Somerset Healthcare Community
Shared Care Protocol
Leflunomide in rheumatology patients

NHS
Somerset
Clinical Commissioning Group

This shared care protocol (SCP) sets out details for the sharing of care for patients requiring subcutaneous methotrexate injection. It should be read in conjunction with the Summary of Products Characteristics (SPC, available at http://www.medicines.org.uk/emc)

As outlined in NHS Circular 1992 (Gen 11), when a consultant considers a patients' condition is stable he/she may seek the agreement of the patients' GP to "share" the patients' care. This document provides information on drug treatment for the shared commitment between the consultant and GP concerned. GPs are invited to participate. If the GP is not confident to undertake these roles, then they are 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. The doctor who prescribes the medication has the clinical responsibility for the drug and the consequences of its use.

Introduction

Leflunomide is a disease-modifying anti-rheumatic drug (usually after Methotrexate/Sulphasalazine treatment contra-indicated, not tolerated or ineffective). Shared care to commence after patient has been prescribed by a consultant for at least one month and the response to treatment has been assessed

For further information please click on the links below or visit;
British National Formulary
Summary of Product Characteristics at the Electronic Medicines Compendium
NICE

Licensed Indication

Leflunomide is indicated for the treatment of adult patients with:

- active rheumatoid arthritis as a "disease-modifying antirheumatic drug" (DMARD)
- active psoriatic arthritis as a "disease-modifying antirheumatic drug" (DMARD)

Dose (posology & method of administration)

Rheumatoid Arthritis

The recommended maintenance dose for rheumatoid arthritis is leflunomide 10 mg to 20 mg once daily. Patients may be started on leflunomide 10 mg or 20 mg depending on the severity (activity) of the disease.

Active psoriatic arthritis

The recommended maintenance dose for psoriatic arthritis is leflunomide 20 mg once daily.

The therapeutic effect usually starts after 4 to 6 weeks and may further improve up to 4 to 6 months.

There is no dose adjustment recommended in patients with mild renal insufficiency.

No dosage adjustment is required in patients above 65 years of age.

Contraindications (click here for details)

Special warnings and precautions for use (click here for details)

Interactions (click here for details)

Pregnancy and Lactation: Pregnancy is contraindicated during treatment with leflunomide and for 2 years after discontinuation of therapy. A wash out procedure may be required (click here for details)

Adverse effects (click here for details)

Shared Care Responsibilities

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to, and accepted by, the patient. This provides an opportunity to discuss drug therapy.

The clinician who prescribes the medication has the clinical responsibility for the drug and the consequences of its use.

Specialist responsibilities:-

1) Decision to prescribe leflunomide.
2) Discuss benefits and side effects of treatment with patient or patient's carers including where appropriate the risks associated with pregnancy and need for reliable method of contraception.
3) Initiate leflunomide and stabilise patient on a therapeutic dose.
4) Refer patient to specialist nurse service where appropriate (e.g. new patient) for advice on taking the drug, its cautions, side effects associated with treatment, monitoring requirements and the timing of re-assessment and by whom.

5) Ascertain immune status by enquiring about history of chickenpox. Measurement of antibodies to varicella-zoster virus is not recommended.
6) Issue a booklet for recording test results to patient.
7) Conduct baseline tests including full blood count, U&Es, LFTs, serum creatinine, blood pressure and weight. Copy test results to GP.
8) Prompt verbal communication followed up in writing to GP of changes in treatment or monitoring requirements, results of monitoring, assessment of adverse events or when to stop treatment. Urgent changes to treatment should be communicated by telephone to GP.
9) Reporting adverse events to MHRA.
10) Issue the first prescription for at least a 4 weeks supply and check response to treatment after 4 weeks.

Consultant monitoring:-
Prior to patients commencing treatment with leflunomide:

- FBC
- U&E
- Creatinine
- LFTs (inc. ALT)
- Blood pressure (<140/90 on 2 consecutive readings 2 weeks apart)
- Body weight
- Exclude pregnancy.

