Bath and North East Somerset,
Swindon and Wiltshire Together

BSW Summary of Shared Care Guidelines And Monitoring of Disease Modifying Drugs (DMARDs) in ADULTS September 2023 Rheumatology/Dermatology/Respiratory/Neurology and Gastroenterology

Based on the British Society for Rheumatology/BHPR Non-Biologic DMARD Guidance 2017

https://academic.oup.com/rheumatology/article/56/6/865/3053478

See also Summary of Product Characteristics or BNF for additional Information

Please note: The medicines in this shared care agreement may only be used as part of this agreement for the conditions mentioned in the following tables. Use of the medicines listed for haematology/oncology or for immunosuppression following transplant are considered to have a RED traffic light status (specialist use only).

General Information

Disease Modifying Anti-Rheumatic drugs (DMARDs) are added at increasingly early stages in the treatment of rheumatoid arthritis (RA) to suppress the processes responsible for the chronic inflammation of RA, they may be used either as mono-therapy or in combination. DMARDs are also used for the treatment of other rheumatology conditions (e.g. connective tissue disorders and vasculitis) and in other specialities, including dermatology, respiratory medicine and gastroenterology.

A number of these drugs are recommended for prescribing in unlicensed indications. All recommendations are based on the practice of a responsible body of peers of similar professional standing (e.g. The British Society for Rheumatology; see References for full details). Prescribers are advised to discuss with the patient if the medicine is used out of licence and document this agreement in the patient's medical record.

These shared care guidelines outline suggested ways in which the responsibilities for managing the prescribing of DMARDs can be shared between the specialist and general practitioner (GP) or other primary care prescriber.

DMARDs should be initiated by hospital specialists only and should not be initiated in the Primary Care setting. GPs are invited to prescribe DMARDs and participate in shared care in accordance with the written instructions given by the Acute Trust Specialists once the patient has reached a stable dose.
If the GP is not confident to undertake these roles, then the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe drugs for this treatment, the GP should only reply if he cannot take on the shared care arrangement. The

intention to share care should be explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

Please consult the manufacturer's Summary of Product Characteristics (SPC) (www.medicines.org.uk) and the current BNF for full prescribing information on contra-indications, side-effects and interactions.

Pre-pregnancy and pregnancy advice:
If the patient is pregnant or is thinking of becoming pregnant (in relation to both maternal and paternal patients) then advice should be sought from the originating prescriber.

Further medicines advice:In the Salisbury (SFT) area, further information can also be obtained from Wessex Drug and Medicines Information Centre, based at Southampton General Hospital. The service may be accessed in the following ways:
By telephone: Available from 09h00-18h00 (Mon-Fri), call 023 8120 6908 or 9
By e-mail: medicinesadvice@uhs.nhs.uk

RUH: Medicines Information telephone: 01225 824633
Patient Information Helpline http://www.ruh.nhs.uk/patients/medicines_helpline/index.asp
01225 825361 Monday to Friday 9.00am - 11.00am, and 2.00pm - 4.30pm
Outpatient pharmacy: 01225 825869
OUT OF HOURS EMERGENCY CONTACT (5pm until 9am Mon to Sat and all weekend) Contact the Medical Admissions Unit Consultant 07818 013823 OUT OF HOURS in the event of severe neutropenia.

GWH: Patient information help-line: 01793 605369 with capacity for leaving messages. This is manned on weekday mornings and is only regarding medication received from the hospital.
In the Swindon area, further information can also be obtained from Wessex Drug and Medicines Information Centre, based at Southampton General Hospital. The service may be accessed in the following ways:
By telephone: Available from 09h00-18h00 (Mon-Fri), call 023 8120 6908 or 9
By e-mail: medicinesadvice@uhs.nhs.uk

National Medicines Advice for healthcare professionals in primary care (including community pharmacy) Via SPS Specialist Pharmacy Services. Email asksps.nhs@sps.direct or call **0300 770 8564**

Rheumatology

SFT Consultants/Nurse Specialists Contact via Secretaries		
Rheumatology Advice and Guidance	Use Cinapsis	
Rheumatology Secretarial team for general enquiries	sft.rheumatology.secretaries@nhs.net.	
Nurse Specialists	01722 429217	
RUH Consultants/Nurse Specialists		
Rheumatology advice line for patients	01225 428823	
GP queries help line	Via consultant connect	
GWH Consultants/Nurse Specialists Contact via Secretaries		
Rheumatology advice line for patients	01793 604323	gwh.rheumatologyadvice@nhs.net
GP queries help line (Mon-Fri except Mon a.m. & Weds p.m.)	01793 6047496	or via cinapsis
Dr Elizabeth Price's secretary	01793 604314	
Dr Carty's secretary	01793 604317	
Dr Collins' secretary		
Dr Ahmed's secretary	01793 604318	
Dr Waller's secretary		
Dr Williams secretary	01793 604314	
Dr Oke's secretary		

