Royal Cornwall Hospitals
NHS Trust

Leflunomide for Adults in Rheumatology Shared Care Guideline

V1.0

May 2024

1. Aim/Purpose of this Guideline

1.1. This guideline supports medical, nursing and pharmacy staff to safely prescribe, dispense, monitor and administer leflunomide when it is used in adults to treat several rheumatological conditions.

1.2. This shared care guideline sets out details for the sharing of care of adults with rheumatological conditions prescribed leflunomide. This guideline is based on the NHS England shared care protocol for leflunomide. As with all shared care guidelines they highlight relevant prescribing issues but should be used in conjunction with relevant NICE guidance, the BNF, Summaries of Product Characteristics and do not replace them.

Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation

The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team

Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

2. The Guidance

2.1. Leflunomide is a disease modifying antirheumatic drug (DMARD). It may be used as monotherapy or in combination with other DMARDs including methotrexate and sulfasalazine. The licensed indications for leflunomide include active rheumatoid arthritis and active psoriatic arthritis. It may also be used off-label for other inflammatory conditions such as e.g. systemic lupus erythematosus, axial spondyloarthopathy, interstitial lung disease, or vasculitis.

2.2. The guideline is for active rheumatoid arthritis or active psoriatic arthritis only and does not cover the treatment of people less than 18 years old.

2.3. **Preparations and Dosage**

2.3.1. Leflunomide is available as 10mg, 15mg, and 20mg tablets. However, the 15mg tablets are significantly more expensive and should only be used where there are concerns about compliance with treatment.

2.3.2. Tablets should be swallowed whole with sufficient amounts of water. Administration with food does not affect absorption.

2.3.3. An initial dose of 10-20mg once daily is normally given in rheumatoid arthritis, or 20mg once daily in psoriatic arthritis. Due to the long half-life, doses of 10mg and 20mg may be given on alternate days. Short loading regimens may be used, however these may increase the risk of adverse effects and are considered optional. The loading period must be prescribed by the initiating specialist. **However, loading regimens are not used by the Rheumatology department at RCHT.**

2.3.4. **Maintenance dose (following initial stabilisation):** 10-20mg once daily in rheumatoid arthritis, or 20mg once daily in psoriatic arthritis. Due to the long half-life, doses of 10mg and 20mg may be given on alternate days. **The initial maintenance dose must be prescribed by the initiating specialist.**

2.3.5. For other indications take specialist advice.

2.3.6. The active metabolite of leflunomide has a half-life of approximately 2 weeks and undergoes extensive enterohepatic recycling and may therefore persist for long periods of time even after administration has stopped. It is not sufficient to only stop the drug because adverse effects may still occur or worsen.

2.3.7. If serious adverse effects occur, the patient becomes pregnant, before starting treatment with an alternative DMARD, or for other reasons which require the rapid elimination of leflunomide, a washout procedure may be necessary. This is given as colestyramine 8g taken three times daily **or** activated charcoal 50g four times daily, usually for 11 days. This should be discussed with a specialist before initiating the procedure. The washout procedure interrupts the enterohepatic recycling mechanism and reduces the half-life of leflunomide to around 1 - 2 days. If the patient cannot manage the full 11 day course, there is evidence that even a few days treatment is likely to be beneficial and that 48 hours of treatment may reduce the active metabolite of leflunomide by 49 - 65% if using colestyramine and by 48% for charcoal. Leflunomide levels can be checked to ensure that it has been adequately removed from the patient's body by the washout procedure.

2.4. Contraindications and Precautions

2.4.1. Contraindications are:

- Hypersensitivity to leflunomide or any excipients.
- Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.
- Serious infection.
- Liver impairment.
- Moderate to severe renal impairment.
- Severe hypoproteinaemia.

- Severe immunodeficiency.

