SHARED CARE PRESCRIBING GUIDELINE
LEFLUNOMIDE IN ADULT PATIENTS WITH RHEUMATOID ARTHRITIS

DOCUMENT DETAILS

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Relevant external law, regulation, standards	
Comments on this document to:	*Clinical Governance Pharmacist c/o Pharmacy Department, Guy's Hospital*

CHANGE HISTORY

Date	*Change details*	*Approved by*

Leflunomide
Rheumatoid Arthritis

NOTES to the GP

The information in the shared care guideline has been developed in consultation with Primary Care and it has been agreed that it is suitable for shared care.
This document should provide sufficient information to enable you to make an informed decision regarding the clinical and legal responsibility for prescribing this drug.

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 prescribing guideline?
- Have you been provided with relevant clinical details including monitoring data?

If you can answer YES to all these questions (after reading this shared care guideline), then it is appropriate for you to accept prescribing responsibility.
If the answer is NO to any of these questions you should contact the requesting consultant or your local PCT medicines management team. It would not normally be expected that shared care prescribing would be declined on the basis of cost.

Prescribing should follow requirements in the South East London Interface Prescribing Policy
The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use. The patient's best interests are always paramount

Date shared care guideline prepared: 28/10/2009

Approved by: PCT Medicines management Committee
NHS Lambeth 3/5/2010
NHS Southwark 29/3/2010

Approved by DTC or equivalent Date approved:
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King's College 24/5/2010

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AGREEMENT TO PARTICIPATE IN SHARED CARE

LEFLUNOMIDE IN ADULT PATIENTS WITH RHEUMATOID ARTHRITIS

Consultant Name:	**Patient name:**
Consultant signature:	**Patient Hospital Number:** **Patient NHS Number:**
Date completed: **Hospital:**	**Patient Agreement** ☐ **Patient agrees to shared care** ☐ **Patient does not agree to shared care**
GP Name	**Specialist Rheumatology Nurse Name**
GP Signature	**Specialist Rheumatology Nurse Signature**
Date completed:	**Date completed:**

ACTION

1. Consultant Rheumatologist

- Explain shared care to patient and obtain agreement.
- Indicate requesting hospital.
- Complete and sign agreement.
- Fax full shared care guideline (including signed agreement to GP) - fax numbers at **http://www.nhs.uk**.
- Place original in notes.

2. General Practitioner

- If **in agreement** to participate in shared care, sign and fax back to Rheumatology Department:
  - Guy's & St Thomas': 020 7407 7532
  - King's College: 020 3299 1734
- If **not in agreement** to participate in shared care, contact consultant and local PCT medicines management team within 2 weeks of receipt to discuss. If after discussion it is agreed not to undertake shared care for this patient, both the consultant and the local PCT Medicines Management team should be informed.
- Once decision reached file copy in patient's notes.

3. Specialist Rheumatology Nurse

- Once received completed agreement by Consultant and GP, sign to confirm awareness that the patient will be under shared care.
- Take any necessary actions prior to shared care commencing (changing of appointments etc).
- Original to be filed in Patient's clinical record.

Attach patient addressograph or enter: Patient name Patient hospital number Patient NHS number Date of Birth

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1. CIRCUMSTANCES WHEN SHARED CARE IS APPROPRIATE

- Prescribing responsibility will only be transferred when the consultant and the GP are in agreement that the patient's condition is stable or predictable.
- The hospital will provide the patient with a supply of therapy until the patient is stable.

