FULL SHARED CARE AGREEMENT FOR

Disease Modifying Anti-Rheumatic Drugs (DMARDs)

in the treatment of

Rheumatological Disease in Adults

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On behalf of:
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Leicester City Clinical Commissioning Group
West Leicestershire Clinical Commissioning Group
University Hospitals of Leicester NHS Trust
Leicestershire Partnership NHS Trust

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Additional medicines information is available from:
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**Full Shared Care Agreement for the prescribing of DMARDS in the treatment of rheumatological diseases in adults**

**Introduction and purpose**

Shared care has been defined as the mechanism of sharing patient care between primary and secondary care providers. This document sets out these responsibilities from initial diagnosis to ongoing support.

**Disease Background**

*Rheumatoid arthritis (RA)* is an inflammatory disease which largely affects synovial joints, which are lined with a specialised tissue called synovium. RA typically affects the small joints of the hands and the feet, although any synovial joint can be affected. It is a systemic disease and so can affect the whole body, including the heart, lungs and eyes.

There are approximately 400,000 people with RA in the UK and approximately 12,000 people develop RA per year in the UK. The overall occurrence of RA is two to four times greater in women than men. The peak age of incidence in the UK for both genders is the 70s, but people of all ages can develop the disease.

Drug management aims to relieve symptoms, as pain relief is the priority for people with RA, and to modify the disease process. Disease modification slows or stops radiological progression. Radiological progression is closely correlated with progressive functional impairment.

Approximately one third of people stop work because of the disease within 2 years of onset, and this prevalence increases thereafter. The total costs of RA in the UK, including indirect costs and work-related disability, have been estimated at between £3.8 and £4.75 billion per year.

*Psoriatic arthritis (PsA)* has been defined as a unique inflammatory arthritis associated with psoriasis. Its exact prevalence is unknown, but estimates vary from 0.3% to 1% of the population. Several clinical features help distinguish PsA from RA. Although RA is more common in women, PsA occurs just as frequently in both sexes.

The specific clinical features include the common involvement of distal joints in PsA. The joint distribution tends to occur in a ray pattern in PsA so that all the joints of a single digit are more likely to get affected than the same joints on both sides, which is typical of RA. This may explain the tendency to asymmetry that occurs even in the polyarticular disease in PsA. The degree of erythema over affected joints, the presence of spinal involvement, the presence of enthesitis, and lower level of tenderness are also typical features of PsA.

*Connective tissue diseases (CTDs)* are a group of closely related multisystem conditions, with many overlapping clinical features. While uncommon, they cannot be considered rare. Sjögren’s syndrome affects 6–10/1000 and systemic lupus erythematosus (SLE) 1/2000 of the UK population. Thus in a practice population of 2000 individuals there may be 12–20 patients with Sjögren’s syndrome, 1 patient with SLE and 1–2 with other CTDs. Although CTDs are associated with much greater morbidity than mortality, an awareness of the potentially dangerous complications is obviously important if avoidable organ damage and death are to be prevented.

*Dermatomyositis & Polymyositis* are connective tissue diseases characterised by inflammation of muscles. Although dermatomyositis affects the skin and muscles, it may also
Affect other parts of the body such as joints, oesophagus, lungs and heart. Both polymyositis and dermatomyositis have an autoimmune basis. In mild disease, topical steroids may suffice. In more severe disease, high doses of systemic steroids are used and tapered off. Improvement is usually apparent by the second or third month. If steroids fail then immunosuppressive drugs such as azathioprine can be used.

**Systemic Vasculitides** include a variety of conditions characterised by inflammation of the blood vessels. It can affect any of the body's blood vessels, causing a variety of symptoms and potential complications. Inflammation causes swelling of the blood vessel walls, reducing or even blocking the flow of blood to tissues and organs. Treatments include high doses of steroids as well as cytotoxic agents, immunosuppressants and biological agents.

**Drugs covered by the agreement**

This agreement relates to adult patients prescribed DMARDS in the treatment of rheumatological disease as indicated in the table below:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Indication</th>
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<tr>
<td><strong>Unlabeled</strong></td>
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</table>

