# SHARED CARE ARRANGEMENT for DMARDs

Azathioprine, Ciclosporin, Leflunomide, Mercaptopurine, Methotrexate, Mycophenolate Mofetil, Penicillamine and Sulfasalazine

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NB: This Shared Care Agreement relates to Isle of Wight NHS hereafter referred to as the Trust.

This shared care guideline has been produced to support the seamless transfer of prescribing and patient monitoring from secondary to primary care and provides an information resource to support clinicians providing care to the patient. It does not replace discussion about sharing care on an individual patient basis.

This guideline was prepared using information available at the time of preparation, but users should always refer to the manufacturer's current edition of the Summary of Product Characteristics (SPC or “data sheet”) and British National Formulary (BNF) for more details.
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1. INTRODUCTION

The treatment of several diseases within the fields of medicine, particularly in rheumatology, gastroenterology, dermatology, and ophthalmology, are increasingly reliant on the use of disease modifying antirheumatic drugs (DMARDs). DMARDs are relatively toxic treatments that are initiated in secondary care. While clinically effective, and accepted practice, patient’s using these medicines require regular blood monitoring due to the potentially serious side-effects that these drugs can occasionally cause.

Once patients are stabilised on their treatment it is feasible for the ongoing prescribing and monitoring to be undertaken in primary care, with review in secondary care when appropriate. Due to the relatively toxic nature of these drugs it is vital that the ongoing prescribing and monitoring is agreed between the specialists in secondary care and the patient’s General Practitioner (GP).

It is optional for GPs to participate in taking on responsibility for shared care for the patient. GPs will take on shared care only if they are willing and able. Sharing of care assumes communication between the specialist, GP and patient and/or patient’s carers.

The doctor who prescribes the medication legally assumes clinical responsibility. He/she is responsible for ensuring blood tests are performed and the results are recorded in the patients monitoring and dosage record.

Patients will be stabilised in secondary care prior to referral for primary care management.

2. INDICATIONS/PATIENT SELECTION

The specialist will be responsible for the prescribing and monitoring of initial dose(s) while treatment is being titrated (usually 3-6 months). The specialist will inform the patient’s GP when the patient has commenced treatment.

When the specialist has confirmed the patient’s condition is stable i.e. the treatment is clinically effective and is free from serious side effects, the intention to share care should be explained to the patient/carer. The specialist will then contact the patient’s GP by secure email and advise that the patient is considered suitable to be managed in primary care by shared care.

The GP should aim to respond to the request to accept or reject the shared care offer within 3 working days and inform the specialist of their decision by fax, these secure numbers are printed at the bottom of the Shared Care request form. In light of exceptional circumstances if the GP is unwilling to undertake shared-care for their patient a reason should be given in the returned shared care request form, it may be beneficial at this point to have a discussion with the specialist.

3. DMARD MEDICINES COVERED BY SHARED CARE

Azathioprine, ciclosporin, leflunomide, 6-mercaptopurine, methotrexate, mycophenolate mofetil, penicillamine, sulphasalazine.

4. GENERAL MEDICINE INFORMATION

The following guidance applies to all of the DMARDs included in this shared care guideline. For specific advice for each medicine please refer to the individual drug summaries. However, the prescriber should always check the Summary of Product Characteristics and/or British National Formulary for complete information, particularly regarding adverse effects and medicine interactions as it is impossible to provide an exhaustive list in this guidance.
• Pregnancy and Breast Feeding
When a patient is prescribed a DMARD there are significant issues regarding pregnancy and family planning posed by the teratogenic potential of these drugs. The decision about when and what medicines should be stopped needs to be made by the specialist. Patients planning a pregnancy should be referred for specialist advice. The decisions potentially affect both male and female patients depending on the medicines being used. The overarching principle is to use the lowest dose to control the disease. Please see the individual drug summaries for specific advice on individual medicines.

Breastfeeding should not be advised if a mother is on any DMARD, even those felt to be safe during pregnancy, as small amounts are excreted in the breast milk.

• Exposure to Varicella Zoster Virus
Immunosuppresssed Varicella Zoster Virus (VZV) naïve patients have a significant risk of disseminated infection if exposed to or contract VZV infection. Therefore, information should be given to all patients taking DMARD / steroid therapy stating what to do if they are exposed to, or contract chicken pox. For patient’s exposed to VZV, contact the specialist or consultant microbiologist in secondary care for management advice.

• Immunisations
Live vaccines should not be given to any immunosuppressed patient. All patients on DMARDs should be offered annual flu vaccination and the one off pneumococcal vaccine unless contraindicated. Oral polio should not be given to patients on DMARDs or household contacts.