Gastroenterology

SFT Consultants/Nurse Specialists		**E-mail addresses**	**Telephone numbers**
IBD nurses	Inflammatory Bowel Disease Specialist Nurse	Preferred contact is via Cinapsis Alternatively sft.admin.gastro@nhs.net 01722 345590	
Dr H Woodland,	Consultant Gastroenterologist		
Dr D Allam , Dr M Islam,	Locum Consultant Gastroenterologist		
RUH Consultants/Nurse Specialists			
Inflammatory Bowel Disease Specialist Nurses		Ruh-tr.ibd@nhs.net	01225 825598
Consultant gastroenterologists		Ruh-tr.gastroadvice@nhs.net	01225 821856 or 01225 821569
GWH Gastroenterology			
GWH IBD nurse specialists		gwh.ibdnurses@nhs.net	

Dermatology

SFT		E-mail addresses	Telephone numbers
Dermatology		shc-tr.Dermatology@nhs.net or via Cinapsis	-
RUH			
Urgent dermatology advice			Via cinapsis
Dr S Woodrow	Consultant dermatologist		01225 826374
Dr I Mauri-Sole	Associate specialist		01225 826225
Dr Caoimhe Fahy	Consultant dermatologist		01225 825326
Dr Sarah Rasool	Consultant dermatologist		01225 826374
Dr Naila Dinani	Consultant dermatologist		01225 826225
Emma Holt	Biologics administrator		01225 826226
GWH			
Dermatology nurse and consultant specialists	Nurse specialist	gwh.dermcnsteam@nhs.net or via cinapsis	01793 604367/68
Spa medical centre dermatology service			
Tom Millard	Consultant dermatologist	tom.millard@nhs.net	01225 898019
Catrinel Wright	Dermatology GPwER	catrinelwright@nhs.net	

Neurology

GWH Consultants/Nurse Specialists		E-mail addresses	Telephone numbers
Dr Hinze/ Dr Yiin	Consultant neurologists	gwh.neurologyrefs@nhs.net or via cinapsis	01793 605099
Dr Lennox/Dr Paul/ Dr Thompson			01793 604767
Dr Zuromskis/ Dr Bajoriene			01793 605105
Dr Mazzucco/ Dr Morrish/ Dr Sarangmat			01793 605114
RUH Consultants/Nurse Specialists		**E-mail addresses**	**Telephone numbers**
Dr Nicola Giffin	Consultant neurologists		X 5456
Dr Paul Lyons			X 4433
Dr C Chohan			X 5378
SFT Consultants/Nurse Specialists		**E-mail addresses**	**Telephone numbers**
Dr Boyd Ghosh	Consultant neurologists	sft.admin.neurology@nhs.net	01722 429233
Dr Chinar Osman			
Joanna Lovett			

Respiratory

SFT
SFT Lead Resp. Nurse Specialists: sft.respiratorynurses@nhs.net 01722 429228 or 01722 429220
SFT Consultant Resp. Physicians: sft.admin.respiratory@nhs.net 01722 429228
RUH
RUH ruh-tr.respiratory@nhs.net or ruh-tr.RespiratoryNurseSpecialists@nhs.net **Or preferably via Cinapsis**
GWH
Via cinapsis

