UK Health Security Agency

NHS

Publications gateway number: GOV-17151

BCG Vaccine AJV Patient Group Direction (PGD)

This PGD is for the administration of BCG Vaccine AJV to individuals up to 16 years of age, who are at increased risk of tuberculosis.

This PGD is for the administration of BCG Vaccine AJV by registered healthcare practitioners identified in section 3, subject to any limitations to authorisation detailed in section 2.

Reference no:	BCG Vaccine AJV PGD
Version no:	v5.00
Valid from:	22 August 2024
Review date:	31 March 2026
Expiry date:	31 August 2026

The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly funded immunisations in England in line with national recommendations.

Those using this PGD must ensure that it is organisationally authorised and signed in Section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2**.

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition, authorising organisations must not alter section 3 (Characteristics of staff). **Sections 2 and 7 can be amended within the designated editable fields provided, but only for the purposes for which these sections are provided, namely the responsibilities and governance of the NHS organisation using the PGD. The fields in section 2 and 7 cannot be used to alter, amend or add to the clinical content. Such action will invalidate the UKHSA clinical content authorisation which is provided in accordance with the regulations**.

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children. Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of UKHSA PGD templates for authorisation can be found from:
Immunisation patient group direction (PGD) templates

Any concerns regarding the content of this PGD should be addressed to:
immunisation@ukhsa.gov.uk

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: england.londonimms@nhs.net

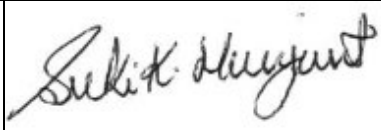
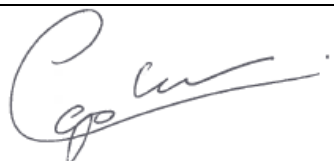
[1] This includes any relevant amendments to legislation

Change history

Version number	Change details	Date
v1.00 and v2.00	See earlier versions of this PGD for change details	23 August 2018 to 13 July 2021
v3.00	BCG Vaccine AJV PGD amended to: • include information in the inclusion and exclusion criteria, actions if excluded and additional information in relation to SCID screening • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	13 July 2021
v4.00	BCG Vaccine AJV PGD amended to: • include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change, gateway requirements and other UKHSA PGDs • amend NHS England and NHS Improvement (NHSEI) to NHSE following completion of merger on 1 July 2022 • add facilities for management of anaphylaxis in cautions • delete risk of apnoea in premature infants in cautions • add use of vaccine during breastfeeding in off-label • update name, route of administration and special considerations as per current SPC • add management of individuals with severe local reactions in identification and management of adverse reactions • add Green Book Chapter 32 advise in reporting procedures for adverse reactions • add signposting to accessible information in written information provided • update key references	26 July 2023
v5.00	BCG Vaccine AJV PGD amended to: • update off-label and route and administration sections in accordance with **UKHSA Briefing Note 2024/034** with reference to the type of needle to be used, as 26G bevelled needles have been discontinued by the manufacturer • added stability of vaccine after reconstitution in storage section • include minor rewording of standard text, layout and formatting changes for clarity and consistency with other UKHSA PGDs • reflect updated Expert Panel • update key references	22 August 2024

1. PGD development

This PGD has been developed by the following health professionals on behalf of UKHSA:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Suki Hunjunt Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA		21 August 2024
Doctor	Dr Colin NJ Campbell Consultant Medical Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		21 August 2024
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation, Immunisation and Vaccine Preventable Diseases Division, UKHSA		21 August 2024

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD and Protocol Policy. It has been ratified by the UKHSA Medicines Governance Committee.

Expert Panel

Dr Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Dr Gayatri Amirthalingam	Deputy Director and Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Alison Campbell	Screening and Immunisation Coordinator, Public Health Commissioning NHS England (NHSE) Midlands
Jane Freeguard	Deputy Director of Vaccination – Medicines & Pharmacy, NHSE
Rosie Furner	Specialist Pharmacist - Medicines Governance, Patient Group Directions and Medicines Mechanisms, NHS Specialist Pharmacist Services (SPS)
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Primary Care Based, Southbourne Surgery
Gemma Hudspeth	Senior Health Protection Practitioner, North East Health Protection Team Regions Directorate, UKHSA
Michelle Jones	Principal Medicines Optimisation Pharmacist, Bristol North Somerset and South Gloucestershire Integrated Care Board
Jacqueline Lamberty	Medicines Governance Consultant Lead Pharmacist, UKHSA
Shamez Ladhani	Paediatric Infectious Disease Consultant, UKHSA
Elizabeth Luckett	Senior Screening and Immunisation Manager, NHSE South West
Dr Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Lesley McFarlane	Lead Immunisation Nurse Specialist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Tushar Shah	Lead Pharmacy Adviser, NHSE London

