SHARED CARE PROTOCOL AND INFORMATION FOR GPs	NHS Lothian
Leflunomide	
Clinical indication: For the treatment of rheumatological inflammatory diseases	
Version 4.0: September 2009	Due for review: **September 2011**

Introduction
With the exception of sulfasalazine, DMARDs are usually started after assessment by a rheumatologist.
'Rheumatological Management and Shared Care Guidelines' available on website: *www.refhelp.scot.nhs.uk*

Shared Care
A shared care protocol is used to **facilitate the sharing of care and transfer of prescribing.** This would usually take place once the patient's condition is stable; the patient is demonstrably benefiting from the treatment and is free from any significant side effects. GPs should only take on the prescribing when they are confident in the use of the drug, in the context of the protocol. Contingency plans must be in place to enable the patient to receive the recommended treatment, should the GP decline to prescribe.

Indication for Therapy
Indications – active joint inflammation usually supported by indices of inflammation.
Duration – most drugs require up to 3 to 4 months trial to assess efficacy. Therapy is continued providing the drug is working and there are no side effects.
Relapse is common after withdrawal of therapy.

Preparations Available
10mg, 20mg and 100mg tablets.

Recommended Dosage and Administration
Maintenance dose is 10mg to 20mg once daily.

Cost
30 days supply of 10mg and 20mg tablets is £51.13.

Adverse Effects and Drug Interactions
Common: mild increases in BP, GI disturbance, rash, reversible alopecia, headache, haematological abnormalities (leucopenia) and raised LFTs.

Rare: Stevens-Johnson Syndrome or toxic epidermal necrolysis, pulmonary infiltration/pneumonitis.
Action: washout for intolerance or prior to starting another DMARD (necessary because active metabolite has long half-life) - Use cholestyramine 8g three times daily for 11 days or if not tolerated, activated charcoal 50g four times daily for 11 days.

Drug interactions include: other hepatotoxic or haematotoxic medication, phenytoin, warfarin, tolbutamide and live vaccines. Patients on warfarin must have their INR monitored closely for several weeks after stopping leflunomide due to its long half-life.

Precautions and Contra-Indications

Hypersensitivity to the active substance or to any of the excipients; impairment of liver function, or moderate to severe renal impairment; severe immunodeficiency states or serious infections; significantly impaired bone marrow function or significant anaemia, leucopenia, neutropenia or thrombocytopenia due to causes other than rheumatoid or psoriatic arthritis; severe hypoproteinaemia.

Pregnancy and Lactation
Contraindicated in women and men who are likely to conceive, in pregnancy and breastfeeding. Consultant will arrange plasma testing for patients established on leflunomide who wish to parent a child.

Contact Points
Rheumatology Clinical Nurse Specialists:
0131 537 1405
Rheumatology SpR (via switchboard):
0131 537 1000
Rheumatology Clinical Pharmacist:
0131 537 1000 (bleep 8461)
Rheumatic Diseases Unit (WGH):
0131 537 1798
Rheumatology Secretary (St John's Hospital):
01506 52 3824

Approved for use by the General Practice Prescribing Committee, LPCD and the Drug & Therapeutics Committee, LUHD.

Shared Care Responsibilities

Aspects of Care for which the Consultant is responsible

- Assessing the need for DMARD.
- Arranging for the patient to receive counselling in verbal and written form.
- Providing relevant baseline investigations.
- Following the patient's response to treatment at the out- patient clinic.
- Communicating advice to the patient's GP re monitoring requirements.
- At any stage of treatment, advising GP of concerns re monitoring or potential adverse effects of treatment.

Aspects of Care for which the General Practitioner is responsible

- Prescribing DMARD under the guidance of the consultant.
- Reporting any suspected adverse reactions to the patient's consultant and complete a yellow card if appropriate. Discuss any significant abnormalities with consultant.
- Liaising with the consultant regarding any complications of treatment.
- Monitoring the general health of the patient.
- Monitoring for specific side effects as detailed in "Monitoring" section.
- Provision of pneumococcal and annual influenza vaccination.

Monitoring

Test	Frequency	Abnormal result	Action if abnormal result
FBC	Monthly for first 6 months If stable and not co-prescribed with another immunosuppressant or hepatotoxic drug, two monthly thereafter.	WBC <3.5 x 10^9/l. neutrophils <2.0 x 10^9/l. platelets <150 x 10^9/l.	Withhold and discuss with specialist team.
LFTs		ASTand/or ALT 2-3 times upper limit of normal reference range.	If dose >10mg daily reduce to 10mg daily and recheck weekly. If AST/ALT normalise, leave on 10mg daily. If AST/ALT remain elevated, withhold leflunomide and discuss with specialist team.
		AST and/or ALT > three times upper limit of normal reference range.	Recheck LFTs within 72hrs; if still >three times upper limit of normal withhold leflunomide and consider washout with cholestyramine or charcoal; discuss with specialist team.
BP	At each visit	>140/85mmHg. >130/80mmHg in patients with diabetes or renal disease.	Give antihypertensives as per Lothian Hypertension Guidelines. If BP remains uncontrolled stop leflunomide and consider washout.
weight		>10% weight loss with no other cause.	Reduce dose or stop and consider washout.

- Abnormal trends should prompt extra vigilance.
- Temporarily withdraw if the patient reports sore throat, unexplained bleeding or bruising, mouth ulcers or other signs of blood dyscrasia or evidence of infection. Perform repeat blood monitoring.
- In the event of an unexplained acute widespread rash, headache, GI upset (beyond loading dose), or hair loss reduce dose of leflunomide, or stop if severe, and consider washout. For rashes: seek urgent specialist (preferably dermatological) advice; for all: inform rheumatologist. If increasing shortness of breath occurs, stop leflunomide and consider washout.
- Trends in ESR are useful in decision-making.

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This information was prepared by the Rheumatic Diseases Unit and Pharmacy Department, Western General Hospital, NHS Lothian through liaison with the General practice Prescribing Committee and LUHD Drug and Therapeutics Committee

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