**Request to Share Care and Agreement Form**

**Azathioprine / Mercaptopurine (MP) use in adults with multisystem autoimmune disease:**

**Dermatology / Gastroenterology / Haematology / Nephrology / Neurology / Ophthalmology / Respiratory / Rheumatology**

**Shared Care Protocol: Guideline No 1; Version 2**

**For use in West Essex**

**This Request to Share Care provides Key Primary Care Information on responsibilities and monitoring. The aim is to support the GP to agree to share care arrangements. Refer to Full Shared Care Protocol for further information (page 6 onwards).**

**GP to review and must respond to provider Trust request to share care within 2 weeks using form provided on page 5.**

**For Completion by Specialist (with page 5 Shared Care Agreement Form)**

Addressograph label

|  |  |
| --- | --- |
| **Patient name** |       |
| **DOB** |       |
| **NHS number** |       |

 **OR**

|  |  |
| --- | --- |
| **Drug(s) Dose and Route at handover:**  |       |
| **Indication:**  |       |
| **Date of first prescription by specialist:**  |       |
| **Patient weight (kg):** |       |
| **Estimated date for prescribing to be continued by the GP:**  |       |
| **Next monitoring tests due and dates if not at 12 weekly monitoring:**  |       |
|
| **Specialist additional comments/advice:**  |       |
|

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Key Primary Care Information (refer to Full Shared Care Protocol for further information)****GP RESPONSIBILITIES*** Consider request to shared care arrangements and prompt completion and emailed return of signed response to the specialist using the Shared Care Agreement Form within 14 days of its receipt.
* If shared care accepted prescribe azathioprine/mercaptopurine once patient is clinically stable in line with protocol.
* Arrange, record and share ongoing monitoring and take appropriate action as per protocol and advised by specialist (see monitoring table), ensuring GP practice systems are in place to recall patients for monitoring blood tests.
* Re-iterating with the patient that non-attendance for blood testing may lead to withdrawal of the medication. Further help and advice can be sought from the hospital specialist team.
* Ascertaining the reason for non-completion of routine blood testing, if one test is missed.
* Appropriately prompt notification to the hospital specialist of any significant and relevant changes in the patient’s condition, medication dose, or of an adverse reaction, according to the protocol and if the patient fails to attend for blood monitoring.
* Ensure no drug interactions with other medicines.
* Administer inactivated influenza vaccine annually unless otherwise advised by the initiating specialist.
* Check patient has had ONE DOSE of pneumococcal vaccine (revaccination is not recommended except every five years in patients whose antibody levels are likely to have declined more rapidly eg. asplenia), see BNF or Green Book.
* COVID-19 vaccination is safe and recommended (see [The Green Book, Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a)).
* For susceptible immunosuppressed individuals with significant exposure to chickenpox (varicella) or shingles (zoster), follow latest national guidance on post exposure prophylaxis and use of anti-virals and varicella zoster immunoglobulin (VZIG) <https://www.gov.uk/government/publications/post-exposure-prophylaxis-for-chickenpox-and-shingles>
* Ask about oral ulceration, sore throat, unexplained rash or unusual bruising/bleeding at every consultation.
* Change dose or stop treatment in line with protocol and as advised by specialist.
* Organization of urgent referral to the specialist team or A&E if severe side effects or potential overdose is apparent.
* Liaising with the initiating clinician if the medicine becomes less effective and patient complains of symptoms.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **MONITORING AND ACTIONS TO BE TAKEN****Monitoring Table – see GP monitoring highlighted in grey**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Monitoring table** | **Hospital specialist** | **Hospital specialist** | **Hospital specialist / GP** | **GP**  | **Hospital specialist** |
| **Test** | **Indication** | Pre-treatment baseline | During TreatmentInitiation | Following Treatment Initiation | Ongoing | Annual review |
| FBC | Baseline and ongoing assessment, including dose adjustment to confirm safe to prescribe | √ | **Phase I monitoring\*** Every 2 weeks until stable dose for 6 weeks | **Phase II monitoring\***Every 4 weeks for next 12 weeks*Hospital specialist will undertake the first 4-week test**GP will undertake the second and third 4-week test* | **Phase III monitoring\***Every 12 weeks | As part of annual review or as clinically indicated |
| LFTs |
| U&Es, eGFR |
| ESR/CRP  | Disease activity scoring | √ | Every 12 weeks | Not routinely required | Every 12 weeks on advice of specialist |
| Height & weight | Baseline assessment for dose | √ | Not routinely required | Not routinely required | If clinically indicated |
| Hepatitis B, C & HIV | Baseline assessment, viral, respiratory and TB screening | If clinically indicated |
| Chest X-ray |
| TB screening if indicated |
| Urinalysis | To assess for or monitor renal disease (proteinuria) or infection | √ |
| TPMT | To assess suitability for treatment and guide dose | √ |
| Ask about oral ulceration, sore throat, unexplained rash or unusual bruising/bleeding | √ | At every consultation | At every consultation | At every consultation |
| **\***If a further DMARD is added as combination therapy, or the dose is increased, the initial starting schedule should be reinstated. **For dose increases monitoring should start back with Phase I monitoring and be every 2 weeks until dose is stable for 6 weeks, then revert to previous schedule.** There may be clinical circumstances where the frequency of monitoring may vary and this should be specified by the initiating specialist. |