- Pregnancy and breastfeeding, or patients who are not using effective contraception during treatment. People of child-bearing potential should use effective contraception for up to 2 years after stopping treatment or undergo the washout procedure (see 2.5.2 below). Avoid where possible in people of child-bearing potential.

2.4.2. Precautions are:

- Anaemia: avoid if significant and due to causes other than rheumatoid or psoriatic arthritis.

- Localised or systemic infection which may be more severe.

- History of HIV, tuberculosis, hepatitis B or C.

- Impaired bone-marrow function, leucopenia, or thrombocytopenia: avoid if significant and due to causes other than rheumatoid or psoriatic arthritis.

- Use of concurrent haematotoxic or hepatotoxic DMARDs e.g. methotrexate. The combination of methotrexate and leflunomide is rarely used in Cornwall.

- There is a theoretical risk of male-mediated foetal toxicity so effective contraception should be used throughout treatment. Those patients wishing to father a child should discuss with the specialist team who may want to follow the washout procedure before advising he attempt conception.

2.5. Pregnancy and breastfeeding

2.5.1. Leflunomide is contraindicated in pregnancy. Patients of child-bearing potential should use effective contraception during and for up to 2 years after treatment, unless a washout procedure is followed (see below). See FSRH statement on contraception for women using known teratogenic drugs for information on contraceptives considered highly effective.

2.5.2. The active metabolite of leflunomide is highly protein bound and because of extensive enterohepatic recycling its half-life is prolonged. The manufacturer currently recommends a two-year waiting period after discontinuation of the medicine before attempting to conceive. The manufacturer also advises that the plasma levels of the active metabolite of leflunomide (teriflunomide) should be below 0.02mg/L at the end of the two-year period, confirmed by a second test after an interval of at least 14 days. If both tests show plasma levels of teriflunomide to be less than 0.02mg/L, then no teratogenic risk is expected. It is important to note that this test may only be available to patients who are taking the branded Arava® leflunomide tablets.

2.5.3. If a waiting period of 2 years using effective contraception is considered unpractical, a washout procedure may be advisable. Following this, the recommendations regarding verification of teriflunomide levels remain. Two tests must be done no less than 14 days apart and conception is not advised until one and a half months after the first plasma concentration below 0.02mg/L. This test may only be available to patients who are taking the branded Arava® leflunomide tablets.

2.5.4. If a woman becomes pregnant while taking leflunomide or within two years after discontinuation, the manufacturer recommends an immediate 11-day washout procedure with colestyramine or activated charcoal.

2.5.5. Breastfeeding: Leflunomide and its metabolites pass into breast milk in animal studies. Manufacturer states that leflunomide is contraindicated for breastfeeding patients.

2.5.6. Paternal exposure: Male patients should be aware of the possible male-mediated foetal toxicity. Effective contraception during treatment with leflunomide should also be guaranteed.

2.6. Monitoring

2.6.1. Specialist Team

- Monitoring at baseline and during initiation is the responsibility of the specialist team; only once the patient is optimised on the chosen medication with no anticipated further changes expected in the immediate future will prescribing and monitoring be transferred to primary care.

Baseline investigations are:

- Height and weight.
- Blood pressure.
- Full blood count (FBC) including a differential white blood cell count and a platelet count.
- Electrolytes, eGFR, and creatinine (creatinine clearance should be calculated).
- Alanine aminotransferase (ALT) and albumin.
- Screening for viral infections as per local policy, e.g. HIV, hepatitis B and C, varicella zoster, Epstein Barr virus, cytomegalovirus.
- Screening for lung disease, including interstitial lung disease, should be undertaken at clinician discretion on a case-by-case basis.
- Provide or request appropriate vaccination prior to treatment initiation, according to local arrangements (e.g. pneumococcal, shingles, influenza, COVID-19).

- Pregnancy should be excluded before starting treatment.

