PATIENT GROUP DIRECTION (PGD)

This PGD is for the administration of combined hepatitis A virus (inactivated) and hepatitis B recombinant DNA (rDNA) (Hep A and B) vaccine (adsorbed) to individuals requiring protection against hepatitis A and hepatitis B virus in accordance with the national recommendations.

This PGD is for the administration by registered healthcare professionals identified in Section 5, subject to any limitations to authorisation detailed in Section 2.

This Patient Group Direction (PGD) has been produced by Dorset Private GP Limited in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer a Hepatitis A virus (inactivated) and hepatitis B recombinant DNA (rDNA) (HepA/B) vaccine (adsorbed) can only use this PGD as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/Summary of Product Characteristics (SmPC) for all vaccines administered in accordance with this PGD.

Dorset Private GP Limited maintains records of staff authorised to operate this PGD. Under PGD legislation there can be no delegation. Administration of the vaccine has to be by the same practitioner who has assessed the patient under the PGD.

This PGD has been produced for Dorset Private GP Limited by:

Doctor – Dr Jon Echebarrieta ……

Compliance Director – Stephen Middleton

Approved on behalf of Dorset Private GP Limited by:

Clinical Director – Dr Tim Alder

Clinical Governance Lead – Dr Jon Echebarrieta ……
Date approved: ……10 February 2026……
Effective from: 10 February 2026 Expiry date: 09 February 2028

This PGD has been developed in line with current national publication of PGD guidelines and Green Book guidelines around the administration of the above named vaccination. The PGD is periodically reviewed for accuracy and update.

Change history

Version number	Change details	Date
Version v1.00	New Dorset Private GP PGD	10/02/2026

1. Organisational Authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation from the Clinical Governance Lead, the Clinical Director and the Compliance Director for Dorset Private GP Ltd.

It is the responsibility of Dorset Private GP to authorise the PGD, to ensure that all legal and governance requirements are met. Dorset Private GP accepts governance responsibility for the appropriate use of the PGD.

DORSET PRIVATE GP authorises this PGD for use by practitioners listed below who adhere to the below requirements, clinical conditions and inclusion/exclusion criteria:

Practitioner Requirements	Practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • 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 • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy **THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.**
Continued training requirements **Continued training requirements** (continued)	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). Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and other sources of medicines information. Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

2. Clinical condition or situation to which this PGD applies.

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 of Immunisation Against Infectious Disease: the Green Book.
Criteria for inclusion	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) • are at increased risk of hepatitis A and hepatitis B infection solely because of their occupation
Criteria for exclusion[1]	Individuals for whom valid consent or best-interests decision in accordance with the Mental Capacity Act 2005, has not been obtained (for further information on consent, see Chapter 2 of the Green Book). Several resources are available to inform consent (see written information to be given to individual or carer section). 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) • 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	Facilities for management of anaphylaxis should be available at all vaccination premises (see Chapter 8 of the Green Book and advice issued by the Resuscitation Council UK). Individuals who are immunosuppressed or have HIV infection may not make a full antibody response and revaccination on cessation of treatment or following recovery may be required. This should be discussed with the 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.
Action to be taken if the patient is excluded	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 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 a GP as appropriate. Refer the individual to an alternative service or setting for vaccination if appropriate.
Action to be taken if the patient or carer declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration and recorded appropriately. Where a person lacks the capacity in accordance with the Mental Capacity Act 2005, a decision to vaccinate may be made in the individual's best interests. For further information on consent, see Chapter 2 of the Green Book. Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and potential complications of disease. Document advice given and the decision reached. Inform or refer to the GP as appropriate.
Arrangements for referral for medical advice	As per local policy

3. Description of Treatment

Name, strength & formulation of drug	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 individual (see Dose and frequency of administration).
Legal category	Prescription Only Medicine (POM).
Black Triangle▼	No
Off-label use	The Twinrix® Adult schedule given at 0, 7 and 21 days is licensed for adults (that is, aged 18 years and above) 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. Though the SPCs for each combined vaccine advise that a course of vaccination should be completed with the same brand, if necessary another product may be used to avoid a delay in protection. 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 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 or carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.
Route / method of administration Continued over page **Route / method of administration**	Administer by intramuscular injection. The deltoid muscle of the upper arm may be used in individuals over one year of age. 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. 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

<table>
<tr><td>(continued)</td><td>the deltoid muscle of the upper arm may result in suboptimal immune response to the vaccine.

The suspension for injection may sediment during storage to leave a fine white deposit with a clear colourless layer. Shake the vaccine vigorously before administration to obtain a uniform hazy white suspension.

The vaccine should be visually inspected for foreign particulate matter and other variation of expected appearance prior to preparation and administration. Should either occur, discard the vial in accordance with local procedures.

The vaccine SPCs provides further guidance on preparation and administration and are available from the electronic Medicines Compendium.</td></tr>
<tr><td>Dose and frequency of administration</td><td>Current UK licensed hepatitis A and B combined vaccines contain different concentrations of antigen (see table below).

<table>
<tr><th>Vaccine</th><th>Age (licensed 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 to 12 months*

*where 0 is the elected start date of the course

For travellers, vaccine should preferably be given at least 2 weeks before departure but can be given up to the day of departure.

Note: Where immunisation has been delayed beyond the recommended intervals outlined , the vaccine course should be resumed and completed.

