This patient group direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction (PGD)

For the administration or supply of

Hepatitis A Virus (inactivated) and Hepatitis B Recombinant DNA (rDNA) (HepA/B) Vaccine (adsorbed)

By registered health care professionals for

individuals requiring protection against Hepatitis A and Hepatitis B Virus in accordance with National Recommendations

Throughout the Manx Care and those contracted by the Manx Care where appropriate within practice

PGD NUMBER 83

Change history (see next page)

1. Change history

Version number	Change details	Date
V01.00	New PHE HepA/B vaccine PGD	12/10/17
V02.00	PHE HepA/B vaccine PGD amended to: • include additional healthcare practitioners in Section 3 • clarify off-label status of the 0, 7, 21-day schedule of Twinrix® Adult when provided to those from 16 to 18 years of age • refer to vaccine incident guidelines in off-label and storage sections • remove reference the protocol for ordering storage and handling of vaccines • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates and updated PHE PGD Policy	12/09/19
V03.00	PHE HepA/B vaccine PGD amended to include: • examples added to chronic liver disease in criteria for inclusion • addition of individuals under one year of age to exclusion criteria • removal of reference to hepatitis vaccine shortages in additional information • minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGD templates and updated UKHSA PGD Policy	08/10/21

2. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care PGD website FAQs

3. PGD development

Refer to the NICE PGD competency framework for people developing PGDs

Job Title & organisation	Name	Signature	Date
Author of the PGD			
Member of the PGD working group			

4. PGD authorisation

Refer to the NICE PGD competency framework for people authorising PGDs

Job Title	Name	Signature	Date
Medical Director			
Chief Pharmacist/ Pharmaceutical Adviser			
Senior Paramedic			
Director of Nursing			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)			

5. PGD adoption by the provider

Refer to the NICE PGD competency framework for people authorising PGDs

Job title and organisation	Signature	Date	Applicable or not applicable to area

6. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the NICE PGD competency framework for health professionals using PGDs

	Requirements of registered Healthcare professionals working under the PGD
Qualifications and professional registration	• Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy Additionally practitioners: • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease ('The Green Book'), and national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the 'cold chain' • must be competent in the recognition and management of anaphylaxis Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD).
Initial training	• Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria • Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD • Local training in the use of PGDs
Competency assessment	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGDs
Ongoing training and competency	The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years

7. Clinical Conditions

Clinical condition or situation to which this PGD applies	Indicated for the active immunisation of individuals against both hepatitis A and B infection in accordance with the recommendations given in Chapter 7, Chapter 17 and Chapter 18 (all removed) of Immunisation Against Infectious Disease: 'The Green Book'.
Inclusion criteria	Individuals over 1 year of age requiring Hepatitis A and Hepatitis B pre-exposure prophylaxis including individuals who: • intend to travel, where hepatitis A and hepatitis B vaccination is currently recommended for travel by NaTHNaC (see the Travel Health Pro website for country-specific advice on hepatitis A and hepatitis B vaccine recommendations) • have chronic liver disease (including alcoholic cirrhosis, chronic hepatitis B, chronic hepatitis C, autoimmune hepatitis, primary biliary cirrhosis) • have haemophilia or receive regular blood products • are at risk of hepatitis A and B infection because of their sexual behaviour, such as commercial sex workers or men who have sex with men (MSM) • are people who inject drugs (PWID) or those who are likely to progress to injecting (see Chapter 18)
Criteria for exclusion[1]	Individuals for whom valid consent, or 'best-interests' decision in accordance with the current Isle of Man legislation, has not been obtained (for further information on consent see Chapter 2 of 'The Green Book'). The Patient information leaflet (PIL) for the vaccine to be used should be available to inform consent. Individuals who: • are under one year of age • have had a confirmed anaphylactic reaction to a previous dose of hepatitis A or hepatitis B vaccine or to any component of the vaccine (including trace components from the manufacturing process such as neomycin) • are at increased risk of hepatitis A and hepatitis B infection solely because of their occupation • require solely hepatitis B vaccination for overseas travel purposes • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)