Initial monitoring and at dose change:

- Repeat every 2 weeks until the dose has been stable for 6 weeks, then monthly for three months. The transfer of prescribing to primary care should normally only take place when the patient has received a stable dose for at least 4 weeks and their blood and physical tests results have been satisfactory. It is anticipated that this should be around 12 weeks after initiation of the medicine but may be sooner in some circumstances.

- Until the transfer of prescribing to primary care has taken place, the specialist team are responsible for requesting and reviewing the results of monitoring blood tests. If blood samples are being taken at the GP surgery during this stage, the requests should be placed on ICE by the specialist team.

- FBC (including differential white cell count and platelet count).

- Electrolytes, eGFR, and creatinine (creatinine clearance should be calculated).

- Alanine aminotransferase (ALT) and albumin.

- Following a dose change, repeat monitoring bloods every 2 weeks until the dose has been stable for 6 weeks, then revert to previous schedule.

- More frequent monitoring is appropriate in patients at higher risk of toxicity; e.g. concurrent use of more than one DMARD. This is particularly important for patients co-prescribed methotrexate and leflunomide. The combination is highly effective but potentially synergistically toxic to liver and bone marrow, and increased monitoring frequency is strongly advised.

- The specialist team will retain the responsibility for monitoring the patient's ongoing response to treatment, and will advise if a dose change or treatment cessation is appropriate. This should usually be undertaken annually.

Ongoing monitoring: The specialist team will retain the responsibility for monitoring the patient's ongoing response to treatment, and will advise if a dose change or treatment cessation is appropriate. This should usually be undertaken at least annually.

- After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in 2.6.2 remains appropriate.

2.6.2. **General Practice**

- Once the dose of leflunomide has been stable for six weeks, the frequency of blood monitoring can reduce to monthly for three months and then once every three months. More frequent monitoring in patients at higher risk of toxicity may be advised by the specialist team. **The exact frequency of monitoring will be communicated by the specialist in all cases**.

- FBC (including differential white cell count and platelet count).

- Electrolytes, eGFR, and creatinine (creatinine clearance should be calculated).

- Alanine aminotransferase (ALT) and albumin.

- BP and weight.

- Rheumatology patients: C-reactive protein (CRP).

- Note that vaccines are safe and recommended for this patient group and should be offered in line with the standard schedule. Refer to Green Book Chapter 6 for further details.

- Shingles vaccination: one course using the non-live (Shingrix) vaccine should be offered to people aged 50 years and over – this patient group became eligible from 1 September 2023.

- Influenza vaccination: annual. It is advisable to add the patient to the influenza vaccine list.

- Pneumococcal vaccination: Patients should receive a single dose of PPV-23. Booster doses may be required at 5-yearly intervals for individuals who have no spleen, splenic dysfunction, or chronic renal disease.

- Covid-19 vaccination: Patients treated with leflunomide are considered to be in the “Immunosuppression” clinical risk group and should be offered vaccination if they have not already received it. They should also receive booster doses in line with JCVI recommendations for people who are immunosuppressed.

2.6.3. **If any of the following occur, repeat the test to confirm the result, consider interrupting treatment, and if required contact the Specialist Team for advice (see contact details later in this document):**

- WCC less than 3.5 $x10^9$/L.

- Lymphocytes less than 0.5 $x10^9$/L.

- Neutrophils less than 1.6 $x10^9$/L.

- Platelets less than 140 $x10^9$/L.

