University Hospitals of Derby and Burton
NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Supply/Administration of SALBUTAMOL cfc-free 100mcg/actuation Metered Dose Inhaler

By Registered Nurses, Emergency Nurse Practitioners (ENP), Emergency Care Practitioners (ECP) and Emergency Physiotherapy Practitioners (EPP)
In Emergency Department and Ambulatory care at Queens Hospital, Burton and Minor Injuries departments at Samuel Johnson and Sir Robert Peel community hospitals

Documentation details

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Change history

Version number	Change details	Date
1	New UHDB format	26/04/2023

Glossary

Abbreviation	Definition

1. PGD template development (PGD Working Group)

PGD Working Group Membership (minimum requirement of consultant, pharmacist and a registered professional who can work under a PGD, or manages the staff who do). If this is a review of existing PGD, replace previous names with the individuals involved for this version

Name	Designation
Dr Thungala	Doctor
James Kerr	Pharmacist
Alannah Davies	Representative of RNMHP Group

Where an antimicrobial is included, confirm the name, designation and date of the antimicrobial pharmacist who has reviewed this version

Name of antimicrobial pharmacist	Designation	Date Reviewed
n/a	n/a	n/a

2. Organisational authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

University Hospitals of Derby & Burton NHS Foundation Trust authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services
In Emergency Department and Ambulatory care at Queens Hospital, Burton and Minor Injuries departments at Samuel Johnson and Sir Robert Peel community hospitals
Limitations to authorisation
Nil

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer *Pharmacist: Medicines Safety Officer, Chief Pharmacist or assigned deputies)*	James Hooley	**Signed copy held in Pharmacy**	**26/05/2023**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Divisional Pharmacist *Clinical Pharmacist from PGD working group*	**James Kerr**	**Signed copy held in Pharmacy**	**04/05/2023**
Consultant *Doctor*	**Dr Thungala**	**Signed copy held in Pharmacy**	**23/05/2023**
Interim Matron Acute Medicine QHB *Registered Professional representing users of the PGD*	**Danielle Murphy**	**Signed copy held in Pharmacy**	**26/04/2023**

Local enquiries regarding the use of this PGD may be directed to UHDB.PGDgovernance@nhs.net

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD.

3. Characteristics of staff

Qualifications and professional registration	Registered professional with current professional registration operating within their usual scope of practice. Must be a profession permitted by current legislation to practice under a patient group direction.
Initial training	- Completion of all Essential-to-role training as outlined in the UHDB PGD policy. - Individual has read and understood full content of this PGD and signed authorisation (section 7) - Completion of Medicines Management Drug Assessment - Deemed competent by their line manager to undertake the clinical assessment of a patient leading to a diagnosis that requires treatment according to the indications listed in this PGD and Trust clinical guidelines for: a) Asthma
Competency assessment	Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required.
Ongoing training and competency	- Annual Medicines Safety Training (essential to role) - Review/repeat initial training above when this PGD is revised - The registered healthcare practitioner will ensure Anaphylaxis/CPR training is kept updated yearly. - The registered healthcare professional must actively take part in CPD and annual individual performance reviews. - Regular training and updating in safeguarding children and vulnerable adults as per trust policy
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.	

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	• Acute episode of moderate (non-life threatening) asthma • Provision of replacement inhaler to be used as normally directed by patient's GP or GPN
Criteria for inclusion	• Any patient > 18 months of age with reversible airway obstruction or clinical features of **acute moderate** asthma. Clinical features include: **Child 18 months - <2 years old** • SpO2 at or >92% • Audible wheezing • Using accessory muscles • Still feeding **Child 2 and over** • Able to talk in sentences • Arterial oxygen saturation >92% • Peak flow >50% of best or predicted • Heart rate <140 BPM in children aged 2-5 years old • Heart rate <125 minute in children over 5 years old • Respiratory rate <40/minute in children ages 2-5 years old • Respiratory rate <30/minute in children over years old **Adult** • Increasing symptoms • Peak flow >50-75% of best or predicted • Speech normal • Respiration rate <25 per minute • Pulse <110BPM
Criteria for exclusion	• Severe pre-eclampsia • Known allergy to salbutamol or other ingredients in preparation
Cautions including any relevant action to be taken	• Salbutamol should be administered cautiously to patients with thyrotoxicosis, coronary insufficiency, hypertrophic obstructive cardiomyopathy, and arterial hypertension, known tachyarrhythmia's, concomitant use of cardiac glycosides or diabetes mellitus. • Patients should be instructed in the proper use of the inhaler and their technique checked, to ensure that the active substance reaches the target areas within the lungs. • The management of asthma should normally follow a stepwise programme, and the patient's response should be monitored clinically and by lung function tests. Increasing use of short-acting inhaled bronchodilators, in particular ß2-agonists to control symptoms, indicates deterioration of asthma control. Under these conditions, the patient's therapy plan should be reassessed.

