NHS
Sunderland
Clinical Commissioning Group

This Patient Group Direction (PGD) must only be used by registered nurses and pharmacists who have been named and authorised by their practice to use it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction

for the administration of

Salbutamol

by registered nurses and pharmacists for

reversibility testing

in GP practices within Sunderland

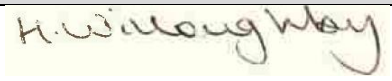
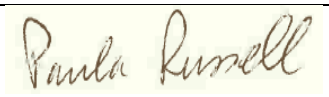
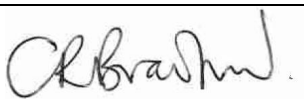
Version number: 1.0

Date PGD comes in to effect:	**March 2016**
Review date:	**January 2018**
Expiry date:	**March 2018**

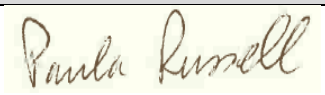
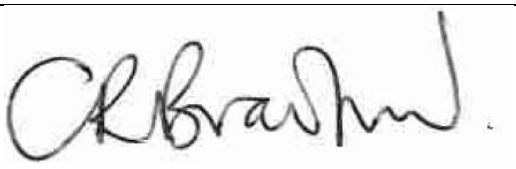
Change history

Version number	Change details	Date
V1.0	Initial approved version	March 2016

PGD development

Name	Job title and organisation	Signature	Date
Medicines optimisation pharmacist Sunderland CCG	**Hannah Willoughby** *(Interface pharmacist)*		March 2016
Medicines optimisation pharmacist Sunderland CCG	**Paula Russell** *(Senior pharmacist)*		March 2016
Practice nurse representative to the executive committee Sunderland CCG	**Florence Gunn** *(Senior nurse)*		March 2016
Medical director Sunderland CCG	**Dr Claire Bradford** *(Senior doctor)*		March 2016
Other members of the PGD working group	Not applicable		

PGD authorisation

Name	Job title and organisation	Signature	Date
Medicines Optimisation Pharmacist Sunderland CCG	**Paula Russell** *(Senior Pharmacist)*		March 2016
Practice Nurse Representative to the Executive Committee Sunderland CCG	**Florence Gunn** *(Senior Nurse)*		March 2016
Medical director, Sunderland CCG	**Dr Claire Bradford** *(Senior Doctor)*		March 2016
Person signing on behalf of authorising body			

PGD adoption by the provider

Name	Job title and organisation	Signature	Date
Signatures to be determined locally, if relevant			

Training and competency of registered practice nurses and pharmacists

	Requirements of registered practice nurses or pharmacists working under the PGD

Qualifications and professional registration	**Healthcare professionals using this PGD must:**
	• **Have a current contract of employment with a GP practice within Sunderland CCG**
	• **Be currently registered with their relevant professional body**
	  o Nurses: the Nursing & Midwifery Council (NMC)
	  o Pharmacists: the General Pharmaceutical Council (GPhC)

Initial training	• Has had training in the use of PGDs. • Have up to date resuscitation skills and anaphylaxis training (and competent to recognise and manage anaphylaxis). • Will have undertaken training in the role, care and administration of the medicine specified in the PGD. • Have access to and can navigate a current BNF. • Any additional training requirements as deemed necessary by your organisation or authorising body. • Must have demonstrated an appropriate level of competence to their clinical manager in salbutamol for reversibility testing
Competency assessment	• Must have demonstrated an appropriate level of competence to their clinical manager in salbutamol for reversibility testing.
Ongoing training and competency	• Annual attendance at an accredited update on resuscitation skills and the management of anaphylaxis within the community/primary care (mandatory). • Maintenance of own level of updating and competence with evidence of continued professional development. • Has undergone regular updating in basic life support and anaphylaxis training • The nurse or pharmacist should ensure she/he is aware of any changes to the recommendations for this medication. It is their responsibility to keep up-to-date with continuing professional development and take part in audit of clinical records on a regular basis • Any continued training requirements as deemed necessary by the organisation or the authorising body • Revalidation of professional qualification as dictated by governing body

