University Hosp
Derby and

PATIENT GROUP DIRECTION (PGD)

Supply of Salbutamol 2.5mg in 2.5ml Nebuliser Solution for Acute Exacerbation of COPD By Impact+ Outreach Service

Documentation details

Reference no:	UHDB 005
Version no:	2.0
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Expiry date:	10/02/2024

Change history

Version number	Change details	Date
2.0	Reviewed and extended following full proposal and authorisation (previously approved for 6 months only due to Covid-19). No changes required.	21/12/2020

Glossary

Abbreviation	Definition
AECOPD	Acute exacerbation of chronic obstructive pulmonary disease
NEWS	National Early Warning Score
NICE	National Institute for Health and Clinical Excellence

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 Gill Lowrey	Consultant Respiratory Physician
Kate Coulthard	Lead Respiratory Nurse Specialist (impact+)
James Kerr	Divisional Pharmacist for Medicine
Robin Evans	Clinical Service Manager (impact+)
Deepak Subramanian	Consultant Respiratory Physician

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

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
Impact+ Service
Limitations to authorisation

Organisational approval (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer	James Hooley	**Signed version held in pharmacy**	**11/2/21**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Clinical Lead	Deepak Subramanian	**Signed version held in pharmacy**	**25/1/21**
Clinical Service Manager	Robin Evans	**Signed version held in pharmacy**	**21/1/21**
Divisional Pharmacist	James Kerr	**Signed version held in pharmacy**	**11/2/21**

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	Impact+ outreach team. Registered professional with current professional registration operating within their usual scope of practice
Initial training	The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate training and successfully completed the competencies to undertake clinical assessment of patient leading to diagnosis of the conditions listed. Has undertaken appropriate training for working under Patient Group Directions for the supply and administration of medicines
Competency assessment	Approved drug assessment 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	Essential to role medicines management / safety training via My Learning Passport
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	Continuing treatment for stable patients with an AECOPD to facilitate early supported discharge to virtual ward. Stable patients with an AECOPD to prevent a hospital admission
Criteria for inclusion Use BNF/BNFC/SPC. Take into account any clinical guidelines or policies that are available locally or nationally, e.g. BASHH/NICE/JCVI	• Patients 16 years and over presenting with the above symptoms; Adults with a history of COPD; • NEWS 0-4 not scoring a 3 on any one parameter • Able to cope at home for activities of daily living • No worsening peripheral oedema, • Normal level of consciousness and no acute confusion • Arterial pH >/= 7.35 • Access to telephone • Support available at home (preferably living with another person) See: NICE and local guidance for further information https://cks.nice.org.uk/chronic-obstructive-pulmonary-disease#!scenario:1 http://www.derbyshiremedicinesmanagement.nhs.uk/assets/Clinical_Guidelines/Formulary_by_BNF_chapter_prescribing_guidelines/BNF_chapter_3/Nebuliser_guideline.pdf
Criteria for exclusion	• Patients under 16 years old • Previous sensitivity or intolerance to the drug or any ingredient • Patients taking non-selective beta-blockers e.g., Propranolol • Pregnancy and breastfeeding
Cautions including any relevant action to be taken	• Patients with chronic respiratory conditions should have their nebulised therapy administered via air driven nebuliser • For inhalation use only. • In the following cases, salbutamol should only be used with caution and if strictly indicated: - serious cardiac disorders, in particular recent myocardial infarction - coronary heart disease, hypertrophic obstructive cardiomyopathy and tachyarrhythmia (due to the positive ionotropic effect of β2 – agonists) severe and untreated hypertension - aneurysm - hyperthyroidism - diabetes which is difficult to control - pheochromocytoma

	• Patients with underlying severe heart disease (e.g. ischemic heart disease, arrhythmia 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. • Due to the hyperglycaemic effects of beta2 – stimulants, additional blood glucose measurements and monitoring are recommended when treatment with Salbutamol Nebuliser Solution is started in diabetic patients. • Potentially serious hypokalaemia may result from β2-agonist therapy, mainly from parenteral and nebulised administration. Particular caution is advised in acute severe asthma as this effect may be potentiated by hypoxia and by concomitant treatment with xanthine derivatives, steroids, and diuretics. Serum potassium levels should be monitored in such situations. • The use of nebulised salbutamol in combination with nebulised anticholinergic agents (e.g. ipratropium) has been reported to precipitate acute angle closure glaucoma. This combination should be used with caution, in particular in patients with actual or potential glaucoma. Patients should be warned
Action to be taken if the patient is excluded	• Record reasons for exclusion in patient notes • Advise patient on alternative treatment • Refer to a prescriber if appropriate
Action to be taken if the patient or carer declines treatment	• Record in patient notes • Refer to medical staff for review and prescribing of alternative agent if appropriate. • Document advice given
Arrangements for referral for medical advice	In hours: Dr G Lowrey, Dr R Aldridge, Dr D Subramanian Out of Hours/Weekend: Respiratory Consultant on Call (via switchboard)

