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 National PGD V2.2 by Medicines Management Specialist Nurse NHS Grampian	**Consultation Group**: See relevant page in the PGD	**Approver:** NoS PGD Group **Authorisation:** NHS Grampian

Signature:		**Signature:**

NoS Identifier: NoS/PGD/BCG/ MGPG1107	**Review Date:** 31 August 2024 **Expiry Date:** September 2024	**Date Approved:** February 2021

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 2.2.2 (Amended January 2024)

(Adapted from the Public Health Scotland PGD Template)

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	Adapted from Public Health Scotland national PGD for Administration of Bacillus Calmette-Guerin (BCG) vaccine AJV (AJ Vaccines) Version 2.2 Supersedes NoS/PGD/BCG/MGPG1107 Version 2.2.1

Date of change	**Summary of Changes**	**Section heading**
August 2020	Update of PGD following the release of version 2 Public Health Scotland national BCG PGD template.	
August 2020	Storage section updated to include additional information on action required following inadvertent or unavoidable deviation from recommended storage conditions.	Storage requirements
February 2021	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.	Inclusion criteria
February 2021	Exclusion section updated to re-format the bullet points.	Exclusion criteria
October 2021	Information regarding SCID test added as per national PHS PGD.	Exclusion criteria and Action if excluded from treatment
March 2022	Wording changed to include all healthcare professionals approved in current legislation that can operate under a PGD.	Professional qualifications and Authorisation of administration
April 2022	Minor amendment to Authorisation of Administration section due to omission of occupational therapist, orthoptist/prosthetists, radiographers and speech and language therapists to include all registered healthcare professionals that may be authorised to operate under this PGD.	Authorisation of administration
January 2024	Amended review date to keep in line with PHS expiry in September 2024	

NoS Identifier: NoS/PGD/BCG/MGPG1107
Keyword(s): PGD Patient Group Direction BCG vaccine AJV tuberculosis nurse midwife health visitor

Policy Statement: It is the responsibility of the individual healthcare professional and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

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.

Document:	Drafted:	August 2020
	Completed:	February 2021
	Approved:	February 2021 (published – February 2021)
	Amended and re-authorised:	October 2021, March 2022 and April 2022, February 2024

Organisational Authorisations

This PGD is not legally valid until it has had the relevant organisational authorisation.

PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr Maggie Watts **Health Board:** NHSO **Title:** Consultant of Public Health Medicine **Contact email:** Maggie.watts@nhs.scot **Signature** ..... **Date Signed:** 17/03/2022
Senior representative of the professional group who will provide care under the direction.	**Name:** Susan Duthie **Health Board:** NHSG **Title:** TB Nurse Specialist **Contact email:** susan.duthie@nhs.scot **Signature** ..... **Date Signature:** 04/04/2022
Lead author	**Name:** Frances Adamson **Health Board:** NHSG **Title :** Medicines Management Specialist Nurse **Contact email:** frances.adamson@nhs.scot **Signature** ..... **Date Signed:** 01/03/2022
Pharmacist	**Name:** Liam Callaghan **Health Board:** NHSWI **Title :** Chief Pharmacist **Contact email:** liam.callaghan@nhs.scot **Signature** ..... **Date Signed:** 17/03/2022

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		31/01/2024

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Adam Coldwells, Inter Chief Executive		02/02/2024

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

Name:	**Title:**
Frances Adamson	**Lead Author:** Medicines Management Specialist Nurse NHSG
Liam Callaghan	**Pharmacist:** Chief Pharmacist NHSWI
Dr Maggie Watts	**Medical Practitioner:** Consultant in Public Health Medicine NHSO
Susan Duthie	**Senior Representative:** Lead TB Specialist Nurse NHSG
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Russell Mackay	Clinical Specialist Pharmacist NHSO
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Clinical indication to which this PGD applies