Special Note on Combination Therapy

• Patients on more than one DMARD
If more than one DMARD is being prescribed, then the monitoring requirements of both drugs should be fulfilled (see individual drug summaries).

• Patients prescribed a DMARD and a Biologic
Where patients are prescribed both a DMARD and a Biologic the prescribing of the biologic will be undertaken in secondary care. If further monitoring is required for the biologic, this will be undertaken in secondary care, if further monitoring is required for the DMARD, this will be undertaken by the GP participating in the shared care. Communication between primary and secondary care in this instance is essential to avoid duplication of work.

As with DMARDs, Clinicians in Primary Care need to be aware of the increased infection risk in patients prescribed Biologics.

Monitoring
Hepatitis serology and HIV tests will be performed during the baseline tests for at risk patients. Patients will be asked to contact their GP if any of the following occur:
Rash, mouth ulcers, bruises, itching, bleeding, fever, sore throat, jaundice or other infection.

All significant abnormal monitoring results must be acted on within 48 hours.

5. SPECIFIC MEDICINE INFORMATION AND SAFETY ISSUES

KEY : UL = unlicenced indication.
5.1 Azathioprine

Prescribing

Indications: Connective Tissue Disorder or vasculitis where steroids are indicated. Ulcerative colitis, Crohn's disease, autoimmune hepatitis (also see SPC)

50-100mg /day or 1mg /kg /day, increased every 4-6 weeks to maximum 3mg /kg /day (further increase in exceptional circumstances).

With or after food in divided doses if preferred.
Caution: - reduce dosage with impaired renal and hepatic function.

Monitoring

Baseline monitoring (By the Specialist)
FBC, U&E, creatinine, LFT, CRP, TMPT assay.

Initial monitoring (By the Specialist unless patient stabilises quickly)
FBC / LFTs, weekly for first 6 weeks and continue every 2 weeks until dose stable for 6 weeks, then monthly once dose is stable for initial 6 months.

Routine monitoring (By the GP)
After initial 6 months, FBC, LFTs, 3 monthly once dose and blood tests are stable.
Monthly in heterozygous TMPT patients
U&Es, 6 monthly
Any increase in dose revert back to initial 2 weekly monitoring advice until dose is stable for 6 weeks.

Indications of when to withhold treatment and seek advice from the Specialist
FBC: Neutrophils <2.0 x 10⁹/L White cell count <3.5 x 10⁹/L Platelets <150 x 10⁹/L
or significant rapid fall within the normal range

MCV > 105fL Check vitamin B12, folate, TSH, treat any underlying abnormality. If normal discuss with specialist.

LFT’s: AST, ALT >2 x upper limit of reference range

Rash or oral ulceration.
Abnormal bruising or sore throat, (urgent FBC) withhold treatment, discuss results with Specialist.

Additional information

Fertility may be reversibly reduced.
Azathioprine should be stopped prior to pregnancy or fathering a child.
TPMT deficiency may be associated with delayed haematotoxicity, inc. bone marrow toxicity.
Sunscreens and protective covering should be encouraged to reduce sunlight exposure.
Opportunistic infections may occur. Infections can require early and vigorous treatment. Azathioprine may need to be stopped until infection is clear (seek Specialist advice)

Drug interactions

Warfarin - anticoagulant effect inhibited.
ACE inhibitors - enalapril and captopril may cause anaemia, especially in renal impairment.
Aminosalisylates – mesalazine, olsalazine, balsalazide, sulfasalazine, may cause bone marrow toxicity.
Co-trimoxazole/trimethoprim – can cause life threatening haematotoxicity.
Phenytoin, carbamazepine, sodium valproate – azathioprine reduces absorption of these drugs.
Allopurinol - Reduce azathioprine to 25% of original dose.
Febuxostat - avoid concomitant use
5.2 Ciclosporin

Prescribing

**Connective tissue disorder or vasculitis where steroids are indicated** - 2.5mg/kg/day, taken in two divided doses. After 6 weeks may be increased at 2-4 week intervals by 25mg until clinically effective or maximum dose of 4mg/kg/day is reached.

**Psoriasis and atopic dermatitis** - 2.5-5mg/kg/day, taken in two divided doses. Max. dose 5mg/kg/day.

Prescribe by brand, using the same brand, different brands have different bioavailability

Capsules available in 25, 50, and 100mg doses (also Neoral 10mg)

Caution - impaired renal function and hypertension

Monitoring

**Baseline monitoring (by the Specialist)**
FBC, U&E, creatinine (mean value and creatinine clearance), LFT, CRP, fasting lipids, BP (should be <140/90)

**Initial monitoring (By the Specialist)**
FBC, LFT, monthly until dose is stable for 3 months, then 3 monthly.
U&E, creatinine, every 2 weeks until dose stable for 3 months, then monthly.
BP, check each time patient attends monitoring clinic, maintain <140/90.
Lipids after 1st month of treatment, then yearly.

