiring about history of chickenpox. Measurement of antibodies to varicella-zoster virus is not necessary if there is a history of previous infection.
	GP	• Ensure that the patient is **NOT** taking allopurinol
	Patient/ Carer	• Report all signs & symptoms suggestive of drug toxicity or infection to specialist team or GP, especially sore throat
HYDROXYCHLOROQUINE	Specialist	• No additional responsibilities.
	GP	• No additional responsibilities.
	Patient/ Carer	• Report all signs & symptoms suggestive of drug toxicity or infection to specialist team or GP, especially sore throat
LEFLUNOMIDE	Specialist	• No additional responsibilities.
	GP	• No additional responsibilities.
	Patient/ Carer	• Report all signs & symptoms suggestive of drug toxicity or infection to specialist team or GP, especially sore throat
MERCAPTOPURINE	Specialist	• As per azathioprine (above)
	GP	• As per azathioprine (above)
	Patient/ Carer	• As per azathioprine (above)
METHOTREXATE	Specialist	• Ascertain immune status by enquiring about history of chickenpox. Measurement of antibodies to varicella-zoster virus is not necessary if there is a history of previous infection. • Comply with NPSA Alert and 2020 MHRA Drug Safety Update for methotrexate. • Provide and complete the initial **Methotrexate patient information and monitoring booklet**. • Make the patient aware that taking aspirin and NSAIDs with methotrexate may cause toxicity. • Exercise caution when initiating methotrexate in patients with impaired renal function.
	GP	• Comply with NPSA Alert and 2020 MHRA Drug Safety Update for methotrexate. • Prescribe weekly folic acid (5mg orally) to be taken the day after the methotrexate, or as advised by specialist. Pause treatment and contact specialist if CrCl < 60mL/min Dose adjustment needed in renal impairment. If CrCl is less than 30mL/min discontinuation may be indicated • Provide subsequent **Methotrexate patient information and monitoring booklets** • **Do not** co-prescribe Methotrexate with Trimethoprim or Co-trimoxazole due to risk of severe blood dyscrasias.
	Patient/ Carer	• Report all signs & symptoms suggestive of drug toxicity or infection to specialist team or GP, especially sore throat
PENICILLAMINE	Specialist	• Ascertain immune status by enquiring about history of chickenpox. Measurement of antibodies to varicella-zoster virus is not recommended.
	GP	• No additional responsibilities.
	Patient/ Carer	• Report all signs & symptoms suggestive of drug toxicity or infection to specialist team or GP, especially sore throat
SULFASALAZINE	Specialist	• No additional responsibilities.
	GP	• No additional responsibilities.
	Patient/ Carer	• Report all signs & symptoms suggestive of drug toxicity or infection to specialist team or GP, especially sore throat

Table 2: Monitoring

Drug	Baseline Monitoring (minor variations within each speciality)	Laboratory monitoring	Other monitoring	PARAMETERS FOR CONCERN
AZATHIOPRINE	• Height • Weight • BP • Full blood count (FBC) • U&Es • Urine analysis • Calculated glomerular filtration rate (GFR) • LFTs • ESR and CRP (rheumatology and gastroenterology patients) • Viral serology; Hepatitis B and C serology, HIV test in all high risk groups, latent TB in at risk groups, EBV serology (in young gastroenterology patients due to start Azathioprine or Mercaptopurine), Varicella serology if history unclear • **Azathioprine and mercaptopurine:** TPMT assay • **Methotrexate:** CXR unless done in last 6 months, & pulmonary function (only in selected service users, e.g. abnormal shadowing on CXR)	Standard monitoring schedule*	None	See **Table 4: Parameters for concern, adverse effects & other management**
HYDROXYCHLOROQUINE		No routine laboratory monitoring	*Annual eye assessment (ideally inc. Optical Coherence Tomography if continued for > 5 years arranged in secondary care. After 1 year if high risk).*	
LEFLUNOMIDE		Standard monitoring schedule*	BP and weight at each monitoring visit	
MERCAPTOPURINE		Standard monitoring schedule*	None	
METHOTREXATE		Standard monitoring schedule*	None	
LEFLUNOMIDE & METHOTREXATE Combined		Extend monthly monitoring longer term	BP and weight at each monitoring visit	
PENICILLAMINE		Fortnightly standard monitoring for 8 weeks*, then monthly;	Urinalysis or blood and protein weekly initially and after dose increase; then monthly	
SULFASALAZINE		Standard monitoring schedule* for 12 months then no routine monitoring needed	None	
See next page for standard monitoring schedule				

Table 3: Standard monitoring schedule

Prescribers should consider individual patient needs for additional monitoring as specified in the drug's SPC

