SHARED CARE AGREEMENT

Name of medicine tenofovir disoproxil

Indication chronic hepatitis B infection (adults)

Version: **2.0** Approval date: **August 2020** Review date: **August 2023**

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 Policy and Procedures for the Shared Care of Medicines, available at:
https://org.nhslothian.scot/Committees/ADTC/MedicinesGovernancePoliciesADTCPolicyStatements/

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

- Initiate prescription and provide initial 3 month supply of tenofovir
- Monitor weight, urea and electrolytes (including phosphate), full blood count, liver function tests and HBV-DNA levels every 6 months at clinic visits and communicate results to the GP
- Making the decision of / advising on when to discontinue treatment with tenofovir.

General Practitioner

- To continue with prescribing once the patient's treatment is stable
- Monitoring of urea and electrolytes (including phosphate) and liver function tests every 3 to 6 months when required between clinic visits as detailed under 'Monitoring' on Page 2
- Sending results to and contacting consultant if concerned about the results if out with normal range.

Patient, Relatives, Carers

- As listed in NHS Lothian Policy and Procedures for the Shared Care of Medicines

Support and Advice for the GP

Contact Points

RIE		**WGH**	
Liver Unit	0131 242 2051	Regional Infectious Disease Unit	0131 537 2820
Hepatology Nurse Practitioner	0131 242 1639	Specialist Nurse Practitioner	0131 537 2856
Secretaries, Liver Unit	0131 242 1223		

Key information on the medicine

Refer to 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
Tenofovir is a nucleoside reverse transcriptase inhibitor. It inhibits viral polymerase by directly competing with the natural deoxyribonucleotide substrate and after incorporation into deoxyribonucleic acid (DNA), by DNA chain termination. Tenofovir disoproxil tablets 245mg are licensed for the treatment of chronic hepatitis B virus (HBV) in adults with compensated and decompensated liver disease, with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis.

Indication
Tenofovir will be used in patients with active chronic hepatitis B infection e-antigen positive and negative, as indicated by at least 2 out of following 3 criteria:

- HBV DNA (>2000 IU/mL)
- persistently abnormal ALT values (>1.3 x upper limit of normal (ULN))
- liver biopsy showing chronic hepatitis and fibrosis

Dosage and Administration
Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk
Tenofovir is eliminated by renal excretion and the exposure to tenofovir increases in patients with renal dysfunction. There is limited data available on the use of tenofovir in renal impairment and therefore it should only be used if the potential benefits outweigh the potential risks. Renal function and serum phosphate should be measured regularly, particularly in patients at risk of renal impairment.

The dose of tenofovir should be adjusted in renal impairment. This should be done in discussion with hospital consultant. Details of dose adjustment can be found in SPC.

Take care to prescribe tenofovir disoproxil, and not tenofovir alafenamide.

Monitoring

- Note that blood tests are monitored by the specialist service at 6 monthly clinic visits.
- Additional blood testing is required in primary care in the first year of treatment and for patients at risk of renal disease (aged >60 years, diabetic, eGFR <60)
- * Patients who require 3 monthly monitoring are provided with pre-labelled forms for blood tests by the specialist service. Bloods are taken in primary care and reported to the specialist service for those patients.

Test	Frequency	Abnormal Result	Action if Abnormal Result
U&Es, Phosphate	First year of treatment **-** 3 monthly: • Months 3 and 9 by GP • Months 6 and 12 by specialist at clinic visit After first year of treatment: • Continue with 3 monthly* monitoring for patients at risk of renal disease (aged >60 years, diabetic, eGFR <60) • 6 monthly at clinic visit for all other patients	Out with normal range	Contact specialist team
LFTs	First year of treatment - 3 monthly After first year of treatment - 6 monthly at clinic visit	Out with normal range In this patient group, ALT <70u/mL can be considered normal, however if GP has any concerns regarding results then this should prompt referral back to consultant	Contact specialist team

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

Adverse effects - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk
Lactic acidosis, usually in association with hepatic steatosis, has been reported with nucleoside analogues.
The risk with tenofovir is thought to be low however cannot be excluded. Treatment should be discontinued under consultant direction. Note that there have been no cases reported in chronic hepatitis B treatment.

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

Supply
Tenofovir tablets 245mg - available as generic product via the standard community pharmacy suppliers
Tenofovir granules 33mg/g - can be ordered by the community pharmacy directly from Alcura Specialised Wholesale (telephone 01420 540 608). The lead time for delivery is next working day if order placed before 3.30pm Monday-Friday.