**Action to be taken if Abnormal Result**Normal reference range may vary slightly between labs. Results should be recorded in the patient’s shared care monitoring record booklet (where in use). Please note an unusual fall or rise or a consistent downward or upward trend in any value should prompt review of the patient and extra vigilance. Some patients may have abnormal baseline values, specialist will advise.

|  |  |
| --- | --- |
| **Abnormal Result** | **Action to be taken by GP** |
| Neutrophils: if < 2.0 x 109/L | Discuss with specialist to consider 50% dose reduction, if < 1.6 x 109/L stop. |
| WCC < 3.5 x 109/L | Repeat, review dose with specialist if still <3.5, if <3.0 stop and contact specialist.NB - It is normal to get a low lymphocyte count, discuss with specialist if any concerns. |
| Unexplained eosinophilia > 0.5 x 109/L  | Contact specialist for advice. Withhold azathioprine/MP if no response from specialist in 5-7 days. |
| Anaemia | If new – investigate in the usual way and monitor weekly, if long standing monitor as schedule. If cause for concern discuss with specialist.  |
| Platelets < 140 x 109/L  | Contact specialist for advice. Withhold azathioprine/MP if no response from specialist in 5-7 days. |
| MCV > 105fL | Check B12 & folate, alcohol history & TFT: if <120fL and folate & B12 are normal continue, if >120fL stop azathioprine/MP and contact specialist.  |
| AST/ALT > 2 times the upper limit of normal (ULN) | If >3 x ULN hold azathioprine and seek specialist advice.For results between 2 - 3 x ULN, continue azathioprine / MP, repeat bloods and seek specialist advice. Minor elevations of AST/ALT are common.  |
| If patient develops pancreatitis  | Discontinue treatment and contact specialist. |
| Rising ESR / CRP | Contact specialist for advice. |
| * If renal impairment develops
* Unexplained fall in serum albumin
 | Contact specialist for advice. Withhold azathioprine/MP if no response from specialist in 5-7 days. |

 |

 |

* The expectation is that this information along with the full protocol provides sufficient information to enable GPs to be confident to take on the clinical & legal responsibility for prescribing and monitoring.
* Prescribing and monitoring responsibility will only be transferred under this shared care protocol when:
* Specialist has initiated treatment and prescribed/monitored treatment for initial stabilisation period.
* Specialist has provided pre-treatment counselling and discussed patient responsibilities, preferences and obtained consent to shared care arrangements.
* Specialist and patient have completed and signed the shared care agreement form (page 5).

**Shared Care Agreement Form**

**This form is used to agree shared care between the specialist, patient and GP.**

**Specialist and patient agreement**

**By signing below we accept:**

* the Herts and West Essex Area Prescribing Committee [shared care principles](https://www.hweclinicalguidance.nhs.uk/all-clinical-areas-documents/download?cid=1739&checksum=752d25a1f8dbfb2d656bac3094bfb81c) (HWE APC) and
* the requirements and responsibilities defined in this drug specific shared care protocol

|  |  |
| --- | --- |
| **Specialist name:**       | **Patient name or addressograph label:**      |
| **Designation:**       |
| **Provider Trust:**       |
| **Direct telephone number:**       |
| **Email:**      **Email (for use by GP to respond to request to share care):**  |
| **Date:**       | **Specialist Signature:**       |
| **Date:**       | **Patient signature or specialist confirmation of patient agreement to shared care arrangement:**       |