5. Description of treatment

Name, strength & formulation of drug	Salbutamol 2.5mg in 2.5ml Nebuliser Solution
Legal category	POM
Route / method of administration	Salbutamol Nebuliser Solution should be administered by a suitable air driven nebuliser, via a face mask or T piece
Dose and frequency of administration	2.5mg four times daily tapering to once daily
Duration of treatment	Up to a maximum of 14 days
Quantity to be supplied	Up to 2 x 20 nebules
Storage	Store below 25 °C. Store in the original packaging.

	Ampoules should be opened immediately before use and any solution remaining after use should be discarded.
Drug interactions	**The following interactions have been identified and should be considered where it is known a patient is on the following medicines:** Salbutamol Nebuliser Solution should be used with caution in patients receiving other sympathomimetics (e.g. alpha- and beta-agonists). Salbutamol and non-selective β – receptor blocking drugs should not usually be prescribed together. In patients with asthma administration of β – receptor blocking drugs is associated with a risk of severe bronchoconstriction. Treatment with salbutamol can lead to hypokalaemia. This effect may be potentiated by the concomitant administration of other drugs, in particular xanthine derivatives (Theophylline Aminophylline), glucocorticoids, diuretics and cardiac glycosides (digoxin). Serum potassium levels should be monitored in these situations. Tricyclic antidepressants may increase the risk of cardiovascular side effects. Corticosteroids may increase the risk of hyperglycaemia. A few cases have been reported where the combination of nebulised salbutamol and ipratropium bromide has given rise to acute angle-closure glaucoma.
Identification & management of adverse reactions	Up to approximately 10% of patients can be expected to experience adverse reactions. These depend upon the dose and the individual sensitivity. Most commonly reported are: taste alteration (bad, unpleasant and unusual taste) and application site reaction (mouth and throat irritation, burning sensation of the tongue), fine tremor (usually of the hands) nausea, sweating, restlessness, headache, dizziness and muscle cramps. These undesirable effects may subside on continuation of treatment within 1-2 weeks. As with other inhalation therapies, in rare cases paradoxical bronchospasm may occur, manifest by an immediate increase in wheezing after dosing. Paradoxical bronchospasm should be treated immediately with an alternative presentation or a different fast-acting inhaled bronchodilator. Salbutamol Nebuliser Solution should be discontinued immediately, the patient should be assessed, and if necessary, alternative therapy instituted. Hypersensitivity reactions such as rash, urticaria, dermatitis, pruritus and erythema have been observed. There have been very rare reports of angioedema (oedema of the face, lips, eyes and throat), bronchospasm, hypotension and collapse. Tachycardia, with or without peripheral vasodilation, may occur. In common with other beta2 agonists, cardiac arrhythmias (including atrial fibrillation, supraventricular tachycardia and extrasystoles),

	palpitations, angina pectoris, and blood pressure effects have been reported in association with the use of salbutamol, usually in susceptible patients. A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
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. • Report via Datix
Written information to be given to patient or carer	Give marketing authorisation holder's patient information leaflet (PIL) provided with the product. Provide leaflet on nebuliser therapy http://www.derbyshiremedicinesmanagement.nhs.uk/assets/Clinical_Guidelines/Formulary_by_BNF_chapter_prescribing_guidelines/BNF_chapter_3/Nebuliser_guideline.pdf
Patient advice / follow up treatment	Inform the individual/carer of possible side effects and their management. The individual/carer should be advised to seek medical advice in the event of an adverse reaction.
Records	Nursing documentation and back of treatment card. State 'administered under PGD' with name and signature of authorised nurse. For EPMA: Document the utilisation of the medicine under PGD by ordering the appropriate drug order item against the correct patient record. Complete all mandated fields on the prescription form, identified by a blue star. Document the administration of the medicine. Document in SystmOne.

6. Key references

Key references	• Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2

7. Registered health professional authorisation sheet

PGD Name [Version]: **Supply of Salbutamol 2.5mg in 2.5ml Nebuliser Solution for Acute Exacerbation of COPD By Impact+ Outreach Service [v2.0]** **PGD ref: UHDB 005**
Valid from: 11/02/2021 **Expiry date: 10/02/2024**

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 the PGD e-Learning package via My Learning Passport (or ESR).
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 should be retained 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.