NHS
Midlands and Lancashire
Commissioning Support Unit

This Patient Group Direction (PGD) must only be used by registered nurses with current NMC registration or registered pharmacists with GPhC registration 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 must be used.

Patient Group Direction

for the supply and/or administration of

Salbutamol 100 microgram/dose metered dose inhaler or 2.5mg nebuliser solution

by registered nurses or pharmacists with current professional registration for

reversibility testing with respiratory symptoms

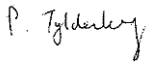
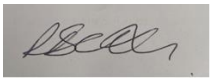
In:

NHS Lancashire and South Cumbria ICB

Version number: MLCSU-ICB-2024.9

Valid from: **21st October 2024**
Review date: **21st July 2027**
Expiry date: **21st October 2027**

PGD authorisation

	Name	Job title and organisation	Signature	Date
Senior Doctor	James Sowery	GP Advisor, MLCSU		11/10/2024
Senior Pharmacist	Paul Tyldesley	Medicines Commissioning Pharmacist, MLCSU		11/10/2024
Senior Nurse	Rachael Berks	Clinical Lead – Nursing and Urgent Care, MLCSU		11/10/2024
Person signing on behalf of authorising ICB	David Levy	Medical Director		30/10/2024

PGD development

	Name	Job title and organisation
Lead author	Paul Tyldesley	Medicines Commissioning Pharmacist, MLCSU
Other members of the working group	Sharon Andrew	Medicines Commissioning Pharmacist, MLCSU
	Adam Grainger	Senior Medicines Performance Pharmacist, MLCSU

YOU MUST BE AUTHORISED BY NAME, UNDER APPENDIX A OF THE CURRENT VERSION OF THIS PGD BEFORE WORKING UNDER IT

Training and competency of registered health professionals

	Requirements of registered nurses working under the PGD
Qualifications and professional registration	Registered nurse with current NMC registration or Pharmacist with current GPhC registration, employed within Lancashire and South Cumbria ICB.
Initial training	Has undertaken appropriate Association for Respiratory Technology and Physiology (ARTP) approved training and training for working under PGD for the supply and administration of medicines. Healthcare professionals performing spirometry in younger children (aged 5-12 years) must have appropriate experience and training in paediatric spirometry (including the use of incentive spirometry). Healthcare professionals interpreting paediatric spirometry should: • have knowledge of age-specific cut offs using appropriate reference values; • be able to recognise acceptable and un-acceptable spirometry; • be able to interpret spirometry in the context of the child's clinical presentation, manage accordingly, and know when referral to secondary/tertiary care is warranted.
Competency assessment	Recognised competency in performing and interpreting spirometry (Full level training) as evidenced on the ARTP national register.
Ongoing training and competency	If you are already on the ARTP national register, you will be called to: Undergo reassessment and recertification every three years Attend at annual anaphylaxis training. Attend at annual basic life support.

CLINICAL CONTENT OF PATIENT GROUP DIRECTION FOR
Inhaled Salbutamol for Reversibility Testing with Respiratory Symptoms
VERSION: MLCSU-ICB-2024.9

NOTE: This Patient Group Direction (PGD) links with the PGD for Terbutaline – where possible, the choice of drug used in testing should reflect the patient's current treatment of short-acting $beta_2$ agonist.

Clinical Details	
Indication	Reversibility testing during respiratory assessment in clinic settings. Selected patients with airflow obstruction (FEV_1/FVC < 70%; or SR <-1.645) where the clinical history remains unclear to make a clear diagnosis of COPD or asthma and allow appropriate treatment. (Definitions - FEV_1: forced expiratory volume in one second; FVC: forced vital capacity; SR: standardised residuals).
Inclusion criteria	As part of reversibility testing during respiratory assessment following standard spirometry for any patient with obstructive spirometry aged 5 years or older experiencing one or more symptoms of: • Shortness of breath • Cough • Wheeze • Chest Tightness.