**GP response to shared care**

**Please return to specialist within two weeks of receipt of request to share care.**

***This form is to be completed by the GP who is requested to share care.***

I agree to accept shared care for this patient as set out in this shared care protocol and HWE [shared care principles](https://www.hweclinicalguidance.nhs.uk/all-clinical-areas-documents/download?cid=1739&checksum=752d25a1f8dbfb2d656bac3094bfb81c) [ ]

I do not accept shared care for this patient [ ]

My reason(s) for not prescribing are given below:

Please note that GP agreement is voluntary, with the right to decline to share care if for any reason you do not feel confident in accepting clinical responsibility. Refusal should not be for financial reasons.

|  |  |
| --- | --- |
| **GP name:**       | **Practice address /stamp:**      |
| **Direct telephone number:**       |
| **Email:**       |
| **Date:**       | **GP Signature:**       |

**Please return a copy of the completed form to the requesting specialist within two weeks of receipt of request to share care (preferably by email).**

1. Specialist to retain copy in patient’s hospital records.
2. Copy to be given to patient.
3. GP to retain copy in patient’s notes.

**Full Shared Care Protocol**

**Azathioprine / Mercaptopurine (MP) use in adults with multisystem autoimmune disease:**

**Dermatology / Gastroenterology / Haematology / Nephrology / Neurology / Ophthalmology / Respiratory / Rheumatology**

**Shared Care Protocol: Guideline No 1; Version 2**

**This full protocol provides prescribing and monitoring guidance. It should be read in conjunction with HWE shared care principles,** [**Summary of Product Characteristics (SPC)**](https://www.medicines.org.uk/emc) **and the** [**BNF**](http://www.bnf.org/bnf/index.htm)**.**

**BACKGROUND AND INDICATION(S) FOR USE**

Azathioprine is an immunosuppressant considered standard treatment for multiple auto-immune conditions, usually when corticosteroid therapy alone provides inadequate control. It is metabolised to mercaptopurine. Patients with side effects to azathioprine sometimes have a trial switch to mercaptopurine on advice of specialist.

Transplant and other indications not specified below are not covered by this Shared Care Protocol.

Azathioprine

**Licensed indications:**

Crohn’s disease, ulcerative colitis, systemic lupus erythematosus, dermatomyositis, polymyositis, autoimmune chronic active hepatitis, pemphigus vulgaris, polyarteritis nodosa, auto-immune haemolytic anaemia, chronic refractory idiopathic thrombocytopenic purpura (ITP), severe rheumatoid arthritis.

**Unlicensed indications:**

**Dermatological indications:** atopic dermatitis, bullous pemphigoid, chronic actinic dermatitis, pyoderma gangrenosum, cutaneous vasculitis.

**Systemic vasculitis:** eg. granulomatosis with polyangiitis (GPA: formerly Wegener’s granulomatosis), microscopic polyangiitis (MPA), Takayasu’s arteritis, eosinophilic granulomatosis with polyangiitis (formerly Churg–Strauss syndrome).

**Other:** pulmonary sarcoidosis, myasthenia gravis, uveitis.

Mercaptopurine

**Unlicensed indications:** Crohn’s disease, ulcerative colitis

**DOSAGE, ROUTE OF ADMINISTRATION AND DURATION OF TREATMENT**

**Adult dosage and administration**

Dosage regimens by mouth may vary between 0.5 - 3mg/kg daily of azathioprine or 1-1.5 mg/kg daily of mercaptopurine specific to the patient and the condition. Dosage may need to be reduced in patients with renal and/or mild to moderate hepatic impairment. Dose reduced if low levels of TPMT on advice of specialist.

Therapeutic effect may be evident after a few weeks or within 3 months. Treatment is ongoing on the advice of the specialist.