Responsibilities of Speciality Team, GP Team, Pharmacy Team & Patient

Specialist responsibilities
1 Provide patient with information on disease and drug treatment options and explain where drugs are used outside of licence. 2 Discuss the benefits and side effects of treatment with the patient and advise women of child bearing age to use reliable contraceptive methods where necessary. Also discuss the effects of the drug on pregnancy if applicable, when the patient may be considering having a family (paternal effects as well) in the future. Also, the intention to share care. 3 To confirm the patient has no contra-indications to treatment and consider the relevance of any cautions. 4 Carry out pre-treatment assessment, including height, weight, blood pressure and necessary blood tests (FBC, Creatinine, ALT &/or AST and albumin). Evaluate patient for respiratory disease and screen for occult viral infection. 5 Confirm that the GP is willing to participate in shared care. 6 Ensure the patient knows to report any side-effects or problems to their GP or specialist. 7 The specialist should report any side-effects to the MHRA via the yellow card scheme. 8 Review pre-treatment assessment, including blood test results. 9 Initiate treatment with DMARD and give at least a 28 day supply to the patient and give the patient a monitoring booklet/ patient info leaflet as appropriate. 10 Send GP details of baseline assessments and results, prescribed dose of DMARD, monitoring requirements and a summary of the information that has been given to the patient. 11 Advise GP that pneumococcus and influenza vaccinations are recommended in patients taking DMARDs. 12 At first review appointment check initial monitoring results and assess response to treatment. 13 Communicate promptly with the GP when treatment is changed or needs to be changed by the GP, and when any changes in monitoring are required. Ensure that arrangements are in place for GPs to obtain advice and support where needed. 14 Have a mechanism in place to receive rapid referral of a patient from the GP in the event of deteriorating clinical condition. 15 Ensure that clear backup arrangements exist for GPs to obtain advice and support.

General Practitioner (or other primary care prescriber) responsibilities
1 Reply to the request as soon as practicable if they are **unable** to support shared care (in writing or via secure email). 2 Prescribe the DMARD at the dose recommended. 3 Carry out monitoring according to the guideline recommendations. 4 Ensure the patient is aware of any treatment change and that where held, the monitoring booklet is up to date. 5 Report to and seek advice from the specialist on any aspect of patient care that is of concern and may affect treatment. 6 Refer patient to specialist if his or her condition deteriorates. 7 Stop treatment on advice of specialist or immediately if an urgent need to stop treatment arises. 8 Report adverse events to the specialist team and MHRA via the yellow card scheme.

Pharmacist responsibilities
1 Ensure appropriate dose prescribed with clear directions not 'as directed'. 2 Provide advice on adverse effects and any drug interactions with prescription and/or OTC medicines. 3 Issue patient information leaflets where appropriate. 4 Monitor frequency of prescription requests and contact GP if quantities in excess of the prescribed dose are ordered. 5. Advise patient to report any malaise, unexplained bruising or sore throats to Specialist / GP

Patient responsibilities
1. Report to the specialist or GP if he or she does not have a clear understanding or has any concerns in relation to treatment 2. Ensure safe storage and handling of medicine 3. Request repeat prescriptions from GP in good time. 4. Ensure Pharmacist is aware of the DMARD they are taking prior to purchase of any OTC medicine. 5. Ensure the GP and specialist are aware of any over- the -counter medicines they may be taking. 6. Where patient-held monitoring booklets have been given ensure these are available at each appointment with their GP or specialist 7. Report any adverse effects to the GP or specialist. 8. Attend blood monitoring appointments

Standard Monitoring Schedule requirements:

For use when starting or adding a new DMARD.

Check FBC, creatinine/calculated GFR, ALT and/or AST and albumin every:

- Two weeks until on stable dose for 6 weeks then
- Once on stable dose, monthly FBC, creatinine/calculated GFR, ALT and/or AST and albumin for 3 months.
- Thereafter FBC, creatinine/calculated GFR, ALT, and/or AST and albumin at least every 12 weeks*

*More frequent monitoring is appropriate in patients at higher risk of toxicity (e.g. prior history of adverse drug reactions, patients at extremes of weight, very elderly, impaired renal function and those with co prescriptions of medications that may interact with DMARDS).

Dose increases should be monitored by FBC, creatinine/calculated GFR, ALT and/or AST and albumin every 2 weeks until on stable dose for 6 weeks then revert back to previous schedule.

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Prescribing Information & Monitoring Requirements

In addition to absolute values for haematological indices a rapid fall or rise and a consistent upward or downward trend in any value should prompt caution and extra vigilance. U/E and creatinine, CRP and/ or ESR should be checked every 6 months. This will enable monitoring of renal disease & disease activity**.**