**Routine monitoring (By the GP)**
FBC, LFT, 3 monthly. U&E, monthly. BP, at clinic visits, ideally monthly. Lipids, once per year.

**Indications of when to withhold treatment and seek advice from the Specialist**

**FBC:** Neutrophils <2.0 x 10^9/L  White Cell Count <3.5 x 10^9/L  Platelets <150 x 10^9/L  Creatinine: Increases >30% of baseline, repeat 1 week later, if still raised seek advice from specialist.

**U&E:** K⁺ >5.5mmol/L

**LFT:** Rises > 2 x upper limit of reference range

**BP:** > 140/90 or >50% baseline on 2 consecutive readings 2 weeks apart, and cannot be controlled

**Lipids:** Significant rise in fasting lipids.

**Abnormal bruising:** Check FBC immediately.

**Additional information**

Concomitant administration of NSAIDs increases the risks of renal impairment.

Avoid grapefruit juice whilst taking ciclosporin.

Contraindicated in abnormal renal function, uncontrolled hypertension, uncontrolled infections and malignancy.

Adverse effects - raised BP, hirsutism, confusion, fatigue, headaches, tremor, rash, oral ulceration, gingival hyperplasia.

**Drug interactions**

Many drugs interact with Ciclosporin. Please refer to the BNF or SPC for a full list, before prescribing any new medicine.
Prescribing
Rheumatoid Arthritis - 10-20mg orally daily. 10mg is the maximum dose if used with methotrexate.

Psoriatic Arthritis - 20mg orally daily

Monitoring
Baseline monitoring (by the Specialist)
FBC, LFT, U&E, creatinine. CRP, BP (should be <140/90), weight.

Initial monitoring (By the Specialist)
FBC, LFT, monthly until stable, then 2 monthly.

Routine monitoring (By the GP)
FBC, LFT 2 monthly if prescribed alone, monthly if prescribed with another immunosuppressant. B P, weight, check at each clinic visit.

Indications of when to withhold treatment and seek advice from the Specialist
FBC: Neutrophils <2.0 x 10^9/L White Cell Count <3.5 x 10^9/L Platelets <150 x 10^9/L
Or significant rapid fall within the normal range.

LFT: Rises > 2-3 x upper limit of reference range, reduce dose to 10mg daily, then recheck weekly until normalised, if AST, ALT returns to normal leave on 10mg daily. If LFTs remain elevated, withdraw and seek Specialist advice. Consider alcohol consumption.

Rises > 3 x upper limit, recheck LFTs within 72 hours, if still > 3x upper limit, stop drug, seek advice from Specialist, patient may need washout.

Weight: Unintentional loss of more than 10% between reviews.
BP: Uncontrolled hypertension (>140/90)

Significant rash, itch, hair loss, increasing shortness of breath, mouth ulcers, unexplained GI upset, abnormal bruising or severe sore throat (check FBC immediately), severe persistent headache.

Additional information
Leflunomide has an extremely long half-life. Men and women should not procreate within 2 years of stopping the drug
If a severe side-effect occurs or if patients intend to conceive, drug levels can be rapidly reduced with a washout regime using colestyramine. Contact Specialist for details
Leflunomide increases susceptibility to infections
Due to the risk of hepatotoxicity, it is recommended that the consumption of alcohol is avoided during therapy with leflunomide and other hepatotoxic drugs such as methotrexate.

Drug interactions
Caution with any other hepatotoxic or haemotoxic drug (e.g. methotrexate). Interacts with warfarin, phenytoin and tolbutamide (CYP2C9 metabolised drugs).
**Prescribing**
Indications: ulcerative colitis (UL), Crohn’s disease (UL), autoimmune hepatitis (UL)
Starting dose is typically 50mg daily, increase to a final dose of 1.5mg/kg after 2-4 weeks.
Can occasionally go higher if non-responsive.

Take 1 hour before or two hours after dairy products (reduces plasma concentration)
Caution - reduce dosage with impaired renal and hepatic function.

**Monitoring**
**Baseline monitoring (By the Specialist)**
FBC, U&E, creatinine, LFT, CRP, TMPT assay.

**Initial monitoring (By the Specialist unless patient stabilises quickly)**
FBC / LFTs, weekly for first 6 weeks and continue every 2 weeks until dose stable for 6 weeks, then monthly once dose is stable for initial 6 months.