Definition of situation/Condition	This Patient Group Direction (PGD) will authorise approved healthcare professionals to administer Bacillus Calmette-Guerin (BCG) vaccine AJV (AJ Vaccines) to individuals for the active immunisation against tuberculosis. This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), The Green Book Chapter 32, TRAVAX, NaTHNaC and individual Summary of Product Characteristics (SmPC).
Inclusion criteria	**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 or Interferon Gamma Release Assay (IGRA) 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 or IGRA tested** and vaccinated if negative • previously unvaccinated tuberculin or IGRA** 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), 2016) • previously unvaccinated, tuberculin or IGRA 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.†

	Individuals at occupational risk: • Unvaccinated, tuberculin or IGRA 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. Prior to the administration of the vaccine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy. † For country information on prevalence see: https://www.gov.uk/government/publications/tuberculosis-tb-by-country-rates-per-100000-people ***** 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. **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.
Exclusion criteria	Individuals: • Who have previously received BCG vaccine • With a past history of active or latent tuberculosis • Receiving anti-tuberculosis treatment • With a positive reaction following Mantoux (AJV) tuberculin skin testing: induration of 5mm or more following Mantoux (AJV) tuberculin skin testing • With a positive Interferon Gamma Release Assay (IGRA)

	• With a history of confirmed anaphylactic reaction to a component of the vaccine. Practitioners must check the marketing authorisation holder's SmPC • Who are children less than two years of age in a household where an active TB case is suspected or confirmed • 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: o Adults and children on high-dose corticosteroids (>40mg prednisolone per day or >2mg/kg/day in children under 20kg) for more than 1 week o Adults and children on lower dose corticosteroids (>20mg prednisolone per day or >1mg/kg/day in children under 20kg) for more than 14 days o 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 o 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 • Who are receiving or have received in the past 12 month's immunosuppressive biological therapy (e.g. anti-TNF therapy such as alemtuzumab, ofatumumab and rituximab) unless otherwise directed by a specialist • Receiving, or have received in the past 6 months, immunosuppressive therapy for a solid organ transplant • If there is a possibility the individual may receive immunosuppressive therapy in the next 6 months for an existing underlying condition, specialist advice should be sought • Who are infants under 6 months old born to a mother who received immunosuppressive biological therapy such as TNFα antagonists during pregnancy • Who are 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

	• With generalised infected skin conditions • With evolving neurological conditions – postpone immunisation until resolved or stabilised • With 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 • Where there is no valid consent.
Precautions and special warnings	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. 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. **NOTE:** 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.
Action if excluded from treatment	Medical advice must be sought – refer to relevant medical practitioner. If clarification is required about an individual meeting the exclusion criteria advice can be sought from the local Health Protection team.

	The risk to the individual of not being immunised must be taken into account. Discussion of the risk and benefits of vaccination should take place. Discussions and decisions taken should be documented in clinical records. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated at a later date and ensure another appointment is arranged. **Temporary exclusion** In case of postponement due to acute illness or fever, arrange a future date for immunisation. 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. Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.
Action if treatment is declined	Advise about the protective effects of the vaccine and the risk of infection and disease complications. Ensure they have additional reading material, e.g. the Patient Information Leaflet (PIL) available to print here. Document advice given and decision reached. Inform/refer to the relevant medical practitioner if individual/person with parental responsibility declines treatment. Document that the administration of the vaccine was declined, the reason and advice given in appropriate clinical records.

Description of vaccine available under the PGD

Name form and strength of vaccine	BCG vaccine AJV® (AJ vaccines) Powder and solvent for suspension for injection.
Legal status	BCG vaccine AJV® is a Prescription-only Medicine (PoM). 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 administrations 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, shingles and MMR vaccines can be administered at any time before or after BCG vaccination. In accordance with the advice in Chapter 32 of the "Green Book", 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. The use of the vaccine as detailed above is outside the terms of the marketing authorisation and constitutes an off-label use of the vaccine. The individual should be informed prior to the administration that the use is off-label.
Dosage/Maximum total dose	0.05mL in infants under 12 months 0.1mL for children aged 12 months or older and adults
Frequency of dose/Duration of treatment	Single dose
Maximum or minimum treatment period	N/A
Route/Method of administration	Administration of the vaccine must be intradermal. The preferred site is in the left arm, over the distal insertion of the deltoid muscle onto the humerus (approximately one third down on the lateral side of the upper arm). BCG Vaccine AJV® should be administered by personnel trained in the intradermal technique. This vaccine **should not be given** by the intravenous, intramuscular or subcutaneous routes under any circumstances. Only solvent provided with the BCG Vaccine AJV® should be used for reconstitution. The stopper must not be wiped with any antiseptic or detergent. If alcohol is used to swab the rubber stopper of the vial, it must be allowed to evaporate before the stopper is penetrated with the syringe needle. The vaccine should be visually inspected both before and after reconstitution for any foreign particulate matter prior to the

