The Rotherham NHS
NHS Foundation Trust

LEFLUNOMIDE SHARED CARE PROTOCOL

This Shared Care Protocol is for patients initiated on Leflunomide under the Rheumatology Department. The consultant will have detailed the expected treatment regimen in the clinic letter. The first 3 months of prescribing and monitoring will be undertaken by the Rheumatology department. Updates of dosages and results will be completed by the specialist nurses and documented in the patient hand held record as well as sent to the GP practice for information.

As part of the Shared Care LES, it is expected that ALL patients will have a transfer of care at 3 months, unless there are exceptional circumstances (such as unstable results). We would be grateful if your practice would take over the responsibility for:

- Prescribing the Leflunomide
- Performing the blood tests and monitoring the results (payment via LES)
- Monitoring blood pressure (same frequency as blood tests)

If patients fail to attend for their monitoring, we would recommend contacting them to arrange one further monitoring appointment but thereafter to stop prescribing their treatment until the monitoring requirements have been met.

The patient carries a hand held monitoring book, which has been kept up to date by the Rheumatology department, and/or GP prescriber, and contains patient information.

Important Information:

- Repeat prescriptions should be retained separately (i.e. highlighted as different to all other repeat prescriptions), so the GP prescriber can ensure monitoring has been undertaken prior to signing and issuing to patient
- Alcohol intake should be limited to 10units per week.
- Leflunomide is contraindicated in pregnancy and when breastfeeding and contraception is therefore advised in patients who are sexually active. Both men and women should be advised to stop Leflunomide at least 2 years before a planned pregnancy, or undergo the “washout procedure” and have blood tests to confirm drug elimination (see SPC or contact Rheumatology department)
- Leflunomide may cause hypertension and Blood Pressure should therefore be monitored regularly
- Side effects include: Headache / dizziness / oral ulceration / rash / nausea / diarrhoea / alopecia – drug continuation depends on severity and patient wishes
- It may be necessary for a “washout procedure” for severe undesirable side effects (half life of 1 to 4 weeks). Details in BNF.
- Live vaccines should not be given
- Annual flu jab is advised recommended (to be given by GP practice)
- Avoid exposure to chickenpox and shingles. If infection develops it should be treated aggressively with antiviral medication and Rheumatology dept. can be contacted for advice

Treatment is usually started at a dose of 20mg daily and increased to a maximum of 30mg according to clinical response. An initial loading dose of 60mg daily for 3 days may be given in some cases.

Monitoring schedule:

- FBC / U&E / LFT / CRP / BP every 2 weeks until on a stable dose for 6 weeks, then monthly for 3 months
- Then every 3 months unless dose changes
- If dose increase: additional FBC / U&E / LFT at 2, 4 and 6 weeks until on stable dose for 6 weeks then revert to previous schedule
- Results to be entered into hand held monitoring booklet

IF:

WCC	$<3.5 \times 10^9$/l
Neutrophils	$<1.8 \times 10^9$/l
Platelets	$<150 \times 10^9$/l
ASTorALT	> 100

OR: Severe sore throat / Oral Ulceration / Fever / Rash

Stop medication and contact Rheumatology service.

If sudden onset breathlessness and cough, assess the patient for infection, stop the leflunomide and contact Rheumatology dept.

If CRP elevated (>25) and patient symptomatic, inform Rheumatology department. If CRP suddenly elevated without significant change to joint symptoms assess patient for infection. Occasionally patients run a persistently high CRP without joint symptoms – this will usually be referred to in clinic letters.

If blood pressure increases significantly and does not settle with anti-hypertensive treatment, the drug should be discontinued (discuss with Rheumatology department).

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Specialist Registrar: available on bleep 101 via Switchboard

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Version:	3 (three)
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Title of originator/author:	Dr Rakesh Kumari, Dr Gillian Smith, Dr Fiona Fawthrop, Rheumatology RFT; Eloise Summerfield, Medicines Management Team RCCG
Title of responsible committee/individual:	Consultants Rheumatology RFT; Medicines Management Team RCCG (BNF 10 Prescribing Advisor)
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Target audience:	TRFT consultants & nurses Rotherham CCG GPs & nurses

Version	Date	Author	Status	Comment
Version 1	July 2012	Dr James Maxwell RFT Eloise Summerfield RCCG	Archived	First version onto a two page format
Version 2	July 2014	Dr Gillian Smith, Dr Fiona Fawthrop, RFT; Eloise Summerfield, RCCG	Archived	Review – minimal changes
Version 3	Nov 2017	Dr Rakesh Kumari, Dr Gillian Smith, Dr Fiona Fawthrop, RFT; Eloise Summerfield, RCCG	Current Version	Extra blood tests at start & dose change. First paragraph re-worded to reflect current practice. Acceptance letter removed as this is now implied under the Shared Care LES