**Routine monitoring (By the GP)**
After initial 6 months, FBC, LFTs, 3 monthly once dose and blood tests are stable.
Monthly in heterozygous TMPT patients
U&Es, 6 monthly
Any increase in dose revert back to initial 2 weekly monitoring advice until dose is stable for 6 weeks.

**Indications of when to withhold treatment and seek advice from the Specialist**
**FBC:** Neutrophils <2.0 x 10^9/L  White cell count <3.5 x 10^9/L  Platelets <150 x 10^9/L
or significant rapid fall within the normal range
MCV > 105fL Check vitamin B12, folate, TSH, treat any underlying abnormality. If normal discuss with specialist.

**LFT's:** AST, ALT >2 x upper limit of reference range
Rash or oral ulceration.
Abnormal bruising or sore throat, (urgent FBC) withhold treatment, discuss results with Specialist.

**Additional information**
Fertility may be reversibly reduced.
6-mercaptopurine should be stopped prior to pregnancy or fathering a child.
Mothers should not breastfeed when taking 6-mercaptopurine
TPMT deficiency may be associated with delayed haematotoxicity, inc. bone marrow toxicity.
Sunscreens and protective covering should be encouraged to reduce sunlight exposure.
Opportunistic infections may occur. Infections can require early and vigorous treatment. Azathioprine may need to be stopped until infection is clear (seek Specialist advice)
Patients should report unexplained bruising, bleeding, mouth ulcers, rash, fever, sore throat, jaundice.

**Drug interactions**
Co-trimoxazole/trimethoprim – can cause life threatening haematotoxicity
Warfarin - anticoagulant effect inhibited.
Allopurinol - Reduce azathioprine to 25% of original dose.
As there is in vitro evidence that aminosalicylate derivatives (eg. olsalazine, mesalazine or sulfazalazine) inhibit the TPMT enzyme, they should be administered with caution to patients receiving concurrent Mercaptopurine therapy.
Prescribing
Indications: Rheumatoid arthritis, psoriatic arthritis, vasculitis, psoriasis, ulcerative colitis (UL), Crohn’s disease (UL), autoimmune hepatitis (UL)

Weeks 1 - 6: 5mg – 15mg once a week, tablets taken as a single dose with food or s.c. injection.

Weekly dose can be increased by 2.5-5mg every 2-6 weeks, to a maximum dose of 25mg weekly (occasionally 30mg).

Only 2.5mg tablets are to be prescribed whatever the dose (NOT 10mg tablets)
Can be given s.c. to improve response and/or decrease side effects.
Folic acid 5mg once weekly – the day after methotrexate is taken, must not be taken on the same day.
(Folic acid dose may be prescribed up to 6 days per week to control methotrexate side effects)

Caution: - impaired renal or liver function, elderly, history of TB, unexplained anaemia.

Monitoring
Baseline monitoring (by the Specialist)
FBC, U&E, LFT, CRP, and chest X-Ray (unless done within last 6 months). Pulmonary function test in selected patients.

Initial monitoring (By the Specialist)
FBC, U&E, LFT - every 2 weeks until dose and monitoring is stable, thereafter monthly for 3 months and if stable, 2 monthly thereafter.

Routine monitoring (By the GP)
FBC, U&E, LFT, every 8 weeks.

Indications of when to withhold treatment and seek advice from the Specialist
FBC: Neutrophils <2.0 x 10⁹/L White Cell Count <3.5 x 10⁹/L Platelets <150 x 10⁹/L
Or significant rapid fall within the normal range.

LFT: AST, ALT - > 2 x baseline levels on 2 occasions (Ascertain alcohol intake, advise abstinence and retest)
Albumin – unexplained fall.
MCV > 105fL Check vitamin B12, folate, TFT, treat any underlying abnormality. If normal discuss with specialist.
Mild to moderate renal impairment
Abnormal bruising or severe sore throat (check FBC immediately), significant dry cough and acute breathlessness, rash, ulceration, unexplained GI upset, signs of infection discuss with Specialist urgently.

Additional information
Mouth ulcers are not infrequent and may respond to an increase in folic acid.
Reversible infertility may occur in both males and females.
Avoid pregnancy, continue contraception for at least 6 months after stopping methotrexate.
Alcohol - The risk of liver toxicity increases with the level of alcohol intake, keep intake well within normal recommended limits, may need to abstain if LFTs rise.
ILD is a contraindication to methotrexate therapy. New shortness of breath needs urgent referral for investigation.
Liver biopsy: Consider only if abnormal LFTs persist despite stopping Methotrexate.
Advise patients of NSAID interaction (consider OTC medicines).