General Practitioner responsibilities:-

1) Accept clinical responsibility for the patient provided the above criteria have been met.
2) Repeat prescribing of oral leflunomide after communication with specialists regarding the need for treatment.
3) Undertake monitoring of full blood count, U&Es, creatine, LFTs, blood pressure and weight as specified. Review results and take any necessary action.
4) Take appropriate action if patient reports sign(s) or symptom(s) specified under Monitoring.
5) Be aware of criteria for referral to Rheumatology team.
6) Report to and seek advice from specialist on any aspect of patient care of concern to GP which may affect treatment. Prompt referral to specialist if there is a change in patient's health status.
7) Report adverse events to specialist.
8) Stop treatment in case of a severe adverse event or as per shared care guideline.

General practitioner monitoring

FBC, LFTs (inc ALT): **Every month during the first 6 months of treatment and, if bloods are within satisfactory parameters, every 8 weeks thereafter.**

N.B. Continue **monthly** monitoring if leflunomide is used in combination with an additional immunosuppressant or another potential hepatotoxic agent.

Blood pressure and weight: **at each monitoring visit**

Monitoring action and advice for the GP

WBC < 3.5x10^9/l	withhold *until discussed* with rheumatologist
Neutrophils < 2x10^9/l	withhold *until discussed* with rheumatologist
Platelets < 150x10^9/l	Reduce dose to 10 mg per day, recheck weekly If platelets remain low withhold until discussed with rheumatologist
ALT/ AST elevations > 2 to < 3 fold the upper limit of normal	Reduce dose to 10 mg per day, recheck weekly If remains elevated withhold until discussed with rheumatologist
ALT/ AST elevations > 3 fold the upper limit of normal	Stop, discuss with rheumatologist and initiate washout as per SPC
Blood pressure > 140/90	withhold *until discussed* with rheumatologist
Weight loss	Monitor, if > 10% , no other cause, reduce dosage, stop and consider washout
Rash, itch or mouth ulcers	reduce dose (+- antihistamine)
If severe rash	withhold *until discussed* with rheumatologist. Consider washout procedure
Hair loss	Dosage reduction, if severe stop, consider washout
Headache	Dosage reduction, if severe stop consider washout
Abnormal bruising, severe sore throat	Stop, check FBC
GI upset (nausea and diarrhoea)	Symptomatic treatment and consider dosage reduction. If severe or persistent, stop and consider washout
Breathlessness	If increasing SOB, stop consider washout

Drug Cost

(Drug tariff March 2015**)**

Leflunomide 10mg 30 / £14.93
Leflunomide 20mg 30 / £15.42

Further support

- Medicines Information department, Musgrove Park Hospital: 01823 342253
- Medicines Information department, Yeovil District Hospital: 01935 384327
- Prescribing & Medicines Management Team, NHS Somerset CCG: 01935 384123

Version:	1.1	Date
Drawn up by:	Version 1.0 by Jill Moore, Prescribing Support Pharmacist, NHS Somerset	June 2012
	Version 1.1 Shared Care Guideline version 1.0 put into Somerset CCG shared care template by Catherine Henley, Medicines Manager, NHS Somerset CCG with advice from Dr Sally Knights, Dr Alex Bourne (YDH rheumatologists) and Teresa Jewell (TST Rheumatology Nurse Specialist).	March 2015
Approved by:	Somerset Prescribing Forum, NHS Somerset	
	Drug & Therapeutics Committee, Taunton & Somerset NHS FT	
	Drug & Therapeutics Committee, Yeovil District Hospital NHS FT	
	Drug & Therapeutics Committee, Somerset Partnership NHS FT	
Review required by:		March 2017

References

- Summary of Product Characteristics, leflunomide tablets last updated on the eMC: accessed 30/12/14
- British National Formulary accessed 30/12/14