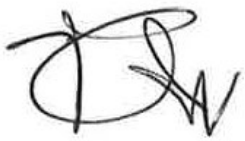
2. Organisational authorisations

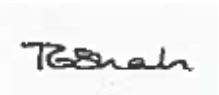
The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

NHS England – London authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
This PGD must only be used by specified registered healthcare professionals working for providers that are directly commissioned by NHS England - London, or who are administering vaccinations as part of a national immunisation programme, and who have been named and authorised to practice under it.
Limitations to authorisation
None

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Chief Nurse, NHS England - London	Jane Clegg		05/09/2024

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Director of Nursing Leadership and Quality, NHS England – London	Gwen Kennedy		02/09/2024
Lead Pharmacy Adviser, NHS England – London	Tushar Shah		02/09/2024

Local enquiries regarding the use of this PGD may be directed to england.londonimms@nhs.net

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy, but this should be an individual agreement, or a multiple practitioner authorisation sheet as included at the end of this PGD.

3. Characteristics of staff

Qualifications and professional registration	**All practitioners should only administer vaccinations where it is within their clinical scope of practice to do so. Practitioners must also fulfil the additional requirements and continued training requirements to ensure their competency is up to date, as outlined in the sections below.** Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: this PGD is not relevant to privately provided community pharmacy services) • paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC) Check Section 2 (Limitations to authorisation) to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
Additional requirements	Additionally, 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 administering BCG using a correct intradermal injection technique • 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	Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation with BCG and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD). Practitioners should be constantly alert to any subsequent recommendations from UKHSA, NHSE 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.

4. 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 up to 16 years of age for the prevention of human tuberculosis (TB) in accordance with the national selective immunisation programme and recommendations given in Chapter 32 of Immunisation Against Infectious Disease: the Green Book.
Criteria for inclusion	BCG vaccine is licensed for administration from birth; however BCG vaccination should be postponed in those screened for severe combined immunodeficiency (SCID) until the screening result is available and reports that 'SCID not suspected' in accordance with JCVI recommendations. Providers are required to check the record for a negative SCID result where SCID screening is offered, or confirmation that the child was not offered SCID screening, before administering the BCG vaccine. Previously unvaccinated individuals living in an area of the UK where the annual incidence of TB is 40/100,000 or greater who: • are aged up to 12 months of age Previously unvaccinated individuals, with a parent or grandparent who was born in a country[2] where the annual incidence of TB is 40/100,000 or greater, who: • are aged up to 12 months of age • are aged one to five years (these children should be identified at suitable opportunities, and can normally be vaccinated without tuberculin or Interferon Gamma Release Assay (IGRA) testing providing they are not a household or equivalent close contact of TB) • are aged from six years to under 16 years and are tuberculin or IGRA[3] negative (these children should be identified at suitable opportunities, tested and vaccinated if negative) Individuals aged under 16 years who are previously unvaccinated and tuberculin or IGRA[3] negative and who: • are household or equivalent close contacts of cases of sputum smear-positive pulmonary or laryngeal TB • 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 Note: Vaccination with BCG for occupational risk or travel (see Chapter 32 for further detail) is not covered by this PGD and individuals should be directed to their occupational health service provider or an appropriate travel health service respectively.
Criteria for exclusion[4] (continued over page)	Individuals who have not given valid consent (or for whom a 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).

[2] For country information on prevalence see: https://www.gov.uk/government/publications/tuberculosis-tb-by-country-rates-per-100000-people

[3] In the absence of a Mantoux tuberculin skin 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.

[4] 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.

