NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Patient Group Direction For The Administration Of Japanese Encephalitis Vaccine For Travel Indications By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Lead Author: Adapted from Public Health Scotland Administration of Japanese encephalitis vaccine for travel indications PGD template Version 2 – PHS Publication date 01 February 2024		**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD/Travel_JapE/1463	**Review Date:** 31st January 2026 **Expiry Date:** 31st January 2026	**Date Approved by NoS:** 6th June 2024

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 2

Revision History for NoS:

NoS PGD that has been superseded	NoS/PGD/Travel_JapE/MGPG1261, Version 1

Most recent changes NoS

Version	Date of change	Summary of Changes	Section heading
2	6 March 2023	Reference to NoS Appendix 1 and 2.	Authorisation
		Training requirements for NoS.	Continuing education and training

Most recent changes

Version	Date	Summary of changes
2	1 February 2024	• This PGD has undergone minor rewording, layout, formatting changes for clarity and consistency with other PHS national specimen PGDs. • Observation following vaccination section updated to include advice on driving post-immunisation.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Contents

Authorisation

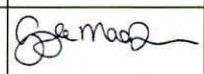
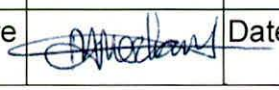
This specimen Patient Group Direction (PGD) template has been produced by Public Health Scotland and adapted by North of Scotland PGD Group (NoS) to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer vaccine under this PGD can only do so 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.

NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. 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.

All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1).

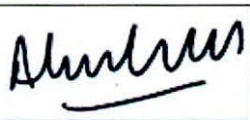
A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.

This PGD has been produced for NoS by:					
Doctor	Jenny Wares	Signature		Date Signed	05/06/2024
Pharmacist	Gayle MacDonald	Signature		Date Signed	19/04/2024
Nurse	Pauline Merchant	Signature		Date Signed	02/04/2024

Approved for use within NoS by:

NoS Group Chair	**Signature**	**Date Signed**
Lesley Coyle		06/06/2024

Authorised and executively signed for use within NoS by:

NHS Grampian Chief Executive	**Signature**	**Date Signed**
Adam Coldwells – Interim Chief Executive		06/06/2024

Version 2 – Approved for NoS from 6th June 2024

1. Clinical situation

1.1. Indication

Active immunisation of individuals who are deemed to be at risk from exposure to Japanese encephalitis virus.

1.2. Inclusion criteria

- Individuals aged 2 months and older who:
    - intend to travel to or reside in countries where Japanese encephalitis vaccination is currently recommended for travel in accordance with national recommendations issued by TRAVAX.

The risk of exposure should be determined after careful risk assessment of an individual's itinerary, season of travel, duration of stay, planned activities and medical history.

Valid consent has been given to receive the vaccine.

1.3. Exclusion criteria

Individuals who:

- are under two months of age
- have had a confirmed anaphylactic reaction to a previous dose of any Japanese encephalitis containing vaccine or to any components of the vaccine including the residues protamine sulphate, formaldehyde, bovine serum albumin, host cell DNA, sodium metabisulphite (refer to relevant SmPC)
- have a history of severe (i.e. anaphylactic reaction) to latex where the vaccine is not latex free
- are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)

1.4. Cautions/need for further advice/ circumstances when further advice should be sought from a doctor

The Green Book advises that there are very few individuals who cannot receive Japanese encephalitis-containing vaccines. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist or from the local immunisation or health protection team.

Individuals with immunosuppression can be given Japanese encephalitis-containing vaccines although these individuals may not make a full antibody response.

The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear.

Co-administration with other vaccines

Japanese encephalitis vaccine can be given at the same time as other vaccines, including other travel vaccines. 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 vaccine was given should be noted in the individual's records.

Syncope

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.

Pregnancy and breastfeeding

As a precautionary measure, administration of Japanese encephalitis vaccine during pregnancy or lactation should be avoided. However, travellers and their medical advisers must make a risk assessment of the theoretical risks of Japanese encephalitis vaccine in pregnancy against the potential risk of acquiring Japanese encephalitis. Miscarriage has been associated with Japanese encephalitis virus infection when acquired in the first two trimesters of pregnancy.