DRUG (Oral)	Indication & dose	Pre-treatment assessment	FBC	U&E, Creatinine (eGFR)	LFT	URINE DipStick Protein	Additional information
Azathioprine **Amber for all indications**	**RA, CTD:** 1mg/kg per day increase at 4-6 weekly intervals to max 3mg/kg per day. **Acute/chronic auto immune hepatitis**: 1-2 or 3mg /kg per day *-see additional info in BSG guidelines in additional information column.* **Gastroenterology** Inflammatory bowel disease (unlicensed): 2-2.5mg/kg per day (see additional info) **Dermatology** Severe refractory eczema, psoriasis, psoriatric arthritis, bullous dermatoses including pemphigoid (unlicensed) : 1-3mg/kg per day **Neurology** Usual maintenance dose 2-3mg/kg per day. SLE (licensed) *All the following are off label, but considered routine treatment:* Neurosarcoidosis, CNS vasculitis or vasculitis neuropathy, neuromyelitis optica, idiopathic CNS	Height, weight, FBC, U&E, LFT, Creatinine (gastro request) (unless done within 6 months). Consider screening for Hepatitis B & C & HIV Consider VZ serology Respiratory history and examination; consider lung function tests and imaging (CXR +/- HRCT) if any concerns **TPMT assay** -gives additional information on risks of treatment **but does not replace** routine monitoring. *Homozygous deficiency* -serious and fatal toxicity- can occur within 6 weeks of starting. *Heterozygous deficiency* - linked to serious adverse events, symptoms may not be evident until 6 months after starting treatment. If patient is found to have heterozygous deficiency, monitoring of blood should take place at monthly intervals.	**As per standard monitoring schedule on page 7**			-	Reduce azathioprine dose to 25% (i.e ¼) of the original when given with allopurinol [see BNF interaction] BSG guidelines for the management of autoimmune hepatitis EFNS guidelines on diagnosis and management of neuromyelitis optica (2010) A randomized double-blind trial of prednisolone alone or with azathioprine in myasthenia gravis 1998 Myasthenia gravis: Association of British Neurologists' management guidelines 2015

	inflammation (inc. idiopathic optic neuritis, clippers, myelitis), myasthenia gravis and Lambert Eaton Myasthenic Syndrome, chronic inflammatory demyelinating polyradiculoneuropathy, sensory neuronopathy (also known as dorsal root ganglionopathy), idiopathic inflammatory neuropathy, stiff person syndrome, autoimmune encephalitis, paraneoplastic neurological disorders. **Respiratory** Azathioprine for sarcoidosis and other interstitial lung diseases (ILD) is off-label but in BTS guidelines. Usually 100mg OD rising to 150mg or as directed.						Sarcoidosis | British Thoracic Society | Better lung health for all (brit-thoracic.org.uk) (2020)
DRUG (Oral)	**Indication & dose**	**Pre-treatment assessment**	**FBC**	**U&E, Creatinine (eGFR)**	**LFT**	**URINE DipStick Protein**	**Additional information**
Mercaptopurine **Amber**	**Gastroenterology** Inflammatory bowel disease, autoimmune chronic and active hepatitis (unlicensed): 0.75-1.5mg/kg per day	See azathioprine (azathioprine is a prodrug which is converted to mercaptopurine *in vivo & m*onitoring requirements are the same) *Note: should NOT be prescribed as 6-mercaptopurine OR 6-MP* Reduce mercaptopurine dose to 25% (i.e ¼) of the original when given with allopurinol [see BNF for interaction]					

DRUG	Indication & dose	Pre-treatment assessment	FBC	U&E, Creatinine (eGFR)	LFT	URINE DipStick Protein	Additional information
Ciclosporin **Red for ALL indications** *Note: monitoring info included in SCA as some GPs might be asked to do the on-going monitoring but not the prescribing.* *Prescribe generically for all except transplant pts* *Monitor when switching between caps & oral solution: differences in bioequivalence.* *Contact Meds Info for advice*	**RA**: 2.5mg/kg per day in 2 divided doses, increasing after 6 weeks by 25mg increments to a maximum of 4mg/kg per day (licensed) **Gastroenterology**: ulcerative colitis (unlicensed) 5 – 6.5mg/kg per day in 2 divided doses for short courses **Dermatology** Severe atopic dermatitis, severe psoriasis: 2.5-5 mg/kg per day in 2 divided doses titrated to skin response (licensed)	FBC, U&E, LFT, Creatinine Creatinine clearance or equivalent Lipid profile VZV serology BP: ≤ 140/90 on 2 occasions at 2/52 apart. Consider screening for Hepatitis B & C & HIV Consider VZ serology Respiratory history and examination; CXR	Fortnightly until dose stable for 6 weeks, then monthly			-	Check **blood pressure** at each attendance. Maintain BP ≤140/90 Vigilance when **NSAID** added, particularly diclofenac. Avoid where possible. Check **fasting lipids** every 6 months
Dapsone **Amber for licensed indications**	Dermatitis herpetiformis (licensed) & other inflammatory dermatoses neutrophilic vasculitis: start 50mg daily gradually increased to 300mg then reduced to lowest dose that achieves symptom control.	FBC, reticulocytes, LFTs, G6PD	Fortnightly for 2 months then at least every 3 months.		Monthly until dose stable then, 3 monthly		