**Preparations available:** Azathioprine 25mg, 50mg tablets / Mercaptopurine 50mg tablets

Also refer to page 1/2

|  |
| --- |
| **SPECIALIST RESPONSIBILITIES INCLUDING PRE-TREATMENT ASSESSMENT*** Assess if patient is suitable for treatment with azathioprine/MP and initiate treatment.
* Where treatment is off-label advise patient.
* Undertake pre-treatment counselling and document discussion in patient’s records. Provide patient/carer with relevant (preferably written) information on use, side effects, need for monitoring of medication and precautions including that no new medicines are started (including over the counter preparations) unless this has been discussed with the GP, specialist or pharmacist.
* Obtain agreement and consent to share care. Complete and sign Specialist and patient agreement section of Shared Care Agreement form. Document in patient’s notes and transfer once patient stabilised.
* Request for GP confirmation of acceptance of shared care by secure emailing of request to share care, protocol and completed agreement form, allowing 2 weeks for response.
* Receipt and recording in patient records/notes that GP has / has not accepted shared care and ensuring appropriate action if not (specialist to continue to prescribe/monitor).
* Prescribe and monitor for initial stabilisation period of 12 weeks.
* Undertake baseline and ongoing tests as indicated in the monitoring table. Review results of safety monitoring and request additional tests as required.
* Continue to review the patient at agreed specified intervals, sending a written summary to the GP whenever the patient is reviewed.
* Monitor disease response and adverse effects to treatment and need to continue therapy. Notify the GP of any changes to dose or cessation of therapy.
* Notify GP if patient does not attend clinic repeatedly and advise on action to take.
* Provide any other advice, information or support for the GP if required. Communicate any clinically important issues and action to be taken.
* Encourage all women aged 25-64 years old to participate in national cervical cancer screening programmes. There is no need to attend more frequently than recommended.
* Advise the patient their skin may be more sensitive to exposure to UV light while taking azathioprine or mercaptopurine. Use appropriate self-care: e.g. sun avoidance, protective clothing, avoiding tanning (including tanning beds) and to purchase and use a broad spectrum sunscreen (at least SPF30).

**GP RESPONSIBILITIES with Specialist Interest in Rheumatology (for West Essex patients under the care of Princess Alexandra Hospital)*** Accept patients with stable disease markers and DAS<3.2 for ongoing case management after 6 months of consultant led care.
* Provide ongoing patient education
* Annual review of all patients as per NICE guidance
* Review the patient annually or as clinically appropriate and advise the GP promptly after these reviews on when to adjust the dose, stop treatment or consult with the Specialist.
* Inform GP, by letter, of each clinic attendance and action taken for the management of the patient ensuring current dose, most recent blood results and frequency of monitoring are stated
* Evaluate any reported adverse effects by GP or patient.
 |

**GP RESPONSIBILITIES**

Refer to page 1/2 and GP Considerations for Shared Care page 12.

|  |
| --- |
| **PATIENT RESPONSIBILITIES IN COOPERATION WITH SPECIALIST AND GP*** Confirm their agreement with the decision to move to a shared care model for their ongoing care and their understanding of the shared care agreement.
* Consent to share care and complete/sign Specialist and patient agreement section of Shared Care Agreement form.
* Confirm their understanding of the treatment and agreeing to contact the specialist/GP if they subsequently do not have a clear understanding of the treatment (patient to be provided with relevant contact details for GP/specialist in and out of hours).
* Attending for blood monitoring and follow up hospital or GP appointments.
* Ensuring a list of all medications are brought to all GP surgery, outpatient and A&E consultations.
* Reporting any change in symptoms and adverse effects promptly to the clinician who is currently prescribing.
* Confirm that no new medicines are started (including over the counter preparations) unless this has been discussed with the GP, specialist or pharmacist.
* Alert GP and/or specialist of any changes of circumstance which could affect management of disease e.g. plans for pregnancy; plans to move/change GP practice.
* Be aware all women aged 25-64 years old should participate in national cervical cancer screening programmes. There is no need to attend more frequently than recommended.
* Be aware skin may be more sensitive to exposure to UV light while taking azathioprine or mercaptopurine. Use appropriate self-care: e.g. sun avoidance, protective clothing, avoiding tanning (including tanning beds) and to purchase and use a broad spectrum sunscreen (at least SPF30).
 |

|  |
| --- |
| **DISPENSING PHARMACIST RESPONSIBILITIES*** Confirming that the patient has received verbal and written patient counselling / information and provide additional counselling should this be required.
* Check the patient is being monitored regularly, e.g. using the patient held monitoring booklet where available, to ensure that it is safe before issuing or dispensing prescriptions.
 |

|  |
| --- |
| **MONITORING AND ACTIONS TO BE TAKEN*** Refer to page 2/3.
 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **SIDE EFFECTS AND ACTIONS TO BE TAKEN (REFER TO** [**BNF**](http://www.bnf.org/bnf/index.htm) **AND** [**SPC**](http://www.medicines.org.uk/emc) **for full details)*** GP to liaise with specialist if any side effects are a cause for concern
* Patients should be instructed to report immediately any evidence of infection, unexpected bruising or bleeding or other manifestations of bone marrow depression - also refer to monitoring section.