Drug interactions
Leflunomide, azathioprine, retinoids, acitretin, sulphasalazine, increased risk of hepatotoxicity
Penicillin, ciprofloxacin, vancomycin, teicoplanin, chloramphenicol, tetracyclines may contribute to methotrexate toxicity.
Co-trimoxazole, trimethoprim, sulphonamides, sulphonylureas, increase methotrexate toxicity – AVOID
Phenytoin, salicylates NSAIDs, loop diuretics, phenylbutazone, probenacid, tolbutamide increase methotrexate levels.
5.6  

**Prescribing**

Mycophenolate mofetil (MMF) is only licensed for organ transplantation, however it is used for Connective tissue disorder or vasculitis where steroids are indicated, autoimmune hepatitis.

Initial dose - 500mg daily for first week, 500mg twice daily for the second week, and increase gradually by 500mg each week until optimal or maximum tolerated dose achieved. Maximum dose - 3g daily.

Typical dose - 1-2g daily.

Care in the elderly/frail.

**Contraindications:**

- Pregnancy and breastfeeding.
- Localised or systemic infections.

**Monitoring**

**Baseline monitoring (by the Specialist)**

FBC, U&E, creatinine, LFT, Chest X-ray within the last 6 months, CRP

**Initial monitoring (By the Specialist)**

FBC weekly until dose is stable for 4 weeks, then fortnightly for 2 months, monthly thereafter.

**Routine monitoring (By the GP)**

FBC - monthly.

**Indications of when to withhold treatment and seek advice from the Specialist**

FBC:
- Neutrophils <2.0 x 10⁹/L
- White cell count <3.5 x 10⁹/L
- Platelets <150 x 10⁹/L

or significant rapid fall within the normal range

Abnormal bruising with or without sore throat, urgent FBC and discuss results with Specialist.

**Additional information**

Women wishing to become pregnant should use contraception for at least 6 weeks after discontinuing treatment.

Increased risk of developing lymphomas and other malignancies, particularly of the skin.

Increased risk for opportunistic infections (bacterial, fungal, viral and protozoal), fatal infections and sepsis.

Risk of gastrointestinal tract ulceration, haemorrhage and perforation. Diarrhoea, nausea, vomiting, dyspepsia and abdominal cramps are more common adverse effects.

Sterile haematuria, urinary tract infection.

It is recommended that MMF should not be administered concomitantly with azathioprine because such concomitant administration has not been studied.

**Drug interactions**

Decreased MMF absorption when antacids, such as magnesium and aluminium hydroxides, and PPIs, including lansoprazole and pantoprazole administered.

Colestyramine may reduce the absorption of MMF and bio-availability by 40%.

Probenecid prevents renal tubular secretion and causes an increase in plasma concentration of MMF.

Aciclovir causes an increase of both MMF and aciclovir (only significant in renal impairment).
Prescribing
Indications: very rarely prescribed for rheumatoid arthritis.
Initial dose - 125 to 250mg daily for the first month. Increase by 125mg every four weeks until remission.
Maintenance dose - 500 to 750mg daily. Care in the elderly.

Renal insufficiency: Initiate at a low dose with intervals between dose increase of at least twelve weeks.
Take on an empty stomach at least half an hour before meals, or on retiring.

Contraindications:
Agranulocytosis, aplastic anaemia or severe thrombocytopenia due to penicillamine.
Lupus erythematosus. Moderate or severe renal impairment. Pregnancy or breastfeeding.

Monitoring
Baseline monitoring (by the Specialist)
FBC, U&E, creatinine, urinary protein, CRP

Initial monitoring (By the Specialist)
FBC and urinalysis every 2 weeks until dose and monitoring stable for 3 months; monthly thereafter. In renal impairment, fortnightly monitoring for toxicity is mandatory.
Ask about skin rash or oral ulceration at every visit

Routine monitoring (By the GP)
FBC, and urinalysis monthly, in renal impairment, fortnightly monitoring for toxicity is mandatory.
Ask about skin rash or oral ulceration at every visit

Indications of when to withhold treatment and seek advice from the Specialist
FBC: Neutrophils <2.0 x 10^9/L White cell count <3.5 x 10^9/L Platelets <150 x 10^9/L
or significant rapid fall within the normal range

Proteinuria is 2+ or more. Haematuria occurring in the absence of other known cause.
Severe rash or oral ulceration. Late rashes are more serious than early ones they may occur after several months or years of therapy.
Abnormal bruising or sore throat, urgent FBC and discuss results with Specialist.

Additional information
Care in patients with renal impairment and the elderly.
Antihistamines, steroid cover, or temporary reduction of dose will control urticarial reactions
Reversible loss of taste may occur.
Breast enlargement has been reported as a rare complication.
Penicillamine increases the requirement for pyridoxine, may be given to patients daily on long term therapy.