DRUG	Indication & dose	Pre-treatment assessment	FBC	U&E, Creatinine (eGFR)	LFT	URINE DipStick Protein	Additional information
Hydroxy-chloroquine Amber	**RA, CTD** systemic & discoid lupus erythematosus, photosensitive dermatological conditions 200 – 400 mg daily. The manufacturers and the BNF state max dose: 6.5mg/kg/day (based on ideal body weight) BUT the RCOphth recommendation to keep dosage **< 5mg/kg/day** based on actual body weight.	FBC, U&E, LFT.	No routine blood monitoring Patients on this medicine for more than 5 years should be referred for ophthalmic monitoring as per the RCOphth guidance 2020 (unless additional risk factors are present e.g. very high dose of drug therapy (greater than 5mg/kg/day hydroxychloroquine), concomitant tamoxifen therapy or renal insufficiency (eGFR less than 60ml/min/1.73m2).).			-	Patients should be monitored as per RCOphth guidance 2020. Advise patients to report changes in vision. Also see: NHSE Hydroxychloroquine and chloroquine retinopathy monitoring
Leflunomide Amber	**RA & psoriatic arthritis:** 10mg – 20 mg daily. Maximum 20mg daily when given as monotherapy. Use 10mg daily in combination with other hepatotoxic drugs such as methotrexate (Not used in dermatology)	FBC, U&E, LFT, Creatinine. Blood Pressure on 2 occasions 2 weeks apart. If > 140/90 treat before starting Rx Body weight Consider screening for Hepatitis B & C & HIV Respiratory history and examination; consider lung function tests and imaging (CXR +/- HRCT) if any concerns	**As per standard monitoring schedule on page 7** If co-prescribed with another immunosuppressant or potential hepatotoxic agent then blood checks should be continued long-term**, at least once a month** Patients who have been stable for 12 months can be considered for reduced frequency monitoring on an individual basis upon discussion with the specialist.				**BP at each visit**. If BP >140/90 treat in line with NICE guidance. If BP remains uncontrolled, stop & consider washout **Weigh at each visit**. If > 10% weight loss with no other cause identified, reduce dose or stop and consider washout.

							Simple dose reduction is unlikely to produce a rapid decrease of adverse effects (half-life is approx. 2 weeks). If a rapid response is required, consider washout and seek specialist advice.
DRUG	**Indication & dose**	**Pre-treatment assessment**	**FBC**	**U&E, Creatinine (eGFR)**	**LFT**	**URINE DipStick Protein**	**Additional information**

Methotrexate **Amber** *For use of subcutaneous methotrexate, see separate BSW SCA Methotrexate (subcut) for Adult Patients*	**RA, Psoriasis, severe atopic dermatitis, Psoriatic arthritis, Crohn's disease, connective tissue disease (SLE, myositis, vasculitis), Felty's Syndrome, inflammatory bowel disease (unlicensed):** 7.5 – 25mg ONCE a week. Increase every 2-6 weeks to a maximum dose of 25mg ONCE weekly. (Rarely) max 30mg ONCE week. ONLY prescribe as 2.5mg strength tablets (do not use 10mg tablets) **Rheumatology /Dermatology** s/c route may be given for patients unable to tolerate oral methotrexate. Monitoring as per this document. **Neurology** Starting dose 7.5 mg weekly, increased as necessary by 2.5 mg increments to a maximum of 15mg weekly. In exceptional circumstances, up to 25 mg weekly. *All the following are off label, but considered routine treatment:* Neurosarcoidosis, CNS vasculitis or vasculitis neuropathy, SLE,	FBC, U&E (eGFR), LFT Respiratory history and examination; consider lung function tests and imaging (CXR +/- HRCT) if any concerns Consider Screening for Hepatitis B & C & HIV. Consider VZ serology P3NP (procollagen peptide assay) in dermatology patients	**As per standard monitoring schedule on page 7** **Dose increase or unstable bloods:** Unless otherwise specified by specialist, repeat **every 2 weeks until dose of methotrexate and monitoring stable for 6 weeks,** then return to standard monitoring schedule on page 7		New or increasing dyspnoea or dry cough – withhold and discuss urgently with the specialist team. Avoid prescribing trimethoprim or cotrimoxazole to patients receiving Methotrexate – greatly increases risk of marrow aplasia. Specialists may recommend co-prescribing of methotrexate and NSAIDs/ aspirin clinically significant interactions are rare **Folic acid** given to minimise side effects is usually given 5mg-10mg once weekly, not on the same days as methotrexate; however doses can vary Ensure patient has a info leaflet/monitoring booklet: http://www.nrls.npsa.nhs.uk/resources/?entryid45=59800

