SHARED CARE AGREEMENT

Name of medicine Tacrolimus

Indication For uveitis

Version: 1.0 **Approval date: September 2023** **Review date: September 2026**

The Shared Care Agreement (SCA) is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface. It does not contain all of the relevant product information, which should be sought using the current British National Formulary and manufacturer's Summary of Product Characteristics. The SCA must be used in conjunction with the NHS Lothian Procedure for the Shared Care of Medicines, available here.

Roles and responsibilities

Listed below are specific responsibilities that are additional to those included in the NHS Lothian Policy and Procedures for Shared Care. Please refer to the policy for core roles and responsibilities that apply to all Shared Care Agreements.

Consultant

- Assessing the need for tacrolimus therapy.
- Stating the target dose of tacrolimus.
- Undertaking and assessing the relevant baseline investigations.
- Arranging for the patient to receive verbal and written information on tacrolimus.
- Advise patient of unlicensed status of treatment if appropriate and what this may mean for their treatment.
- Advising the patient regarding fertility, pregnancy and the need for contraception as appropriate.
- Treatment will be initiated by the specialist service and the supply made by secondary care for the first 8 weeks. During this time the specialist service will provide comprehensive patient support including monitoring for adverse effects, addressing any treatment-related issues and responding to patient queries.
- Making arrangements for the results of blood tests to be reviewed during the initial 6 weeks of treatment.
- Making arrangements for the patient to be reviewed 3-4 months after initiation of treatment to assess response.
- Consultant will advise GP on brand of tacrolimus to prescribe.
- Providing advice to the GP regarding monitoring, adverse effects and dose modifications when required.
- Making arrangements for the patient to be kept under long term review.
- Specialist service to refer patients for vaccinations which are out with routine vaccination schedules or recall programmes via the clinician referral form (http://intranet.lothian.scot.nhs.uk/Directory/publichealth/Immunisation/Pages/VTP-(Vaccine-Transformation-Programme).aspx). Please note that Patient Specific Directions (PSD) are required for bespoke vaccination schedules where there is no PGD in place. The referral forms should be sent to the partnership that is responsible for administering vaccinations to their residents.

General Practitioner and primary care non-medical prescribers

- Prescribing of tacrolimus therapy in conjunction with the specialist after the initial 8 weeks.
- Patient should be prescribed and maintained on the same brand of tacrolimus.
- On initiation of treatment, the specialist service will provide patients with pre-labelled forms for blood tests for the first 6 weeks.
- Bloods are taken in primary care and reported to the specialist service during the first 6 weeks of treatment. The GP is to arrange for blood tests to be taken at appropriate intervals thereafter as detailed in "Monitoring".
- Monitoring for side effects after the first 8 weeks of treatment as detailed in the manufacturer's Summary of Product Characteristics and "Monitoring".
- Advising on a suitable form of contraception and ongoing provision where relevant.
- Additional blood monitoring to be carried out as requested by consultant if needed and cannot be practically done by secondary care.

Patient, Relatives, Carers

- As listed in the NHS Lothian Policy and Procedures for the Shared Care of Medicines.
- Ensuring adherence to phlebotomy requirements throughout treatment
- Be aware of need to use contraception where appropriate.

- Patients are advised to purchase and use sunscreens (SPF 50 or above) and protective clothing to reduce sunlight exposure.
- Patients can access advice from the relevant specialist team as follows:
  - Secretaries: 01315361628 (option 4)
  - Ophthalmology Pharmacist: 0131 536 2849 or Bleep 5122

Support and Advice for the GP and primary care non-medical prescribers

Ophthalmology

For patient-related queries, contact the relevant consultant, as detailed on any correspondence or discharge letter, directly either via phone or e-mail. E-mail requests should copy in the practice's clinical e-mail address and ask that the reply is sent to all, so that the reply is picked up even if the sender is not available. Urgent queries will be managed by triage number listed for the Princess Alexandra Eye Pavilion

Ophthalmology Specialist Team Numbers

Princess Alexandra Eye Pavilion Triage and Ophthalmology Pharmacist numbers as per page 1.

The names and contact details of the patient`s consultant and their secretary are given on the discharge letter or clinic letter. Please phone directly if there is an urgent enquiry.

Key Information on the Medicine

Please refer to the current edition of the British National Formulary (BNF), available at www.bnf.org, and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information and specific guidance.

Background to disease and use of drug for the given indication:

Tacrolimus is only licensed for prophylaxis of acute transplant rejection in adult patients receiving allogeneic renal or liver transplants. However it has been used by other specialities off label historically.