|  |  |
| --- | --- |
| **SIDE EFFECTS** | **Action to be taken by GP** |
| Nausea | If symptoms mild, change time to with evening meal. |
| Hypersensitivity reactions (fever, rigors, rash, myalgia, arthralgia, hypotension, dizziness)  | Advise immediate withdrawal (as per SPC), contact specialist |
| Alopecia  | If mild, reassure and continue.If significant, contact specialist team to discuss treatment alternatives. |
| Flu like symptoms/myalgia/headache | Mild – continue – recommend taking dose at night.Moderate / Severe – **STOP DRUG** and discuss with specialist team. |
| Fever, sore throat, mouth ulceration | Check FBC and **STOP DRUG** if WCC low (see monitoring section) |
| Abnormal bruising or bleeding | **STOP DRUG** until recovery and check FBC (see monitoring section). Do not restart if blood test abnormal, contact specialist team. |
| SuspectedPancreatitis | **Check amylase level and STOP DRUG** until result of amylase is available. If amylase raised,withhold until discussed with specialist team.Make clinical assessment and refer to hospital if appropriate. Check Amylase, FBC, LFT, U&E, CRP. |

 |

**CONTRAINDICATIONS AND PRECAUTIONS**  **(REFER TO** [**BNF**](http://www.bnf.org/bnf/index.htm) **AND** [**SPC**](http://www.medicines.org.uk/emc) **for full details)**

**Renal impairment**: Caution is advised regarding adequacy of renal function if azathioprine/MP is to be used concomitantly with NSAIDs, ACE inhibitors or angiotensin II antagonists.

**Elderly:** dosages should be used at the lower end of the range.

I**nfection**: Immunosuppressants can increase susceptibility to infection. It is advisable not to commence treatment with azathioprine when patients have a confirmed or established local or systemic infection. For minor infection requiring a short oral course of antibiotics eg dental, URTI or uncomplicated UTI, depending on the circumstance thiopurines may be continued in patients. Check FBC and STOP DRUG if WCC low (see monitoring section).

**Nausea:** can occur initially but can be reduced by taking the tablets after food.

**Blood disorders**: leucopenia, anaemia and thrombocytopenia. GPs should be alert to any oral ulceration, sore throat, unexplained rash or abnormal bruising/bleeding.

**Pregnancy / contraception**: Relevant patients should receive information on risk benefit in pregnancy and contraception before initiation. If pregnancy occurs while on treatment, advise patient to continue with azathioprine/mercaptopurine and to contact their specialist.

**Breastfeeding**: Azathioprine considered compatible with breast feeding at a dose less than 2mg/kg/day.

**Cancer risk**: Patients receiving long-term immunosuppressive drugs are at increased risk of developing a malignancy. The most frequently occurring types are lymphoma and skin malignancy. The avoidance of excessive exposure to the sun, and the use of high factor sunscreen and protective clothing are advised. Adherence to population screening programmes is particularly important in this population e.g. cervical screening every 3 years.

**Live vaccines:** Consult the Green Book and take additional advice from initiating specialist if required. **Contraindications** include:

• Hypersensitivity to azathioprine/mercaptopurine

• Severe hepatic impairment

• TPMT deficiency - avoid if deficient or reduce dose if low levels of TPMT on advice of specialist

**What to do if Chickenpox or shingles exposure:** For susceptible immunosuppressed individuals with significant exposure to chickenpox (varicella) or shingles (zoster), follow latest national guidance on post exposure prophylaxis and use of anti-virals and varicella zoster immunoglobulin (VZIG) <https://assets.publishing.service.gov.uk/media/63e230638fa8f50e86ff1ae4/UKHSA-guidelines-on-VZ-post-exposure-prophylaxis-january-2023.pdf>. Stop azathioprine / MP and contact specialist team for advice if there are any concerns.

**NOTABLE DRUG INTERACTIONS (REFER TO** [**BNF**](http://www.bnf.org/bnf/index.htm) **AND** [**SPC**](http://www.medicines.org.uk/emc) **for full details)**

**Common drug interactions**

**ACE inhibitors:** predicted to increase risk of anaemia/leucopenia when given with azathioprine.

**Allopurinol:** prolongs activity of azathioprine/mercaptopurine increasing risk of severe myelosuppression. **If it must be given concomitantly contact specialist, it is essential that only a quarter of the usual dose of azathioprine/mercaptopurine is given.**

**Aminosalicylates:** (eg. sulfasalazine) contribute to bone marrow toxicity and increased monitoring is recommended – some gastroenterology patients will be on both – specialist will confirm.

