

SHARED CARE AGREEMENT



Name of medicine Ciclosporin (Neoral[®])

Indication For use in solid organ transplant adult patients

Version: **4.0**

Approval date: December 2023

Review date: December 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

- Monitoring blood pressure, weight, liver function tests and renal function with communication of those results to GP.
- Blood level monitoring and adjustment of ciclosporin dosage.
- If a dose change is necessary then this is communicated to the patient immediately by telephone and/or letter and the GP is also informed by telephone, letter or email.
- Frequency of follow up will depend on transplant type and time from transplant.
- Patient education is the responsibility of the specialist team. The patient information leaflet for Neoral[®] can be found at www.medicines.org.uk.

General Practitioner and primary care non-medical prescribers

- Prescribing of ciclosporin therapy as recommended by consultant.
- Liaison with the hospital consultant regarding any complications of treatment.
- Although blood level monitoring is routinely carried out by the specialist team during clinic visits, in exceptional circumstances the team may request that the GP arranges for blood tests to be taken locally for patient convenience – see Monitoring section below.
- **It is important that the patient is maintained on the same brand of ciclosporin. The Neoral[®] brand is used in NHS Lothian. in solid organ transplant.**

Patient, Relatives, Carers

- Importance of maintaining treatment with the same brand of ciclosporin (Neoral[®]).
- Patients are advised to purchase and use sunscreens [SPF 50 or above] and protective clothing to reduce sunlight exposure.

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

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.

Specialist Team Numbers

Transplant Unit Ward: 0131 242 2068

Renal Transplant Pharmacist: 0131 536 1000 Bleep 2294

Liver Transplant Pharmacist: 0131 536 1000 Bleep 5132

The names and contact details of the patient's consultant and their secretary are given on the discharge 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

Ciclosporin, a calcineurin inhibitor, is licensed for use in the prevention of graft rejection following organ transplantation. It acts as a powerful immunosuppressant selectively inhibiting adaptive immune responses. It appears to specifically act on lymphocytes mainly helper T cells, and inhibits the production of lymphokines including interleukin 2.

Indication

Ciclosporin is licensed for prophylaxis of graft rejection in kidney, liver and pancreas transplantation and is used in combination with other immunosuppressants. It is often used in patients with intolerable side effects to tacrolimus.

Dosage and Administration

Different generic preparations of ciclosporin may vary in bioavailability and should not be considered interchangeable.

*Within NHS Lothian the formulation in use for solid organ transplantation is Neoral®. As ciclosporin is a drug with a narrow therapeutic index drug it is vital that patients are not switched between formulations. Therefore **care must be taken to prescribe and dispense ciclosporin by BRAND NAME** to avoid potential toxicity or potential graft rejection.*

Preparations used in solid organ transplant adult patients are: Neoral® capsules 25mg (blue/grey), 50mg (yellow/white) and 100mg (blue/grey). Neoral® oral solution 100mg/mL is also available.

Ciclosporin is taken twice daily. Patients are instructed to take the drug at the same times each day. This is necessary to facilitate interpretation of blood levels. Although there are large interpatient variations, patients are usually stabilised on total daily doses of 100-600mg.

Ciclosporin trough blood concentrations require to be monitored with a target range as indicated below. However, the target blood level for an individual patient will depend on the time since transplant, history of rejection and side effects and will be advised by a transplant specialist.

Renal transplant 50-150 µg/L

Liver transplant (first six months) 100-150 µg/L

Liver transplant (six months onwards) 70-100 µg/L

Communication regarding dose changes to GP will be through letter predominantly and occasionally via telephone or e-mail. Patients will be informed of immediate dose changes in clinic as face to face conversations or phoned out with clinic.

The transplant pharmacists extensively counsel the patients on their medications prior to discharge. At this point they receive supply of their new medications and a green book (specifically outlining their medication regimen). Patients are therefore well rehearsed at managing immediate dose changes.

Monitoring

The following blood tests are carried out by the specialist team during clinic visits.

Test	Frequency	Action if Abnormal Result
Urea & electrolytes Renal function Liver function tests Drug Trough levels	Monthly for first 6 months, thereafter according to clinic follow-up frequency	Testing is undertaken and reviewed by the transplant consultant
Weight and BP	Monthly for first 6 months, thereafter according to clinic follow-up frequency	Testing is undertaken and reviewed by the transplant 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.

To obtain a trough level - take a morning blood sample (5mL in an EDTA pink tube) when the patient has omitted the morning dose. Send the sample to the clinical chemistry laboratory, locally (if available) or Royal Infirmary of Edinburgh. No special transport arrangements are needed.

Cautions, contraindications

For full detail please refer to the current Summary Product Characteristic (SPC) available at www.medicines.org.uk

Experience with ciclosporin in pregnant women is limited. Ciclosporin should not be used during pregnancy unless the potential benefit to the mother justifies the potential risk to the foetus.

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 transplant consultant.

Pregnancy - Pregnant women receiving immunosuppressive therapies after transplantation, including ciclosporin and ciclosporin containing regimens, are at risk of premature delivery (<37 weeks).

Breastfeeding - Patients wishing to breastfeed should discuss this with the transplant consultant. Ciclosporin passes into breast milk. Mothers receiving treatment with ciclosporin should not breastfeed.

Adverse effects

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

As with other immunosuppressive agents, exposure to UV light and sunlight should be limited by wearing protective clothing and using sunscreen with a high protection factor. This is because of the potential for malignant skin changes.

Increased susceptibility to infection, especially severe chicken pox.

Vaccinations may not give full protection against disease and live vaccines should be avoided.

Drug interactions

For full detail of the numerous drug interactions with ciclosporin please refer to the current Summary of Product Characteristics (SPC) available at www.medicines.org.uk

Ciclosporin is extensively metabolised in the liver via the cyochrome P450 enzyme system and may have an inducing or inhibitory effect on these enzymes. Therefore care should be taken when co-administering other drugs known to be metabolised by this system.

- Grapefruit and grapefruit juice contain a compound which may potentially inhibit ciclosporin metabolism.
- Care should be taken when prescribing additional nephrotoxic drugs such as trimethoprim and NSAIDS.
- Caution in concomitant use of ACE inhibitors and potassium sparing diuretics due to increased risk of hyperkalemia.
- Risk of myopathy increased with concurrent administration of HMG-CoA reductase inhibitors (statins) and ciclosporin - consult SPC for dosage adjustment information. Simvastatin and rosuvastatin are contra-indicated with ciclosporin.

Great care should be taken when prescribing any new medicines. Refer to the current SPC or seek advice from the transplant unit.

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 5th December 2023