Leflunomide Shared Care Agreement

For treatment of rheumatoid arthritis / connective tissue disease / autoimmune rheumatic disease in adults

SECONDARY CARE SECTION TO BE COMPLETED BY INITIATING CLINICIAN

Patient's Name: ..... NHS Number: .....

Date of Birth: ..... Date Treatment Started: .....

Copy of information given to patient ☐

Copy of agreement to general practitioner ☐

Name of Initiating Nurse Specialist / Doctor:

Consultant:

Speciality: RHEUMATOLOGY

Email: trauma.ortho@nhs.net

PRIMARY CARE SECTION TO BE COMPLETED BY GENERAL PRACTITIONER

I agree*/don't agree* to enter into a shared care arrangement for the treatment of the above patient with this medicine (*delete as appropriate)

GP Name: _____

Signature: _____ Date: .....

Once signed please detach this sheet and return to the email address shown above.

BACK-UP ADVICE AND SUPPORT

Contact details	Telephone No.	Extension:	Fax or e-mail address
Consultant Rheumatologists: **Dr. Situnayake** **Dr Elamanchi** **Dr DePablo** **Dr Prabu** **Dr Tosounidou** **Dr Baskar** **Dr Chandatre** **Dr McGrath**	01922 721172	Ext.7882(secretary)	deva.situnayake@nhs.net srinivasa.elamanchi@nhs.net paola.de-pablo@nhs.net a.prabu@nhs.net stosounidou@nhs.net sangeetha.baskar@nhs.net priyankachandatre@nhs.net catherine.mcgrath@nhs.net
Rheumatology Nurse Specialists: **Susan Ward** **Marcia Daley**	01922 721172	Ext 7265 Bleep 8053	susan.ward31@nhs.net marciadaley@nhs.net

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Hospital Pharmacy Dept: **Jiten Vyas**	01922 721172	Ext. 7534	

AREA OF RESPONSIBILTY FOR THE SHARING OF CARE

This shared care agreement outlines ways in which the responsibilities for managing the prescribing of Leflunomide in rheumatic diseases can be shared between the specialist and general practitioner (GP). GPs are **invited** to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. **If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.**

Sharing of care assumes communication between the specialist, GP and patient. 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.**

Aspects of Care for which the Hospital Specialist is Responsible:

- Perform baseline tests (FBC, LFTs, U+E's, ESR, CRP, Blood Pressure and Weight.
- Discuss the benefits and side effects of treatment with the patient.
- Initiation of Leflunomide and blood monitoring of patient for the initial 3 month period
- Ask the GP whether he or she is willing to participate in shared care.
- Provide results of baseline tests and recommend frequency of monitoring to GP.
- Periodically review the patient's condition and communicate promptly with the GP when treatment is changed.
- Advise the GP on when to adjust the dose, stop treatment, or consult with specialist.
- Report adverse events to the MHRA and GP.
- Ensure that clear backup arrangements exist for GPs to obtain advice and support.

Aspects of Care for which the General Practitioner is Responsible:

- Reply to the request for shared care as soon as practicable.
- Prescribe Leflunomide at the dose recommended and adjust the dose as advised by the specialist.
- Ensure compatibility with other concomitant medication.
- Monitor FBC, LFTs, U+E's, ESR and CRP at recommended frequencies, and refer if abnormal.
- Stop treatment on the advice of the specialist and prompt referral to specialist when clinical suspicion of adverse effects, loss of efficacy, worsening of disease related symptoms
- Report adverse events to the specialist and MHRA.

Aspects of Care for which the Patient is responsible:

- Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
- Attend for regular review by the Rheumatology team.
- Attend for regular blood tests at the Hospital of G.P surgery.

- Inform specialist or GP of other medication being taken, including over-the-counter products.
- Report any adverse effects or symptoms to the GP or specialist (Rheumatology Helpline 01922 721172 ext 7265).

Dosage and Administration

- Leflunomide is given once daily by mouth and is available as 10mg or 20mg tablets.
- Maintenance dose of 10-20mg once daily.
- When used in combination with other potentially hepatotoxic DMARDs such as methotrexate, a dose of 10mg is recommended.