**Febuxostat:** avoid concomitant use.

**Ribavarin**: increases risk of myelosuppression.

**Trimethoprim and co-trimoxazole:** there is a risk of haematological abnormalities.

**Warfarin:** effect may be reduced requiring an increased dose of warfarin.

**Drugs that can cause myelosuppression:** concurrent use may increase risk.

**Drugs that can cause hepatotoxicity:** concurrent use may increase risk.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **CONTACT DETAILS for BACK-UP INFORMATION / ADVICE** **Princess Alexandra Hospital NHS Trust**

|  |  |  |  |
| --- | --- | --- | --- |
| **Department** | **Contact number** | **Specialist Team designated nhs.net email** | **Out of hours contact / switchboard** |
| **Gastroenterology** | 01279 278223(IBD advice line – answer machine)01279 278224(Gastro Pharmacist) | Tpa-tr.gastroadminclinicalcorrespondence@nhs.netPaht.ibd@nhs.net - IBD Specialist Nurse | 01279 444455 |
| **Haematology**  | 01279 444455 Ext 7035 | tpa-tr.haematologyadminclinicalcorrespondence@nhs.net  |
| **Neurology**  | via switchboard | tpa-tr.neurologyadminclinicalcorrespondence@nhs.net  |
| **Dermatology**  | 01279 827227Derm Secretaries | tpa-tr.dermatologyclinicalcorrespondence@nhs.net  |
| **Rheumatology** | 01279 827434 – DMARD helpline01279 827819 Nurse helpline | tpa-tr.rheumatologyadminclinicalcorrespondence@nhs.net  |
| **Respiratory** | via switchboard | tpa-tr.respiratoryadminclinicalcorrespondence@nhs.net  |
| **Ophthalmology** | via switchboard | pa-tr.ophthalmologyadminclinicalcorrespondence@nhs.net  |
| **Renal** | via switchboard | nephadmin.enh-tr@nhs.net Pharmacy Team shared care admin contact sharedcare.enh-tr@nhs.net 01438 284032 | 01438 314333  |

**Communication**For any queries relating to a patient’s treatment with azathioprine or MP, please contact the specialist as documented at the top of this document. Read in conjunction with HWE shared care principles document.For advice if you have any concerns contact the specialist team. If unable to contact specialist team or out of hours, contact medical registrar on call. |

|  |
| --- |
| **SUPPORTING INFORMATION***Crohn’s disease, ulcerative colitis** NICE NG 129. May 2019. Crohn’s disease: management <https://www.nice.org.uk/guidance/ng129>
* NICE NG 130. May 2019. Ulcerative Colitis: management <https://www.nice.org.uk/guidance/ng130>
* Lamb CA, et al. British Society of Gastroenterology consensus guidelines on the management of inflammatory bowel disease in adults, Gut 2019;0:1–106 <https://www.bsg.org.uk/resource/bsg-consensus-guidelines-ibd-in-adults.html>

*Autoimmune chronic acute hepatitis** Gleeson D & Henehgan MA. British Society of Gastroenterolgy (BSG) guidelines for management of autoimmune hepatitis. Gut 2011; 60:1611-29. <https://www.bsg.org.uk/resource/bsg-guidelines-for-the-management-of-autoimmune-hepatitis.html>

*Systemic lupus erythematosus* * Gordon C, Amissah-Arthur M\_B, Gayed M, et al, for the British Society for Rheumatology Standards, Audit and Guidelines Working Group, The British Society for Rheumatology guideline for the management of systemic lupus erythematosus in adults, Rheumatology 2018; 57: e1–e45, <https://doi.org/10.1093/rheumatology/kex286>
* Fanouriakis A, Kostopoulou M, Alunno A, et al. 2019 update of the EULAR recommendations for the management of systemic lupus erythematosus. Annals of the Rheumatic Diseases 2019;78:736-745) <https://ard.bmj.com/content/78/6/736>

*Autoimmune haemolytic anaemia** Hill QA, Stamps R, Massey E *et al*, on behalf of the British Society for Haematology. The diagnosis and management of primary autoimmune haemolytic anaemia. British J Haematol 2016; 176:395-411. <https://doi.org/10.1111/bjh.14478>