Drug interactions
If concomitant oral iron, digoxin, zinc or antacid therapy is indicated, this should not be given within two hours of taking penicillamine
Digoxin levels may be reduced by penicillamine
Clozapine may increase risk of agranulocytosis.
Concomitant or previous treatment with gold may increase the risk of side effects.
Concomitant use of NSAIDs and other nephrotoxic drugs may increase the risk of renal damage.
5.8 Sulfasalazine

Prescribing
Indications: Ulcerative colitis, Crohn's disease, rheumatoid arthritis, and other similar arthritic conditions.
Week 1 - 500mg daily.
Week 2 - 500mg twice daily.
Week 3 - 500mg every morning and 1g every night
Week 4 and thereafter - 1g twice daily (1g t.d.s. is occasionally used)
Taken with food – enteric coated is the only licensed preparation for rheumatoid arthritis.

Contraindications:
History of sulphonamide or aspirin sensitivity.
G6PD deficiency based on a drug or family history, - risk of acute haemolytic anaemia

Monitoring
Baseline monitoring (by the Specialist)
FBC, U&E, creatinine, LFT, CRP, G6PD assay in patients at risk.

Initial monitoring (By the Specialist)
FBC, LFT, monthly for first 3 months, then 3 monthly.

Routine monitoring (By the GP)
FBC, LFT, if dose and blood results have been stable - 3 monthly in first year, then 6 monthly in second year, thereafter if dose and blood results have been stable monitoring of blood for toxicity may be discarded.
Following dose changes monitor FBC, LFT one month after dose change.

Indications of when to withhold treatment and seek advice from the Specialist
FBC: Neutrophils <2.0 x 10^9/L White cell count <3.5 x 10^9/L Platelets <150 x 10^9/L or significant rapid fall within the normal range
MCV > 105fL Check vitamin B12, folate, TSH, treat any underlying abnormality. If normal discuss with specialist.
LFT’s: AST, ALT >2 x upper limit of reference range
Oral ulceration.
Abnormal bruising or sore throat, urgent FBC and discuss results with Specialist.
Widespread unexplained rash, seek urgent Specialist advice (preferably Dermatologist)

Additional information
There is no evidence of teratogenic hazards if sulfasalazine is used during pregnancy. Oral sulfasalazine inhibits the absorption and metabolism of folic acid and may cause folic acid deficiency. Because the possibility of harm cannot be completely ruled out, sulfasalazine should be used during pregnancy only if clearly needed
Small amounts of sulfasalazine may be excreted in breastmilk. Patients should avoid breastfeeding while taking this medicine
Males should be warned about the possibility of reversible azospermia,
Patients should be warned about the possibility of orange urine and discolouration of contact lenses.
Because sulfasalazine causes crystalluria and kidney stone formation, adequate fluid intake should be ensured during treatment
Nausea, dyspepsia, headache, taste disorders loss of appetite and skin rashes are quite common. They may necessitate reducing the dose or stopping the drug temporarily.

Drug interactions
Azathioprine may contribute to bone marrow toxicity.
Digoxin absorption possibly reduced by sulfasalazine.
Patients receiving sulphasalazine and hypoglycemic agents should be closely monitored
6 RESPONSIBILITY OF SECONDARY CARE TEAM

- Diagnosis and assessment, ensuring there are no interactions with concurrent therapy or disease states.
- Notify the patient’s GP that treatment has commenced
- Approach GP requesting shared care once the patient’s medicine regimen and monitoring is stable. (See Appendix B for a copy of the shared care request form)
- Baseline monitoring along with monitoring until the patient is stabilised
- Ensure patient is fully informed of potential benefits and side effects of treatment
- Ensure patient’s guardian/carer is fully informed of the treatment
- Provide a comprehensive treatment package in addition to medications including appropriate information/monitoring sheet(s)
- Ensure that shared care arrangements are in place before transfer of treatment:
  - That the GP has been contacted with a request they take over prescribing and monitoring
  - The patient’s GP has been notified of the results of the baseline and initial tests.
  - That the patient/carer is clear what is being monitored and by whom
  - That the patient knows what significant adverse effects/events to report urgently and to whom they should report (specialist or GP)
  - That the patient has signed the agreement form (Appendix C)
- Any dose changes once the patient is established on treatment will be conveyed in writing to the GP for the GP to prescribe
- Extra monitoring needed for dose changes will be organised by Specialist team and conveyed to the GP and patient
- Monitor side effects of medication via routine out-patient visits
- Report adverse events to the MHRA.
- Monitor patient’s response to treatment

Patients will be monitored in secondary care until shared care has been accepted by the patients’ GP.

Baseline Tests and routine tests
See individual medicines in section 5.

