Bacillus Calmette-Guerin (BCG) Vaccine

GG&C PGD ref no: 2018/1617

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

Clinical Condition

Indication:	Immunisation against tuberculosis
Inclusion criteria:	• Children and adults not previously vaccinated against tuberculosis and considered to be at elevated risk (refer to Green Book) • Parent/carer/patient consent

Exclusion criteria:	• Previous immunisation against tuberculosis
	• Past history of TB
	• Positive reaction to tuberculin skin testing
	• History of confirmed anaphylactic reaction to a component of the vaccine
	• Neonates in a household where an active TB case is confirmed or suspected
	• Patient is immunocompromised e.g. Receiving or has received in the past 3 months immunosuppressive therapy including:
	  • Adults and children on high-dose corticosteroids (>40mg prednisolone per day or >2mg/kg/day in children under 20kg) for more than 1 week
	  • Adults and children on lower dose corticosteroids (>20mg prednisolone per day or >1mg/kg/day in children under 20kg) for more than 14 days
	  • non-biological oral immune modulating drugs e.g. methotrexate >25mg per week, azathioprine >3.0mg/kg/day or 6-mercaptopurine >1.5mg/kg/day
	• Receiving, or have received in the past 6 months immunosuppressive chemotherapy or radiotherapy for malignant disease or non-malignant disorder
	• Receiving, or have received in the past 6 months immunosuppressive therapy for a solid organ transplant
	• Those who are receiving or have received in the past 12 month's immunosuppressive biological therapy (e.g. anti-TNF therapy such as alemtuzumab, ofatumumab and rituximab) unless otherwise directed by a specialist.
	• Patient is HIV +ve
	• Acute illness or fever, immunisation should be postponed until fully recovered
	• Patient with generalised infected skin conditions
	• Evolving neurological condition, immunisation should be deferred until resolved or stabilised
	• History of severe (i.e. anaphylactic reaction) to latex where

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	vaccine is not latex free. • Infants under the age of 6 months whose mothers have received immunomodulating biologics (such as monoclonal antibodies or receptor antagonists which interfere with the immune system e.g. anti-TNF agents) in pregnancy • Infants being breast fed by a mother receiving immunomodulating biologics (such as monoclonal antibodies or receptor antagonists which interfere with the immune system e.g. anti-TNF agents) until 6 months after cessation of breastfeeding • Non consent
Cautions/Need for further advice/Circumstances when further advice should be sought from the prescriber:	• Pregnancy • Other vaccines to be administered at the same time should not be given into the same arm • Live vaccines rotavirus, live attenuated influenza vaccine (LAIV), oral typhoid vaccine, yellow fever, varicella, zoster and MMR may be administered at any time before or after BCG
Action if patient declines or is excluded:	Refer to appropriate clinician e.g. GP, Travel Health Consultant, Sexual Health, GUM or ID Consultant. If declined advise regarding protective effect of immunisation and potential disease complications. Document advice given and refer to appropriate clinician.
Referral arrangements for further advice cautions:	As above

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Drug Details	
Name, form & strength of medicine:	M. bovis, BCG (live) (BCG Vaccine AJV Vaccines®)
Route/Method of administration:	Intradermal
Dosage (include maximum dose if appropriate):	• 0.05ml up to 12 months of age • 0.1 ml > 12 months
Frequency:	Once only
Duration of treatment:	NA
Maximum or minimum treatment period:	NA
Quantity to supply/administer:	NA
Supply, Administer or Both:	Administer only
▼ Additional Monitoring:*	Yes
Legal Category:	POM
Is the use outwith the SPC:**	Yes The SPC suggests that if not given at the same time an interval of not less than four weeks should normally be allowed to lapse between administration of any two live vaccines. This is superseded by the tuberculosis chapter of the green book which states that live vaccines, such as rotavirus, live attenuated influenza vaccine (LAIV), oral typhoid vaccine, yellow fever, varicella, zoster and MMR can be administered at any time before or after BCG vaccination
Storage requirements:	Store between 2^0C-8^0C in locked storage. NHS GG&C Vaccine Ordering, Storage and Handling Guidelines should be observed http://www.staffnet.ggc.scot.nhs.uk/Info%20Centre/PoliciesProcedures/GGCClinicalGuidelines/GGC%20Clinical%20Guidelines%20Electronic%20Resource%20Direct/Vaccine%20Ordering%20Storage%20and%20Handling%20Guideline.pdf Vaccine storage history e.g. temperature charts must be checked and deemed satisfactory before administration to patient.