*Chronic refractory idiopathic thrombocytopenic purpura (ITP)** Provan D, Stasi R, Newland AC, *et al*. International consensus report on the investigation and management of primary immune thrombocytopenia. Blood. 2010; 115:168-186. <https://ashpublications.org/blood/article-lookup/doi/10.1182/blood-2009-06-225565>

*Pemphigus vulgaris, atopic dermatitis, bullous pemphigoid, chronic actinic dermatitis, pyoderma gangrenosum, dermatomyositis, polymyositis, cutaneous vasculitis** Harman KE, Brown D, Exton LS *et al*, British Association of Dermatologists guidelines for the management of pemphigus vulgaris 2017 Br J Dermatol 2017; 177: 1170-1201 <https://onlinelibrary.wiley.com/doi/full/10.1111/bjd.15930>
* Meggitt SJ *et al*, British Association of Dermatologists' guidelines for the safe and effective prescribing of azathioprine Br J Dermatol 2011; 165; 711-734 <https://onlinelibrary.wiley.com/doi/pdf/10.1111/j.1365-2133.2011.10575.x>
* Venning VA, Taghipour K, Mohd Mustapa MF et al British Association of Dermatologists' guidelines for the management of bullous pemphigoid 2012. Br J Dermatol 2012; 167: 1200-1214. <https://onlinelibrary.wiley.com/doi/full/10.1111/bjd.12072>

*Systemic vasculitis: granulomatosis with polyangiitis (GPA: formerly Wegener’s granulomatosis), microscopic polyangiitis (MPA), eosinophilic granulomatosis with polyangiitis (formerly Churg–Strauss syndrome)** Ntatsaki E et al, BSR and BHPR guideline for the management of adults with ANCA-associated vasculitis, Rheumatology, Volume 53, Issue 12, December 2014, Pages 2306–2309, <https://doi.org/10.1093/rheumatology/ket445>
* Yates M, Watts RA, Bajema IM, et al. EULAR/ERA-EDTA recommendations for the management of ANCA-associated vasculitis. Annals of the Rheumatic Diseases 2016;75:1583-1594 <https://ard.bmj.com/content/75/9/1583>
* Meggitt SJ et al, British Association of Dermatologists' guidelines for the safe and effective prescribing of azathioprine Br J Dermatol 2011; 165; 711-734 <https://onlinelibrary.wiley.com/doi/pdf/10.1111/j.1365-2133.2011.10575.x>

*Takayasu’s arteritis** Clinical Commissioning Policy: Tocilizumab for Takayasu arteritis (adults) – (references use of azathioprine), Aug 2016 <https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/08/clinical-com-pol-16056p.pdf>

*Myasthenia Gravis** Sussman J, Farrugia ME, Maddison P, et al. Myasthenia gravis: Association of British Neurologists’ management guidelines. Practical Neurology 2015;15:199-206. <http://dx.doi.org/10.1136/practneurol-2015-001126>
* NHS England Clinical Commissioning Policy Statement: Rituximab bio-similar for the treatment of myasthenia gravis (adults) – (references use of azathioprine), Sep 2018 <https://www.england.nhs.uk/wp-content/uploads/2018/10/Rituximab-biosimilar-for-the-treatment-of-myasthenia-gravis-adults-1.pdf>

*Uveitis** Adalimumab and dexamethasone for treating non-infectious uveitis NICE TA460, July 2017 – (references use of immunosuppressants) <https://www.nice.org.uk/guidance/ta460/chapter/1-Recommendations>
* NHS England Clinical Commissioning Policy: Infliximab (Remicade) as Anti-TNF Alpha Treatment Option for Paediatric Patients with Severe Refractory Uveitis – (references use of azathioprine) <https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2015/11/d12pb-paediatric-pats-uveitis-inflixi-fin.pdf>
* NHS England Clinical Commissioning Policy: Infliximab (Remicade) and Adalimumab (Humira) As Anti-TNF Treatment Options For Adult Patients with Severe Refractory Uveitis - (references use of azathioprine) <https://www.engage.england.nhs.uk/consultation/specialised-services-consultation/user_uploads/uveitis-adults-policy.pdf>

*Pulmonary Sarcoidosis** NHS England Clinical Commissioning Policy: Infliximab for Progressive Pulmonary Sarcoidosis in adults – (references use of azathioprine) <https://www.england.nhs.uk/wp-content/uploads/2018/11/infliximab-progressive-pulmonary-sarcoidosis-adults.pdf>
 |