	administration. Using a syringe fitted with a long needle, transfer to the vial the volume of solvent given on the label. Carefully invert the vial a few times to re-suspend the lyophilised BCG completely. **Do Not Shake**. Gently swirl the vial of re-suspended vaccine before drawing up each subsequent dose. When drawn up into the syringe the vaccine suspension should appear homogeneous, slightly opaque and colourless. 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 **must** be given in different limbs to allow monitoring of local reactions to the BCG Vaccine AJV® and due to the risk of regional lymphadenitis. The site at which each vaccine was administered should be noted in the individual's records.
Quantity to be administered	0.05mL in infants under 12 months 0.1mL for children aged 12 months or older and adults
Storage requirements	Vaccine will be stored in a temperature controlled refrigerator between +2°C and +8°C. Refrigerators should have maximum and minimum temperatures recorded daily. Store in original packaging in order to protect from light. Vaccine should be stored according to the conditions detailed above. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS board guidance on storage and handling of vaccines or Health Protection Scotland vaccine incident guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed. Individual NHS Board guidance on the storage, handling and cold chain in relation to vaccines must be observed. Likewise, individual NHS Board guidance in relation to waste management and the disposal of all spent, partially spent or unused vaccines must also be observed.
Follow-up (if applicable)	Individuals should not leave if they are feeling unwell without speaking to the healthcare professional who administered the vaccine first. If necessary a doctor or the individuals GP should be contacted for advice.
Advice (Verbal)	Advise individual/person with parental responsibility what to expect and what to do for minor and major reactions.

	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. If serious adverse or persistent effects occur, the individual/person with parental responsibility should be advised to contact their GP/Accident and Emergency department/NHS24. When administration is postponed advise the individual/person with parental responsibility when to return for vaccination.
Advice (Written)	The PIL contained in the medicine(s) should be made available to the individual/person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand. Provide/refer to national leaflet BCG and your baby or Tuberculosis (TB) – The disease, its treatment and prevention. More information regarding this vaccine can be found at: https://www.nhsinform.scot/healthy-living/immunisation
Identifying and managing possible adverse reactions	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. 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. As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.

	This list is not exhaustive. Please also refer to current BNFC/BNF and manufacturers SmPC for details of all potential adverse reactions. **BNFC/BNF**: https://www.bnf.org/products/bnf-online/ **SmPC/PIL/Risk Minimisation Material:** https://www.medicines.org.uk/emc/ http://www.mhra.gov.uk/spc-pil/index.htm https://www.medicines.org.uk/emc/rmm-directory If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Report any severe reactions using the MHRA using the Yellow Card System https://yellowcard.mhra.gov.uk/.
Facilities and supplies required	The following are to be available at sites where the vaccine is to be administered: • Pharmaceutical refrigerator (or a validated cool box for storing vaccine if mobile unit) • An acceptable level of privacy to respect individual's right to confidentiality and safety • Basic airway resuscitation equipment (e.g. bag valve mask) • Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection • Access to a working telephone • Another competent adult, who can summon urgent emergency support if required should ideally be present • Access to medical support (this may be via the telephone) • Approved equipment for the disposal of used materials • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of this PGD in print or electronically.

