LEFLUNOMIDE SHARED CARE AGREEMENT (SCA) FOR ADULTS

FOR USE IN RHEUMATOLOGY

SPECIALIST RESPONSIBILITIES

1. Assess patient, confirm diagnosis and discuss benefits and risks of treatment with the patient.
2. Confirm women of childbearing age are not pregnant. Ensure that the requirement for contraception is understood and prolonged risk of conception after use of leflunomide.
3. Perform pre-treatment assessments and on-going monitoring as detailed on page 3.
4. Advise patient and GP if any vaccinations are required (e.g. influenza, pneumococcal).
5. Prescribers should familiarise themselves with the drug indication, dose, administration, contra-indications, cautions, side-effects, interactions and preparation by referring to the current version of the Summary of Product Characteristics (https://www.medicines.org.uk/emc/product/4943/smpc) or the BNF (http://www.medicinescomplete.com/mc/index.htm).
6. Initiate and titrate treatment with leflunomide therapy and supply for 6 weeks.
7. Provide appropriate written information on leflunomide to the patient.
8. Review efficacy of treatment and ensure any drug treatment changes are communicated to the GP.
9. Act on pathology lab results if initiated by the hospital.
10. Advise the GP on frequency of monitoring and what to do when the parameters change.
11. Communicate any changes in frequency of pathology testing to the GP if relevant.
12. Ensure clear back-up arrangements exist for GPs, including telephone number for advice and support and regularly checked e-mail account.
13. Discuss proposed SCA with the patient.
14. Send a letter to the patient's GP to request participation in the SCA, along with this current SCA and the clinic letter (containing full details of the prescribing and treatment plan). The GP must respond to the specialist within 14 days by signing this agreement and sending to the hospital.
15. Full clinical responsibility for the patient and the prescribed treatment will remain with the specialist if the GP declines to participate.

Once the GP has agreed to participate in the SCA, the specialist will:

1. Make a record in the patient's secondary care notes that treatment is being given as part of an SCA.
2. Inform the patient of the aspects of care that will be provided by the specialist and by the GP.
3. Ensure ongoing treatment is provided before prescribing is transferred.
4. Inform the patient when to contact their GP practice.
5. Ask the patient to report any adverse effects about their treatment to the specialist or GP. Adverse events should be reported by the specialist or GP to the MHRA (http://yellowcard.mhra.gov.uk/). Female patients must be asked to inform the specialist or GP if they are pregnant or planning a pregnancy.
6. Review the patient as clinically appropriate and inform the GP of any changes to treatment, the next date for blood reviews and when the prescription is due.
7. Advise the GP of the on-going monitoring required as detailed on page 3.
8. Advise the GP of when and how to discontinue treatment (if necessary).
9. Ensure clear arrangements exist for GPs to obtain advice and support.

GP RESPONSIBILITIES

1. Offer flu and pneumococcal vaccination as required for patients on immunosuppressive agents.
2. Review request from the specialist to participate in the SCA and respond to the specialist as soon as possible (within 14 days). To accept shared care please return a signed copy of this agreement to the specialist. Prescribing should not be refused on the grounds of drug cost. Leflunomide is included in the local Shared Care Enhanced Service.

Once shared care accepted, the GP will:

3. Make a record in the patient's primary care notes that treatment is being given as part of an SCA.
4. Familiarise themselves with the drug indication, dose, administration, contra-indications, cautions, side-effects, interactions and preparation by referring to the current version of the Summary of Product Characteristics (https://www.medicines.org.uk/emc/product/4943/smpc) or the BNF (http://www.medicinescomplete.com/mc/index.htm).

Written and approved by Ipswich and East Suffolk CCG, Ipswich Hospital NHS Trust, North East Essex CCG, Colchester Hospital University NHS Foundation Trust, West Suffolk CCG and West Suffolk NHS Foundation Trust. June 2020. Review June 2022.

5. Prescribe leflunomide in accordance with the specialist prescribing and treatment plan.
6. Check for possible drug interactions when newly prescribing or stopping concurrent medication.
7. Report any adverse effects to the specialist and to the MHRA (http://yellowcard.mhra.gov.uk/).
8. Follow advice from the specialist regarding any changes required to treatment.
9. Perform on-going monitoring as advised by the specialist and detailed on page 3.
10. Refer to the specialist if the patient's clinical condition deteriorates, if intolerance to treatment develops, or if contra-indications/cautions arise that prevent continued prescribing. Female patients must be asked to inform the specialist or GP if they are pregnant or planning a pregnancy.
11. Discontinue treatment (if necessary) on the advice of the specialist.
12. Contact the specialist for any necessary advice and support via the telephone helpline numbers provided.

Special Instructions

- It is common practice to use combination Disease Modifying (DMARD) Therapies e.g. sulfasalazine, methotrexate. Where a new DMARD is started then the frequency of monitoring should reflect that of the drug requiring most frequent monitoring.
- When patients are taking combination therapy or have individual risk factors, e.g. liver / renal disease, it may be necessary to monitor bloods more frequently than usual. The patient should be monitored as advised by the Specialist for individual patients.

