This patient group direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction (PGD)

For the administration of

BCG Vaccine AJV

By registered health care professionals for

Individuals up to 16 years of age, who are at increased risk of tuberculosis

Throughout the Manx Care and those contracted by the Manx Care where appropriate within practice

PGD NUMBER 10

1. Change History

Version number	Change Details	Date
V1.00	New PHE PGD	23/08/2018

V2.00	BCG Vaccine AJV PGD amended to: • remove reference to the protocol for storage and handling of vaccines • remove reference to 'Revised recommendations for the administration of more than one live vaccine (PHE 2015)' and reference Chapter 11 of the 'Green Book' • update references • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	16/05/2020
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	13/07/2021
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	26/07/2023

2. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care PGD website FAQs

3. PGD development

Refer to the NICE PGD competency framework for people developing PGDs

Job Title & organisation	Name	Signature	Date
Author of the PGD			
Member of the PGD working group			

4. PGD authorisation

Refer to the NICE PGD competency framework for people authorising PGDs

Pre Signatures			
Job Title	**Name**	**Signature**	**Date**
Pharmaceutical Adviser			
Head of Ambulance Services			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)	N/A	N/A	N/A
Final signatures			
Medical Director			
Director of Nursing			

5. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the NICE PGD competency framework for health professionals using PGDs

	Requirements of registered Healthcare professionals working under the PGD
Qualifications and profession al registration	Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy The practitioners above must also fulfil the Additional requirements detailed below. Check Section 2 Limitations to authorisation to confirm whether all practitioners listed above have organisational authorisation to work under this PGD. Additionally practitioners: • 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 in administering BCG using a correct intradermal injection technique • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the 'cold chain' • must be competent in the recognition and management of anaphylaxis • must have access to the PGD and associated online resources **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.**
Initial training	• Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria • Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD • Local training in the use of PGDs
Competency assessment	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGDs

Ongoing training and competency	The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years.

6. Clinical Conditions

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'
Inclusion criteria *(continued)*	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[1] 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[2] 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 IGRA3 negative and who: • are household or equivalent close contacts of cases of sputum

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

[2] 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.

Inclusion criteria *(continued)*	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.
Exclusion criteria[3] [4] *(continued)*	Individuals for whom no valid consent has been received. 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: o immunosuppressive chemotherapy or radiotherapy for malignant disease or non-malignant disorders o immunosuppressive therapy for a solid organ transplant • are receiving or have received in the past 12 months: o 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: o high-dose corticosteroids (>40mg prednisolone per day or >2mg/kg/day in children under 20kg) for more than 1 week

[3] 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.

[4] 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.

Exclusion criteria *(continued)*	○ 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/child is excluded from 6 weeks post exposure (see Special considerations and additional information section) • are pregnant • have a generalised septic skin condition
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. • 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 (see Off-label section), 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. • 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.
Arrangements for referral for medical advice	Patient should be referred to a more experienced clinical practitioner for further assessment

Action to be taken if patient excluded *(continued)*	• 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. • 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. • 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

Action to be taken if patient excluded *(continued)*	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 patient declines treatment	• A verbal explanation should be given to the patient on: the need for the medication and any possible effects or potential risks which may occur as a result of refusing treatment • This information must be documented in the patients' health records • Any patient who declines care must have demonstrated capacity to do so (see the Manx Care Policy for Capacity, Best Interests Decisions and Deprivation of Liberty) • Where appropriate care should be escalated • Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration

7. Details of the medicine

Name, form and strength of medicine	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
Indicate any off-label use (if relevant)	• 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. • Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD • Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.
Route/method of administration *(continued)*	• 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 particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine. • 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 suspend the lyophilised

Route/method of administration *(continued)*	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 sub-graduated into hundredths of ml (1/100 ml) syringe, fitted with a 26G 10mm (0.45mm x 10mm) short bevelled needle[5] for each individual. The correct dose of BCG vaccine should be drawn into the tuberculin syringe and the 26G short bevelled 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). 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 administration and is available from: electronic Medicines Compendium website
Dose and frequency	A single intradermal dose of: • 0.05ml for infants under 12 months of age • 0.1ml for individuals aged 12 months and over
Quantity to be administered	A single dose
Maximum or minimum treatment period	A single dose

[5] The product literature states that a 25G/0.50 mm or 26G/0.45 mm short bevel needle may be used. However, the 'Green Book' recommendations are specifically to use a 26G, 10mm (brown) needle.

