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

Patient Group Direction For The Administration Of Bacillus Calmette-Guerin (BCG) Vaccine AJV (AJ Vaccines) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Lead Author: Adapted from Public Health Scotland Administration of Bacillus Calmette-Guerin (BCG) vaccine AJV (AJ Vaccines) Patient group direction (PGD) template Version 2.3 – PHS Publication date 18 March 2024		**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD/BCG/1501	**Review Date:** 31st March 2026 **Expiry Date:** 31st March 2026	**Date Approved by NoS:** 31st October 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 2.3

Revision History for NoS:

NoS PGD that has been superseded	NoS/PGD/BCG/MGPG1107, Version 2.2.2

Most recent changes NoS

Version	Date of change	Summary of Changes	Section heading
2.3	28th March 2024	Reference to NoS Appendix 1 and 2.	Authorisation
		Training requirements for NoS.	Continuing education and training

Most recent changes

Version	Date	Summary of changes
2.3	18 March 2024	This PGD has undergone minor rewording, layout, formatting changes for clarity and consistency with other PHS national specimen PGDs. The following sections have been updated: • Inclusion criteria section updated to remove all reference to IGRA testing and inclusion on use of BCG in those over the age of 35 years. • Exclusion criteria section updated to remove all reference to IGRA testing. • Exclusion criteria section updated with updated advice that infants under 12 months old (previously six months) born to a mother who received immunosuppressive biological therapy such as TNFα antagonists during pregnancy should not be vaccinated. • Disposal – new section added. • 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

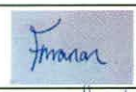
This specimen Patient Group Direction (PGD) template has been produced by Public Health Scotland and adapted by North of Scotland PGD Group (NoS) to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

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).

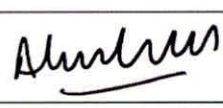
A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.

This PGD has been produced for NoS by:					
Doctor	Dr Danny Chandler	Signature		Date Signed	27/09/2024
Pharmacist	Fiona Marion	Signature		Date Signed	15/10/2024
Nurse	Pauline Merchant	Signature		Date Signed	09/10/2024

Approved for use within NoS by:

NoS Group Chair	**Signature**	**Date Signed**
Lesley Coyle		23/10/2024

Authorised and executively signed for use within NoS by:

NHS Grampian Chief Executive	**Signature**	**Date Signed**
Adam Coldwells – Interim Chief Executive		31/10/2024

Version 2.3 – Approved for NoS from 31st October 2024

1. Clinical situation

1.1. Indication

Active immunisation against tuberculosis.

1.2. Inclusion criteria

Valid consent has been given to receive the vaccine.

Individuals not previously vaccinated against tuberculosis and considered to be at elevated risk:

- all infants (aged 0 to 12 months) with a parent or grandparent who was born in a country where the annual incidence of TB is 40/100,000 or greater†
- all infants (aged 0 to 12 months) living in areas of the UK where the annual incidence of TB is 40/100,000 or greater*
- previously unvaccinated children aged one to five years with a parent or grandparent who was born in a country where the annual incidence of TB is 40/100,000 or greater.† These children should be identified at suitable opportunities, and can normally be vaccinated without tuberculin testing.
- previously unvaccinated, tuberculin-negative children aged from six to under 16 years of age with a parent or grandparent who was born in a country where the annual incidence of TB is 40/100,000 or greater.† These children should be identified at suitable opportunities, tuberculin tested and vaccinated if negative.
- previously unvaccinated tuberculin negative individuals under 16 years of age household or equivalent close contacts of cases of sputum smear-positive pulmonary or laryngeal TB (following recommended contact management advice – see National Institute for Health and Clinical Excellence (NICE) guideline.
- previously unvaccinated, tuberculin negative individuals under 16 years of age who were born in or who have lived for a prolonged period (at least three months) in a country with an annual TB incidence of 40/100,000 or greater.†

† see country information on prevalence: Tuberculosis by country: rates per 100,000 people - GOV.UK (www.gov.uk)

* Universal vaccination operates in areas of the country where the TB incidence is 40/100,000 or greater. This is applied for operational reasons since these geographical areas generally have a high concentration of families who come from regions of the world where the TB incidence is 40/100,000 or greater and therefore a higher potential for transmission events. The decision to introduce universal vaccination in an area is based on geography in order to target vaccination to children who may be at increased risk of TB in an effective way. It does not imply that living in areas that have an incidence of TB 40/100,000 or greater puts children at increased risk of TB infection. This is because most infections of children are likely to occur in household settings. Further, there has been little evidence of TB transmission in schools in the UK.

Individuals at occupational risk

Unvaccinated, tuberculin negative Healthcare worker (HCW) or laboratory worker, who has either direct contact with TB patients or with potentially infectious clinical materials or derived isolates, regardless of age.

BCG vaccination may also be considered for staff working with prisoners, homeless persons, persons with drug and alcohol misuse and those who work with refugees and asylum seekers.