Disease monitoring
The frequency of review of the patient will depend on the individual patient. The review period must be specified on the shared care referral request.

7 RESPONSIBILITY OF GP

- When the specialist requests shared care using the shared care request form, reply to the specialist by secure email/fax within working 3 days.
- Ensure that shared care arrangements are in place before transfer of care
- At each appointment ensure that the patient/carer is clear what is being monitored and by whom
- At each appointment ensure the patient knows what significant adverse effects/events to report urgently and to whom they should report (Specialist or GP)
- Check drug interactions with any new medication started or any new conditions diagnosed. Contact Specialist Team if possible interactions found and discuss with Specialist.
- Confirm the Specialists have provided the patient/carer with appropriate information sheet(s) for monitoring.
- Monitor DMARD treatment as stated in the shared care arrangement guidelines
- Amend prescription as per requests from Specialist for dose changes in patients on established treatment
- Seek Specialist advice promptly as advised in the shared care arrangement guidelines or if signs/symptoms or changes occur consistent with DMARD adverse event
- Report adverse events to the MHRA.
- Report adverse events to the Specialist Consultant sharing the care of the patient
- Stop treatment on advice of Specialist, or immediately if intolerable side effects occur provided that it is safer to do so than to continue. If in doubt contact the Specialist.
8 RESPONSIBILITY OF PATIENT

- Discuss potential benefits and side effects of treatment with the Specialist and GP and to raise any outstanding queries
- Check that they have been given a patient information sheet for treatment and monitoring for their own reference and/or to alert other clinical staff to the treatment they are receiving
- Report any adverse effects to their Specialist or GP whilst taking the medicine
- Ask the Specialist or GP if they do not have a clear understanding of their treatment/monitoring
- Attend to have blood monitoring as advised.
- Attend all requested GP and specialist appointments for the monitoring of therapy and the assessment of outcomes, to assist the health professionals to provide safe and appropriate treatment

9 IMMEDIATE ADVICE AND SUPPORT

Contact details

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<thead>
<tr>
<th>Consultant/Nurse Specialist (NS)</th>
<th>Telephone Number</th>
<th>Email</th>
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<tbody>
<tr>
<td><strong>Rheumatologist</strong></td>
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<tr>
<td>Dr Mark Pugh</td>
<td>534909</td>
<td><a href="mailto:mark.pugh@iow.nhs.uk">mark.pugh@iow.nhs.uk</a></td>
</tr>
<tr>
<td>Dr Ildiko Telegdy</td>
<td>534909</td>
<td><a href="mailto:ildiko.telegdy@iow.nhs.uk">ildiko.telegdy@iow.nhs.uk</a></td>
</tr>
<tr>
<td>Elaine Healey (NS)</td>
<td>552218</td>
<td><a href="mailto:elaine.healey@iow.nhs.uk">elaine.healey@iow.nhs.uk</a></td>
</tr>
<tr>
<td>Carolyn Goddard (NS)</td>
<td>552023</td>
<td><a href="mailto:carolyn.goddard@iow.nhs.uk">carolyn.goddard@iow.nhs.uk</a></td>
</tr>
<tr>
<td><strong>Gastroenterologist</strong></td>
<td></td>
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<tr>
<td>Dr Christopher Sheen</td>
<td>534228</td>
<td><a href="mailto:christopher.sheen@iow.nhs.uk">christopher.sheen@iow.nhs.uk</a></td>
</tr>
<tr>
<td>Dr Leonie Grellier</td>
<td>552416</td>
<td><a href="mailto:leonie.grellier@iow.nhs.uk">leonie.grellier@iow.nhs.uk</a></td>
</tr>
<tr>
<td>Amanda Gough</td>
<td>534939</td>
<td><a href="mailto:amanda.gough@iow.nhs.uk">amanda.gough@iow.nhs.uk</a></td>
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<tr>
<td><strong>Dermatologist</strong></td>
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<tr>
<td>Dr Omar Aziz</td>
<td>552590</td>
<td><a href="mailto:omar.aziz@iow.nhs.uk">omar.aziz@iow.nhs.uk</a></td>
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10. REFERENCES

British National Formulary via https://www.medicinescomplete.com/mc/bnf/current/

National Institute for Health and Care Excellence, Clinical Knowledge Summaries, DMARDS http://cks.nice.org.uk/dmards


Electronic Medicines Compendium. Available at www.emc.medicines.org.uk


NPSA rapid response report on the risks of incorrect dosing of oral anti-cancer medicines (NPSA/2008/RRR001)

Guidelines for the management of IBD in adults- on behalf of the IBD section of the British Society of Gastroenterology GUT 2011; 60;5, 571-607.