- **Methotrexate oral**
  - It is recommended that only the 2.5mg strength of methotrexate tablet is prescribed and dispensed
  - Rheumatoid arthritis
  - Psoriatic arthritis
  - Connective tissue disease (systemic lupus erythematosus, myositis, vasculitis, giant cell arteritis)
  - Spondyloarthropathy
  - Polymyalgia rheumatica
- **Azathioprine**
  - Rheumatoid arthritis
  - Dermatomyositis & Polymyositis
  - Psoriatic Arthritis
  - Connective tissue disease (systemic lupus erythematosus, myositis, vasculitis, giant cell arteritis)
- **Sulfasalazine**
  - Rheumatoid arthritis
  - Psoriatic arthritis
  - Spondyloarthropathy
- **Penicillamine**
  - Rheumatoid arthritis
- **Leflunomide**
  - Rheumatoid arthritis
  - Psoriatic arthritis
  - Spondyloarthropathy
- **Hydroxychloroquine**
  - Rheumatoid arthritis
  - Discoid and systemic lupus erythematosus
  - Inflammatory arthritides including spondyloarthropathy and psoriatic arthritis
- **Gold intramuscular**
  - Note risk of anaphylaxis following injection
  - Rheumatoid arthritis

**Secondary Care Clinician Responsibilities**

- Diagnosis of condition and ensuring other treatment options have been fully explored
- Perform baseline tests (as detailed in Appendix 1).
- Discuss the benefits and side effects of treatment with the patient.
  - Methotrexate: Ensure that the patient understands that dosing is at weekly intervals and which warning symptoms to report. Provide patient with patient information leaflet and
blood monitoring booklet. Record that information has been given and is understood by the patient in the notes.

- Prescribe initial course of medication and arrange testing and full monitoring of blood tests during the initial course (see Appendix 1).
- Liaison with the general practitioner (GP) to share the patient’s care when a stable dose has been achieved and proven benefit has been established using the Shared Care Request Form.
- Provide results of baseline tests and recommend frequency of monitoring.
- Methotrexate: Recommend dose and timing of any concomitant folic acid.
- Review the patient’s condition annually and communicate promptly with the GP when treatment is changed.
- Communicate promptly with the GP in writing when to adjust the dose, stop or change treatment and when to consult with specialist.
- Report adverse events to the MHRA and GP.
- Ensure that clear backup arrangements exist for GPs to obtain advice and support.

**GP Responsibilities**

- Confirm or decline the request for shared care within 10 working days, using the shared care request form.
- Prescribe medication at the dose recommended.
- Arrange testing and full monitoring of test results and response to treatment (see Appendix 1). Check recent results are available (as specified in appendix 1) before issuing a prescription. Seek advice from Rheumatology Nurse Specialist in cases of concern.
- **Gold IM**: administration of injection in GP practice. Note risk of anaphylaxis following injection; patient should remain under medical observation for a period of 30 minutes after drug administration. Anaphylaxis may occur after any course of therapy, usually within the first ten minutes following drug administration. Discuss treatment options with secondary care for any patient unable to attend GP practice for administration or if the GP practice does not have the appropriate resources to manage a possible anaphylactic reaction.
- Ensure compatibility with other concomitant medication.
- Monitoring the patient’s overall health and well being and observing patient for evidence of ADRs/abnormalities. Report adverse events to the MHRA and specialist.
- Adjust the dose as advised by the specialist.
- Stop treatment on the advice of the specialist, or immediately if an urgent need to stop treatment arises.
- Ensuring advice is sought from the secondary care clinician if there is any significant change in the patient’s physical health status.

**Community Pharmacist Responsibilities**

- Ensure that the patient is taking the medication as prescribed.
- Ensure regular blood tests are being taken (see Appendix 1).
- Ensure compatibility with other concomitant medication, including over the counter medicines.
- Seek advice from GP in cases of concern.

**Patient’s role/responsibilities:**

- Attend all blood tests and appointments with GP and specialist. Methotrexate: bring monitoring booklet to all appointments.
- Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
- Share any concerns in relation to treatment.
- Inform specialist or GP of any other medication being taken, including over-the-counter products.
- Report any adverse effects or warning symptoms to the specialist or GP.
- Inform other professionals of current treatment as necessary.
- Report any suspected pregnancy of the patient or partner to the GP or specialist.
- Avoid alcohol if advised to do so by the specialist.