	neuromyelitis optica, idiopathic CNS inflammation (inc. idiopathic optic neuritis, clippers, myelitis), myasthenia gravis and Lambert Eaton Myasthenic Syndrome, chronic inflammatory demyelinating polyradiculoneuropathy, sensory neuronopathy (also known as dorsal root ganglionopathy), idiopathic inflammatory neuropathy **Respiratory** Methotrexate for sarcoidosis and other interstitial lung diseases (ILD) is off-label but in BTS guidelines. Usually 15mg weekly up to 25mg weekly or as directed.						EFNS guidelines on diagnosis and management of neuromyelitis optica (2010) Myasthenia gravis: Association of British Neurologists' management guidelines 2015 Sarcoidosis | British Thoracic Society | Better lung health for all (brit-thoracic.org.uk) (2020)
DRUG	**Indication & dose**	**Pre-treatment assessment**	**FBC**	**U&E, Creatinine (eGFR)**	**LFT**	**URINE DipStick Protein**	**Additional information**
Mycophenolate (off-label use) **Amber for Autoimmune Conditions** **RED in dermatology for severe**	**RA, connective tissue disorders, SLE, lupus nephritis, dermatomyositis, polymyositis, systemic sclerosis, vasculitis, psoriasis, atopic dermatitis**: Start 500mg daily increase weekly by 500mg to optimal or max. tolerated dose. Max – 3g/day.	FBC, U&E, LFT & CXR (within the last 6 months) Respiratory history and examination; consider lung function tests and imaging (CXR +/- HRCT) if any concerns Consider Screening for Hepatitis B & C & HIV.	**As per standard monitoring schedule on page** 7			-	Advise patients to report any signs or symptoms of bone marrow suppression- inexplicable bruising or bleeding See MHRA Drug Safety Update 14

inflammatory disease & pemphigus (unlicensed)	**Autoimmune hepatitis (used in in pts intolerant of AZA):** 2g/day of MMF in divided doses; *-see additional info in BSG guidelines in additional information column.* **Neurology** Start 500mg once daily, increasing after one week to 500mg twice daily. Thereafter, if there are no adverse effects up to the usual maintenance dose of 1g twice daily (maximum dose 1.5g twice daily). *All the following are off label, but considered routine treatment:* Neurosarcoidosis, CNS vasculitis or vasculitis neuropathy, SLE, neuromyelitis optica, idiopathic CNS inflammation (inc. idiopathic optic neuritis, clippers, myelitis), myasthenia gravis and Lambert Eaton Myasthenic Syndrome, chronic inflammatory demyelinating polyradiculoneuropathy, sensory neuronopathy (also known as dorsal root ganglionopathy), idiopathic inflammatory neuropathy, stiff person syndrome, autoimmune encephalitis, paraneoplastic neurological disorders.				Dec 2015: https://www.gov.uk/drug-safety-update/mycophenolate-mofetil-mycophenolic-acid-new-pregnancy-prevention-advice-for-women-and-men BSG guidelines for the management of autoimmune hepatitis EFNS guidelines on diagnosis and management of neuromyelitis optica (2010) Myasthenia gravis: Association of British Neurologists' management guidelines 2015

	Respiratory MMF for sarcoidosis and other interstitial lung diseases (ILD) is off-label but in BTS guidelines. Usually 1g BD rising to 1.5g BD or as directed.						Sarcoidosis | British Thoracic Society | Better lung health for all (brit-thoracic.org.uk) (2020)
DRUG	**Indication & dose**	**Pre-treatment assessment**	**FBC**	**U&E, Creatinine (eGFR)**	**LFT**	**URINE DipStick Protein**	**Additional information**
D-Penicillamine **Amber**	**RA, Wilson's disease:** Start 125–250mg/day increase by 125mg, 4 weekly initially to 500mg. Max dose 750mg/day in divided doses	FBC, U&E, Creatinine & Urinary Protein	**Every 2 weeks** until stable for 3 months**. Monthly** thereafter.	-	-	**Every 2 weeks** until stable for 3 months. Then monthly	Ask about skin rash or oral ulceration at every visit. Alteration of taste usually settles spontaneously.

