University Hospitals of Derby and Burton
NHS Foundation Trust

# PATIENT GROUP DIRECTION (PGD)

## Administration of IPRATROPIUM BROMIDE NEBULES By Registered Nurses, Emergency Nurse Practitioners (ENP), Emergency Care Practitioners (ECP) and Emergency Physiotherapy Practitioners (EPP) In the Emergency Department at Queens Hospital, Burton and Minor Injuries departments at Samuel Johnson and Sir Robert Peel community hospitals

## Documentation details

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| Reference no: | UHDB120 |
| Version no: | V2 |
| Valid from: | 28/11/2024 |
| Review date: | 28/05/2027 |
| Expiry date: | 27/11/2027 |

## Change history

| Version number | Change details | Date |
|---|---|---|
| 1 | Use of new UHDB template | 10/08/2021 |
| 2 | Planned review and update | October 2024 |
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## Glossary

| Abbreviation | Definition |
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## 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 Venkata Thungala | Consultant Emergency Medicine |
| Nida Halim | Pharmacist |
| Nadine Watson | Emergency Nurse Practitioner |
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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 |
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## 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** |
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| In the Emergency Department 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).** | | | |
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| **Role** | **Name** | **Sign** | **Date** |
| Medication Safety Officer<br><br>*Pharmacist: Medicines Safety Officer, Chief Pharmacist or assigned deputies)* | James Hooley | **Signed copy held by Pharmacy** | **28/11/2024** |

| **Additional signatories (required as per legislation and locally agreed policy)** | | | |
|---|---|---|---|
| **Role** | **Name** | **Sign** | **Date** |
| Pharmacist<br><br>*Clinical Pharmacist from PGD working group* | **Nida Halim** | **Signed copy held by Pharmacy** | **01/11/2024** |
| Lead ED Consultant<br>*Doctor* | **Dr Venkata Thungala** | **Signed copy held by Pharmacy** | **14/11/2024** |
| Senior ENP<br>*Registered Professional representing users of the PGD* | **Nadine Watson** | **Signed copy held by Pharmacy** | **29/10/2024** |

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

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| **Qualifications and professional registration** | • Registered professional with current professional registration operating within their usual scope of practice.<br>• 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 including core PGD training.<br>• Individual has read and understood full content of this PGD and signed authorisation (section 7)<br>• Completion of Medicines Management Drug Assessment<br>• 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:<br>a) **Asthma –** UHDB Paediatric Guidelines<br>b) **Adults -** Severe acute asthma BTS/Sign guidelines. (See references) |
| **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<br>• 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 authorising manager (section 7) or the manager within the PGD working group (section 1) so that further training can be provided as required. |
| **On-going training and competency** | • Annual Medicines Safety Training (essential to role)<br>• Organisation PGD eLearning<br>• Review/repeat initial training above when this PGD is revised<br>• Up to date mandatory training including CPR and anaphylaxis.<br>• The registered healthcare professional must actively take part in CPD and annual individual performance reviews<br>• 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

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| **Clinical condition or situation to which this PGD applies** | • Treatment of reversible bronchospasm in COPD<br>• Treatment of acute bronchospasm<br>• Treatment of severe or life-threatening asthma alongside salbutamol or if little/poor initial response to salbutamol nebuliser |
| **Criteria for inclusion** | • Any adult patient with reversible airways obstruction presenting with the above conditions.<br>• Child >1 month of age presenting with severe acute asthma or acute bronchospasm (see also paediatric guideline - in references – *Children who require oxygen to keep saturations 92% or higher should be given nebulisers. Once oxygen saturations can be safely maintained at 92% or higher then bronchodilators (see PGD 247) are best given by spacers (a facemask may be required for younger children).*<br>• Consent gained.<br>• Use only if benefits outweigh risk in pregnancy, breastfeeding, or glaucoma – you may need to seek additional advice (decision to treat remains with the practitioner operating under this PGD) |
| **Criteria for exclusion** | • Patients with prostate hyperplasia and bladder outflow obstruction<br>• Children under 1 month of age<br>• Known hypersensitivity to ipratropium, atropine or any components of the formulation<br>• It should not be used in pregnancy or lactation unless the expected benefits to the mother are considered to outweigh any potential risks to the foetus or neonate<br>• Glaucoma – unless benefit outweighs risk (see cautions below) |
| **Cautions including any relevant action to be taken** | • Patients with glaucoma or other ocular conditions predisposing to glaucoma: It is recommended that the nebulised solution is administered via a mouthpiece. If this is not available and a nebuliser mask is used, it must fit properly. Patients who may be predisposed to glaucoma should be warned specifically to protect their eyes<br>• Ipratropium bromide should be used with caution in patients with pre-existing urinary outflow tract obstruction (e.g. prostatic hyperplasia or bladder outflow obstruction)<br>• Cystic fibrosis – ipratropium in an anticholinergic, therefore avoid or use judiciously in those prone to gastro-intestinal disturbance<br>• Use only if benefits outweigh risk in pregnancy or breastfeeding – you may need to seek additional advice. |
| **Action to be taken if the patient is excluded** | • If a patient is excluded, referral to secondary care may be required including 999 transfer if necessary.<br>• Discuss with ED Doctor and consider prescribing an alternative medication.<br>• Discuss with the patient and advise alternative treatment.<br>• Document in patient's notes the reason for exclusion and actions taken |