- Unexplained eosinophilia; greater than 0.5 x10^9/L.
- Unexplained fall in albumin; less than 30g/L.
- MCV >105 fL - Consider interruption in treatment. Check serum folate, B12, alcohol history and TSH and treat any underlying abnormality. If results of these additional investigations are normal discuss with specialist team urgently.
- Blood pressure - Treat hypertension in line with NICE guidance. If BP remains uncontrolled, withhold leflunomide and discuss with specialist team.
- Weight - If >10% weight loss with no cause identified, withhold leflunomide and discuss with specialist team.
- Signs or symptoms of bone marrow suppression, e.g. unexplained bleeding or bruising with or without sore throat, mouth ulcers. Check FBC immediately, withhold treatment while awaiting results, and discuss with the specialist team. See haematological monitoring above.
- Acute infection. During serious infections (e.g. requiring intravenous antibiotics or hospitalisation) temporarily withhold leflunomide until the patient has recovered. Consider if additional investigations (e.g. FBC) and washout procedure required – discuss with specialist team.
- **Liver function tests below:** Withhold and discuss with specialist team. Consider washout procedure. Check any other reason for risk of hepatic dysfunction such as alcohol history and drug interactions, including OTC or complementary medication.
    - ALT greater than 100units/L or a sudden increase (e.g. doubling of baseline) OR Unexplained fall in serum albumin <30g/L.
    - Jaundice.
- **Renal function tests below:** Withhold and discuss with specialist team.
    - Creatinine increase of greater than 30% from baseline in the last 12 months or eGFR reduces to less than 60mL/min.

2.7. Side Effects

Side effects include:

- Gastrointestinal disorders Nausea: Review for reversible causes. Discuss with specialist team if persistent or severe. Washout, under specialist advice, may be required if severe. Diarrhoea: Diarrhoea is common and usually settles. If persistent or severe, withhold and discuss with specialist team.

- Ulcerative stomatitis, haematemesis, black or bloody stools, or suspected pancreatitis: Withhold and discuss with specialist team. Washout, under specialist advice, may be required if severe.

- Symptoms of interstitial lung disease e.g. persistent cough, dyspnoea, fever: If leflunomide-induced lung disease is suspected, discuss with specialist team urgently. Consider washout procedure. Treat with corticosteroids as advised by specialist and do not restart leflunomide.

- Generalised rash: Discuss with specialist, washout may be required if severe.

2.8. **Advice to patients and carers**

2.8.1. The specialist team will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.

2.8.2. **The patient should be advised to report any of the following signs or symptoms to their primary care team without delay:**

- Symptoms of chickenpox or contact with a person with chickenpox or shingles.

- Persistent cough, shortness of breath, or any other problems with breathing.

- Sore throat, high temperature, skin rash, swollen glands, or any other signs or symptoms of infection.

- Signs or symptoms of liver problems, such as yellow skin or eyes (jaundice), itching all over, nausea or vomiting.

- Unexplained bleeding or bruising, black stools, or blood in the vomit or stools.

- Suspected or confirmed pregnancy.

- Any tingling, numbness or weakness in extremities that may indicate peripheral neuropathy.

2.8.3. **The patient should be advised:**

- Moderate their alcohol intake to no more than 4 units per week while taking leflunomide. Taking alcohol and leflunomide together increases the risk of liver injury.

- Tell anyone who prescribes them a medicine that they are taking leflunomide. Always ask a pharmacist before purchasing any medicines over the counter, including herbal remedies, and ask if they are safe.

- To use effective contraception, and to take a pregnancy test if they think they could be pregnant. Patients should inform the specialist or GP as soon as possible if they become pregnant. All patients, both male and female, should inform their specialist well in advance if they are planning a pregnancy so that changes can be made to their treatment regime.

2.9. Significant Drug Interactions

- Anticoagulants: The anticoagulant effect of vitamin K anticoagulants may be increased by leflunomide. Close INR monitoring and follow-up is recommended.

- Live vaccines (e.g. oral polio, oral typhoid, MMR, BCG) should generally be avoided. There is evidence that doses at or below 20mg leflunomide, as either monotherapy or in combination with 20mg prednisolone per day or less, can safely receive live shingles vaccinations. Clinician discretion is advised.

- JAK kinase inhibitors, e.g. baricitinib, filgotinib: due to the increased risk of immunosuppression.

- Colestyramine and activated charcoal: Co-administration leads to a rapid and significant decrease in plasma levels of leflunomide metabolites by interrupting enterohepatic recirculation.