1.5. Action if excluded

Specialist advice must be sought on the vaccine and circumstances under which it could be given. Immunisation using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account.

Advise the individual on other preventative measures that may be implemented such as mosquito bite avoidance.

Document the reason for exclusion and any action taken in accordance with local procedures.

Inform or refer to the clinician in charge.

1.6. Action if patient declines

Advise the individual about the protective effects of the vaccine, the risks of infection and potential complications of disease.

Advise the individual on other preventative measures that may be implemented such as mosquito bite avoidance.

Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine.

Document advice given and decision reached.

Inform or refer to the clinician in charge.

2. Description of treatment

2.1. Name of medicine/form/strength

Japanese encephalitis vaccine (inactivated, absorbed) available as IXIARO® suspension for injection, 0.5mL.

2.2. Route of administration

Japanese encephalitis-containing vaccines should be administered by intramuscular (IM) injection preferably into the deltoid area of the upper arm. Where administration into the deltoid is not possible the anterolateral thigh can be considered. However, for individuals who have a bleeding disorder, IXIARO® should be given by deep subcutaneous injection to reduce the risk of bleeding.

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.

2.3. Dosage

Individuals aged two months to under 3 years – 0.25mL.

Individuals aged three years and over, and adults – 0.5mL.

2.4. Frequency

Primary pre-exposure immunisation:

Children from two months and adults:

Standard schedule:

- First dose on day 0
- Second dose on day 28

Rapid schedule*

- First dose on day 0
- Second dose on day 7

*licensed for adults aged 18-64 years of age. For age 2 months to 17 years and adults 65 years of age and older, the rapid schedule can be used (off label) in circumstances where there is genuinely insufficient time to complete the standard schedule prior to travel (see 'Is the use out with the SmPC section' of this PGD).

With both schedules, primary immunisation should ideally be completed at least one week prior to potential exposure but can be given up to the day of departure. Travellers should be reminded that optimum protection will not be immediate and should practice mosquito bite avoidance measures.

Reinforcing Immunisation:

First booster

Children (from two months) and adults:

Individuals who remain at risk of exposure should be given a booster dose 12 months after primary immunisation.

Second booster

Adults 18-64 years of age: A second booster dose (4th dose) should be offered at 10 years from the first booster to those who remain at risk or prior to potential re-exposure to Japanese Encephalitis.

Children <18 years and adults 65 years of age and older: The length of protection following the first booster dose is not known. Refer to lead clinician.

IXIARO® may be used as a booster for those who received Green Cross vaccine or Biken vaccine previously.

2.5. Duration of treatment

See frequency section.

2.6. Maximum or minimum treatment period

See frequency section.

2.7. Quantity to supply/administer

See dosage and frequency sections.

2.8. ▼ black triangle medicines

No.

2.9. Legal category

Prescription only medicine (POM).

2.10. Is the use outwith the SmPC?

The rapid schedule administered at days 0 and 7 is 'off label' for age 2 months to 17 years and adults 65 years of age and older.

Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.

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 NHS Board guidance on the storage and handling of vaccines or National Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.

2.11. Storage requirements

General requirements

Vaccine should be stored at a temperature of +2° to +8°C.

Do not freeze.

During storage it is recommended that the syringes are stored in the original packaging/cartons, away from direct sunlight to protect from light and kept upright.

NHS Board guidance on Storage and Handling of vaccines should be observed.

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 use or appropriate disposal.

2.12. Additional information

Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation should be postponed until they have fully recovered.

Immunological response may be diminished in those receiving immunosuppressive treatment.

3. Adverse reactions

3.1. Warnings including possible adverse reactions and management of these

Localised reactions such as redness, swelling or pain at the site of injection within 24 to 48 hours of administration.

Other reactions commonly reported are headache, myalgia, erythema, hardening, swelling and itching at the injection site, influenza-like illness, pyrexia and fatigue.

As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.

In the event of a severe adverse reaction individuals should be advised to seek medical advice.

For full details/information on possible adverse reactions, refer to manufacturer's product literature or SmPC.

3.2. Reporting procedure for adverse reactions

Healthcare professionals and individuals/carers should report all suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on http://www.mhra.gov.uk/yellowcard.

Any adverse reaction to a vaccine should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed.

3.3. Advice to patient or carer including written information

Written information to be given to individual:

- Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine.