**REFERENCES**

* NICE CKS DMARDs: Last revised in July 2018; What monitoring is required for azathioprine? <https://cks.nice.org.uk/dmards#!scenarioRecommendation:3>
* BSR and BHPR guideline for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs, Rheumatology 2017;56:865868 <https://www.rheumatology.org.uk/practice-quality/guidelines>
* The Green Book Immunisation against infectious disease <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>
* Interface Pharmacist Network Specialist Medicines (Northern Ireland Health & Social Care) Azathioprine - Adult (non-transplant indications) Shared Care Guidelines <http://www.ipnsm.hscni.net/download/shared_care_guidelines/AzathioprineSCG2017.pdf>
* BSR and BHPR guideline on prescribing drugs in pregnancy and breastfeeding—Part I: standard and biologic disease modifying anti-rheumatic drugs and corticosteroids, Rheumatology, Volume 55, Issue 9, September 2016, Pages 1693–1697, <https://doi.org/10.1093/rheumatology/kev404>

**GP Considerations for Shared Care**

This shared care agreement outlines suggested management for the prescribing of the specified drug(s) and indication(s) when the responsibility is shared between the specialist and general practitioner (GP). Sharing of care assumes communication between the specialist, GP and patient. It is important that patients are consulted about treatment and are in agreement with it. The intention to share care should be explained to the patient by the doctor initiating treatment and consent obtained.

Prescribing is to be initiated in secondary care by a provider Trust specialist and will usually be prescribed for 12 weeks unless otherwise stated within the agreed individual shared care protocol**. The expectation is that these shared care guidelines should provide sufficient information to enable GPs to be confident to take on the clinical and legal responsibility for the prescribing and the monitoring of this / these drug(s) in stable patients.** The questions below will help you confirm this:

* Is the patient’s condition predictable or stable?
* Do you have the relevant knowledge, skills and access to equipment to allow you to monitor treatment as indicated in this shared care document?
* Have you been provided with relevant clinical details including monitoring data?
* Have this document and BNF/SPC provided sufficient information for you to feel confident in accepting clinical and legal responsibility for prescribing?

**If you can answer YES to all of these questions (after reading this shared care guideline), then it is appropriate for you to accept the prescribing responsibility. GPs need to formally accept shared care by completing and returning the form provided within this protocol to the specialist within two weeks of receipt of request to share care.**

If the answer is NO to any of these questions, you should not accept prescribing responsibility. You should respond back to the consultant outlining your reasons for NOT prescribing on the agreement form within two weeks of receiving the request to share care. If you do not have the confidence to prescribe, you still have the right to decline. In such an event, the total clinical responsibility for prescribing the medication and any monitoring required remains with the specialist. Please note that medication cost is not an acceptable reason for refusal to take on shared care.

The prescribing doctor legally assumes clinical responsibility for the drug and the consequences of its useas well as responsibility of monitoring (securing and reviewing blood test results).

Prescribing and monitoring responsibility will only be transferred when the consultant and the GP agree that the patient’s condition is stable or predictable. This will usually be 12 weeks of treatment unless otherwise stated within the agreed individual shared care protocol.

**Approval Information**

|  |  |
| --- | --- |
| Version  | 2.0 Harmonisation of Hertfordshire Medicines Management Committee (HMMC) guidance and West Essex Medicines Optimisation Programme Board (WEMOPB) guidance updates include:* Rebadging with HWE ICB and removal of ENHCCG and HVCCG headers
* Review date removed and replaced with standard statement.
 |
| Developed by | East and North Hertfordshire NHS Trust Pharmacy department and relevant specialisms supported by Hertfordshire CCGs Pharmacy and Medicines Optimisation Teams |
| Approved by | HMMC APC |
| Date approved/updated | Approved subject to minor amendments December 2019 published August 2020 APC April 2024 |
| Review date:  | The recommendation is based upon the evidence available at the time of publication. This recommendation will be reviewed upon request in the light of new evidence becoming available.  |
| Superseded version | 1.0* Addition of GP responsibilities Specialist Interest in Rheumatology (for West Essex patients under the care of Princess Alexandra Hospital) agreed at WEMOPB Oct 2017
* Addition of Ophthalmology, Nephrology and Respiratory indications
* Addition of recommendation for Covid-19 vaccination
* Amendment of Phase II monitoring in line with wording agreed HWE APC February 2024
* Addition of recommendation for sun protection and cervical screening under specialist and patient responsibilities
* Clarity on prescribing antibiotics for minor infections under Contraindications and Precautions section
 |