BCG efficacy data in adults over the age of 35 years is scarce. Nevertheless, because these groups have a high exposure risk, and given the absence of safety concerns, it is likely that benefits outweigh risks for vaccinating individuals over the age of 35 years with BCG.

1.3. Exclusion criteria

- Previously received BCG vaccine.
- Past history of active or latent tuberculosis.
- Receiving anti-tuberculosis treatment.
- Positive reaction following Mantoux (AJV) tuberculin skin testing: induration of 5mm or more following Mantoux (AJV) tuberculin skin testing.
- Children less than two years of age in a household where an active TB case is suspected or confirmed. **Seek specialist advice**.
- Confirmed anaphylactic reaction to any component of the vaccine. Practitioners must check the marketing authorisation holder's summary of product characteristics (SmPC) for details of vaccine components.
- Known to be suffering from malignant conditions (e.g. lymphoma, leukaemia, Hodgkin's disease or other tumours of the reticulo-endothelial system.
- Known to have primary or secondary immune-deficiencies.
- Receiving or have received in the past 3 months immunosuppressive therapy including:
  - Adults and children on high-dose corticosteroids (>40mg prednisolone per day or >2mg/kg/day in children under 20kg) for more than 1 week
  - Adults and children on lower dose corticosteroids (>20mg prednisolone per day or >1mg/kg/day in children under 20kg) for more than 14 days
  - Adults on non-biological oral immune modulating drugs, e.g. methotrexate >25mg per week, azathioprine >3.0mg/kg/day or 6-mercaptopurine >1.5mg/kg/day
  - Children on non-biological oral immune modulating – specialist advice must be sought
- Receiving, or have received in the past 6 months immunosuppressive chemotherapy or radiotherapy for malignant disease or non-malignant disorders.
- Receiving, or have received in the past 6 months immunosuppressive therapy for a solid organ transplant.
- Those who are receiving or have received in the past 12 months immunosuppressive biological therapy (e.g. anti-TNF therapy such as alemtuzumab, ofatumumab and rituximab) unless otherwise directed by a specialist.

- Infants aged under 12 months old who were born to a mother who received immunosuppressive biological therapy such as TNFα antagonists during pregnancy.
- Infants being breastfed by a mother receiving immunosuppressive biological therapy such as TNFα antagonists. If there is any doubt as to whether an infant due to receive a live attenuated vaccine may be immunosuppressed due to the mother's therapy, including exposure through breast-feeding, specialist advice should be sought.
- HIV positive regardless of CD4 cell count, ART use, viral load, and clinical status.
- Known to be pregnant.
- Generalised infected skin conditions.
- Evolving neurological conditions – postpone immunisation until resolved or stabilised.
- Acute illness or fever - postpone immunisation until patient has fully recovered.
- Have a severe combined immunodeficiency (SCID) screening result (taken in NHS England) reported as SCID suspected.
- Are awaiting a SCID screening result (taken in NHS England) or where a repeat is needed, until the result is available and reports that SCID is not suspected.

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

Infants born to HIV positive mothers should not receive BCG vaccine until specialist advice has been sought. Infants born to HIV positive mothers should only be given BCG vaccine when the exclusively formula-fed infant is confirmed HIV uninfected at 12–14 weeks.

In persons whose immune status is in question, BCG vaccination should be postponed until their immune status has been evaluated.

If eczema exists, an immunisation site should be chosen that is free from skin lesions.

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.

Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation.

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

Administration in pregnancy is excluded – see above.

Breast-feeding is not a contraindication to BCG, however if there is any doubt as to whether an infant due to receive BCG vaccine may be immunosuppressed due to the mother's therapy, including exposure through breastfeeding, specialist advice should be sought.

Coadministration with other vaccines

Inactivated and live vaccines, such as rotavirus, live attenuated influenza vaccine (LAIV), oral typhoid vaccine, yellow fever, varicella, zoster and MMR can be administered at any time before or after BCG vaccination.

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.

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

Inform or refer to the clinician in charge.

Individuals known to have been screened in NHS England for SCID for whom a SCID not suspected result is unavailable should not be vaccinated under this PGD.

Individuals known to have been screened in NHS England for SCID but do not have a result, or are awaiting a repeat, should have vaccination postponed until a SCID not suspected result becomes available.

Temporary exclusion

In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.

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 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

BCG vaccine AJV (AJ vaccines) Powder and solvent for suspension for injection.

2.2. Route of administration

Intradermal only.

BCG vaccine is normally administered into the lateral aspect of the left upper arm at the level of the insertion of the deltoid muscle (just above the middle of the left upper arm – as recommended by WHO).

2.3. Dosage

0.05mL in infants under 12 months.

0.1mL for children aged 12 months or older and adults.

2.4. Frequency

Single dose.

2.5. Duration of treatment

Single dose.

2.6. Maximum or minimum treatment period

Single dose.

2.7. Quantity to supply/administer

Single dose.

2.8. ▼ black triangle medicines

No.

2.9. Legal category

Prescription only medicine (POM).