Monitoring

- Initial monitoring by Rheumatology team for the first 3 months - FBC, U&E, LFT, ESR ,CRP every 2 weeks until on a stable dose for 6 weeks then
- Once on a stable dose, monthly bloods for 3 months (Blood pressure and weight will be monitored at each clinic visit).
- Thereafter, FBC, U+E, LFT, at least every 12 weeks (more frequent monitoring is appropriate in patients at higher risk of toxicity)
- Dose increases should be monitored by FBC, U+E and LFT, every 2 weeks until on a stable dose for 6 weeks then revert back to previous schedule.

GP's responsible for: <u>at least</u> 12 weekly FBC, LFTs, U&E, CRP and ESR (more frequently if there is any reason to suspect deteriorating renal or liver function or if recommended by Specialist team). BP and weight should also be checked at each visit.

NB. 8-12 weekly blood monitoring may be recommended by Specialist team in select patients on long-term Leflunomide.

Action to be taken:

- **WBC <3.5x10^9/l** - withhold *<u>until discussed</u>* with Rheumatology team
- **Neutrophils <1.8x10^9/l** - withhold *<u>until discussed</u>* with Rheumatology team
- **Platelets <135x10^9/l** - withhold *<u>until discussed</u>* with Rheumatology team
- **>2-fold rise in ALT** (*from upper limit of reference range*) - withhold *<u>until discussed</u>* with Rheumatology team
- **Rash or oral ulceration** - withhold *<u>until discussed</u>* with Rheumatology team
- **Abnormal bruising or sore throat** - withhold until FBC result available
- **Hypertension** (BP>140/90) if not controlled with standard anti-hypertensives - withhold *<u>until discussed</u>* with Rheumatology team
- **Breathlessness** - withhold *<u>until discussed</u>* with Rheumatology team
- **Unexplained weight loss >10%** - withhold *<u>until discussed</u>* with Rheumatology team

Please note that in addition to absolute values for haematological indices a rapid fall or a consistent downward trend in any value should prompt caution and extra vigilance.

If the patient is unwell with abnormal results out-of-hours and the Rheumatology team is not available to discuss, STOP the drug and seek advice from the General Medical on-call team.

Adverse effects

Common non-life-threatening adverse effects of leflunomide are rash, diarrhoea, reversible alopecia, weight loss, nausea and mouth ulceration. Mild hypertension is reported in up to 10% of patients. In severe uncontrolled cases it is necessary to consider stopping the drug. Serious but rare side-effects include bone marrow suppression, hepatotoxicity and pulmonary infiltration /

pneumonitis. Annual influenza vaccination and pneumococcal vaccination every 5 years is recommended.

Drug Interactions

- Leflunomide may enhance the effects of phenytoin and tolbutamide.
- Leflunomide also interacts with warfarin and the INR should be closely monitored in patients on warfarin who are given leflunomide.

Contraindications:

- Severe immunodeficiency
- Serious infection
- Impaired liver function due to any cause or severe unexplained hypoproteinaemia
- Moderate to severe renal impairment
- Impairment of bone marrow function
- **Pregnancy/breast feeding -** Leflunomide is teratogenic. Effective contraception must be used whilst taking leflunomide and for two years after stopping the drug in women, and three months after treatment for men (or consider the wash out procedure to reduce this). If a patient wishes to start a family, specialist advice should be sought before conception. Women who are breastfeeding should not take leflunomide.

Washout procedure

Leflunomide elimination can be achieved by a washout regimen of cholestyramine 8gm, 3 times daily for 11 days or activated charcoal 50 gm, 4 times daily for 11 days.

References

Prescribing and monitoring of DMARDs for inflammatory arthritis. Arthritis Research Council, 2005
http://www.arthritisresearchuk.org/shop/products/publications/information-for-medical-professionals/hands-on/series-4/ho8.aspx

BSR and BHPR guideline for the prescription and
monitoring of non-biologic disease-modifying
anti-rheumatic drugs 2017

Summary of Product Characteristics (SPC) of Leflunomide.

British National Formulary 70th edition, March 2015

BNSSG Joint Formulary DMARD Monitoring Advice Guidance.
http://www.bnssgformulary.nhs.uk/includes/documents/LEF%20concise%20advice%20sheet%20Sept12.pdf