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| **Action to be taken if the patient or carer declines treatment** | • Advise patient on alternative treatment<br>• Document any advice given<br>• Refer to medical staff if appropriate<br>• Referral to secondary care may be required including 999 transfer if necessary |
| **Arrangements for referral for medical advice** | • Follow up by GP/Practice Nurse/Asthma or COPD Nurse<br>• If patient continues to have breathing problems referral to secondary care via 999 as appropriate |

## 5. Description of treatment

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| **Name, strength & formulation of drug** | Ipratropium Bromide 250 micrograms/1ml OR 500 micrograms / 2ml nebuliser solution |
| **Legal category** | Prescription-only Medicine (POM) |
| **Route / method of administration** | Inhaled via oxygen driven nebuliser or electronic air nebuliser. This will depend on the oxygen requirements of the patient e.g COPD patients would need air driven nebuliser. |
| **Indicate any off-label use (if relevant)** | Doses differ from those recommended by manufacturer (BNF reference below) as per NICE guideline for Acute exacerbation of asthma – How should I manage an acute exacerbation of asthma? (Reference below)<br><br>As part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence |
| **Dose and frequency of administration** | **<u>Acute Bronchospasm</u>**<br>**1 month–2 years–** 125 micrograms (maximum 500 micrograms per day)<br>**2 – 11 years –** 250 micrograms (maximum 1mg per day)<br>**12 – 17 years –** 250 - 500 micrograms (maximum 2 mg per day)<br>**Adult –** 500 micrograms (maximum 2mg per day)<br><br>**<u>Severe or LIFE-THREATENING acute asthma</u>**<br>• **Child 1 month – 11 years**<br>○ 250 micrograms every 20 - 30 minutes for the first two hours<br>○ Then 250 micrograms every 4 - 6 hours as required.<br>• **Child 12 – 17 years**<br>○ 250 – 500 micrograms every 4 - 6 hours as required<br>• **Adult**<br>○ 500 micrograms every 4 – 6 hours as required. |
| **Duration of treatment** | Emergency treatment within department only |
| **Quantity to be supplied** | *N/A* |
| **Storage** | Stocks must be securely stored according to UHDB Medicine policy and in conditions in line with SPC.<br>• Do not store above 25ºC room temperature.<br>• Store in the original package.<br>• The ampoule should be used immediately after opening. Any remaining solution should be discarded. |

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| **Drug interactions** | Ipratropium belongs to a class of drugs known as antimuscarinics. See BNF listing (reference below) for a full list of interacting drugs.<br>However, interactions do not generally apply to antimuscarinics used by inhalation. |
| **Identification & management of adverse reactions** | The following side effects are common:<br>**Allergy**<br>• Immediate hypersensitivity reactions following the use of ipratropium with rare cases of urticarial, angiodema, rash, bronchospasm, oropharyngeal oedema and anaphylaxis<br>• For anaphylaxis – treat as per Trust emergency guidelines<br><br>**Nervous System**<br>• Headache<br>• Dizziness<br>**Respiratory**<br>• Throat irritation<br>• Cough<br>• Paradoxical bronchospasm<br>• As with other inhalation therapy, inhalation induced bronchoconstriction may occur with an immediate increase in wheezing after dosing. This should be treated straight away with a fast acting inhaled bronchodilator. ATROVENT UDVs should be discontinued immediately, the patient assessed and, if necessary, alternative treatment instituted<br><br>**Gastro-intestinal**<br>• Dry mouth<br>• Nausea<br>• Gastro-intestinal motility disorder<br>• Constipation<br>**Occular**<br>• There have been isolated reports of ocular complications (i.e. mydriasis, increased intra-ocular pressure, narrow-angle glaucoma, eye pain) when aerolised ipratropium has come into contact with the eyes during nebuliser therapy.<br>• Eye pain or discomfort, blurred vision, visual halos, or coloured images in association with red eyes from conjunctival congestion and corneal oedema may be signs of narrow angle glaucoma. Should any of these symptoms occur, miotic eye drops are needed and medical advice sought immediately<br>• Acute angle closure glaucoma has been reported with nebulised ipratropium, particularly when given with nebulised salbutamol. **Care is needed to protect the patient's eyes from nebulised drug.**<br>• Inhalation of Ipatropium can also cause cardiac arrythmias<br>A detailed list of adverse reactions is available in the SPC, which is available from the electronic medicines compendium website (see reference below) |