***The black triangle symbol has now been replaced by European "additional monitoring (▼)**
** **Summary of Product Characteristics**

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Warnings including possible adverse reactions and management of these:	Please refer to current BNF, eBNF www.medicinescomplete.com or SPC for full details Use the Yellow Card System to report adverse drug reactions directly to the CMS. Yellow Cards and guidance on their use are available at the back of the BNF or online at http://yellowcard.mhra.gov.uk/ 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.
Advice to patient/carer including written information provided:	Explain expected reaction and care of immunisation site Give patient a copy of relevant patient information leaflet. PIL available at http://emc.medicines.org.uk/ Further Information available to patients at www.immunisationscotland.org.uk and www.fitfortravel.nhs.uk
Monitoring (if applicable):	NA
Follow up:	See advice to patient/carer

Staff Characteristics	
Professional qualifications:	Those registered health care professionals that are listed and approved in legislation as able to operate under patient group directions and have current registration.
Specialist competencies or qualifications:	Has undertaken appropriate training and competence to undertake immunisation including recognition and treatment of anaphylaxis Has undertaken appropriate training for working under PGDs for the supply and administration of medicines
Continuing education & training:	All health care professionals working under the direction will be expected to maintain their competence as specified in hospital, local and national policies e.g. Nursing & Midwifery Council guidelines. The practitioner should be aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual to keep up-to-date with continued professional development in all aspects of immunisation including recognition and treatment of anaphylaxis.

Referral Arrangements and Audit Trail	
Referral arrangements	As per local arrangements/national guidelines
Records/audit trail:	• Patient's name, address, date of birth and consent given • Contact details of GP (if registered) • Dose and form administered (batch details and expiry date) • Advice given to patient (including side effects) • Signature/name of staff who administered or supplied the medication, and also, if relevant, signature/name of staff who removed/discontinued the treatment • Details of any adverse drug reaction and actions taken including documentation in the patient's medical record • Referral arrangements (including self-care) • Administration must be recorded on the GP, Travel Health clinic or Primary Care clinic record as appropriate • Child immunisations should be recorded on the parent held record if possible

References/Resources and comments:	Notes: SPC – Summary of Product Characteristics http://emc.medicines.org.uk/ BNF – British National Formulary www.medicinescomplete.com TRAVAX www.travax.nhs.uk NMC (2010) Standards for Medicines Management NMC (2015) The NMC Code of Professional Conduct: standards for conduct, performance and ethics http://www.nmc-uk.org/ NHS GG&C Immunisation Best Practice Guideline http://www.staffnet.ggc.scot.nhs.uk/Info%20Centre/PoliciesProcedures/GGCClinicalGuidelines/GGC%20Clinical%20Guidelines%20Electronic%20Resource%20Direct/Immunisation%20Best%20Practice%20Guideline.pdf NHS GG&C Vaccine Ordering Storage and Handling Guidelines http://www.staffnet.ggc.scot.nhs.uk/Info%20Centre/PoliciesProcedures/GGCClinicalGuidelines/GGC%20Clinical%20Guidelines%20Electronic%20Resource%20Direct/Vaccine%20Ordering%20Storage%20and%20Handling%20Guideline.pdf Immunisation against Infectious Diseases (2006). DOH (green book) always refer to on-line version NHS HealthScotland website https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book http://www.healthscotland.com/topics/health/immunisation/index.aspx Health Protection Scotland Immunisation and Vaccine Preventable Diseases website http://www.hps.scot.nhs.uk/immvax/guidelines.aspx Immunisation Scotland www.immunisationscotland.org.uk Revised recommendations for the administration of more than one live vaccine PHE publications gateway number: 2014303 Published: September 2014 available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/353085/11092014_PHE_live_vaccine_interval_v3.pdf

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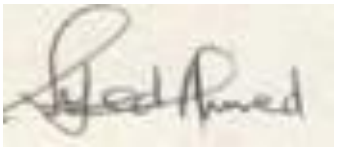
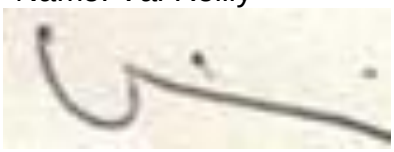
This Patient Group Direction must be agreed to and signed by all healthcare professionals involved in its use. The original signed copy will be held at PPSU, 1st Floor, Main Building, West Glasgow ACH. The PGD must be easily accessible in the clinical setting.