2. AREAS OF RESPONSIBILITY

Consultant	GP
▪ Establish or confirm diagnosis and assess patient suitability for treatment ▪ Baseline monitoring: FBC, U&E's, Creatinine, LFT's, ESR, CRP, weight, BP If >140/90 mm/Hg on 2 consecutive readings 2 weeks apart, treat before commencing the drug. ▪ Discuss treatment (including adverse effects) with patient and ensure they have a clear understanding of it. Where appropriate obtain signed consent. ▪ Provide patient with Arthritis Research Campaign Patient information leaflet on leflunomide ▪ Prescribe and monitor treatment according to local guideline or formulary until patient's condition is stable or predictable ▪ Enter blood results in patient held monitoring booklet ▪ Once the patient's condition is stable or predictable fax a completed and signed shared care guideline to GP for consideration ▪ Fax a signed shared care guideline with patient details completed to GP for consideration of shared care request ▪ Continue to monitor all patients on biologic therapy. Shared care will not be sought for biologic therapy (anti-TNF's, rituximab). ▪ Exclude pregnancy in women of child baring age prior to initiation of treatment ▪ Ensure contact details (section 4) are up to date. *After agreement to shared care* ▪ Inform GP when patient is stable ▪ Inform GP of abnormal monitoring results and any changes in therapy or disease state ▪ Evaluate adverse events reported by GP or patient ▪ Report suspected adverse effects to the MHRA: http://www.yellowcard.gov.uk ▪ Carry out ongoing monitoring and follow up accordingly to shared care guidelines including continued need for therapy.	▪ Consider shared care once the patient's condition is stable or predictable ▪ Respond within 2 weeks of receipt ▪ If named GP is not available over the next week pass request to a GP colleague ▪ If in agreement to share care, confirm by faxing a signed copy of page 3 back to the Rheumatology Department ▪ If not in agreement to share care discuss with requesting consultant or local PCT medicines management team within 2 weeks of receipt of shared care request *After agreement to shared care* ▪ Prescribe dose as recommended once the patient's condition is stable or predictable ▪ Monitor general health of patient (discuss with rheumatologist if concerned) and check adverse effects as appropriate ▪ Inform specialist consultant of suspected adverse effects ▪ Report suspected adverse effects to the MHRA: http://www.yellowcard.gov.uk ▪ Stop treatment on advice of specialist or immediately if urgent need arises ▪ Check compatibility interactions when prescribing new or stopping existing medication ▪ Carry out monitoring and follow up according to shared care guideline ▪ Enter blood results in patient held monitoring booklet ▪ Discuss any abnormal results with specialist consultant and agree any action required ▪ After discussion with Consultant, ask to take back prescribing should unmanageable problems arise. Allow an adequate notice period of at least 4 weeks

3. PATIENT'S RESPONSIBILITIES

- Attend all hospital and GP appointments
- Take medicines as agreed
- Keep a medicines monitoring booklet and show it to any healthcare professional involved in their care
- Report any adverse effects to GP, hospital doctor or specialist nurse immediately
- Do not share medicines
- Inform hospital and GP of any changes in address or telephone numbers
- Inform GP, hospital doctor, specialist nurse or pharmacist about any medicines taken (including over-the-counter)

4. COMMUNICATION AND SUPPORT

Hospital contacts

Kings College Hospital

Rheumatology Consultants: 0203 299 9000 Telephone (Secretary)

Dr E.Choy	Ext 1732
Dr P.Gordon	Ext 1735
Professor Scott	Ext 1731
Dr S.Steer	Ext 1733
Locum	Ext 5611

Rheumatology Nurse Specialist Advice Line (Monday to Friday 09:00 – 17:00)
Tel: 020 3299 8568 Fax: 020 3299 1734

Rheumatology Specialist Registrar via hospital switchboard 020 3299 9000

Pharmacist:
For Drug Information queries: 0203 299 9000 ext 3007

Guys and St Thomas's Hospital

Rheumatology Consultants:
Dr T Gibson, 020 7188 5867 or pager 881870 via switchboard.
Prof A. Cope 020 7188 5884
Dr B. Kirkham 020 7188 5884
Dr S. Agarwal 020 7188 5867

Rheumatology Nurse Specialist Advice Line (Monday to Friday 09:00 – 17:00)
Tel: 020 7188 5896 Fax: 020 7407 7532

Rheumatology Registrar via hospital switchboard 020 7188 7188 (Monday to Friday 09:00 – 17:00)

Rheumatology Consultant oncall available via hospital switchboard 020 7188 7188

Medicines Information 020 7188 5008 (St Thomas'), 020 7188 8748 (Guy's)

Attach patient addressograph or enter: Patient name Patient hospital number Patient NHS number Date of Birth

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5. CLINICAL INFORMATION

Indication(s):	Rheumatoid Arthritis
Place in Therapy:	Disease modifying anti-rheumatic drug (DMARD)
Dose & route of administration:	10-20mg/day oral.
Duration of treatment	Indefinitely if patient is responding well to treatment and in absence of significant side effects
Criteria for stopping treatment	Failure to respond to treatment or adverse effects necessitating withdrawal. **Withhold and discuss with Rheumatologist if any of the following occur:** WBC < 3.5 x 10^9/l Neutrophils < 2.0 x 10^9/l Platelets <150 x 10^9/l Rise in AST, ALT from upper limit of reference range: 2-3 x – discuss with rheumatologist > 3 x – stop drug and discuss with rheumatologist Abnormal bruising or severe sore throat – check FBC immediately and withhold until results available, discuss with rheumatologist. Rash, pruritus or hair loss – discuss with rheumatologist Hypertension – If BP > 140/90 treat in line with NICE guidance. If uncontrolled stop and discuss with rheumatologist. Headache – if severe or persistent stop and discuss with rheumatologist GI disturbances (nausea/diarrhoea) – if symptoms severe or persistent discuss with rheumatologist Weight loss – if > 10% weight loss from baseline with no other cause identified discuss with rheumatologist. Breathlessness – in increasing shortness of breath occurs, stop and discuss with rheumatologist. Hair loss – discuss with rheumatologist Renal Impairment (GFR < 20 ml/min)