[1] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

Cautions (including any relevant action to be taken)	• Individuals who are immunosuppressed or have HIV infection may not make a full antibody response and revaccination on cessation of treatment/recovery may be required. This should be discussed with the appropriate/relevant specialist. • Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.
Arrangements for referral for medical advice	Patient should be referred to a more experienced clinical practitioner for further assessment
Action to be taken if patient excluded	• Patient should be referred to a more experienced clinical practitioner for further assessment • Individuals who have had a confirmed anaphylactic reaction to a previous dose of hepatitis A or hepatitis B containing vaccine or any components of the vaccine should be referred to a clinician for specialist advice and appropriate management • Individuals who are solely at occupational risk of hepatitis A and/or B exposure should be referred to their employer's occupational health provider for vaccination • Individuals requiring solely hepatitis B vaccination for overseas travel purposes should be administered hepatitis B in accordance with local policy. However, hepatitis B vaccination for travel is not remunerated by the NHS as part of additional services and is therefore not covered by this PGD unless hepatitis A vaccination is also indicated, and a combined HepA/B vaccine is used • Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered; immunisers should advise when the individual can be vaccinated and ensure another appointment is arranged • Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required • The risk to the individual of not being immunised must be taken into account • Document the reason for exclusion and any action taken in the individual's clinical records • Inform or refer to the GP or a prescriber as appropriate • Refer the individual to an alternative service or setting for vaccination if appropriate

Action to be taken if patient declines treatment	• A verbal explanation should be given to the patient on: the need for the medication and any possible effects or potential risks which may occur as a result of refusing treatment • This information must be documented in the patients' health records • Any patient who declines care must have demonstrated capacity to do so • Where appropriate care should be escalated • Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications • Inform or refer to the GP as appropriate

8. Details of the medicine

Name, form and strength of medicine	Hepatitis A virus (inactivated) and hepatitis B recombinant DNA (rDNA) (HepA/B) vaccine (adsorbed), either: • Twinrix® Adult, suspension for injection in a pre-filled syringe or vial, hepatitis A virus (inactivated) 720 ELISA units and hepatitis B surface antigen 20 micrograms • Twinrix® Paediatric, suspension for injection in a pre-filled syringe or vial, hepatitis A virus (inactivated) 360 ELISA units and hepatitis B surface antigen 10 micrograms • Ambirix®, suspension for injection in a pre-filled syringe, hepatitis A virus (inactivated) 720 ELISA units and hepatitis B surface antigen 20 micrograms An appropriate vaccine product should be selected for the patient see Dose and frequency of administration section
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Indicate any off-label use (if relevant)	• The Twinrix® Adult schedule given at 0, 7 and 21 days is licensed for adults (that is those from 18 years of age) but may be used off-label in those from 16 to 18 years of age where it is important to provide rapid protection and to maximise compliance (this includes PWID) in accordance with Chapter 18 of 'The Green Book'. • Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to PHE Vaccine Incident Guidance or any subsequent UKHSA update. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, this would constitute off-label administration under this PGD. • Where a vaccine is recommended off-label, as part of the consent process, consider informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.

<table>
<tr><td>Route/method of administration</td><td>• Administer by intramuscular injection. The deltoid region of the upper arm may be used in individuals over one year of age</td></tr>
<tr><td>Dose and frequency</td><td>Current UK licensed HepA/B vaccines contain different concentrations of antigen (see table below):

<table>
<tr><th>Vaccine</th><th>Age (licenced use)</th><th>Dose HepA</th><th>Dose HepB</th><th>Volume</th></tr>
<tr><td>Twinrix® Adult</td><td>16 years or over</td><td>720 ELISA units</td><td>20 micrograms</td><td>1.0ml</td></tr>
<tr><td>Twinrix® Paediatric</td><td>One to 15 years</td><td>360 ELISA units</td><td>10 micrograms</td><td>0.5ml</td></tr>
<tr><td>Ambirix®</td><td>One to 15 years</td><td>720 ELISA units</td><td>20 micrograms</td><td>1.0ml</td></tr>
</table>

Licensed dose to provide Hepatitis A and B protection:
• Twinrix® Adult: 1ml administered at 0, 1 and 6 months*
• Where insufficient time is available to allow the standard 0, 1, 6 month* schedule to be completed, a schedule of three intramuscular injections given at 0, 7 and 21 days* may be used (see Off-label Use Section). When this schedule is applied, a fourth dose is recommended 12 months after the first dose
• Twinrix® Paediatric: 0.5ml administered at 0, 1 and 6 months* Ambirix®: 1ml administered at 0 and 6-12 months*
• *where 0 is the elected start date of the course
• For travellers, vaccine should preferably be given at least two weeks before departure but can be given up to the day of departure</td></tr>
<tr><td>Quantity to be administered</td><td>• Dose of 0.5ml to 1.0ml per an administration depending on the age of the individual and vaccine product used, see Dose and frequency of administration
• HepA/B vaccine is not usually centrally supplied and should be obtained directly from manufacturers/wholesalers
• Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book Chapter 3)</td></tr>
<tr><td>Maximum or minimum treatment period</td><td>Dependent of vaccine schedule, see Dose and frequency of administration</td></tr>
<tr><td>Storage</td><td>• Store at between +2°C to +8°C
• Store in original packaging to protect from light
• Do not freeze
• In the event of an inadvertent or unavoidable deviation of these conditions vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal, refer to PHE Vaccine Incident Guidance</td></tr>
</table>