**The responsibility for arranging and taking action on blood test results where necessary remains with the prescribing doctor.**

**Contact for support and advice**

Email [Hinesh.J.Patel@uhl-tr.nhs.uk](mailto:Hinesh.J.Patel@uhl-tr.nhs.uk) (rheumatology blood monitoring administrator who will contact the responsible consultant if required)

**Rheumatology Patient Helpline** (0116) 258 5264

**Arthritis Research UK Patient Information Leaflets** available at [Drugs | Arthritis Research UK](https://www.arthritisresearchuk.org/drugs)

**Supervising Consultant**

**Supporting Information**


<table>
<thead>
<tr>
<th>Version</th>
<th>Section</th>
<th>Description of amendments</th>
<th>Date</th>
<th>Author / amended by</th>
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<tbody>
<tr>
<td>1.1</td>
<td>Added in reference to methotrexate monitoring booklet</td>
<td>Dec 2013</td>
<td>HH</td>
<td></td>
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<tr>
<td>1.2</td>
<td>Clarified that the prescriber is responsible for the arranging and follow up of all blood tests. Psoriatic arthritis is a type of inflammatory arthritis &amp; specifically stated in the agreement following a query. SCA form updated; GP only needs to return form if shared care is declined. Annual review by specialist required.</td>
<td>Feb 14</td>
<td>HH</td>
<td></td>
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<tr>
<td>1.3</td>
<td>Risk of anaphylaxis following gold administration. Methotrexate monitoring reduced to 3 monthly for patients stable for 2 years. Monitoring after dose increase added to azathioprine and methotrexate in appendix. Annual FBC for hydroxychloroquine patients.</td>
<td>July 14</td>
<td>HH</td>
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<tr>
<td>1.4</td>
<td>Partial update of monitoring (appendix 1) to bring in line with BSR guideline. Appendix 1 split into 1 and 2. Extension of review date to bring in line with review programme for full review</td>
<td>September 19</td>
<td>DK/RD</td>
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Appendix 1: Summary of recommended monitoring requirements for DMARDs (Table adapted from Nottingham area prescribing committee based on BSR and BHPR guideline for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs 2017)

Note: It is the prescriber’s responsibility to ensure that all monitoring requirements are undertaken. This includes providing blood monitoring tests and reviewing results of these tests.

| DMARD (including azathioprine, cyclosporin, leflunomide, methotrexate, mycophenolate, sulfasalazine and tacrolimus) | Time period on treatment | Monitoring frequency | FBC | LFT | U+E | BP | Visual | Urinary protein |
|---|---|---|---|---|---|---|---|---|---|
| All DMARDs | 0-6 weeks | Fortnightly | X | X | X | | | |
| | 6 weeks – 3 months | Monthly | X | X | X | | | |
| | >3 months and stable dose for 6 weeks | 3 monthly | X | X | X | | | |
| | Any dose increase | 2 weeks post dose increase (Secondary care to conduct and review) then revert to frequency above | X | X | X | | | |

Special considerations

<table>
<thead>
<tr>
<th>Leflunomide</th>
<th>As for all DMARDs above</th>
<th>As per recommendations above</th>
<th>X</th>
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</thead>
<tbody>
<tr>
<td>Methotrexate with leflunomide</td>
<td>&gt;3 months</td>
<td>Continue monthly monitoring</td>
<td>X</td>
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<tr>
<td>Gold</td>
<td>As for all DMARDs above</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Sulfasalazine</td>
<td>&gt;12 months</td>
<td>Standard monitoring as for all DMARDs above for initial 12 months, then routine monitoring not required</td>
<td></td>
</tr>
<tr>
<td>Hydroxychloroquine</td>
<td>Any time</td>
<td>Routine monitoring not required</td>
<td></td>
</tr>
<tr>
<td>Penicillamine</td>
<td>Any time</td>
<td>FBC and urinalysis upon initiation then every 2 weeks until dose and monitoring stable for 3 months; monthly thereafter</td>
<td></td>
</tr>
</tbody>
</table>

Patients prescribed hydroxychloroquine should have baseline formal ophthalmic examination [ideally including objective retinal assessment; for example, using optical coherence tomography (OCT)] within 1 year of commencing an antimalarial drug and annually after 5 years of treatment.
Appendix 2:
Monitoring parameters requiring urgent review and discontinuation of the medicine

In the event of any of the following monitoring parameters being identified the medication should be suspended and urgent review and discussion with Rheumatology should occur.

- White cell count <3.5 x 10^9/l
- Neutrophils <1.6 x 10^9/l
- Unexplained Eosinophils >0.5 x 10^9/l
- Platelet count <140 x 10^9/l
- MCV > 105 f/l
- Creatinine increase >30% of baseline over 12 months and/or eGFR <60ml/min/1.73m²
- ALT or AST >100U/l
- Methotrexate - new or increasing dyspnoea or dry cough
- Severe rash or bruising or ulceration of mucous membranes.
- Any unexplained illness occurs including nausea or diarrhoea.
- Unexplained reduction in albumin <30g/l

Following review and guidance individual patient parameters may be appropriate and advised by secondary care. Individual patient parameters should be consulted where available.