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

Criteria for exclusion
(continued)
	Individuals who:
	• have had a confirmed anaphylactic reaction to a component of the vaccine
	• are 16 years of age or over
	• are awaiting a SCID screening result or where a repeat is needed, until the result is available and reports that 'SCID not suspected'
	• have a SCID screening result reported as 'SCID SUSPECTED'
	• are suffering from malignant conditions (such as lymphoma, leukaemia, Hodgkin's disease or other tumours of the reticulo-endothelial system)
	• have primary or secondary immune-deficiencies or who are HIV positive
	Note: Infants born to mothers living with HIV should only be given BCG vaccination when the exclusively formula-fed infant is confirmed HIV uninfected at 12–14 weeks. However, 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 earlier.
	• are receiving or have received in the past 6 months:
	  ○ immunosuppressive chemotherapy or radiotherapy for malignant disease or non-malignant disorders
	  ○ immunosuppressive therapy for a solid organ transplant
	• are receiving or have received in the past 12 months:
	  ○ immunosuppressive biological therapy (for example anti-TNF therapy such as alemtuzumab, ofatumumab and rituximab)
	• are receiving or have received in the past 3 months immunosuppressive therapy including:
	  ○ high-dose corticosteroids (>40mg prednisolone per day or >2mg/kg/day in children under 20kg) for more than 1 week
	  ○ lower dose corticosteroids (>20mg prednisolone per day or >1mg/kg/day in children under 20kg) for more than 14 days
	  ○ non-biological oral immune modulating drugs, such as methotrexate, azathioprine or 6-mercaptopurine, except those on low doses, see Chapter 6 of the Green Book, specialist advice should be sought prior to vaccination
	• are infants born to a mother who received immunosuppressive biological therapy during her pregnancy or breastfeeding, for as long as a postnatal influence on the immune status of the infant remains possible
	• have already had a BCG vaccination
	• have a past history of active or latent TB
	• are tuberculin positive (such that they have an induration of 5mm or more following Mantoux tuberculin skin testing)
	• have a positive Interferon Gamma Release Assay (IGRA)
	• are receiving anti-tuberculosis drugs
	• are less than 2 years of age and in a household where an active TB case is suspected or confirmed, until potential latent TB in the infant or child is excluded from 6 weeks post exposure (see Additional information)
	• are pregnant
	• have a generalised septic skin condition
	• are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)

Cautions including any relevant action to be taken	Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book) and advice issued by the Resuscitation Council UK.

Cautions including any relevant action to be taken (continued)	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. Breastfeeding is not a contraindication to BCG vaccination (see Off-label section). Specialist advice should be sought 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. It is important that premature infants have their immunisations at the appropriate chronological age, according to the schedule. Administering the vaccine too deep increases the risk of discharging ulcer, lymphadenitis and abscess formation. 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 individual is excluded (continued over page)	If 16 years of age and over, BCG vaccination is not usually recommended unless the risk of exposure is great (such as those at occupational risk through direct clinical contact with a patient diagnosed with TB or contact with infectious TB materials). Such individuals should be appropriately referred, for example to their occupational health service provider. Individuals screened for SCID for whom a 'SCID not suspected' result is unavailable should not be vaccinated under this PGD. Individuals who have been screened for SCID but do not yet have a result, or are awaiting a repeat, should be booked in for immunisation once a 'SCID not suspected' result becomes available. Individuals with a 'SCID SUSPECTED' screening result should not be vaccinated under this PGD. These children will be referred for a specialist immunology review and urgent investigations undertaken. The GP and Health Visitor will be alerted to the outcome. They should only be offered BCG vaccine once there is an explicit instruction to do so, and in accordance with a PSD. Note: Individuals for whom SCID screening has been declined or for whom SCID screening is not offered may be clinically assessed for BCG vaccination under this PGD. Individuals who may be immunosuppressed through disease or treatment, including those suffering from malignant conditions, primary or secondary immune-deficiencies or who are HIV positive should not receive BCG vaccination unless their immune status resolves and they fulfil the criteria for inclusion. Immunisation with BCG should be delayed for 6 months in children born of mothers who were on immunosuppressive biological therapy during pregnancy. If there is any doubt as to whether an infant may be immunosuppressed due to the mother's therapy, including exposure through breastfeeding, specialist advice should be sought. Individuals with a past history of active or latent TB, prior BCG vaccination, a positive Mantoux tuberculin skin test (induration of 5mm or more) or a positive IGRA result should be advised that they do not require BCG vaccination as there is an increased risk of adverse reactions and there is no evidence that repeat BCG offers additional protection.