Adverse effects	• Adverse reactions to hepatitis vaccines are usually mild and confined to the first few days after immunisation. The most common reactions are mild, transient pain, redness and swelling at the injection site • Other commonly reported reactions to hepatitis A vaccination include other injection site reactions (haematoma, pruritus, bruising), general symptoms such as fever, malaise, fatigue, irritability, drowsiness, headache, and gastrointestinal symptoms including nausea, diarrhoea and loss of appetite • Hypersensitivity reactions and anaphylaxis can occur but are very rare • A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Records to be kept	The administration of any medication given under a PGD must be recorded within the patient's medical records

9. Patient information

Verbal/Written information to be given to patient or carer	• Verbal information must be given to patients and or carers for all medication being administered under a PGD • Where medication is being supplied under a PGD, written patient information leaflet must also be supplied • A patient information leaflet is available on request
Follow-up advice to be given to patient or carer	• If symptoms do not improve or worsen or you become unwell, seek medical advice immediately • Inform the individual/parent/carer of possible side effects and their management • The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction • When applicable, advise individual/parent/carer when the subsequent dose is due • When administration is postponed advise the individual/parent/carer when to return for vaccination • Advise individuals of preventative measures to reduce exposure to hepatitis A (such as careful attention to food and water hygiene and scrupulous hand washing, further details can be found on www.nhs.uk) and preventative measures to reduce exposure to hepatitis B (such as avoiding exposure to blood and bodily fluids, further details can be found on www.nhs.uk)

10. Appendix A

References

1. British National Formulary (BNF) 2019 available online: https://bnf.nice.org.uk
2. Nursing and Midwifery (2018) "The code" available online: https://www.nmc.org.uk
3. Current Health Care Professions Council standards of practice
4. General Pharmaceutical Council standards
5. The General Optical Council
6. Electronic medicines compendium available online: https://www.medicines.org.uk

Product

- Immunisation Against Infectious Disease: The Green Book Chapter 4, updated June 2012, Chapter 7, updated October 2016, Chapter 17, updated December 2013 and Chapter 18, updated June 2017. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book
- Summary of Product Characteristic for Twinrix® Adult, GlaxoSmithKline UK. Last updated 8 October 2018. https://www.medicines.org.uk/emc/medicine/2061
- Summary of Product Characteristic for Twinrix® Paediatric, GlaxoSmithKline UK. Last updated 8 October 2018. https://www.medicines.org.uk/emc/medicine/2062
- Summary of Product Characteristic for Ambirix®, GlaxoSmithKline UK. Last updated 05 November 2018. https://www.medicines.org.uk/emc/medicine/20491
- NaTHNaC resources. Accessed 18 July 2019. https://travelhealthpro.org.uk/countries

General

- Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013. https://www.gov.uk/government/publications/guidance-on-the-safe- management-of-healthcare-waste
- National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for- registered-healthcare-practitioners
- NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2
- NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources
- PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation
- PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident- guidance-responding-to-vaccine-errors

11. Appendix B

Health professionals agreed to practice
• Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor • A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves

12. Appendix C

Route/method of administration	• The buttock should not be used because vaccine efficacy may be reduced • When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each was given should be noted in the individual's records • The suspension for injection may sediment during storage to leave a fine white deposit with a clear colourless layer. Shake the vaccine well before administration to obtain a uniform turbid white suspension • The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine • The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: www.medicines.org.uk • For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given in accordance with the recommendations in the 'Green Book' Chapter 4. Note that administration by routes other than intramuscular administration into the deltoid region of the upper arm may result in suboptimal immune response to the vaccine
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013)

Drug interactions	• Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited • May be given at the same time as other vaccines • A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Records to be kept	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via PGD Records should be signed and dated (or a password-controlled immuniser's record on e-records). All records should be clear, legible and contemporaneous. When vaccine is administered to individuals under 19 years of age, notify the local Child Health Information Systems team (Child Health Records Department) using the appropriate documentation/pathway as required by any local or contractual arrangement. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.
Special considerations/ additional information	• Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination • There is no evidence of risk from vaccinating pregnant women or those who are breast feeding with inactivated vaccines. Since HepA/B vaccine is an inactivated vaccine, the risks to the foetus are negligible and it should be given where there is a definite risk of infection • Monovalent vaccine is preferred where vaccination is recommended post-exposure or for outbreak/incident management • HepA/B vaccine will not prevent infection caused by other pathogens known to infect the liver such as hepatitis C and hepatitis E viruses