	Asthmatic patients whose conditions deteriorates despite salbutamol therapy, or where a previously effective dose fails to give relief for at least three hours, should seek medical advice in order that any necessary additional steps may be taken. • The dosage or frequency of administration should only be increased on medical advice. • Patients requiring long term management with inhalers should be kept under regular surveillance. • Care should be taken when treating acute asthma attacks or exacerbation of severe asthma as increased serum lactate levels, and rarely, lactic acidosis have been reported after the use of high doses of salbutamol have been used in emergency situations this is reversible on reducing the dose of salbutamol • Cardiovascular effects may be seen with sympathomimetic drugs, including salbutamol. There is some evidence from post-marketing data and published literature of rare occurrences of myocardial ischaemia associated with salbutamol. Patients with underlying severe heart disease (e.g. ischaemic heart disease, arrhythmias or severe heart failure) who are receiving salbutamol should be warned to seek medical advice if they experience chest pain or other symptoms of worsening heart disease. Attention should be paid to assessment of symptoms such as dyspnoea and chest pain, as they may be either respiratory or cardiac in origin. • Potentially serious hypokalaemia may result from ß2-agonist therapy mainly from parenteral and nebulised administration. Particular caution is advised in acute severe asthma as this effect may be potentiated by concomitant treatment with xanthine derivatives, steroids and diuretics and by hypoxia. It is recommended that serum potassium levels are monitored in such situations • In common with other beta-adrenoceptor agonists, salbutamol can induce reversible metabolic changes such as increased blood glucose levels. Diabetic patients may be unable to compensate for the increase in blood glucose and the development of ketoacidosis has been reported. Concurrent administration of glucocorticoids can exaggerate this effect. • As with other inhalation therapies, the potential for paradoxical bronchospasm should be considered. If it occurs the preparation should be discontinued immediately and alternative therapy given. Solutions which are not of neutral pH may rarely cause paradoxical bronchospasm in some patients. Salbutamol and non-selective beta blocking drugs such as propranolol should not usually be prescribed together.
Action to be taken if the patient is excluded	• Refer to a Doctor (e.g. GP or A&E) for further assessment
Action to be taken if the patient or carer declines treatment	• Discuss need for treatment • Document advice given • Advise patient on alternative treatment • If patient chooses not to take treatment, patient may need referral to secondary care.

Arrangements for referral for medical advice	• Follow up by GP/Practice Nurse/Asthma/COPD nurse. If patient continues to have breathing problems referral to secondary care via 999 as appropriate

5. Description of treatment

Name, strength & formulation of drug	Salbutamol cfc-free 100mcg/actuation Metered dose inhaler
Legal category	POM
Route / method of administration	**Inhalation**
Indicate any off-label use (if relevant)	None
Dose and frequency of administration	**<u>Treatment of an acute attack</u>** **Child > 18 months old** 2–10 puffs, each puff is to be inhaled separately every 30 – 60 seconds according to response, repeat every 10–20 minutes or when required, give via large volume spacer (and a close-fitting face mask in children under 3 years); each puff is equivalent to 100 micrograms. **Adult** 2–10 puffs, each puff is to be inhaled separately every 2 minutes according to response, repeat every 10–20 minutes or when required, give via large volume spacer, each puff is equivalent to 100 micrograms. **<u>Doses for purposes of continued treatment or provision of emergency supply only</u>** **Child 2-17 years:** 1-2 puffs (100mcg-200mcg) every 4 hours of required/as needed via spacer. **Adult:** 1-2 puffs (100mcg- 200mcg) up to FOUR times a day as needed.
Duration of treatment	AS above
Quantity to be supplied (leave blank if PGD is administration ONLY)	ONE Salbutamol cfc-free 100mcg/actuation Metered dose inhaler
Storage	Store below 25°C and protect from light. Do not refrigerate or freeze. Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below:

