Northern Lincolnshire and Goole NHS
NHS Foundation Trust

Prescribing Framework for Leflunomide in Rheumatic Diseases

Patient's Name:…… Unit Number: ……

Patient's Address:……(Use addressograph sticker)

GP's Name:……..

Communication

We agree to treat this patient within this Prescribing Framework. Consultant's Signature:…….. GP's Signature:…….

If the General Practitioner is unable to accept prescribing responsibility for the above patient the consultant should be informed within one week of receipt of this framework and consultant's / nurse specialist's letter. In such cases the GP are requested to update the consultant, by letter, of any relevant changes in the patient's medication / medical condition.

APPROVAL PROCESS

Written by:	**Dr Tim Gillott, Consultant Rheumatologist**
Reference:	**Yorkshire Monitoring Guidelines 2014**
Approved by:	**Northern Lincolnshire and Goole Medicines and Therapeutics Committee**
Ratified by:	**Northern Lincolnshire Area Prescribing Committee**
Review date:	**May 2021**

Background

DMARDs are fundamental to arresting the disease process in Rheumatoid Arthritis and other inflammatory arthritides. While early initiation of therapy is essential to arrest the disease process, sustained use is vital if disease suppression is to be maintained. Prolonged therapy requires long-term monitoring for toxicity and safety profile.

Leflunomide is a DMARD that may be used for rheumatoid arthritis (NICE Clinical Guideline 79, www.nice.org.uk/cg79) and other rheumatic diseases.

These guidelines aim to provide a framework for the prescribing of leflunomide by GPs and to set out the associated responsibilities of GPs and hospital specialists who enter into the shared care arrangements.

The guidelines should be read in conjunction with the general guidance on prescribing matters given in EL (91) 127 "Responsibility for prescribing between hospitals and GPs".

LEFLUNOMIDE	
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Dose:	Usually considered for patients with active RA/ PsA who have failed methotrexate and sulphasalazine. Loading dose of 100mg daily for three days IS NOT recommended 20mg (or 10mg) daily as a single tablet should be used. Timing of dose is not important. Patients with uncertain alcohol intake or other hepatotoxic drugs may warrant increased vigilance.
Baseline tests:	FBC/U&E and LFT BP Consider Pregnancy test Consider Chest X-ray and PFTs Note: use is contra-indicated in hepatic impairment, severe immunodeficiency states (AIDS), moderate to severe renal impairment, severe hypoproteinaemia (nephrotic syndrome) and impaired bone marrow function.
Routine monitoring:	2 Weekly FBC/LFT/U&E and BP for 2 months (0 - 2) Monthly for 4 months (2-6) Then 3 monthly (stable dose). Patients should be guided to have a blood test (e.g. for CRP) just prior to their secondary care appointment.
Indications for stopping treatment:	□ Ulcerative stomatitis – stop and contact specialist □ Skin/mucosal reaction (risk of Stephen Johnson) – stop and contact specialist (washout recommended – cholestyramine 8g tds for 11 days or charcoal). □ Peripheral neuropathy – stop and contact hospital specialist. □ Abnormal LFT's – ALT greater than 3 x the upper limit of normal, stop medication, consider washout and contact hospital specialist.

	In addition, Stop medication and hospital specialist if: □ WCC <3.5 10^9/L or below local normal range □ Neutrophils < 2.0 10^9/L or below local normal range □ Platelets <150 10^9/L or below local normal range □ Significant BP rise or > 160/95 □ Abdominal pain/Nausea/Diarrhoea/Weight loss/Pruritis/Rash/ □ Breathlessness or infection - perform CXR +/- PFT
Assessment of Response:	Clinical effect usually within 2 to 4 months.
Additional information:	Can be associated with pulmonary toxicity (?more in East Asian Groups) Live vaccines must not be administered. Avoidance of alcohol recommended Important drug interactions: hepatoxic/haemotoxic drugs, cholestyramine, rifampicin, warfarin, tolbutamide and phenytoin. Contains lactose and soya lecithin – avoid in lactose, soya or peanut allergy.
Pregnancy & Breastfeeding:	Effective contraception should be used in both males and females. Females should use reliable contraceptive measures for 2 years after stopping treatment (if impracticable to wait refer to datasheet with regards to wash-out and monitoring of plasma levels). Men wishing to conceive should perform a washout – see datasheet regime plus monitoring of plasma levels. Breastfeeding is not recommended
Please refer to licensed datasheet for more comprehensive prescribing information: http://www.medicines.org.uk/EMC/medicine/7480/SPC/Arava+10%2c+20+and+100mg+Tablets/	

Information to patient

Patients should be informed about benefits and risks of treatment and need for monitoring.

Patients should be told to go to their GP immediately if they experience any fever, rash, bruising, bleeding, sore throat, oral ulceration, jaundice or infection.

Patients should be advised on need for effective contraception during and after treatment, where relevant.

Patients will be given a DMARD alert card which records the name of the medicines started and dose.

Responsibilities of clinicians involved

Stage of Treatment	Hospital Specialist	General Practitioner
Initiation	Assess the patient following referral by GP Recommend appropriate treatment to the GP Carry out baseline full blood count, differential WCC, platelets, U&Es and LFTs Give patient DMARD alert card Prescribe first month of treatment	
Maintenance	Assess clinical response to treatment Provide adequate advice and support for the GP. Provide information to GP on frequency of monitoring if doses are changed Update DMARD alert card where relevant	Prescribe on FP10 Monitor for adverse effects, refer to consultant where necessary. Blood tests for monitoring as above Patients should be asked about the presence of rash or oral ulceration at each visit.

Contact Details:

Rheumatology Specialist Nurses: 03033 304849