SHARED CARE AGREEMENT: ENTECAVIR

NHS GREATER GLASGOW AND CLYDE

NB: This document should be read in conjunction with the current Summary of Product Characteristics (SPC)

DRUG AND INDICATION:

Generic drug name:	**Entecavir**
Formulations:	Film-coated tablet containing 0.5mg or 1mg entecavir
Intended indication:	Chronic hepatitis B infection in adults with compensated liver disease with evidence of active viral replication, liver inflammation and/or fibrosis.
Status of medicine or treatment:	Licensed medicine Formulary medicine for above indication

RESPONSIBILITIES OF ACUTE CARE/SPECIALIST SERVICE (CONSULTANT):

- Undertake baseline investigations/monitoring and initiate treatment or ask GP to initiate treatment.
- If appropriate, ensure that the patient has an adequate supply of medication (usual minimum of 28 days) until the shared care arrangements are in place.
- Dose adjustments.

Acute care/specialist service will provide the GP with:

- An initiation letter (which includes diagnosis, relevant clinical information, treatment plan, duration of treatment before consultant review).
- Treatment should also be prescribed on clinic portal for the GP to see- Forms & Pathways -> Add New form -> Request to GP to prescribe medication.
- Letter of outpatient consultations, ideally within 14 days of seeing the patient.

Acute care/specialist will provide the patient with relevant drug information to enable:

- Understanding of potential side effects.
- Understanding of the role of monitoring.

RESPONSIBILITIES OF PRIMARY CARE (GENERAL PRACTITIONER):

- To prescribe in collaboration with the acute specialist according to this agreement.
- To ensure the continuous prescription of medication until treatment is discontinued at specialist instruction.
- Liaison with the hospital specialist in the event of symptoms or abnormal results thought due to this treatment.

RESPONSIBILITIES OF PATIENT:

- To attend hospital and GP clinic appointments. Failure to attend appointments may result in medication being stopped.
- To report adverse effects to their specialist.
- To request repeat prescriptions from the GP prior to current prescription finishing.

ADDITIONAL RESPONSIBILITIES:

- None

CAUTIONS:

- Renal impairment: dosage adjustment is recommended for patients with creatinine clearance < 50 ml/min, (see SPC).
- Exacerbations of hepatitis.
- Patients with decompensated liver disease: a higher rate of serious hepatic adverse events.
- Lactic acidosis and severe hepatomegaly with steatosis.
- Patients with lamivudine-resistance or previous lamivudine exposure.
- Liver transplant recipients.
- Co-infection with hepatitis C or D.
- Human immunodeficiency virus (HIV)/HBV co-infected patients.
- Pregnancy and breastfeeding.

CONTRAINDICATIONS:

- Hypersensitivity to the active substance or to any of the excipients.

TYPICAL DOSAGE REGIMEN:

Route of administration:	Oral administration
Recommended starting dose:	• Patients not previously treated with nucleoside analogues: 0.5mg every 24 hours at least 2 hours before or after food. • In lamivudine refractory patients, 1mg every 24 hours at least 2 hours before or after food.
Titration of dose:	Not applicable
Maximum dose:	1mg daily
Conditions requiring dose adjustment:	Lamivudine refractory patients with compensated liver disease. Renal impairment – see SPC.
Usual response time:	Variable, depends on HBV viral load and host factors
Duration of treatment	Treatment with entecavir is usually for many years. Treatment may be discontinued if there is HBsAg loss or HBeAg seroconversion.

All dose adjustments or discontinuations will be decided in acute care and directions specified in a medical letter to the GP.

SIGNIFICANT DRUG INTERACTIONS:

- None

UNDESIRABLE EFFECTS:

- Document the likely adverse drug reactions and the suggested management of them in the table below.

ADR details (where possible indicate if common, rare or serious)	Management of ADR
Insomnia [common]	Can usually be managed symptomatically and do not usually require treatment discontinuation
Headache, dizziness, somnolence [common]	
Vomiting, diarrhoea, nausea, dyspepsia [common]	
Elevated transaminases [common]	
Fatigue [common]	
Rash [uncommon]	

The above list should not be considered exhaustive. For further documented ADRs and details of likelihood etc, see Summary of Product Characteristics or BNF.

BASELINE INVESTIGATIONS (ACUTE SECTOR):

- Urea and electrolytes, eGFR, LFTs, HIV and serum phosphate.

MONITORING (PRIMARY CARE):

- No monitoring is to be undertaken in Primary Care.

MONITORING (ACUTE SECTOR):

- The following monitoring is to be undertaken in Acute Care

Monitoring Parameters	Frequency	Laboratory results	Action to be taken
U&Es, LFTs	Every 3-6 months		
Hepatitis B Viral load	Every 3-6 months		

PHARMACEUTICAL ASPECTS:

- Shelf life is dependent on manufacturer.

COST:

- BNF price £363.26 for 30 tablets, i.e. 1 month supply (BNF accessed online 1/6/26)

INFORMATION FOR COMMUNITY PHARMACISTS:

- Supplies of generic entecavir are available from all major wholesalers.

ACUTE CARE/SPECIALIST SERVICE CONTACT INFORMATION:

- Contact details for suitable persons within acute care to get further information from (including the likely consultants who will be initiating the treatment)

Name	Designation	Acute Site	Department phone number
Dr Erica Peters Dr Celia Jackson Dr Kali Perrow Dr Jamie McAllister	Consultant in Infectious Diseases	Ward 7B Gartnavel General Hospital	0141 301 7489
Dr Helen Cairns Dr Matt Priest	Consultant Gastroenterologist	Gartnavel General Hospital	0141 301 7489
Dr Stephen Barclay Dr Ewan Forrest	Consultant Gastroenterologist	Glasgow Royal Infirmary	0141 211 4911
Dr Judith Morris Dr Shouren Datta Dr Rachael Swann	Consultant Gastroenterologist	Queen Elizabeth University Hospital Victoria Infirmary	0141 201 2177 0141 347 8320
Dr Michael Johnston Dr Kathleen Bryce	Consultant Gastroenterologist	Royal Alexandra Hospital	
Fiona Marra Alison Boyle	BBV Specialist Pharmacists	Gartnavel General Hospital	0141 211 3383

SUPPORTING DOCUMENTATION:

- NHS GGC Hepatitis B Treatment Guideline

https://www.rightdecisions.scot.nhs.uk/ggc-clinical-guidelines/adult-infection-management/blood-borne-viruses/hepatitis-b-infection-assessment-and-management-in-adults-059/