Monitoring Requirements including frequency:	**Consultant:** **<u>Baseline</u>** Full blood count, urea, electrolytes, creatinine, liver function tests, erythrocyte sedimentation rate, c-reactive protein, chest X-ray. Blood pressure: If >140/90 on two consecutive readings 2 weeks apart, treat as per NICE guidance before commencing the drug. Weight: to allow assessment of weight loss **<u>Ongoing</u>** Full blood count, urea and electrolytes, creatinine and liver function tests monthly until dose and blood monitoring stable for 6 weeks. Blood tests should be continued long term, at least once a month, if co-prescribed with other immunosuppressant or potentially hepatotoxic agents. If in doubt discuss with rheumatologist. Ask patient about side effects at each visit. Shared care will be sought after 3 months providing the patient has been stable for 6 weeks. **<u>Following dose changes</u>** As for ongoing monitoring by consultant. **GP:** **<u>Ongoing</u>** Full blood count, urea and electrolytes, creatinine and liver function tests every month for 6 months, if stable 2 monthly thereafter. Blood tests should be continued long term, at least once a month, if co-prescribed with other immunosuppressant or potentially hepatotoxic agents. If in doubt discuss with rheumatologist. Blood pressure and weight should be checked at each visit.
Follow up arrangements	**Consultant Rheumatologist:** Subject to response to treatment: 3 monthly, 6 monthly or 12 monthly if well controlled and stable. At each clinic attendance update the patient held monitoring booklet. Ask patient if adverse effects experienced. Report suspected adverse effects to the MHRA: http://www.yellowcard.gov.uk Within 2 weeks of each clinic attendance, write/fax or telephone GP to advise on: • review, duration or discontinuation of treatment • recent blood test results • frequency of monitoring • any adverse effects experienced and consequent actions • non-attendance and any consequent actions **GP** Blood tests as outlined in monitoring section. At each appointment update the patient held monitoring booklet. Ask patient if adverse effects experienced. Request patient seen earlier if: • disease flare • adverse effects experienced • recurrent infections

Practical issues including other relevant advice/information:	**Adverse Effects** Hypertension Regular monitoring of blood pressure is necessary during treatment and if there is a significant rise in blood pressure, then this should be treated as per NICE guidelines. In severe uncontrolled cases, it is necessary to consider stopping the drug, therefore discuss with rheumatologist. Respiratory If patient develops new onset of shortness of breath or cough, leflunomide should be stopped immediately and the patient should be discussed with the rheumatologist. Hepatotoxicity Leflunomide can cause hepatotoxcity and caution is advised when patients are prescribed other hepatotoxic drugs or if there is evidence of current or recent hepatitis B or C infection. Most cases of hepatotoxicity have occurred in the first 6 months of treatment and in the presence of multiple risk factors. Patients should limit alcohol intake within national limits of 4 -8 units a week. Contact rheumatologist if there are any concerns over hepatotoxicity or co-prescribing with other drugs (see monitoring requirements above). **Pregnancy, Breast Feeding and Contraceptives** Leflunomide is contraindicated in pregnancy and breast feeding. Men and women taking leflunomide must use reliable contraceptives. Women must wait 2 years between stopping Leflunomide and becoming pregnant. This can be reduced to 3 months if patients are referred to the rheumatologist and treated with rapid washout. Men should continue to use effective contraceptives for 3 months after stopping treatment. Any patient considering family planning should be discussed with the rheumatologist. **Vaccinations** Patients must not receive immunisations with live vaccines such as oral polio, MMR, BCG or yellow fever. Inactivated injectable polio vaccine is available but suboptimal response may be seen. Seasonal and pandemic influenza vaccination and Pneumovax are safe and recommended. Patients exposed to Chicken Pox / shingles should receive passive immunisation with VZIG (varicella-zoster immunoglobulin), if they are varicella-zoster virus (VZV) susceptible (VZV IgG undetectable on blood testing). **Drug Interactions** (full list in BNF) • **Methotrexate** -↑ risk of hepatotoxicity • **Vaccines** – avoid live vaccines (see above) NOTE: Lefluonamide has a very long half life (2 weeks) therefore the interactions can be potentially serious and more actions may be required beside just discontinuation of the drug such as wash out.

Information provided	Arthritis Research Campaign Leaflet: Leflunomide. Monitoring Booklet
Evidence Base for treatment and Key references:	NICE National Clinical Guideline: Rheumatoid Arthritis, February 2009 BSR/BHPR guideline for disease-modifying anti-rheumatic drug (DMARD) therapy in conjunction with the British Association of Dermatologists. 2008. BSR/BHPR DMARD quick reference guideline November 2009. British National Formulary 58 Summary of Product Characteristics Renal Drug Handbook, 3rd Edition, Radcliffe Publishing.

NB: for full details of adverse effects and drug interactions refer to latest Summary of Product Characteristics