Clinical condition

Clinical condition or situation to which this PGD applies	Salbutamol for reversibility testing

Inclusion criteria	• Adults and children over 5 years of age who require assessment of asthma or COPD by means of reversibility testing
	and
	• Patient is clinically stable and free from infection
	• Patient able to use a peak flow meter or a spirometer
	• Patient able to use an inhaler with a spacer device
	• Patient should not have:
	  ○ Smoked for at least 24 hours prior to test
	  ○ Eaten a large meal before the test
	  ○ Consumed alcohol in the 4 hours before the test
	  ○ Taken vigorous exercise before the test
	  ○ Wear tight clothing when attending for the test
	• Patient has not used bronchodilators for:
	  ○ 6 hours for salbutamol or other short acting β2 agonists or ipratropium
	  ○ 12 hours for long acting β2 agonists
	  ○ 24 hours for long acting antimuscarinics (tiotropium) or MR theophylline preparations

Exclusion criteria	• Known hypersensitivity to salbutamol or any other excipient • Children 5 years and under • Thyrotoxicosis • Unstable respiratory status • Hyperthyroidism • Pneumothorax • Pregnancy, risk of pregnancy or breastfeeding • Unstable cardiovascular disease including: myocardial infarction within the last 3 months, unstable angina, uncontrolled hypertension, or pulmonary embolism • Arrhythmias or susceptibility to prolonged QT interval • History of haemorrhagic event • Recent thoracic, abdominal or eye surgery • Haemoptysis (coughing of blood) of unknown origin • Previous sensitivity to beta-2 agonist

	• Patients on beta-blocker medication • Check drug history and refer to current BNF for more details and potential drug interactions and ask for advice on management if necessary. All patients taking a medication that interacts significantly (indicated with a black dot in the paper version, or shaded red in the online version) with salbutamol should be excluded.
Cautions (including any relevant action to be taken)	• Check drug history and refer to current BNF for more detail and potential drug interactions and ask for advice on management if necessary. • Cardiovascular disease • Arrhythmia • Susceptibility to QT-interval prolongation; • Diabetes (monitor blood glucose); • Patients on inhaled or oral corticosteroids • Check drug history and refer to current BNF for more detail and potential drug interactions and ask for advice on management if necessary. • As with other inhalation therapy, **paradoxical bronchospasm** may occur with an immediate increase in wheezing after dosing. This should be treated immediately with an alternative presentation or a different fast-acting inhaled bronchodilator and medical advice sought. • Note: Before doing the reversibility test the healthcare professional must ensure they have: o Access to adrenaline if required in anaphylaxis o Access to resuscitation equipment
Arrangements for referral for medical advice	N/A
Action to be taken if patient excluded	• Seek medical advice. • Ensure reason for exclusion and all actions/decisions are documented in patient record
Action to be taken if patient declines treatment	• Seek medical advice. • Ensure patient/carer fully understands reasons for administration and consequences of not administering treatment. • Give advice about alternative options if available. • Document refusal in patient's notes.

Details of the medicine

Name, form and strength of medicine *Include ▼for black triangle medicines*	Salbutamol metered dose inhaler (cfc-free) 100 micrograms per inhalation
Legal category	Prescription only medication
Indicate any off-label use (if relevant)	The use of inhaled salbutamol for reversibility testing is off-license, but recommended by BTS guidance. https://www.brit-thoracic.org.uk/guidelines-and-quality-standards/asthma-guideline/
Route/method of administration	Inhalation (via a large volume spacer) Procedure: • Check expiry and shake inhaler before use • Take initial peak flow (PEF) measurement (best of 3 good blows) or FEV1 if using a spirometer • Give test dose of 400 micrograms of salbutamol (inhaled). Each puff should be inhaled via a spacer device at 30 second intervals. • Repeat PEF/FEV1 after 15 minutes
Dose and frequency	• Single dose of 400 micrograms (4 puffs)
Quantity to be administered and/or supplied	Single episode of care
Maximum or minimum treatment period	400 micrograms (4 puffs of 100 mcg inhaler)
Adverse effects	See manufacturers summary of product characteristics or current BNF for full details of relevant warnings and potential adverse effects. **Common** • Tachycardia (less than 3% to 7%) • Nausea (10%), pharyngitis (14%), viral gastroenteritis (1%) • Backache (2%) • Feeling nervous (7%), headache (5% to 7% or more), sinus headache (1%), tremor (5% to 7% or more) • Urinary tract infectious disease (1%) • Bronchitis (5% or more), cough (5% or more), nasopharyngitis (5% or more), pain in throat (5% or more), rhinitis (5% to 16%), sinusitis (5% or more),