2.10. Is the use out with the SmPC?

Yes.

The SmPC suggests that if not given at the same time an interval of not less than four weeks should normally be allowed to lapse between administration of any two live vaccines. This is superseded by the tuberculosis chapter of the green book which states that live vaccines, such as rotavirus, live attenuated influenza vaccine (LAIV), oral typhoid vaccine, yellow fever, varicella, zoster and MMR can be administered at any time before or after BCG vaccination.

In accordance with the advice in the "Green Book, Chapter 32, BCG Vaccine AJV may be administered off-label to an infant born to an HIV positive mother only once the exclusively formula-fed infant is confirmed HIV uninfected at 12–14 weeks. Infants considered at low risk of HIV transmission (maternal VL <50 HIV RNA copies/mL at or after 36 weeks' gestation) but with a high risk of tuberculosis exposure may be given BCG Vaccine AJV off-label at birth.

Vaccine should be stored according to the conditions detailed below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS board guidance on storage and handling of vaccines. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed.

2.11. Storage requirements

The unreconstituted vaccine and its diluent should be stored in the original packaging at +2˚C to +8˚C and protected from light.

If the vaccine and/or diluent has been frozen, it must not be used.

The vaccine should be reconstituted with the diluent supplied by the manufacturer and used immediately. Unused reconstituted vaccine should be discarded after four hours. The vaccine is usable for up to four hours at room temperature after reconstitution.

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 off-label use or appropriate disposal.

2.12. Disposal

BCG vaccine waste should be disposed of in accordance with the recommendations for waste classified as potentially cytotoxic / cytostatic (in a purple-lidded container). Used needles/syringes should be disposed of in a small yellow bodied bin with a purple lid, all vials or unused vaccine disposed of in a blue bodied bin with a purple

lid and all other equipment including PPE used in its administration disposed of in a larger yellow bodied bin with a purple lid separate to sharps.

2.13. Additional information

No further immunisation should be given in the arm used for BCG immunisation for at least three months because of the risk of regional lymphadenitis.

It is important that premature infants have their immunisations at the appropriate chronological age, according to the schedule. The potential risk of apnoea and the need for respiratory monitoring for 48 to 72 hours should be considered when administering to very premature infants (born ≤28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.

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

3. Adverse reactions

3.1. Warnings including possible adverse reactions and management of these

Adverse reactions to the vaccine include headache, fever and enlargement of a regional lymph node to greater than 1cm, which may ulcerate.

Allergic reactions (including anaphylactic reactions), more severe local reactions such as abscess formation, and disseminated BCG complications (such as osteitis or osteomyelitis) are rare and should be managed by a specialist.

Severe injection site reactions, large, local discharging ulcers, abscesses and keloid scarring are most commonly caused by faulty injection technique, excessive dosage or vaccinating individuals who are tuberculin positive. It is essential that all health professionals are properly trained in all aspects of the process involved in tuberculin skin tests and BCG vaccination.

For full details/information on possible side effects, refer to the marketing authorisation holder's SmPC.

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 individual should be advised to seek medical advice.

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.
- Supply immunisation promotional material as appropriate.

Individual advice/follow up treatment:

- Inform the individual/carer of possible side effects and their management.
- 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

3.4. Observation following vaccination

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.

Following immunisation, patients remain under observation in line with NHS Board policy.

3.5. Follow up

See advice to patient/carer.

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:

- 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 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] chapter 32
- Current edition of British National Formulary (BNF) and BNF for children
- Marketing authorisation holder's Summary of Product Characteristics
- All relevant Scottish Government advice including the relevant CMO letter(s)
- Professional Guidance on the Administration of Medicines in Healthcare Settings 2019
- Professional Guidance on the Safe and Secure Handling of Medicines

7. PHS Version history

Version	Date	Summary of changes
1.0	September 2018	Version1.0 developed
2.0	June 2020	The following changes from version 1.0 of the PGD have been made: • Use outwith SmPC section updated to recommend assessment following inadvertent or unavoidable deviation from recommended storage conditions. • Storage section updated to include additional information on action required following inadvertent or unavoidable deviation from recommended storage conditions. • References section updated.
2.1	1 February 2021	The following changes from version 2.0 of the PGD have been made: • Inclusion section updated to recommend in the absence of a Mantoux tuberculin skin testing test, persons with negative IGRA results should only be given BCG in the absence of a BCG scar and in the absence of a reliable history of BCG vaccination.
2.2	1 September 2021	This PGD has undergone minor rewording, layout, formatting changes for clarity and consistency with other PHS national specimen PGDs. The following sections have been updated: • Exclusion section updated to include detail about (SCID) screening results (taken in NHS England). • Action if excluded section updated to include detail about (SCID) screening results (taken in NHS England).

Version	Date	Summary of changes
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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 Bacillus Calmette-Guerin (BCG) Vaccine AJV (AJ Vaccines) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 2.3

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 Bacillus Calmette-Guerin (BCG) Vaccine AJV (AJ Vaccines) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 2.3
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**