DRUG	**Indication & dose**	**Pre-treatment assessment**	**FBC**	**U&E, Creatinine (eGFR)**	**LFT**	**URINE DipStick Protein**	**Additional information**

Sulfasalazine **TLS amber**	**Ulcerative colitis, Crohn's disease:** 1g twice daily increasing to 4g daily in divided doses. Use plain sulfasalazine **RA:** Start at 500mg/day increasing by 500mg weekly to maximum of 2-3 grams/daily (Licensed) Sero-negative spondyloarthropathy, psoriasis (unlicensed): Dose as in RA above Use Enteric-Coated (EC) sulfasalazine	FBC, U&E, LFT, Creatinine Consider Screening for Hepatitis B & C & HIV.	**As per standard monitoring schedule on page 7 for first three months.** **Once stable, common practice is to monitor U&Es annually.** **Dose increase or unstable bloods:** Unless otherwise specified by specialist, repeat **every 2 weeks until dose of sulfasalazine and monitoring stable for 6 weeks,** then return to annual monitoring.		Ask about skin rash, oral ulceration at each visit.

Monitoring – Actions to be taken if any of the following applies:

WBC <3.5 x 10^9/l	Withhold until discussed with specialist team
Neutrophils <1.6 x 10^9/l	Withhold until discussed with specialist team
Eosinophils > 0.5x 10^9/l	Withhold until discussed with specialist team
Platelets <140 x 10^9/l	Withhold until discussed with specialist team
Haemoglobin reduction of > 3g/dl	Withhold until discussed with specialist team
AST or ALT >100U/l rise (All drugs) (from upper limit of reference range)	Withhold until discussed with specialist team ***Leflunomide****- special rules: ALT/AST 2-3x upper limit normal – reduce dose to 10mg,* ***recheck weekly****. If normalized – continue 10mg; if remains elevated withdraw drug and discuss with specialist team. If ALT/AST >3x normal, stop drug,* ***recheck within 72 hours****. If still >3x, withdraw drug and consider washout*. Check other reason e.g alcohol or other medicines or drug interactions
Albumin –unexplained fall (<30g/l)	Withhold until discussed with specialist team
MCV >105 fl	Investigate (and check if B12 or folate or TSH low start supplementation)
1. Creatinine increase >30% over 12 months and/or calculated GFR <60ml/min 2. For use of ciclosporin in dermatology, if creatinine rises to >30% of baseline (on 2 consecutive occasions)	1. Withhold until discussed with specialist team 2. Dose reduction will be required, discuss with specialist for advice.
Potassium rise to above normal range	Withhold until discussed with specialist team and recheck it remains raised
Urinary protein on dipstick is 2+ (**D-Penicillamine)**	Send a MSU requesting protein + C&S. If >++ withhold drug. If MSU confirms infection, treat appropriately. If sterile proteinuria – seek advice from specialist team.
Blood pressure >140/90mm Hg (Leflunomide and ciclosporin)	Manage hypertension according to NICE hypertension guidance (Ciclosporin – discuss with specialist team)
Fasting lipids –significant rise (Ciclosporin)	Withhold until discussed with specialist team
Any unexplained illness e.g. nausea/dizziness/headache	If symptoms severe withhold until discussed with specialist team & consider review
Abnormal bruising or sore throat	Withhold until FBC result available
Unexplained acute widespread rash/ hair loss	Withhold – seek urgent specialist (preferably dermatological) advice
New Oral ulceration	Withhold until discussed with specialist
New increasing dyspnoea or cough (methotrexate /leflunomide)	Withhold & discuss urgently with specialist team
As well as responding to absolute values in laboratory tests, it is also relevant to observe trends in results (e.g. gradual decrease in WBC or albumin or climbing liver enzymes).	

Vaccination - Chapter 7 of the JCVI Green Book deals specifically with patients commencing immunosuppression and should be regarded as the definitive source of information on vaccination:
https://www.gov.uk/government/publications/immunisation-of-individuals-with-underlying-medical-conditions-the-green-book-chapter-7

Also see the BSR and BHPR guideline for the prescription and monitoring of **non-biologic DMARDS** which notes:

- Although rheumatologists are responsible for the initiation of immunosuppressive agents**, it remains in the domain of primary care to ensure vaccination**. Primary care practices are commissioned to vaccinate people >65 years old and those <65 years old at risk (including patients with rheumatic diseases on DMARDs).

- **All patients should be offered influenza vaccine (administered annually) and pneumococcus**. Pneumococcal vaccination should be administered as a single dose of PPV23 (Pneumovax). Ideally, the pneumococcal vaccine should be administered prior to the initiation of DMARDs; however, if this is not possible it should be administered irrespective.