Ophthalmology: Uveitis (also known as iritis) is inflammation of the uveal tract (iris, ciliary body, and choroid). Inflammation of nearby tissues, such as the retina, the optic nerve, and the vitreous humour may also occur. Uveitis is a potentially blinding condition and approximately 5–10% of visual impairment worldwide. Corticosteroids are used to reduce inflammation and prevent adhesions in the eye. People with severe or chronic uveitis may also be given systemic immunosuppressive drugs like mycophenolate, mycophenolic acid and tacrolimus. Tacrolimus is used to reduce inflammation whilst being a steroid sparing agent when mycophenolate has not been tolerated or has been ineffective.

Dosage and administration

Dose to be advised by specialist.

Due to teratogenic effects tacrolimus capsules should not be opened or crushed and inhalation or direct contact with skin or mucous membranes should be avoided.

Monitoring

On initiation of treatment, patients are provided with pre-labelled forms for blood tests. Bloods are taken in primary care and reported to the specialist service during the first 6 weeks of treatment. Note that abnormal trends in blood monitoring should prompt extra vigilance and may be a sign of toxicity even if absolute levels are normal.

Test	Frequency	Abnormal Result		Action if Abnormal Result
Full blood count (FBC)	Every 2 weeks until dose stable for 6 weeks Then monthly for 3 months Then every 3 months thereafter Revert to initial schedule in the event of a dose increase or when a new DMARD is added.	Platelets WCC Neutrophils	100-140 2.0-3.5 1.0-1.6	Withhold therapy for 2 weeks and recheck.
		Platelets WCC Neutrophils Lymphocytes	< 100 < 2.0 < 1.5 <0.5	Withhold treatment and contact the specialist service.
		MCV	>105	Check B12, folate, TFTs and consider discussing with specialist service.
Liver Function Test (LFTs)		ALT	>100	Withhold treatment for 2 weeks, and recheck.
		ALT	50-100	Continue treatment and recheck. If ALT stable, continue treatment. If ALT rising, contact specialist. Repeat LFTs in 2-4 weeks
Urea & Electrolytes (U&Es)		Increase in creatinine of more than 30% over 12 months and/or calculated eGFR of less than 60ml/min		Refer to consultant
Blood Pressure (BP)		Elevation from patient baseline.		Treat hypertension as per pathway.
Blood Glucose (random)		Elevation from patient baseline		Arrange HbA1c and treat as per primary care diabetes guidance. Advise consultant.
Lipid Profile	Baseline, then 3 monthly	Elevation in from patient baseline.		Treat as per primary care guidance
Magnesium		Results outside of lab reference ranges		Refer to consultant

In exceptional circumstances the team may request that the GP arranges for repeat blood tests to be taken at the GP practice for patient convenience. If the GP agrees to this, the specialist will give advice on the management of abnormal results.

Trough tacrolimus levels may be requested though not routinely. Patients should omit dose the morning of a tacrolimus trough level. Therapeutic range of 5ng/dL-10ng/dL for ophthalmic use.

Due to the sight threatening nature of ophthalmology conditions being treated advice to withhold treatment due to monitoring results, should be highlighted to the relevant consultant and ophthalmology pharmacist as soon as possible via email.

Cautions, contraindications
Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Pregnancy and Fertility
For full detail please refer to the current Summary of Product Characteristics (SPC) available at www.medicines.org.uk

Any patients planning pregnancy should discuss this with their consultant

For full details please refer to the current Summary of Product Characteristics (SPC) available on: www.medicines.org.uk

Any patients planning pregnancy should discuss this with their consultant.

Patients wishing to breastfeed should discuss this with the consultant. Tacrolimus can be considered in pregnant woman due to the need for continued treatment, when there is no safer alternative and when the perceived benefit justifies the potential risk to the fetus.

Adverse effects
Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

As with other immunosuppressive agents, tacrolimus increases the risk of developing malignancies of the skin. Therefore exposure to UV light and sunlight should be limited by wearing protective clothing and using sunscreen with a high protection factor.

Drug interactions
Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Vaccinations

- Individuals who on immunosuppressant therapy should be given inactivated vaccines in accordance with national recommendations.
- It is recommended that patients with autoimmune inflammatory diseases on immunosuppressant therapy should be offered pneumococcal, COVID19 and influenza vaccination.
- Immunosuppressed patients who are 70 to 79 years of age should be offered the varicella-zoster vaccine, Shingrix, to help protect them against shingles. Shingrix is a non-live alternative to the live shingles vaccine, Zostavax.
- When considering suitability for live vaccines concurrent DMARD therapy should also be taken into account. · For further information see: https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book

The presence of this SCA does not compel a primary care prescriber to prescribe if they feel that it is out with the scope of their competencies (as per GMC guidance on safe prescribing) or resources, as ultimate responsibility lies with the prescribing, not the recommending, clinician.

For office use only:
Approved by the General Practice Prescribing Committee (GPPC) on 12th September 2023