Action to be taken if the individual is excluded (continued)	Individuals receiving anti-tuberculosis drugs (such as for chemoprophylaxis) should have vaccination postponed until latent TB infection is excluded. Note: BCG vaccination is contraindicated in individuals with TB or a past history of TB. Individuals less than 2 years of age in a household where an active TB case is suspected or confirmed should receive chemoprophylaxis and be tuberculin and/or IGRA tested after 6 weeks to exclude latent TB prior to BCG vaccination. BCG vaccination is not recommended during pregnancy and vaccination should be postponed until after the pregnancy. Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered; immunisers should advise when the individual can be vaccinated and ensure another appointment is arranged. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in the individual's clinical records. Inform or refer to the GP or a prescriber as appropriate.
Action to be taken if the individual 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 the 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 the Green Book Chapter 2. Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and potential complications. Document the advice given and the decision reached. Inform or refer to the individual's GP or a prescriber as appropriate.
Arrangements for referral for medical advice	As per local policy

5. Description of treatment

Name, strength and formulation of drug	BCG Vaccine AJV, powder and solvent for suspension for injection. Mycobacterium bovis BCG (Bacillus Calmette-Guerin), Danish strain 1331, live attenuated. This is a multidose container. One vial of reconstituted vaccine contains 1 ml, corresponding to 10 declared doses (of 0.1 ml) for individuals aged 12 months and over or 20 declared doses (of 0.05 ml) for infants under 12 months of age. These are declared number of doses and not the actual number of doses that can be removed in practice. The extractable number of doses that can be removed from the vial of reconstituted BCG Vaccine AJV depends on the specific type of syringe and needle used as well as on the surplus of vaccine removed by the individual vaccine administrator during vaccination. After reconstitution, 1 dose (0.1 ml) for individuals aged 12 months and over contains: • *Mycobacterium bovis* BCG (Bacillus Calmette- Guérin), Danish strain 1331, live attenuated, 2-8 x 10^5 cfu. After reconstitution, 1 dose (0.05 ml) for infants under 12 months of age contains: • *Mycobacterium bovis* BCG (Bacillus Calmette- Guérin), Danish strain 1331, live attenuated, 1-4 x 10^5 cfu.
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	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 earlier off-label. Administration of a live vaccine within 4 weeks of BCG Vaccine AJV is off-label but in accordance with the recommended intervals between vaccines in Chapter 11 of the Green Book. The SPC states that vaccination of the mother is not recommended during lactation, however, the vaccination can be given to females during breast-feeding in accordance with the Green Book Chapter 32. The SPC states that the vaccine should be administered with a 1ml syringe (1/100) that is fitted with a short bevel needle (25G/0.50 mm or 26G/0.45 mm). However, in accordance with the UKHSA Briefing Note, a short 25 or 26G needle between 9 to 12mm in length with either a short (preferred) or normal bevel should be used (see route and method of administration section below). Vaccines 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. Where vaccines are 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

(continued over page)

Off-label use (continued)	is being offered in accordance with national guidance but outside of product licence.
Route and method of administration	BCG Vaccine AJV is administered strictly by the intradermal route, only by those suitably trained and competent to do so (see Section 3, Characteristics of staff). See the Green Book Chapter 32 and the manufacturer's SPC for further details on the intradermal administration technique. The vaccine's normal appearance is a white powder in a vial (which might be difficult to see due to the small amount of powder in the vial) and a clear colourless solvent in a vial without any visible particles. Following reconstitution, the vaccine is a colourless, slightly opaque, homogenous 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, do not administer the dose and discard the vaccine in accordance with local procedures. The multidose vial of BCG Vaccine AJV must be reconstituted prior to administration. Only solvent provided with the BCG Vaccine AJV should be used for reconstitution. Using a syringe fitted with a long needle which is included in the packaging, transfer to the vial the volume of solvent given on the label in accordance with the manufacturer's instructions. Carefully invert the vial a few times to resuspend the lyophilised BCG completely. **Do not shake**. Gently swirl the vial of resuspended vaccine before drawing up each subsequent dose. The injection site should be clean and dry. If the skin is visibly dirty, it should be washed with soap and water. The vaccine 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. To ensure correct intradermal administration, the needle size is important. The vaccine is administered through either a specific tuberculin syringe or, alternatively, a 1ml syringe sub-graduated into hundredths of ml (1/100 ml), fitted with a 25G or 26G needle between 9-12mm in length with either a short (preferred) or normal bevel, for each individual. The correct dose of BCG vaccine should be drawn into the tuberculin syringe and the needle attached to give the injection. The needle must be attached firmly, and the intradermal injection administered with the bevel facing up. BCG vaccine must be administered strictly by intradermal injection, normally 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 – the left arm is recommended by WHO) (see Green Book Chapter 4 for further information). Sites higher on the arm, and particularly the tip of the shoulder, are more likely to lead to keloid formation and should be avoided. The vaccine should be used immediately after reconstitution. Constituted vaccine should be used within 4 hours. Any unused vaccine or waste material should be disposed of in accordance with local requirements. The vaccine's SPC provides full guidance on preparation and administration.
Dose and frequency of administration	A single intradermal dose of: 0.05ml for infants under 12 months of age 0.1ml for individuals aged 12 months and over