For patient starting treatment or after dose increase:	1. **Rheumatology and dermatology patients:** Every 2 weeks until stable for 6 weeks; followed by monthly monitoring for 3 months; then maintenance monitoring, as below. 2. **Gastroenterology patients:** Every 2 weeks; until stable for 8 weeks; repeat again in another 4 weeks; then maintenance monitoring, as below.	FBC U&E (inc Creatinine & CrCl) LFT Albumin
Maintenance Monitoring: **Individual Advice will be given for:**	At least every 12 weeks* Patients with risk factors for toxicity e.g. age > 80, renal impairment, abnormal results, comorbidities, multiple prescriptions, concurrent use of other hepatotoxic or myelosuppressive drugs, high alcohol consumption, elevated BMI; more frequent monitoring is needed	FBC U&E (inc Creatinine & CrCl) LFT Albumin CRP (prior to every secondary care review)

* For patients without risk factors for toxicity and following an individual benefit-risk assessment, once a patient has completed the induction phase and achieved stability on csDMARD therapy, the specialist may decide to extend a patient's maintenance monitoring interval up to 6 monthly, (as per 2025 BSR Guidance Recommendation 26). **It is the responsibility of the specialist to determine the appropriate risk group and the appropriate monitoring schedule.**

Table 4: Parameters for concern, adverse effects & other management

Parameters for concern, adverse effects & other management **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	
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	
Parameters for concern / Adverse effects	**Action for primary care**
Full blood count: • White blood cells less than $3.5x10^9$/L • Lymphocytes less than $0.5x10^9$/L • Neutrophils less than $1.6x10^9$/L • Platelets less than $140x10^9$/L • Eosinophilia greater than $0.5x10^9$/L • *Mean cell volume (MCV) >105 fL	Withhold drug and discuss with specialist team straight away. On specialist advice the dose may need to be reduced and bloods rechecked after an appropriate interval, or the drug stopped. *Note: MCV has not been shown to be a reliable standalone predictor of clinically significant haematological toxicity or a clear indicator for treatment discontinuation (2025 BSR guidance) – discuss with specialist team.
Liver function: • ALT or AST >100 units/L, or any sudden increases (e.g. double of baseline) • Unexplained fall in serum albumin <30g/L • Jaundice	Withhold and discuss with specialist team straight away. Assess for other causes 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 <60ml/min	Withhold and discuss with specialist team straight away.
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.
Peripheral neuropathy	Withhold and discuss with specialist team straight away.

Skin/mucosal reaction e.g. rash, pruritus, mouth, or throat ulceration	Withhold and discuss with specialist team straight away.
Diarrhoea of concern/unknown cause (e.g. not IBD related), ulcerative stomatitis, haematemesis, black or bloody stools, or suspected pancreatitis	Withhold and discuss with specialist team straight away.
Infections requiring antibiotics	Temporarily withhold until the patient has recovered (**except for hydroxychloroquine and sulfasalazine** which can normally be continued, although sulfasalazine may need to be withheld if severe infection). Consider additional investigations (e.g. FBC), if clinically appropriate. Contact specialist for advice as needed.
Symptoms of interstitial lung disease e.g. persistent cough, dyspnoea, fatigue,	If DMARD-induced lung disease is suspected, discuss with specialist team and withhold treatment.
Skeletal muscle myopathy or neuromyopathy **(hydroxychloroquine)**	Review for reversible causes; withhold and discuss with specialist team
Vision disturbances including blurred vision, changes in visual acuity or abnormal colour vision **(hydroxychloroquine)**	Refer to optometrist / ophthalmologist; discuss with specialist team
Symptoms or signs of cardiomyopathy e.g. breathlessness, swelling in the abdomen and ankles, palpitations, cardiac conduction disorders and ECG changes **(hydroxychloroquine)**	Review for reversible causes. Discuss with specialist team urgently and consider withholding. If cardiomyopathy occurs due to hydroxychloroquine treatment, hydroxychloroquine must be withheld.
Other symptoms / concerns with any DMARD medication	Discuss with specialist team.

Further support

- Contact specialist team via agreed channels
- Prescribing & Medicines Management Team, NHS Somerset ICB Tel: 01935 384123 Email: somicb.medicinesmanagementteam@nhs.net