- Repaglinide, paclitaxel, pioglitazone, ceflaclor, benzylpenicillin, ciprofloxacin, indomethacin, ketoprofen, furosemide, cimetidine, zidovudine, venetoclax: Leflunomide may increase the exposure to these products.

- Rosuvastatin levels may be increased by leflunomide. A maximum rosuvastatin dose of 10mg is recommended. Caution is recommended with other statins and dose reduction may be required.

2.10. Areas of Responsibility for the Sharing of Care

2.10.1. These are suggested ways in which the responsibilities for the management of Rheumatology patients who are prescribed sulfasalazine can be shared between the specialist team and the general practice. The expectation is that these guidelines should provide sufficient information to enable GPs to be confident to take clinical and legal responsibility for prescribing these drugs. If a specialist team asks the GP to prescribe this drug the GP should reply to this request as soon as practical. Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient and be accepted by them.

2.10.2. **In the NHS England guidelines on responsibility for prescribing (January 2018) between hospitals and GPs, it is advised that legal responsibility for prescribing lies with the doctor who signs the prescription.**

2.10.3. **Specialist Team:**

- Assess the patient and provide diagnosis; ensure that this diagnosis is within scope of this shared care guideline and communicated to primary care.

- Use a shared decision-making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling to enable the patient to reach an informed decision. Obtain and document patient consent. Provide an appropriate patient information leaflet.

- Assess for contraindications, cautions, and potential interactions.

- Conduct required baseline investigations and initial monitoring.

- Initiate and optimise treatment as outlined. Transfer to primary care normally occurs once the patient has been treated for 3 months and has had satisfactory investigation results for at least 4 weeks. Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.

- Once treatment is optimised, complete the shared care documentation and send to patient's GP practice detailing the diagnosis, current and ongoing dose and formulation, baseline and most recent test results, confirm the monitoring schedule and when the next monitoring is required. Include contact details.

- Conduct the required annual reviews and monitoring and communicate the results to primary care. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined remains appropriate.

- Give advice to primary care on continuing treatment if a woman becomes or wishes to become pregnant.

- Provide advice to primary care on the management of adverse effects if required.

2.10.4. **General Practitioner:**

- Respond to the request from the specialist team for shared care in writing. It is asked that this be undertaken within 14 days of the request being made, where possible.

- If accepted, prescribe ongoing treatment as detailed in the specialist team's request, taking into account any potential drug interactions.

- Adjust the dose of leflunomide as advised by the specialist team.

- Conduct the required monitoring as outlined. Communicate any abnormal results to the specialist team.

- Manage adverse effects as detailed and discuss with specialist team when required.

- Stop leflunomide and seek urgent specialist advice if signs of myelosuppression, hepatic or renal dysfunction develop or a serious skin reaction or oral ulceration is observed.

- Seek advice from the specialist team if the patient becomes or plans to become pregnant.

- Stop treatment as advised by the specialist team.

2.10.5. **Patient / carer:**

- Take leflunomide as prescribed and avoid abrupt withdrawal unless advised by the primary care prescriber or specialist team.

- Attend regularly for monitoring and review appointments with primary care and the specialist team, and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend for review appointments and/or blood tests.

- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in 2.8.2 and 2.8.3.

- Report the use of any OTC medicines to their primary care prescriber and be aware they should discuss the use of leflunomide with their pharmacist before purchasing any OTC medicines.

- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant, and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.

- **BACK-UP ADVICE AND SUPPORT IS AVAILABLE FROM THE RELEVANT CLINICAL TEAM.**

2.10.6. Contact Details

- Patients can contact the Rheumatology department via the Advice Line on 01872 252202. This service is available between 13:00 and 15:30 Monday to Friday, excluding Bank Holidays.

- Healthcare Professionals with routine queries should submit these through the Advice and Guidance service. This is reviewed daily by the on-call consultant. Please do not send letters or emails.