Patient's / Carer's role
1. Report any adverse effects to the specialist or GP whilst taking leflunomide tablets.
2. Share any concerns in relation to treatment with leflunomide.
3. Report to the specialist or GP if he or she does not have a clear understanding of their treatment.
4. Female patients must inform the specialist or GP if they are pregnant or planning a pregnancy. Following administration to woman conception should be avoided by using an effective contraceptive method for at least 2 years after using leflunomide tablets (or after a suitable 'washout' with cholestyramine and check of leflunomide levels). For male patients, the decision should be discussed between the specialist clinician and the patient.
5. Ensure any healthcare professional, including community pharmacist, offering treatment to patient is aware that leflunomide is being taken.
6. Participate in regular screening and monitoring.
7. Inform your GP before starting to take any new over the counter medicine or supplement as this may interact with your leflunomide.

CONTACT DETAILS

ESNEFT - Ipswich site		
Rheumatology	Dr Lane / Dr Watts: 01473 702362 Dr Weerakoon / Dr Shand: 01473 702039 Dr Abdulkader/Dr Ntatsaki: 01473 707324	Email ihn-tr.rheum-sharedcare@nhs.net (for non-urgent correspondence) Advice and guidance on NHS e-referrals
ESNEFT - Colchester site		
Rheumatology	Dr Byrne: paul.byrne@esneft.nhs.uk Dr Walton: tom.walton@esneft.nhs.uk Dr Davies: rachel.davies@esneft.nhs.uk Dr Lauren Steel: Lauren.steel@esneft.nhs.uk Rheumatology Department (01206) 742165/742279	Clinical Nurse Specialist Jayne Brooks: jayne.brooks@esneft.nhs.uk Clinical Nurse Specialist Lucy Mascurine: lucy.mascurine@esneft.nhs.uk
West Suffolk Hospital		
Rheumatology	Dr Katerina Achilleos 01284 713484 Dr Mark Sykes 01284 713440 RheumatologyNurses@wsh.nhs.uk	Dr Shweta Bhagat 01284 712977 Dr Catherine Bevington 01284 712907 RheumatologySecretaries@wsh.nhs.uk

GP to complete and return to specialist within 14 days	
Patient name:	
Date of birth:	
Hospital Number:	
GP name	
GP signature to accept shared care:	
Date	

Reference:

- British Society of Rheumatology and British Health Professional in Rheumatology. Guideline for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs (2017)

SHARED SPECIALIST & GP RESPONSIBILITIES: MONITORING

On-going monitoring will be transferred from the specialist to the GP after the specialist has stabilised the patient on treatment

	Parameter	Frequency
	In addition to absolute values for haematological indices, a rapid fall or rise and a consistent upward or downward trend in any value should prompt caution and extra vigilance	
Specialist	Pre-screening as per speciality guidelines	• Prior to starting treatment. Take appropriate action prior to transferring care to GP
	Height, weight and blood pressure	• Prior to starting treatment

	Parameter	Frequency	Action to take if abnormal result
Specialist moving to GP once shared care accepted	Urea & Electrolytes (U&Es) including creatinine	• Prior to starting treatment • During treatment: every 2 weeks until dose and monitoring stable for 6 weeks, then monthly for 3 months, thereafter consider reducing frequency of monitoring to every 2-3 months based on clinical judgement and following discussion with specialist • Dose increases: every 2 weeks until on a stable dose for 6 weeks; then revert back to previous schedule.	• Creatinine rise >30% over 12 months and/or calculated GFR <60: withhold leflunomide until discussed with specialist
	Full Blood Count (FBC)		• White blood count (WBC) <3.5x10^9/l • Unexplained eosinophilia >0.5x10^9/l • Neutrophils <1.6x10^9/l • Platelets <140x10^9/l Withhold leflunomide until discussed with specialist
			• Mean corpuscular volume (MCV) >105 fl: consider withholding leflunomide; check serum B12, folate, thyroid function tests and discuss with specialist
	Liver Function Tests (LFTs)		• Albumin – unexplained fall (in absence of active disease) <30g/l: withhold leflunomide until discussed with specialist • Aspartate transaminase (AST), alanine aminotransferase (ALT) > twice upper limit of reference range or >100 U/l: withhold leflunomide until discussed with specialist
	C-Reactive Protein (CRP)	• Prior to starting treatment • During treatment: monthly or with routine monitoring when on a stable dose	• Discuss with specialist if unexpected results
	Blood pressure	• At each monitoring visit	• Hypertension is a recognised side-effect of leflunomide - for increases in blood pressure requiring introduction/increase in medication, inform specialist
	Weight		• Leflunomide has been associated with significant weight loss in some individuals – discuss with specialist if this occurs

	Symptom (ask patient at each visit)	Action for GP to take if symptom occurs
Specialist and GP	New or increasing unexplained dyspnoea or dry cough	• Withhold leflunomide and discuss **urgently** with specialist
	Severe sore throat, abnormal bruising	• Immediate FBC and withhold leflunomide until the result of FBC is available; discuss with specialist
	Rash or oral ulceration, nausea and vomiting, diarrhoea	• Withhold leflunomide until discussed with specialist
	Infection requiring antibiotics	• Withhold leflunomide whilst on antibiotics. Consider restarting leflunomide at least one week after stopping antibiotic treatment.

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