	Available from the electronic Medicines Compendium website accessed: https://www.medicines.org.uk/emc/product/3351/smpc On 14/12/21.
Drug interactions	**Interactions are unlikely to occur from inhalation via inhaler.** • Propranolol and other non-cardioselective ß-adrenoreceptor blocking agents antagonise the effects of salbutamol, and should not usually be prescribed together. • Monoamine oxidase inhibitors (MAOIs), tricyclic antidepressants, digoxin: risk of increased cardiovascular effects. • Patients should be instructed to discontinue salbutamol at least 6 hours before an intended anaesthesia with halogenic anaesthetics, wherever possible. • Hypokalaemia occurring with β2-agonist therapy may be exacerbated by treatment with xantines, steroids, diuretics and long-term laxatives. • Because of the content of ethanol, there is theoretical potential for interaction in patients taking disulfiram or metronidazole
Adverse reactions	• Arrhythmias, headaches, hypokalaemia (with high doses), muscle spasms, nasopharyngitis, nausea, palpitations, rash, tremor.
Management of and reporting procedure for 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 on: https://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record. • Serious adverse reactions (moderate harm or above as per NRLS definition) should be reported via trust incident management system (e.g. Datix) to ensure duty of candour and learning from harm during clinical use. • If Anaphylaxis occurs treat as per local emergency protocols and transfer to A&E via 999 if appropriate to area.
Written information to be given to patient or carer	Give marketing authorisation holder's patient information leaflet (PIL) provided with the product.
Patient advice / follow up treatment	**Patients who have received treatment for an acute attack**: - Counsel patient/carer on treatment given, their understanding if their condition, possible reasons for exacerbation and concordance with prescribed treatment. - Advised patient that this is a rescue measure and it is essential patient visits GP/GPN/Asthma Nurse for an assessment/follow up review within 2 working days (as per BTS guidelines). - Check inhaler and space technique - Check compliant with preventer therapy and advised patient

	of importance of using preventer therapy as prescribed. - The patient's GP practice should be informed within 24 hours of discharge from emergency department or hospital following an asthma attack. - Patient should be followed up by GP within 2 working days (as per BTS guidelines). **<u>For patients who are attending for replacement salbutamol inhaler</u>** - Advised patient to ensure they are up to date with their repeat prescriptions of salbutamol inhaler and keep adequate supplies. - Check patient has not run out due to excessive usage, indicating their condition is becoming less controlled. - Refer patient to GP for further supplies or with any concerns regarding excessive use. Patient will require a review of their condition.
Records	Either the system holding the record, or the healthcare practitioner working under the PGD, must capture/document all of the following: • name of individual, address, date of birth and GP with whom the individual is registered (if relevant) • name of registered health professional • name of medication supplied/administered • date of supply/administration • dose, form and route of supply/administration • quantity supplied/administered • batch number and expiry date (if applicable e.g. injections and implants) • advice given, including advice given if excluded or declines treatment • details of any adverse drug reactions and actions taken • Confirm whether <u>supplied and/or administered</u> and that this was done via Patient Group Direction (PGD) Records should be signed and dated (or a password controlled e-records). All records should be clear, legible and contemporaneous. If you are not recording in ePMA (or other electronic system which has ability to generate audit reports) then a record of all individuals receiving treatment under this PGD should also be in the clinical area for audit purposes as per UHDB PGD policy.

6. Key references

Key references	• *Expired "PGD for administration of SALBUTAMOL CFC FREE INHALER by NMHP employed by QHB in MIU" expired 31/10/2021 at community hospitals* • *Electronic Medicines Compendium: Available at: https://www.medicines.org.uk/emc/product/12983/. Accessed 14/12/21* • *Electronic BNF, Available at: <https://bnf.nice.org.uk/drug/salbutamol.html> Accessed 10/01/22* • *NICE guidelines for Asthma, Available at: <https://www.nice.org.uk/guidance/ng80> Accessed 10/01/22.* • *NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2* • *https://medusa.wales.nhs.uk*

7. Registered health professional authorisation sheet

PGD Name [version]: Emergency Department, Ambulatory Care QHB and MIU SJCH and SRP – Salbutamol cfc-free 100mcg [v1]

PGD ref: UHDB247

Valid from: 26/05/2023 Expiry date: 25/05/2026

Before signing check that the document you have read is published on Koha or is an in-date hard-copy with all necessary authorisations signed in section 2. The Name/Version/Ref of the document you have read MUST match this authorisation form.

Registered health professional

By signing this patient group direction you are indicating that

a) You agree to and understand all content and commit to only work within this framework.
b) You have completed any core PGD e-Learning or training records on My Learning Passport or within your department.
c) You meet the staff characteristics and have completed any additional learning/competency outlined in Section 3 of this PGD.

Patient group directions do not remove inherent professional obligations or accountability.
It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager / Assessor

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of University Hospitals of Derby & Burton NHS Foundation Trust for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet must be retained by a manager in the clinical department where the PGD is in-use to serve as a record of those registered health professionals authorised to work under this PGD.