Duration of treatment	A single dose.
Quantity to be supplied and administered	A single dose.
Supplies	Centrally purchased vaccines for individuals at increased risk of tuberculosis can be ordered via ImmForm. Vaccines for use in accordance with this PGD are provided free of charge. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book, Chapter 3).
Storage	Store between +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. From a microbiological point of view, the product should be used immediately after reconstitution. In-use stability in terms of viability has been demonstrated for 4 hours after reconstitution. Any unused vaccine or waste material should be disposed of in accordance with local requirements. 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 manufacturer where more specific advice is required about managing temperature excursions. BCG Vaccine AJV should be reconstituted with the diluent supplied by the manufacturer in the container and used immediately. Reconstituted vaccine may be used for up to 4 hours at room temperature, after which time any unused reconstituted vaccine should be discarded.
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). Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe, should be disposed of safely in a UN-approved puncture-resistant sharps box, according to local authority regulations and NHSE guidance (HTM 07-01): safe and sustainable management of healthcare waste.
Drug interactions	May be given at the same time as other vaccines, including other live vaccines which can also be administered at any time before or after BCG vaccination (for full details, see Chapter 11 of the Green Book). Other vaccines to be given at the same time as BCG Vaccine AJV should not be given into the same arm. No further vaccination should be given in the arm used for BCG vaccination for 3 months because of the risk of regional lymphadenitis. A detailed list of drug interactions associated with BCG Vaccine AJV is available from the product's SPC.
Identification and management of adverse reactions (continued over page)	The expected reaction to successful vaccination with BCG Vaccine AJV includes induration at the injection site followed by a local lesion that may ulcerate some weeks later and heal over some months leaving a small, flat scar. A local site reaction may include erythema and tenderness. It also may include enlargement of a regional lymph node to less than 1 cm. Other side-effects are uncommon but may include headache and fever.

Identification and management of adverse reactions (continued)	Individuals with severe local reactions (ulceration greater than 1cm, caseous lesions, abscesses or drainage at the injection site) or with regional suppurative lymphadenitis with draining sinuses following BCG vaccination should be referred to a TB physician or paediatrician for investigation and management. An excessive response to the BCG Vaccine AJV may result in a discharging ulcer. This may be attributable to inadvertent subcutaneous injection or to excessive dosage. The ulcer should be encouraged to dry and abrasion (by tight clothes, for example) should be avoided. Expert advice should be sought regarding the appropriate treatment regimen for the management of systemic infections or persistent local infections following vaccination with BCG Vaccine AJV. Hypersensitivity 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. A detailed list of adverse reactions associated with BCG Vaccine AJV is available from the product's SPC.
Reporting procedure of adverse reactions	Healthcare professionals, 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. All serious or unusual adverse reactions possibly associated with BCG vaccination (including abscess and keloid scarring) should be recorded and reported through the Yellow Card scheme, and vaccination techniques should be reviewed. Every effort should be made to recover and identify the causative organism from any lesion constituting a serious complication. 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 individual or carer	Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. 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. Immunisation promotional material may be provided as appropriate: • A guide to immunisation for babies up to 13 months of age • TB, BCG and your baby leaflet
Advice and follow up treatment (continued over page)	Inform the individual, parent or carer of possible side effects and their management. Advise the individual, parent or carer of the expected site reaction to successful BCG vaccination which includes: • a slight swelling, redness and tenderness at the injection site followed by a local lesion • some weeks later this lesion evolves into a small ulcer • after some months, this ulcer will heal leaving a small, flat scar • a slight swelling of the lymph nodes in the armpit may be experienced