Characteristics of staff authorised to administer vaccine under PGD

Professional qualifications	Those registered healthcare professionals that are listed and approved in legislation as able to operate under Patient Group Directions, as identified and included in individual Board immunisation delivery plans.
Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual's/person with parental responsibilities capacity to understand the nature and purpose of vaccination in order to give or refuse consent

	• Competent to undertake administration of the vaccine and discuss issues related to vaccination • Competent in the handling and storage of vaccines, and management of the "cold chain" • Competent to work under this PGD.
Ongoing training and competency	**All professionals working under this PGD must:** • Have undertaken PGD training as required/set out by each individual Health Board • Have undertaken immunisation training where available • Have attended basic life support training which is required to be updated annually • Have undertaken NHS e-anaphylaxis training or equivalent (including annual updates) which covers all aspects of the identification and management of anaphylaxis • Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct • Have knowledge and familiarity of the following; o Current edition of the Green Book o SmPC for the vaccine to be administered in accordance with this PGD o Relevant policy relating to vaccine storage and immunisation procedures for use within their Health Board o Relevant Scottish Government Health Directorate advice including the relevant CMO letter(s).
Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above. Maintain up to date record of all staff authorised to administer the vaccine specified in this direction.

Documentation

Authorisation of administration	Qualified healthcare professionals working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles listed and approved in legislation as able to operate under PGD can be authorised to administer the vaccine specified in this PGD in accordance with local delivery plans and by agreement at individual Board level as per the following:

	Nurses, midwives and health visitors can be authorised by their line manager. Pharmacists working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to administer the medicine(s) specified in this PGD when they have completed local Board requirements for service registration. The following list of healthcare professionals can be authorised by their Line Manager, Head of Service or Vaccine Coordinator: Chiropodists, dental hygienists, dental therapists, dieticians, occupational therapists, optometrists, orthoptists, orthotist/prosthetists, paramedics, physiotherapists, podiatrists, radiographers and speech and language therapists. 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.
Record of administration	An electronic or paper record for recording the screening of individuals and the subsequent administration, or not of the vaccine specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum: • Date and time of vaccine administration • Individuals name and CHI • Exclusion criteria, record why the vaccine was not administered (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, brand, dose, form, batch number, expiry date, route/site of the vaccination administered • Advice given, including advice given if excluded or declined treatment under this PGD • Signature and name in capital letters of the healthcare professional who administered the vaccine • Where childhood immunisations are given information of the administration must be provided to the GP Practice and Practitioner Services Division (PSD) for inclusion on the Scottish Immunisation Recall System (SIRS) • Record of any adverse effects (advise individuals GP/relevant medical practitioner). Depending on the clinical setting where administration is undertaken, the information should be recorded manually or

	electronically on the individual service specific system, as appropriate. • Child Health Information Services if appropriate • BadgerNet – Digital Maternity Notes • Hand–held records such as red book if appropriate • Individual's GP records if appropriate • Secondary Care Medical Notes • Occupational health systems • Individual service specific systems.
Audit	All records of the vaccine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.
References	Medicines and Healthcare Products Regulatory Agency http://www.mhra.gov.uk/spc-pil/ BCG vaccine AJV® – Date of revision of text 19/012/19 accessed 06/10/21. British National Formulary and British National Formulary for Children https://www.bnf.org accessed 06/10/21. Department of Health (2006): Immunisation against Infectious Disease [Green Book] https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book Department of Health (2006): Immunisation against Infectious Disease [Green Book] chapter 32 Tuberculosis https://www.gov.uk/government/publications/tuberculosis-the-green-book-chapter-32 American Academy of Pediatrics (2003) Active immunisation. In: Pickering LK (ed.) Red Book: 2003 Report of the Committee on Infectious Diseases, 26th edition. Elk Grove Village, IL: American Academy of Pediatrics, p 33.

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

Appendix 1

Healthcare Professional Agreement to Administer Vaccine Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the vaccine 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 2.2.2

I have completed the appropriate training to my professional standards enabling me to administer the vaccine 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 Vaccine 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 vaccine under this PGD is responsible for ensuring that he or she is 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 vaccine under this PGD is responsible for ensuring that he or she understands and is 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 his or her individual code of professional practice and conduct.
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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**