Administration of Tuberculin Purified Protein Derivative (PPD) 2TU per 0.1ml to patients attending BCG clinics with identified ‘TB at risk’ factors.

Special notes
- PPD is an unlicensed medicine and therefore a Patient Group Direction (PGD) is not possible
- A Patient Specific Direction (PSD) is used once a patient has been assessed by a prescriber and that prescriber instructs another healthcare professional in writing to supply or administer a medicine directly to that named patient or, to several named patients on a clinic list
- A PSD is a direct instruction. However, assessment of the patient against criteria for inclusion, exclusion and cautions detailed in this document must be undertaken by the healthcare professional carrying out the procedure
- It is the responsibility of the person issuing the PSD to ensure that the individual supplying or administering the medicine is competent to do so

This protocol was originally authorised in: July 2010
This protocol was authorised in: July 2013
This protocol will be reviewed by: July 2015

Clinician Responsible for training and review: Chris Faldon, Health Protection Nurse Specialist
| **Name of Medicine** | Tuberculin Purified Protein Derivative (PPD) made by Statens Serum Institut (SSI) 2TU per 0.1ml – routine use. Presentation: 1.5ml multidose vial  
**NB: Other manufacturers’ dosage and evaluation instructions differ.** Clear colourless to light yellow solution for injection. Supplied in glass vials with a non-latex rubber stopper. |
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<tbody>
<tr>
<td><strong>Legal status</strong></td>
<td>Unlicensed medicine in the UK. POM (Prescription only medicine)</td>
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<tr>
<td><strong>Storage</strong></td>
<td>+2°C to +8°C in a refrigerator. Protect from light. Don’t freeze</td>
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<td><strong>Dose</strong></td>
<td>0.1ml (2TU) routinely (0.05ml under 1 years)</td>
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<td><strong>Route/method</strong></td>
<td>Intradermal (intracutaneous) injection into the middle third of the left forearm. Use 1ml syringe with short bevel 26G needle. Bevel faced up and insert needle about 3mm into superficial layers of dermis. Should meet some resistance when injecting and produce a bleb of at least 6mm diameter. Without this the needle should be withdrawn and the test repeated 5cm from original site</td>
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<td><strong>Frequency</strong></td>
<td>Single dose except when a retest is considered appropriate for clinical purposes</td>
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<td><strong>Total dose number</strong></td>
<td>See dose range above</td>
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| **Advice Follow up Arrangements** | Patient must return for evaluation of reaction. Give out patient information leaflet  
Evaluate the reaction after 48 – 72 hours.  
- **Negative** reactions followed up with a BCG vaccination (supplied under a PGD) unless otherwise indicated  
- **Strongly positive** reactions should be referred to Public Health for further consideration. Do not give BCG  
- **Positive** reactions - Do not give BCG. These require no further action when Mantoux tests are being performed as part of a routine immunisation programme. In other contexts, where the subject has not previously been vaccinated with BCG (e.g. new entrant screening, contact-tracing programmes) referral to a chest clinic may be considered for further investigation and treatment, taking into account the precise size of the reaction and the circumstances of the case. Action – inform Public Health.  
See document ‘Reading the Mantoux Test’ |
| **Adverse outcomes** | Rarely anaphylaxis. Some local pain or irritation at injection site. Uncommonly, headache / fever. |
Advice on concurrent medication

Not within 4 weeks of receiving a live viral vaccine, such as MMR, due to suboptimal response

Clinical Condition to be treated

Assessment for immunisation against tuberculosis in line with Public Health requirements. Assess potential exposure to tuberculosis

Criteria for inclusion

- All patients aged 6 years and over, as specified in the Patient Group Direction “BCG Vaccine”
- Children under 6 years of age * who
  - Have lived for more than three months in a country with an annual incidence of TB of 40/100,000 or greater
  - Where there is a history of contact with a known case of tuberculosis
  - those who have a family history of TB within the last five years

Mantoux testing is unnecessary for children under 6 years who do not fall into one or more of the above three categories. Such children who are in school but under 6 years old can therefore proceed straight to a BCG. Pre-school children will be seen at the Borders General Ambulatory Care Clinic

- Adults requesting it for travel purposes to assess need for BCG (private pre-vaccine test)

Criteria for exclusion

- No valid consent (see Consent Form)
- Children under 6 years of age (other than those listed above) do not require Mantoux testing prior to BCG vaccination
- Tuberculin PPD SSI should not be administered to patients known to be hypersensitive to any component of the medicinal product or to patients who previously have experienced a severe skin reaction to Tuberculin products.
- No special precautions need to be considered. Although anaphylaxis is extremely rare, facilities for its management should always be available during skin testing.
- Should not be administered within 4 weeks of receiving a live vaccine as this may interfere with the interpretation of the result. Also if performed to assess need for a BCG vaccine it should be noted that BCG cannot be given within 4 weeks of receiving a live vaccine.

Cautions

- Eczema, at injection site - If acute episode test should be postponed. If chronic condition, an alternative site should be considered.
- Patients who have a negative test but who may have had an upper respiratory tract or other viral
Subjects who have a negative test but who may have had an upper respiratory tract or other viral infection at the time of testing or at the time of reading should be considered for re-testing at least two to three weeks after clinical recovery before being given BCG. If a second tuberculin test is necessary it should be carried out on the other arm: repeat testing at one site may alter the reactivity either by hypo- or more often hyper-sensitising the skin, and a changed response may reflect local changes in skin sensitivity only.

TB contacts with a negative tuberculin skin test when first seen may still be in the early stages of infection before tuberculin sensitivity has developed. A further skin test may be required once six weeks has lapsed since the last period of possible exposure.

**Records**
The following record should be completed

- ‘Mantoux/BCG Clinic - Patient Record’

The data captured will assist the nurse working under the PGD for BCG administration

**Anaphylaxis Emergency Treatment**
Refer to NHS Borders Anaphylaxis/Adrenaline protocol
Professional Responsibility

- All Health Professionals will ensure he/she has the relevant training and is competent in all aspects of medication, including contra-indications and the recognition and treatment of adverse effects. He/she will attend training updates as appropriate. For those involved in immunisation, regular anaphylaxis updates are mandatory.

- Nurses will have due regard for the NMC – The Code, standards of conduct, performance and ethics (2008) and NMC Standards for Medicines Management (2007)

References