Version:	3.0	Date
Drawn up by:	Version 1.0 by Catherine Henley, Medicines Manager, Somerset CCG with advice from Dr Sally Knights, Dr Alex Bourne (YDH Consultant Rheumatologists), Dr Cathy Laversuch (TST Consultant Rheumatologist), Teresa Jewell (TST Rheumatology Nurse Specialist), Dr Nicola Hare (TST Consultant Gastroenterologist) and Dr Rachael Wachsmuth (Consultant Dermatologist). The original azathioprine, leflunomide, methotrexate, sodium aurothiomalate and sulfasalazine shared care guidelines have been combined into this document in response to new BSR monitoring guidance which aligns the monitoring for all immunomodulatory drugs.	June 2018
Updated by:	Version 2.0 by Hels Bennett, Medicines Manager, Somerset CCG Updated to reflect new NICE guidance (NG100) & addition of Myasthenia Gravis indication to azathioprine and methotrexate as per PAMM committee & SPF Nov 2020 Minor formatting changes	December 2020
Updated by:	Version 3.0 updated by Hels Bennett & Sam Morris, Medicines Managers, NHS Somerset ICB Reviewed by Dr Luke Gompels & Rebecca Rowland-Axe (Rheumatology SFT), Dr Daniel Wheatley (Gastroenterology SFT). Full review & update following publication of new 2025 BSR guideline, which includes recommendation on extending routine monitoring interval for low-risk patients. Updated with reference to 2022 BSR Pregnancy & breastfeeding guidelines and 2025 Global Consensus Statement on the Management of Pregnancy in IBD. Sodium aurothiomalate (Myocrisin®) removed as discontinued. New table added for parameters of concern/adverse effects with actions for primary care. MHRA alerts added for relevant drugs. Title updated from *Shared Care Protocol Immunomodulatory therapies in rheumatology /gastroenterology and dermatology conditions* to *Shared Care Protocol For disease-modifying anti-rheumatic drugs (DMARDs) in rheumatology/ gastroenterology/ neurology and dermatology conditions*. Updated to ICB format. Reinforced throughout document re: patients reporting signs of drug toxicity or infection, following coroner's report Alan Crabtree: Prevention of future deaths report - Courts and Tribunals Judiciary Minor formatting following MPB approval.	March 2026
Approved by:	NHS Somerset Medicines Programme Board (MPB)	18.03.2026
	Drug & Therapeutics Committee, Somerset NHS FT	
	MH Drug & Therapeutics Committee, Somerset NHS FT	
Review:		March 2029

References:

- National Shared Care Protocol: Azathioprine and mercaptopurine for patients within adult services (non-transplant indications) 4 July 2022, Version 1 https://www.england.nhs.uk/publication/shared-care-protocols/
- National Shared Care Protocol: Hydroxychloroquine for patients within adult services 4 July 2022, Version 1 https://www.england.nhs.uk/publication/shared-care-protocols/
- National Shared Care Protocol: Leflunomide for patients within adult services 4 July 2022, Version 1 https://www.england.nhs.uk/publication/shared-care-protocols/
- National Shared Care Protocol: Methotrexate (oral and subcutaneous) for patients in adult services (excluding cancer care) 4 July 2022, Version 1
- https://www.england.nhs.uk/publication/shared-care-protocols/
- National Shared Care Protocol: Sulfasalazine for patients within adult services 4 July 2022, Version 1 https://www.england.nhs.uk/publication/shared-care-protocols/
- Rheumatoid arthritis | Treatment summaries | BNF | NICE
- Summary of Product Characteristics available at: http://www.medicines.org.uk/emc/
- NICE guideline NG100 Rheumatoid arthritis in adults: management Last updated: 12 October 2020
- BSR and BHPR guideline for the prescription and monitoring of non-biologic Disease Modifying Anti-Rheumatic Drugs 27 February 2017
- 2025 British Society for Rheumatology guideline for the prescription and monitoring of conventional synthetic disease-modifying anti-rheumatic drugs 14 November 2025
- British Society for Rheumatology guideline on prescribing drugs in pregnancy and breastfeeding: immunomodulatory anti-rheumatic drugs and corticosteroids | Rheumatology | Oxford Academic 02 November 2022
- UKHSA Green Book Immunisation against infectious disease - GOV.UK
- Myocrisin (Sodium aurothiomalate) injection: Permanent discontinuation end of supply in 2019
- Monitorings – NHS SPS - Specialist Pharmacy Service – The first stop for professional medicines advice
- DMARDs | Health topics A to Z | CKS | NICE
- NICE NG197: Shared decision making. Last updated June 2021. https://www.nice.org.uk/guidance/ng197/
- UK Teratology Information Service (UKTIS) https://uktis.org/
- e-lactancia. Is this compatible with breastfeeding? https://www.e-lactancia.org/
- Drugs and Lactation Database (LactMed®) https://www.ncbi.nlm.nih.gov/books/NBK501922/
- British Society of Gastroenterology guidelines on inflammatory bowel disease in adults: 2025 https://gut.bmj.com/content/74/Suppl_2/s1.full
- Global Consensus Statement on the Management of Pregnancy in Inflammatory Bowel Disease, Clinical Gastroenterology and Hepatology 2025;23:S1–S60 October 2025 https://www.cghjournal.org/action/showPdf?pii=S1542-3565%2825%2900322-2