	upper respiratory infection (5% to 21% or more) **Serious** • Angina, atrial fibrillation, chest pain (3%), ECG: extrasystole, electrocardiogram abnormal, hypertension, hypotension, myocardial infarction, palpitations (5% or more), supraventricular tachycardia • Diabetic ketoacidosis, hyperglycaemia • Hypersensitivity reaction (6%) • Bronchospasm, exacerbation of asthma, p**aradoxical bronchospasm**, pulmonary oedema Urticaria, angioedema, hypotension and collapse have also been reported; **Paradoxical bronchospasm** (occasionally severe) may occur with an immediate increase in wheezing after dosing. **This should be treated immediately** with an alternative fast acting bronchodilator.
Records to be kept	Records to be kept in accordance with HCPC/NMC guidance and SCCG policy and procedures and to include: • Patient name, address, date of birth and GP details (if registered). • Diagnosis (with appropriate read code for outcome – positive or negative reversibility with salbutamol) • Dose and form supplied. • Advice given to patient. • Manufacturer of product, batch and expiry date. • Member of staff who administered or supplied the medication. • Referral arrangements including self-care. • “Supplied and administered under PGD” • Details of any adverse drug reaction and actions taken including documentation in the patient’s record. Report ALL suspected reactions in children under 18 and severe reactions in adults via the yellow card reporting scheme or at www.yellowcard.mhra.gov.uk.

Patient information

Written and verbal advice to be given to patient or carer	• Explain the treatment, its purpose and possible side effects; • Explain future therapy including referral to doctor or nurse or pharmacist-led respiratory clinic as appropriate • Explain use of inhaled salbutamol for reversibility testing is off-license, but recommended by BTS guidance • Ensure patient information leaflet is discussed with patient (and parent/ guardian/ carer if present) prior to supply, especially potential side effects (see current BNF/ PIL) and what to do if these occur. • Patients should be offered a patient information leaflet which can be accessed via the electronic medicines compendium • Advise on proper inhaler technique • Discuss health issues – smoking, environmental factors etc • Advise on recommencing treatments that were delayed for the purposes of reversibility testing • Contact GP if any serious adverse effects such as paradoxical bronchospasm (immediate increase in wheezing after dosing), sensitivity reaction, peripheral dilation, palpitations.
Follow-up advice to be given to patient or carer	Explain the referral and follow up process appropriate to test result.

Appendices

Appendix A key references

References:

- British National Formulary http://www.evidence.nhs.uk/formulary/bnf/current
- HSC 2000/026 (9/8/00) Patient Group Directions
- NMC Standards for Medicines Management. www.nmc-uk.org
- Manufacturers' Summary of Product Characteristics (www.emc.medicines.org.uk)
- British Thoracic society / SIGN guideline for the management of asthma (2014) https://www.brit-thoracic.org.uk/guidelines-and-quality-standards/asthma-guideline/
- NICE Chronic obstructive pulmonary disease in over 16s: diagnosis and management [CG101] (June 2010).
- NICE Quality Standard 25 (Asthma) www.nice.org.uk
- Drugdex by Micromedex solutions, Truven Healthcare solutions

Appendix B Health professionals' agreement to practise

I have read and understood the Patient Group Direction and agree to supply and/or administer this medicine only in accordance with this PGD.

Name of health professional	Signature	Senior medical representative authorising health professional	Date