- Healthcare Professionals with urgent queries should contact the on-call Rheumatology Consultant/SpR via the RCHT switchboard, 01872 252000. Please note there is no out-of-hours on-call service for Rheumatology.

3. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Compliance with prescribing and administration in accordance with this guideline (or other safe practice).
Lead	Head of Prescribing Support Unit.
Tool	Audit and review tool using patient documentation.
Frequency	As required according to clinical incident reports.
Reporting arrangements	Via Cornwall Area Prescribing Committee / Medication Practice Committee.
Acting on recommendations and Lead(s)	Relevant Clinical Staff.
Change in practice and lessons to be shared	Lessons and changes in practice will be communicated through various channels to relevant staff.

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the Equality Diversity And Inclusion Policy or the Equality and Diversity website.

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Leflunomide for Adults in Rheumatology Shared Care Guideline V1.0
This document replaces (exact title of previous version):	New document
Date Issued/Approved:	May 2024
Date Valid From:	May 2024
Date Valid To:	May 2027
Directorate / Department responsible (author/owner):	Rheumatology Team / Pharmacy - Head of Prescribing Support Unit
Contact details:	01872 253548
Brief summary of contents:	Some clinical issues and details of prescribing responsibilities for GP and specialists
Suggested Keywords:	Leflunomide
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** Yes
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Cornwall Area Prescribing Committee
General Manager confirming approval processes:	Richard Andrzejuk
Name of Governance Lead confirming approval by specialty and care group management meetings:	Kevin Wright
Links to key external standards:	None required
Related Documents:	Summary of Product Characteristics.
Training Need Identified?	No

Information Category	Detailed Information
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Pharmacy

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
May 2024	V1.0	Original document	M Wilcock, Head of Prescribing Support Unit

All or part of this document can be released under the Freedom of Information Act 2000

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Leflunomide for Adults in Rheumatology Shared Care Guideline V1.0
Directorate and service area:	Pharmacy
Is this a new or existing Policy?	New
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	M Wilcock, Pharmacy RCHT
Contact details:	01872 253548

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	To provide information on prescribing of sulfasalazine to enable General Practitioners to take over prescribing responsibility from secondary care.
2. Policy Objectives	To promote a consistent level of shared care between primary and secondary care (in relation to RCHT catchment area).
3. Policy Intended Outcomes	Confident and competent prescribers, enabling medicines to be access in a primary care setting.
4. How will you measure each outcome?	Six monthly review.
5. Who is intended to benefit from the policy?	General practitioners, hospital specialists and community pharmacists – from understanding local guidance around use of these medicines. Patients/carers, from being able to access medicines from their GP.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: Yes • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Cornwall Area Prescribing Committee.
6c. What was the outcome of the consultation?	Agreed.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff or patient surveys:** No.

7. The Impact
Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	
Marriage and civil partnership	No	

Protected Characteristic	(Yes or No)	Rationale
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Mike Wilcock, Pharmacist, Royal Cornwall Hospitals NHS Trust

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis

Appendix 3. Suggested wording for Specialist communication regarding commencement of shared care

This patient is suitable for treatment with (insert drug name) for the treatment of (insert indication) which has been accepted for Shared Care. I am therefore requesting your agreement to share the care of this patient, as they are now stable on the treatment. Where baseline investigations are set out in the shared care protocol, I have carried these out.

Treatment was started on (insert date started) (insert dose).

If you are in agreement, please undertake monitoring and treatment from (insert date). (please note: date must be at least 1 month from stabilisation of treatment).

Baseline tests: (insert information).

Next review with this department: (insert date).

You will be sent a written summary within (XX) days. The medical staff of the department are available at all times to give you advice. The patient will not be discharged from out-patient follow-up while taking (insert drug name).

Please could you reply to this request for shared care and initiation of the suggested medication to either accept or decline within 14 days.