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| **Management of and reporting procedure for adverse reactions** | If adverse reactions suspected/occurs:<br>• Assess patient using ABCDE and provide medical intervention appropriately.<br>• Refer to ED or Medical Consultant immediately.<br>• Use the MHRA Yellow Card scheme to report any suspected adverse reactions. Go to: https://yellowcard.mhra.gov.uk<br>• Document all adverse drug reactions in the patient's medical notes<br>• Complete incident report via UHDB Trust incident management system (Datix) |
| **Written information to be given to patient or carer** | Not routinely required for administration in department.<br>May give marketing authorisation holder's patient information leaflet (PIL) if required (link in references below) |
| **Patient advice / follow up treatment** | • Advise patient of the treatment given, understanding condition, possible reasons for exacerbation and concordance with prescribed treatment.<br>• If applicable, check inhaler technique.<br>• If applicable, check compliance with preventer therapy, and advise patient of importance of using preventer therapy as prescribed.<br>• Advise patient that this is a rescue measure and it is essential patient visits own GP practice for assessment as soon as possible (advisable to do so within 2 working days)<br>• Advise patient of above possible adverse reactions<br>• Advise if adverse reactions are experienced they should avoid driving or operating heavy machinery |
| **Records** | Record the following information on ePMA (Electronic Prescribing system) UHDB – Meditech<br><br>Either the system holding the record, or the healthcare practitioner working under the PGD, must capture/document all of the following:<br>• name of individual, address, date of birth and GP with whom the individual is registered (if relevant)<br>• name of registered health professional<br>• name of medication supplied/administered.<br>• date of supply/administration<br>• dose, form, and route of supply/administration<br>• quantity administered<br>• batch number and expiry date (if applicable e.g., injections and implants)<br>• advice given, including advice given if excluded or declines treatment<br>• details of any adverse drug reactions and actions taken<br>• Confirm administered via Patient Group Direction (PGD)<br><br>Records should be signed and dated (or password-controlled e-records). All records should be clear, legible, and contemporaneous.<br><br>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

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| **Key references** | • Electronic Medicines Compendium https://www.medicines.org.uk/emc/product/3818/smpc accessed online 27/08/2024.<br>• Electronic BNF https://bnf.nice.org.uk/drugs/ipratropium-bromide/ accessed online 27/08/2024.<br>• Medicines Complete https://www.new.medicinescomplete.com/#/content/bnf/_229441824 Accessed 27/08/2024<br>• SIGN 158 British Guideline on the management of Asthma https://www.sign.ac.uk/media/1383/qrg158.pdf Accessed online 27/08/24.<br>• Scenario: Acute exacerbation of asthma https://cks.nice.org.uk/topics/asthma/management/acute-exacerbation-of-asthma/ Accessed online 27/08/2024<br>• Acute management of wheeze and asthma paediatric guidelines https://derby.koha-ptfs.co.uk/cgi-bin/koha/opac-retrieve-file.pl?id=d5c31e2ab59c919aa2195a879b3f33a5 Accessed online 27/08/24<br>• NICE Medicines practice guideline “Patient Group Directions” https://www.nice.org.uk/guidance/mpg2 |

## 7. Registered health professional authorisation sheet

**PGD Name [version]:** QHB - ED/MIU - Ipratropium Bromide Nebules [v2]
**PGD ref:** UHDB304
**Valid from: 28/11/2024 Expiry date: 27/11/2027**

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.** | | | |
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| **Name** | **Designation** | **Signature** | **Date** |
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### 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.** | | | |
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| **Name** | **Designation** | **Signature** | **Date** |
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**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.