Individual advice / follow up treatment:

- Inform the individual/carer of possible side effects and their management.
- Advise the individual on other preventative measures that may be implemented such as mosquito bite avoidance.
- When applicable, advise individual/parent/carer when the subsequent dose is due.
- The individual should be advised to seek medical advice in the event of a severe adverse reaction.

- Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: http://www.mhra.gov.uk/yellowcard
- Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine and they should continue to take appropriate measures to protect themselves against this infection.
- When administration is postponed advise the individual how future vaccination may be accessed.

3.4. Observation following vaccination

Following immunisation, patients remain under observation in line with NHS Board policy. As syncope (fainting) can occur following vaccination, all vaccinees should either be driven by someone else or should not drive for 15 minutes after vaccination.

3.5. Follow up

See frequency section.

3.6. Additional facilities

A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given. Immediate treatment should include early treatment with intramuscular adrenaline, with an early call for help and further IM adrenaline every 5 minutes.

The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

4. Characteristics of staff authorised under the PGD

4.1. Professional qualifications

The following classes of registered healthcare practitioners are permitted to administer this vaccine:

- nurses and midwives currently registered with the Nursing and Midwifery Council (NMC).
- pharmacists currently registered with the General Pharmaceutical Council (GPhC).
- chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC).
- dental hygienists and dental therapists registered with the General Dental Council.
- optometrists registered with the General Optical Council.

4.2. Specialist competencies or qualifications

Persons must only work under this PGD where they are competent to do so.

All persons operating this PGD:

- demonstrate appropriate knowledge and skills to work under this PGD.
- must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it.
- must be familiar with the vaccine product and alert to changes in the manufacturer's product information/summary of product characteristics information.
- must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent.
- must be competent in the correct storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine.
- must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions.
- must have access to the PGD and associated online resources.
- should fulfil any additional requirements defined by local policy.

Employer

- The employer is responsible for ensuring that persons have the required knowledge and skills to safely deliver the activity they are employed to provide under this PGD.
- As a minimum, competence requirements stipulated in the PGD must be adhered to.

4.3. Continuing education and training

All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of vaccines included. If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under this PGD.

Have undertaken NoS PGD module training on TURAS Learn

- Have attended basic life support training either face to face or online and updated in-line with individual Board requirements
- Have undertaken immunisation training where available
- Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis updated in-line with individual Board requirements
- Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct.

5. Audit trail

Record the following information:

- valid informed consent was given
- name of individual, address, date of birth and GP with whom the individual is registered if possible
- name of person that undertook assessment of individual's clinical suitability and subsequently administered the vaccine
- name and brand of vaccine
- date of administration
- dose, form and route of administration of vaccine
- batch number
- where possible 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
- administered under PGD

Records should be kept in line with local procedures.

Local policy should be followed to encourage information sharing with the individual's General Practice.

All records should be clear, legible and contemporaneous and in an easily retrievable format.

6. Additional references

Practitioners operating the PGD must be familiar with:

- Immunisation against Infectious Disease [Green Book].
- Immunisation against Infectious Disease [Green Book] Japanese Encephalitis
- Professional Guidance on the Safe and Secure Handling of Medicines
- Professional Guidance on the Administration of Medicines in Healthcare Settings 2019
- Educational resources for registered professionals produced by National Education for Scotland
- Marketing authorisation holder's Summary of Product Characteristics

7. Version history

Version	Date	Summary of changes
1	1 February 2022	Version 1.0 New PGD
2	1 February 2024	• This PGD has undergone minor rewording, layout, formatting changes for clarity and consistency with other PHS national specimen PGDs. • Observation following vaccination section updated to include advice on driving post-immunisation.

Appendix 1 - Healthcare Professional Agreement to Administer Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the medicine(s) contained within the following Patient Group Direction:

Patient Group Direction For The Administration Of Japanese Encephalitis Vaccine For Travel Indications By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 2

I have completed the appropriate training to my professional standards enabling me to administer the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 2 - Healthcare Professionals Authorisation to Administer Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to administer the medicine(s) under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to administer the medicine(s) under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.
Patient Group Direction For The Administration Of Japanese Encephalitis Vaccine For Travel Indications By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 2
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

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Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**