SHARED CARE AGREEMENT

Name of medicine Valganciclovir

Indication Prevention of CMV infection in solid organ

Version: **3.0** 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

- Monitor weight, urea and electrolytes, whole blood count and liver function tests at clinic visits and communicate results to GP
- Frequency of follow up will depend on transplant type and time from transplant
- Care will be shared with GP when the patient is stable
- Patient education is the responsibility of the specialist team. The patient information leaflet for valganciclovir can be found at www.medicines.org.uk.
- Dose adjustment in response to changes in creatinine clearance communicated to patient by telephone with additional written confirmation. The letter will be sent to the GP informing of any change in dose
- Discussion around contraception advice if applicable
- Raise awareness of the need for caution if handling the powder, reconstituted solution or broken tablets by the patient, carers and children.

General Practitioner and primary care non-medical prescribers

- Prescribe dose of valganciclovir in response to changes in creatinine clearance as recommended by hospital medical staff
- Monitor for adverse drug reaction or drug interaction and liaise with the hospital consultant regarding any complications of treatment
- Although patients will be seen regularly in clinic following transplant, GP practices may be requested on rare occasions to take blood tests in between clinic visits. These results would then be reviewed by transplant unit staff and any required dose adjustments recommended to the patient and GP.

Patient, Relatives, Carers

- Be aware of potential for dose to change according to renal function
- Be aware of need to use contraception where appropriate
- As listed in NHS Lothian Policy and Procedures for the Shared Care of Medicines
- Be aware dosages alter according to treatment doses versus prophylaxis doses.
- Be aware not to break or crush tablets and avoid direct skin contact with broken tablets
- 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
Cytomegalovirus (CMV) is a common virus that is part of the herpes family of viruses. Valganciclovir is a pro- drug of ganciclovir and inhibits replication of human herpes viruses by inhibiting viral DNA synthesis. It can be used to reduce the risk of CMV infection in immunosuppressed patients.

Indication
Valganciclovir is licensed for the prevention of cytomegalovirus (CMV) in CMV-negative patients who have received a solid organ transplant from a CMV-positive donor. Treatment should be commenced within 10 days of transplantation and should continue for 90 days post-transplant. In kidney transplant patients' treatment may continue for 180 days post transplant.

Dosage and Administration
Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk
The initial and ongoing valganciclovir dose is dependent on renal function. Please contact the transplant team pharmacists if further information on dosing required.

Although it is rarely used, an oral solution (50mg/ml) is available directly from Roche. Please note that the dosing in renal impairment differs from the tablet. Please contact the transplant unit pharmacist if further information on dosing is required.

Monitoring
Following transplant monitoring is routinely carried out during the patient's regular review in the specialist clinic. On rare occasions, the GP may be requested to take blood tests in between clinic visits. The results would then be reviewed by transplant unit staff and any required dose adjustments recommended to the patient and GP.

Test	Frequency	Abnormal Result	Action if Abnormal Result
FBC	Monthly	Out with normal range	Specialist team will advise
Creatinine	Fortnightly	Significant change	Specialist team will advise

Cautions, contraindications
For full detail please refer to the current Summary of Product Characteristics (SPC): www.medicines.org.uk
Valganciclovir is a potential carcinogen, mutagen and teratogen. It may cause temporary or permanent inhibition of spermatogenesis and suppression of female fertility. Barrier contraception is recommended in male patients during therapy and for 90 days following treatment. Women of childbearing potential should use effective contraception during treatment. The tablets should not be broken or crushed. Caution should be observed in handling broken tablets. Direct contact of broken tablets with skin or mucous membranes should be avoided.

Pregnancy and Fertility
Any patients planning pregnancy should discuss this with their transplant consultant.
Valganciclovir is not suitable for use during pregnancy. Both men and women of child-bearing potential should use effective contraception during treatment with valganciclovir. In addition, men should continue to use condoms for 90 days after treatment stops. When used in men, valganciclovir may cause an irreversible and permanent decrease in the number of sperm.

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

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