Storage	• Store at +2°C to +8°C. • Store in original packaging to protect from light. • Do not freeze. • 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, refer to PHE Vaccine Incident Guidance • BCG Vaccine AJV should be reconstituted with the diluent supplied by the manufacturer (Diluted Sauton AJV) and used immediately. Reconstituted vaccine may be used for up to four hours at room temperature, after which any unused reconstituted vaccine should be discarded.
Adverse effects *(continued)*	• 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. • 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 is available in the vaccine's SPC, which is available from: electronic Medicines Compendium website **Reporting procedure of adverse reactions** • Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme: Yellow Card reporting scheme or

Adverse effects *(continued)*	search 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.
Records to be kept	The administration of any medication given under a PGD must be recorded within the patients' medical records Please see Appendix C for more details

8. Patient information

Verbal/Written information to be given to patient or carer	• Verbal information must be given to patients and or carers for all medication being administered under a PGD • Where medication is being supplied under a PGD, written patient information leaflet must also be supplied • A patient information leaflet is available on request Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Immunisation promotional material may be provided as appropriate: • Immunisations up to 13 months of age • TB, BCG and your baby leaflet Available from: UKHSA Immunisation Collection
Follow-up advice to be given to patient or carer *(continued)*	• If symptoms do not improve or worsen or you become unwell, seek medical advice immediately • When administration is postponed advise the individual/carer/parent when to return for vaccination • The individual/parent/carer should be advised to seek medical advice if the lesion looks like it may have become infected Inform the individual/parent/carer of possible side effects and their management. Advise the individual/parent/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

Follow-up advice to be given to patient or carer *(continued)*	• 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 Advise the individual/parent/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 any oozing occur, a temporary dry dressing may be used until a scab forms. It is essential that air is not excluded. If absolutely essential (eg 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. 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/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/carer when to return for vaccination.

9. Appendix A

References

1. British National Formulary (BNF) available online: https://bnf.nice.org.uk
2. Nursing and Midwifery "The code" available online: https://www.nmc.org.uk
3. Current Health Care Professions Council standards of practice
4. General Pharmaceutical Council standards
5. Electronic medicines compendium available online: https://www.medicines.org.uk
6. Manx Care Policy for Capacity, Best Interests Decisions and Deprivation of Liberty http://edrmgi/sites/hospital/Clinical%20Policies%20and%20Procedures/Policy%20for%20Capacity,%20Best%20Interests%20Decisions%20and%20Deprivation%20of%20Liberty.pdf#search=deprivation

BCG Vaccine AJV

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- NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017.
  www.nice.org.uk/guidance/mpg2/resources
- UKHSA Immunisation Collection. www.gov.uk/government/collections/immunisation
- Vaccine Incident Guidance.
  www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

10. Appendix B

Health professionals agreed to practice
• Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor • A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves

11. Appendix C

Special considerations/ additional information *(continued)*	• 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

Special considerations/ additional information *(continued)*	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, 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 two years of age who have contact with a smear-positive case of pulmonary or laryngeal TB should be given chemoprophylaxis immediately, even if their initial tuberculin skin test is negative and then tuberculin tested after six weeks. If the skin test is negative, BCG vaccine should be given.
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 guidance in the technical memorandum 07-01: Safe management of healthcare waste (NHSE, 2022).
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 (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. It is advisable not to give further vaccination in the arm used for BCG vaccination for 3 months because of the risk of regional lymphadenitis. • A detailed list of drug interactions is available in the SPC, which is available from: electronic Medicines Compendium website

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)
Records	• that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via PGD Records should be signed and dated (or a password-controlled immuniser's record 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 Systems team (Child Health Records Department) must be notified using the appropriate documentation/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