It is preferred that the primary course of vaccination is completed with the same vaccine brand throughout. The course may be completed with a different vaccine to avoid a delay in protection.</td></tr>
<tr><td>Duration of treatment</td><td>Dependent on vaccine product and schedule, see Dose and frequency of administration above.</td></tr>
</table>

Quantity to be supplied / administered	Dose of 0.5ml to 1.0ml per administration, depending on the age of the individual and vaccine product used (see Dose and frequency of administration).
Supplies	Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book Chapter 3).
Storage	Store at +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. In the event of an inadvertent or unavoidable deviation of these conditions, vaccines that have been stored outside the conditions stated above should be quarantined and risk assessed on a case-by-case basis for suitability of continued off-label use or appropriate disposal. Refer to Vaccine Incident Guidance. Contact the vaccine manufacturer where more specific advice is required about managing a temperature excursion.
Disposal	Follow local clinical waste policy and standard operating procedures to ensure safe and secure waste disposal. Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in an UN-approved puncture-resistant sharps box, according to local authority arrangements and NHSE guidance (HTM 07-01): safe and sustainable management of healthcare waste. guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).
Drug Interactions Continued over page **Drug Interactions** (continued)	The immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group. 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 associated with the combined hep A and B vaccines are provided in the respective SPCs, available from the electronic Medicines Compendium.
Identification & Management of Adverse Reactions	Adverse reactions to combined hepatitis A and B vaccines are usually mild and confined to the first few days after immunisation. Very common reactions include mild, transient pain and redness at the injection site, headache and fatigue. Other commonly reported reactions include other injection-site reactions such as bruising and swelling, general symptoms such as fever, malaise, loss of appetite, irritability and drowsiness, and gastrointestinal symptoms such as nausea and diarrhoea. Hypersensitivity reactions and anaphylaxis can occur but are very rare. A detailed list of adverse reactions associated with combined hep A/B vaccines is available from the electronic Medicines Compendium..
Reporting procedure of Adverse Reactions	Healthcare professionals and individuals, parents and carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the

	Yellow Card reporting scheme or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.
Written information to be given to patient or carer	Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Immunisation promotional material may be provided as appropriate: For resources in accessible formats and alternative languages, please visit Home- Health Publications. Where applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SPC.
Patient advice /Follow up treatment	Inform the individual, parent or carer of possible side effects and their management. The individual, parent or carer should be advised to seek medical advice in the event of an adverse reaction and report this via the Yellow Card reporting scheme. When applicable, advise individual, parent or carer when the subsequent dose is due. When administration is postponed advise the individual, parent or 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), and preventative measures to reduce exposure to hepatitis B (such as avoiding exposure to blood and bodily fluids).
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 combined hepatitis A and B vaccine is an inactivated vaccine, the risks to the fetus are negligible and it should be given where there is a definite risk of infection. In situations where a booster dose of hepatitis A, hepatitis B or both is desired, either monovalent or combined hepatitis A and hepatitis B vaccines may be given. The combined vaccine should not be used for post-exposure prophylaxis, such as in managing needlestick injuries. Monovalent vaccine should be given where vaccination is recommended for post-exposure or for management of outbreaks or incidents. Hepatitis A and B combined vaccine will not prevent infection caused by other pathogens known to infect the liver such as hepatitis C and hepatitis E viruses. Individuals, their parent or carer should be advised that protection against hepatitis B may not be obtained until after the second dose of

	Ambirix®. Therefore Ambirix® should be used only where there is a relatively low risk of hepatitis B infection during the vaccination course.
Records Continued over page **Records** (continued)	The practitioner must ensure the following is recorded: • that valid informed consent was given or a decision to vaccinate made in the individual's best interests in accordance with the Mental Capacity Act 2005 • name of individual, address, date of birth and GP with whom the individual is registered (or record where an individual is not registered with a GP) • 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 password-controlled 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 Service (CHIS) using the appropriate documentation or 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..

4. Key References

Key references	**Product** • Immunisation Against Infectious Disease: The Green Book Chapter 4, updated June 2012, Chapter 7, updated 10 January 2020, Chapter 17, updated 7 February 2022 and Chapter 18, updated 7 February 2022 https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of Product Characteristic for Twinrix® Adult, GlaxoSmithKline UK. Last updated 21 July 2023 https://www.medicines.org.uk/emc/medicine/2061 • Summary of Product Characteristic for Twinrix® Paediatric, GlaxoSmithKline UK. Last updated 21 July 2023 https://www.medicines.org.uk/emc/medicine/2062 • Summary of Product Characteristic for Ambirix®, GlaxoSmithKline UK. Last updated 21 July 2023 https://www.medicines.org.uk/emc/medicine/20491 • NaTHNaC resources. Accessed 20 September 2023.

Key references (continued)	https://travelhealthpro.org.uk/countries **General** • NHSE Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Updated 7 March 2023. https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • 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. Last updated 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 • UKHSA Immunisation Collection https://www.gov.uk/government/collections/immunisation • Vaccine Incident Guidance. Last updated July 2022 https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

5. Practitioner authorisation sheet

Hepatitis A and B combined vaccine PGD v1.00 Valid from: 10 February 2026 Expiry: 09 February 2028

Before signing this PGD, check that the document has had the necessary authorisations in section 1. Without these, this PGD is not lawfully valid.

Practitioner

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of DORSET PRIVATE GP for the above named health care professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.