Exclusion criteria	**Contraindications**
	
	• Patients under 5 years of age
	• Children unable to undertake a reliable quality assured spirometry test (although experienced healthcare professionals can obtain accurate spirometry on children aged five years and upwards, the ability to perform consistently is from age eight onwards)
	• Hypersensitivity to salbutamol or any excipients
	
	Temporary exclusions
	
	Spirometry is a very safe procedure. However, it is physically demanding as it requires maximum effort and it involves the generation of high airway and intrathoracic pressures. **It is advisable that spirometry is rearranged/abandoned for patients who have experienced**:
	
	• Unstable respiratory status – exacerbation requiring antibiotics or steroids within the last 6 weeks
	• Use of:
	  ○ short acting bronchodilator within past 4 hours
	  ○ long acting $beta_2$-agonist bronchodilators within past 8 hours
	  ○ long acting anticholinergic bronchodilators within past 36 hours
	• Evidence of active infection (including significant secretions, oral lesions or oral bleeding) -test when resolved
	• Middle ear infection/ perforated ear drum (test when resolved)
	• Thyrotoxicosis
	• Pneumothorax – perform test after 8 to 12 weeks, or do not test until stable
	• Myocardial infarction or cerebrovascular accident – perform test after 8 to 12 weeks or when stable
	• Systemic hypotension, severe hypertension, significant arrhythmia, or non-compensated heart failure
	• Uncontrolled pulmonary hypertension or acute cor pulmonale
	• Pulmonary embolism – perform test after 8 to 12 weeks
	• Unstable Cardiovascular status including unstable angina, uncontrolled hypertension, aortic, thoracic, abdominal or cerebral aneurysm (test when stable)
	• Current Haemoptysis of unknown cause (perform test when resolved, TB must be treated for at least 2 weeks prior to testing)
	• History of syncope related to forced expiration/cough
	• Neuro, ophthalmic, cerebrovascular, sinus, middle ear, thoracic or abdominal Surgery within last 3 months.

	• Raised Intra-Ocular Pressure (perform test once controlled with treatment) • Recent concussion with continuing symptoms • Late term pregnancy • Acute disorders affecting test performance – i.e. nausea/vomiting • Inability to comprehend instructions
Management of excluded patients	• Refer to GP for assessment and treatment • If temporary exclusion applies, counsel patient, defer and re-arrange testing.
Action for patients not wishing to receive care under this PGD	• Document refusal and course of action taken following advice • Give advice about alternative sources of testing. Refer as appropriate

Description of Treatment	
Name of medicine	Salbutamol
Formulation and route	Inhalation via: • Nebuliser solution **OR** • Metered dose inhaler (MDI) & single use large volume spacer device N.B. In children, a MDI and spacer are the preferred method of delivery of beta$_2$-agonists. A face mask is required until the child can breathe reproducibly using the spacer mouthpiece.
Strength	• 2.5mg/2.5ml nebuliser solution OR • 100 microgram per actuation MDI
Dosage	Adults and children over 5 years of age • 2.5mg via nebuliser solution OR • 400microgram via MDI & single use large volume spacer device (i.e. 4 puffs)
Duration of treatment	Single Treatment
Quantity to administer	One dose to be administered – (i.e. One 2.5mg nebule) or 4 puffs (i.e. 400microgram) MDI
Legal status	Prescription Only Medicine **The use of inhaled salbutamol for reversibility testing is off-license but recommended by NICE guidance**
Special Precautions	• Single use only mask and tubing to be used with nebuliser solution • Nebuliser of recommended type serviced according to manufacturer's instructions • For MDI delivery four separate doses (total dose 400 micrograms) are to be delivered at 30 second intervals via a spacer device appropriate to the age of the patient. • Disposal of clinical waste facilities should be available • Facilities & equipment for treating anaphylaxis must be available • 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

Adverse effects

System Organ Class	Frequency classification	Adverse Drug reaction
Immune system disorders	Very rare (<1/10,000)	Hypersensitivity reactions including angioedema, bronchospasm, hypotension and collapse
Metabolism and nutrition disorders	Rare (≥1/10,000 to <1/1,000)	Hypokalaemia.
Nervous system disorders	Common (≥1/100 to <1/10)	Tremor, headache
	Very rare (<1/10,000)	Hyperactivity
Cardiac disorders	Common (≥1/100 to <1/10)	Tachycardia
	Uncommon (≥1/1,000 to <1/100)	Palpitations
	Very rare (<1/10,000)	Cardiac arrhythmias (including atrial fibrillation, supraventricular tachycardia and extrasystoles)
	Frequency unknown	Myocardial ischaemia
Vascular disorders	Rare (≥1/10,000 to <1/1,000)	Peripheral vasodilatation
Respiratory, thoracic and mediastinal disorders	Very rare (<1/10,000)	Paradoxical bronchospasm
Gastrointestinal disorders	Uncommon (≥1/1,000 to <1/100)	Mouth and throat irritation
Musculoskeletal and connective tissue disorders	Uncommon (≥1/1,000 to <1/100)	Muscle cramps

For up-to-date SPCs and PILs consult www.medicines.org.uk/emc

Document and report suspected adverse reactions to the GP/duty doctor and any serious suspected adverse reactions to Medical and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme (www.mhra.gov.uk/yellowcard).