Organisation:	**NHS Greater Glasgow & Clyde**

Professionals drawing up PGD/Authors

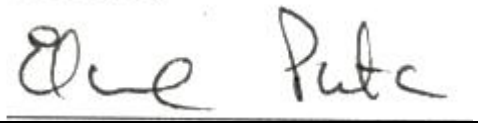
	Designation and Contact Details
Name : Dr Syed Ahmed  Signature: Date: 23/0/2018	Designation: Consultant in Public Health Medicine Public Health Protection Unit NHS GG&C E-mail address: syed.ahmed@ggc.scot.nhs.uk
*Name: Val Reilly  Signature: Date: 23/08/2018	Designation: Public Health Pharmacist E-mail address: val.reilly@ggc.scot.nhs.uk
Name: Hilda Crookshanks  Signature: Date:23/08/2018	Designation: Health Protection Nurse Specialist Public Health Protection Unit West House, NHSGGC E-mail address: Hilda.crookshanks@ggc.scot.nhs.uk

*** Lead Author**

AUTHORISATION:

NHSGG&C PGD & Non-medical Prescribing Sub-Committee of ADTC		
Chairman in BLOCK CAPITALS	**Signature:**	**Date:**
Dr Craig Harrow		**23/08/2018**

NHSGG&C PGD Sub-Committee of ADTC		
Professional Nurse Advisor, Primary Care in BLOCK CAPITALS	**Signature:**	**Date:**
Karen Jarvis		**23/08/2018**

Pharmacist representative of PGD & Non-Medical Sub-Committee of ADTC		
Name: in BLOCK CAPITALS	**Signature:**	**Date:**
Elaine Paton		**23/08/2018**

Antimicrobial use **If the PGD relates to an antimicrobial agent, the use must be supported by the NHS GG&C Antimicrobial Management Team (AMT). A member of this team must sign the PGD on behalf of the AMT.**		
Microbiology approval	Name:	Designation:
	Signature: (on behalf of NHS GG&C AMT)	Date:

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Local Authorisation:

Service Area for which PGD is applicable:			
I authorise the supply/administer medicines in accordance with this PGD to patients cared for in this service area.			
Lead Clinician for the service area (Doctor)			
Name:	**Signature:**	**Designation:**	**Date:**
E-Mail contact address:			

I agree that only fully competent, qualified and trained professionals are authorised to operate under the PGD. Records of nominated individuals will be kept for audit purposes.			
Name (Lead Professional)**:**	**Signature:**	**Designation:**	**Date:**
E-Mail contact address:			

Description of Audit arrangements:			
Frequency of checks: (Generally annually)		**Names of auditor(s):**	

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY.

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct.

Note to Authorising Managers: authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

I have read and understood the Patient Group Direction. I acknowledge that it is a legal document and agree to supply/administer this medicine only in accordance with this PGD.

Name of Professional	**Signature**	**Date**

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Patient Group Direction Audit Form
Form for the audit of compliance with PGD or PGDs

To ensure best practice all PGDs should be audited on a 6 monthly basis.

Name and post of Designated Lead person within each practice/clinic base:			
Location/Clinic Base: **Date of audit:**			
Tick as appropriate. If 'no', state action required	**Y**	**N**	**Action**
Is the PGD or PGDs utilised within the clinical area?			
Has the PGD or PGDs been reviewed within the 2 year limit?			
Do the managers listed on the PGD or PGDs hold a current list of authorised staff?			
Are all staff authorised to work under the PGD or PGDs members of one of the health professions listed in the PGD?			
Do all staff meet the training requirements identified within the PGD?			
Are you confident that all medicines supplied or administered under the PGD or PGDs are stored according to the PGD where this is specified?			
Do the staff working under the PGD or PGDs have a copy of the PGD which has governance sign off and is in date and, available for reference at the time of consultation?			
Where the medicine requires refrigeration. (Delete if not required).			
Is there a designated person responsible for ensuring that the cold chain is maintained?			
Is there a record that the fridge temperature has been monitored to required levels?			
If there is regular and sustained reliance on PGDs for service provision has a Non Medical Prescribing approach been considered as an alternative? (Please note reasons for either a Y/N response).			

Name:	Date of audit:

Keep copies of completed audits alongside your PGD for local reference.
Please retain at local level and ensure audit forms are readily available as they may be required for clinical governance audit purposes.