British Association of Dermatologists’ guidelines for the safe and effective prescribing of azathioprine 2011.

Specification for Local Enhanced Service (Shared Care for DMARDS) Isle of Wight NHS 2011-2012
Appendix A  
Process for initiating Shared Care

Patient initiated on DMARD in secondary care.

Yes

Patient stabilised on DMARD in secondary care.

Yes

Explain to patient possible Shared Care arrangement monitoring / management by their GP

Complete and send Shared Care arrangement form to GP. Consultant to continue to monitor and prescribe until GP has responded to request for shared care.

Consultant to review patient at routine follow up appointments

GP accepts Shared Care responsibilities and prescribing by returning completed arrangement form within 3 working days by secure fax

Yes

GP to enter patient into practice monitoring system and undertake blood test and prescribing when appropriate

Patient remains stable and blood results normal

Yes

Continue prescribing and monitoring as per shared care guideline

No

Patient to remain in care of Secondary Care.

If suitable and agreed, patient may transfer back to primary care once stable.

Patient to remain in care of Secondary Care.

If suitable and agreed, patient may transfer back to primary care once stable.

Discuss with Specialist in secondary care / Specialist Nurse. Patient may need to transfer back to secondary care.
# Shared Care Arrangement (SCA) for DMARDs - Dermatology

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<th>GP</th>
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<th>Specialist follow up arrangements</th>
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I confirm that the patient’s condition and DMARD regimen is clinically effective, stable and therefore suitable for treatment under the shared care arrangement in Primary Care. Please review for monitoring in ............... weeks according to SCA guidance.

Signed

Print name

Title

For GP/authorised deputy to complete (Delete as applicable)

I agree to take over prescribing and monitoring responsibility for this patient as per shared care arrangement.

In light of exceptional circumstances I am not willing to undertake shared-care for this patient because

Signed .................................................. Print name..................................................

Title .................................................. Surgery ..................................................
## Shared Care Arrangement (SCA) for DMARDs - Gastroenterology

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Signed

Print name

Title

For GP/authorised deputy to complete (Delete as applicable)

I agree to take over prescribing and monitoring responsibility for this patient as per shared care arrangement.

In light of exceptional circumstances I am not willing to undertake shared-care for this patient because

Signed ........................................Print name..................................................

Title ................................................... Surgery ..............................................

Please return a copy of this signed form to Gastroenterology on fax number 01983 534872 within 3 working days.

Thank you in anticipation

Gastroenterology Department, St Mary’s Hospital, Newport Isle of Wight, PO30 5TG. Tel. 01983 534228 / 552416

Returned copy to be filed in patient's notes and scanned into ISIS
Shared Care Arrangement (SCA) for DMARDs - Rheumatology

Date
GP
Surgery
Patient Name
DOB
IW Number
NHS number
Diagnosis

Drug name (DMARD regimen) | Current Dose | Date initiated
--- | --- | ---

Existing acceptable side effects

Specialist follow up arrangements

I confirm that the patient's condition and DMARD regimen is clinically effective, stable and therefore suitable for treatment under the shared care arrangement in Primary Care. Please review for monitoring in ………………… weeks according to SCA guidance.

Signed
Print name

Title

For GP/authorised deputy to complete (Delete as applicable)

I agree to take over prescribing and monitoring responsibility for this patient as per shared care arrangement.

In light of exceptional circumstances I am not willing to undertake shared-care for this patient because

…………………………………………………………………………………………………………………………

Signed ........................................ Print name.................................................................

Title ........................................... Surgery .................................................................

Please return a copy of this signed form to Rheumatology on fax number 01983 534278 within 3 working days.
Thank you in anticipation

Rheumatology Department, St Mary’s Hospital, Newport Isle of Wight, PO30 5TG. Tel. 01983 534909

Returned copy to be filed in patient's notes and scanned into ISIS
Appendix C

Patient Agreement to Shared Care
(To be completed in Secondary Care)

I …………………………….. the patient, agree to take responsibility for the following:

- I have discussed the potential benefits and side effects of treatment with the specialist and understand the course of treatment
- I have shared any concerns I have in relation to treatment with the medicine
- I have been given written information about the medicine I am being treated with and how I will be monitored
- I will report any adverse effects, particularly rash, mouth ulcers, bruises, itching, bleeding, fever, sore throat, jaundice or other infection, to my specialist or GP whilst taking the medicine
- I will attend to have blood monitoring as advised
- I will attend all requested GP and specialist appointments for the monitoring of therapy and the assessment of outcomes, to assist the health professionals to provide safe and appropriate treatment

Signed ………………………………………………….. Date ……………………..

Copy to be filed in patient notes and scanned into ISIS