Advice and follow up treatment (continued)	Advise the individual, parent or carer that it is not necessary to protect the site from becoming wet during washing and bathing. The injection site is best left uncovered to facilitate healing. The ulcer should be encouraged to dry, and abrasion (by tight clothes, for example) should be avoided. Should oozing occur, a temporary dry dressing may be used until a scab forms. It is essential that air is not excluded. If absolutely essential (for example, to permit swimming), an impervious dressing may be used but it should be applied only for a short period as it may delay healing and cause a larger scar. The possibility of bacterial superinfection in a discharging lesion should be considered. Inform the individual, parent, carer that other immunisations are not recommended to be given in the same arm for 3 months following BCG vaccination. The individual, parent or carer should be advised to seek medical advice if the lesion looks like it may have become infected. When administration is postponed, advise the individual, parent or carer when to return for vaccination.
Special considerations and additional information (continued over page)	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. 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. There are few data on the protection afforded by BCG vaccine when it is given to adults (aged 16 years or over), and virtually no data for persons aged 35 years or over. BCG is not usually recommended for people aged over 16 years, unless the risk of exposure is great (such as healthcare or laboratory workers at occupational risk through direct clinical contact with a patient diagnosed with TB or contact with infectious TB materials). Such individuals are not eligible for management under this PGD and should be referred appropriately. Evidence of a previous BCG vaccination includes: documentary evidence, a clear and reliable history of vaccination, or evidence of a characteristic scar. Individuals with an uncertain history of prior BCG vaccination should be tuberculin or IGRA tested before being given BCG vaccine (see Chapter 32). In the absence of a Mantoux tuberculin skin test, individuals 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. Household contact or contacts with exposure equivalent to that of household contacts or equivalent contacts of cases of sputum smear-positive pulmonary or laryngeal TB should be managed in line with NICE guidance. Individuals less than 2 years of age who have contact with a smear-positive case of pulmonary or laryngeal TB should be given

Special considerations and additional information (continued)	chemoprophylaxis immediately, even if their initial tuberculin skin test is negative and then tuberculin tested after 6 weeks. If the skin test is negative, BCG vaccine should be given. Newborn babies who are contacts of a non-infectious TB case should be immunised with BCG at the earliest opportunity and, if screened for SCID, as soon as a SCID screening result is available and reports that 'SCID not suspected.'
Records	The practitioner must ensure the following is recorded: • that valid informed consent was given or a decision to vaccinate was 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 the individual is 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. This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting, appropriate health records should be kept and the individual's GP informed. The local Child Health Information Services team must be notified 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.

6. Key references

Key references	**BCG Vaccine AJV** • Immunisation Against Infectious Disease: The Green Book Chapter 32: Tuberculosis, updated 3 August 2018 and Chapter 11: The UK Immunisation Schedule, updated 11 March 2022. www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • UKHSA Briefing Note. Supply of needles for the BCG Vaccination Programme, Serial number 2024/034, created 22 August 2024 • NICE guideline (NG33): Tuberculosis. Last updated 16 February 2024 www.nice.org.uk/guidance/NG33 • Summary of Product Characteristics for BCG Vaccine AJV, AJ Vaccines, last updated 19 October 2023, www.medicines.org.uk/emc/product/9890 • BCG immunisation programme: changes from September 2021 letter, published 27 July 2021 www.gov.uk/government/publications/bcg-immunisation-programme-changes-from-september-2021-letter/bcg-immunisation-programme-changes-from-september-2021-letter • UKHSA Vaccine Update, issue 327, May 2022 Vaccine update Issue 327-May 2022 SCID and TB **General** • NHSE Health Technical Memorandum 07-01: safe and sustainable 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 7 February 2018. www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published 27 March 2017. www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated 27 March 2017. www.nice.org.uk/guidance/mpg2/resources • UKHSA Immunisation Collection. www.gov.uk/government/collections/immunisation • Vaccine Incident Guidance, last updated 7 July 2022 www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

7. Practitioner authorisation sheet

BCG Vaccine AJV PGD v5.00 Valid from: 22 August 2024 Expiry: 31 August 2026

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

Practitioner

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

PGDs 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 PGD 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 the following named organisation ……. 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.