Advice necessary

- Check if patient has any relevant contraindications or cautions
- Explain the use of inhaled salbutamol for reversibility testing is off-licence but recommended by NICE guidance
- All patients should be offered a patient information leaflet including advice regarding potential adverse events
- Counsel on inhalation technique and check patient understanding
- Reversibility testing to be performed approximately 15 minutes after bronchodilator dose administered
- Advise on results of the reversibility test and if appropriate future therapy including referral or recommencing treatments that were stopped for the purposes of reversibility testing

Records and Follow Up

Referral arrangements

The nurse or pharmacist must be able to identify and contact a doctor / nurse in the practice when undertaking the respiratory assessment.

Records to be kept

Completion of local documentation to include:

- Name and signature of health professional providing treatment
- Details of drug dosage and method of delivery
- Brand, batch number and expiry date
- Date and time of administration
- Result - i.e. positive or negative reversibility
    - Regard an improvement in FEV_1 of 12% or more together with an increase in FEV_1 of 200ml as a positive result for reversibility in adults

	○ Regard an improvement in FEV_1 of 12% or more as a positive result in children • Any advice given to the patient • Any adverse events (see precautions)
Follow up	Advise/ arrange for patient to consult with their GP or Respiratory Nurse following initial respiratory assessment.

Protocol, organisation and individual authorisation signatures can be found on the managerial content sheet along with other non-clinical details relating to this patient group direction.

Key references

1. Accord Uk Ltd. Summary of Product Characteristics: salbutamol nebuliser solution 5mg/2.5ml. Accessed via: https://www.medicines.org.uk/emc/product/3214/smpc [accessed online: 11th September 2024].
2. GlaxoSmithKline UK. Summary of Product Characteristics: Ventolin Evohaler 100microgram. Accessed via: https://www.medicines.org.uk/emc/product/850/smpc [accessed online: 11th September 2024]
3. Joint Formulary Committee. *British National Formulary* (online) London: BMJ Group and Pharmaceutical Press http://www.medicinescomplete.com [Accessed September 2021]
4. British Thoracic Society. BTS/SIGN: British Guideline on the Management of Asthma, 2019. Accessed via: https://www.sign.ac.uk/media/1773/sign158-updated.pdf [accessed online: 16th September 2021].
5. National institute for Health and Care Excellence: NG80 Asthma: diagnosis, monitoring and chronic asthma management. Accessed via: https://www.nice.org.uk/guidance/ng80 [accessed online: 11th September 2024].
6. National institute for Health and Care Excellence: NG115: Chronic obstructive pulmonary disease in over 16s: diagnosis and management. Accessed via: https://www.nice.org.uk/guidance/ng115 [accessed online: 11th September 2024].
7. Graham et al (2019).Standardization of Spirometry 2019 Update. An Official American Thoracic Society and European Respiratory Society Technical Statement. Accessed via: https://www.atsjournals.org/doi/full/10.1164/rccm.201908-1590ST
8. Association for Respiratory technology and physiology. A Guide to Performing Quality Assured Diagnostic Spirometry 2013. Accessed at: https://www.pcrs-uk.org/sites/pcrs-uk.org/files/SpirometryUpdated2017_V2.pdf
9. National institute for Health and Care Excellence. Patient Group Direction Medicines practice guideline [MPG2]. Accessed via: https://www.nice.org.uk/guidance/mpg2 [accessed online: 11th September 2024].
10. NHS England. Spirometry commissioning guidance (2020). Accessed via: https://www.england.nhs.uk/wp-content/uploads/2020/03/spirometry-commissioning-guidance.pdf [accessed online: September 2024].
11. Association Respiratory Technology and Physiology Standard Operating Procedure: Lung Function Reporting. Accessed via https://www.artp.org.uk/CoreCode/Modules/Content/ResourceLibrary/AjaxHandlers/ResourceAccessHandler.aspx/17c42d9b-64b7-49e2-bedf-27259c4a2e63 [Accessed online: October 2024]

Appendix A

Health professionals' agreement to practice

Individual Authorisation

BY SIGNING THIS AGREEMENT YOU ARE INDICATING THAT YOU AGREE WITH THE CONTENTS OF THIS PGD, THAT YOU HAVE READ AND UNDERSTOOD IT AND AGREE TO SUPPLY AND/OR ADMINISTER THE MEDICINE ONLY IN ACCORDANCE WITH THIS PGD

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

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 AUTHORISATION SHEET SHOWING THEIR AUTHORISATION

Name of Professional	Signature	Authorising Manager or senior representative	Date