- The green book recommends **in severely immunocompromised adults, a different schedule using a single dose of the conjugate PCV-13 (Prevenar) followed by PPV-23 at least 2 months later be used. It also gives examples of severe immunocompromise; liaison with immunology specialists may be appropriate.**

- **Live vaccines are not recommended in patients on immunosuppression**. This is relevant for patients seeking vaccination for foreign travel (e.g. yellow fever vaccination).

Shingles vaccination – For full details see Green Book Chapter 28a

From Sep 2023, Shingrix is replacing Zostavax in the routine immunisation programme. Shingrix is a recombinant vaccine and contains varicella zoster virus glycoprotein E antigen produced by recombinant DNA technology, adjuvanted with AS01B. Additionally, eligibility has been expanded to include severely immunosuppressed individuals aged 50 years and over (with no upper age limit) who should be offered two doses of Shingrix. The 2nd dose should be given 8 weeks to 6 months after the 1st dose for this cohort, in line with Shingrix SmPC. Definition of severe immunosuppression for the Shingrix vaccine programme (in the context of this DMARD SCA):

Individuals with chronic immune mediated inflammatory disease who are receiving or have received immunosuppressive therapy

- moderate to high dose corticosteroids (equivalent ≥20mg prednisolone per day) for more than 10 days in the previous month
- long term moderate dose corticosteroids (equivalent to ≥10mg prednisolone per day for more than 4 weeks) in the previous 3 months
- any non-biological oral immune modulating drugs e.g. methotrexate >20mg per week (oral and subcutaneous), azathioprine >3.0mg/kg/day; 6-mercaptopurine >1.5mg/kg/day, mycophenolate >1g/day) in the previous 3 months
- certain combination therapies at individual doses lower than stated above, including those on ≥7.5mg prednisolone per day in combination with other immunosuppressants (other than hydroxychloroquine or sulfasalazine) and those receiving methotrexate (any dose) with leflunomide in the previous 3 months.
  If there is any doubt, individual patients should be discussed with their specialist. Severely immunosuppressed individuals who have already received 2 doses of Shingrix do not need re-vaccination.

For other details related to immunisation see

- The British Society for Rheumatology **biologic** DMARD safety guidelines in inflammatory arthritis https://doi.org/10.1093/rheumatology/key298
- JCVI green book Chapter 14a **COVID-19** https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1057798/Greenbook-chapter-14a-28Feb22.pdf
- Principles for COVID-19 Vaccination in Musculoskeletal and Rheumatology for Clinicians COVID-19 vaccination and MSK (arma.uk.net)
- PGDs **for NHS primary care services** https://www.england.nhs.uk/south/info-professional/pgd/south-west/

Useful references

- British National Formulary https://bnf.nice.org.uk/
- Electronic Medicines Compendium. Available at: Home – electronic medicines compendium (emc)
- BSR/BHPR Non-biologic DMARD guidelines 2017: BSR and BHPR guideline for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs https://academic.oup.com/rheumatology/article/56/6/865/3053478
- BSR biologic DMARD safety guidelines in inflammatory arthritis 2019: https://academic.oup.com/rheumatology/article/58/2/e3/5076446
- 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. https://pubmed.ncbi.nlm.nih.gov/21464096/
- RCOphth guidelines https://www.rcophth.ac.uk/standards-publications-research/clinical-guidelines/ Hydroxychloroquine and Chloroquine Retinopathy Monitoring Guideline and Recommendations 2020 https://www.rcophth.ac.uk/resources-listing/2609/
- BTS Clinical Statement on Pulmonary Sarcoidosis December 2020 https://www.brit-thoracic.org.uk/quality-improvement/clinical-statements/sarcoidosis/

Version control:

Version	Author	Purpose/change	Date
1.1	Rachel Hobson	• Added neurology for MTX/AZA/Mycophenolate • Added contact details for the Spa Dermatology Service (to use oral MTX)	1/3/21
1.2	Rachel Hobson	• Updated logos and dates • Added RCOpth dose for HCQ and link to NHSE monitoring guidance	19/8/22
1.3	Jill Forrest	• Changes to some contact details and updated links	17/11/2022
1.4	Jill Forrest	• Respiratory indications included	12/06/2023
1.5	Jill Forrest	• Added GWH gastro service and contact details • Update to sulfasalazine monitoring section • Updated shingles vaccination national programme information • Minor typographical corrections	Sept 2023
1.6	RH	• Updated HCQ monitoring, no ophthalmology baseline needed.	March 2025