University Hospitals of Derby and Burton NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Administration of Ipratropium Nebules
By Registered UHDB Staff in Adult UHDB services

Documentation details

Reference no:	UHDB192*
Version no:	1
Valid from:	12/07/2022
Review date:	12/01/2025
Expiry date:	11/07/2025

Change history

Version number	Change details	Date
1	New template – Extended for all UHDB staff on any site	

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
James Hooley	Medicines Safety Officer (Pharmacist)
Core Adult PGD list maintained by Medicines Safety Group.	Note: No PGD working group convened as this PGD is created by merging detail from multiple authorised PGDs in active use across UHDB which have been developed previously with nursing and medical input.

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	-	-

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
All UHDB staff providing UHDB services (includes UHDB staff/services undertaken on non-UHDB premises) This is a core PGD and can be implemented in all adult services where training and resources have been allocated by senior staff to do so (see policy and limitations below if in doubt).
Limitations to authorisation
It is the responsibility of the practitioner working under this PGD to ensure that this PGD is in place in the area they are practising at the time of use. In most cases, this is implicit when a senior manager requests the staff to undertake training and then authorises them in section 7 of this document. However, when working in alternative areas (e.g. internal bank or redeployment) it is important that the practitioner confirms with a departmental manager in the new department that the core PGDs are in-use in their area.

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Chief Pharmacist	**Clive Newman**	**Signed copy held by Pharmacy**	**12/07/2022**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer (pharmacist) *Clinical Pharmacist from PGD working group*	**James Hooley**	**Signed copy held by Pharmacy**	**14/06/2022**
Medical Director or Deputy *Doctor*	**Dr James Crampton**	**Signed copy held by Pharmacy**	**22/06/2022**
Chief Nurse or deputy *Registered Professional representing users of the PGD*	**Garry Marsh**	**Signed copy held by Pharmacy**	**07/07/2022**

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	All Divisions, Adult Areas, 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
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 either the authorising manager (section 7) or the manager within the PGD working group (section 1) so that further training can be 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 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	• Treatment of reversible bronchospasm in COPD • Treatment of acute bronchospasm • 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 above conditions 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 • Known hypersensitivity to ipratropium, atropine or any components of the formulation Please see https://www.medicines.org.uk/emc/product/7467/smpc
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. • Cystic Fibrosis – ipratropium in an anticholinergic, and therefore avoid or use judiciously in those prone to gastro-intestinal disturbance • 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)
Action to be taken if the patient is excluded	• Record reasons for exclusion in patient notes • Advise patient on alternative treatment • Refer to medical staff or prescriber for review and prescribing of alternative agent if appropriate.
Action to be taken if the patient or carer declines treatment	• Document advice given • Advise patient on alternative treatment • Refer to medical staff if appropriate.
Arrangements for referral for medical advice	Contact your ward or clinic medical team in the first instance except in the event of anaphylaxis/cardiac arrest when you should follow your local medical emergency procedures (e.g. 2222 / 3333 / 999 procedures)

5. Description of treatment

Name, strength & formulation of drug	Ipratropium Bromide 250micrograms/1ml or 500micrograms/2ml nebuliser solution
Legal category	POM
Route / method of administration	Inhaled via air-driven nebuliser.

Indicate any off-label use (if relevant)	Doses differ from those recommended by manufacturer. See BNF https://www.new.medicinescomplete.com/#/content/bnf/_229441824 NICE https://cks.nice.org.uk/topics/asthma/management/acute-exacerbation-of-asthma/
Dose and frequency of administration	Adult 500 micrograms as required; maximum 2 mg per day PGD **FOR SEVERE ACUTE ASTHMA** **Adult 500 micrograms every 4-6 hours as required** This is in accordance with current BTS/SIGN GUIDELINES available at https://www.sign.ac.uk/media/1383/qrg158.pdf and the UHDB asthma guideline on Net-i
Duration of treatment	Emergency treatment within department only – refer for medical review / prescription at earliest opportunity
Quantity to be supplied (leave blank if PGD is administration ONLY)	n/a
Storage	Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below: Do not store above 25°C. Store in the original package. The nebule should be opened immediately before use and any solution remaining after use should be discarded. https://www.medicines.org.uk/emc/product/7467
Drug interactions	The following interactions have been identified and should be considered where it is known a patient is on the following medicines: Ipratropium belongs to a class of drugs known as antimuscarinics. See BNF for a full list of interacting drugs. However, interactions do not generally apply to antimuscarinics used by inhalation. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: https://www.medicines.org.uk/emc/product/7467
Identification & management of adverse reactions	The following side effects are common: ALLERGY □ Immediate hypersensitivity reactions following the use of ipratropium have been demonstrated by rare cases of urticarial, angioedema, rash, bronchospasm, oropharyngeal oedema and anaphylaxis **NERVOUS SYSTEM** • Headache, dizziness **RESPIRATORY** • Throat irritation, cough, paradoxical bronchospasm **GI** • Dry mouth, nausea, gastro-intestinal motility disorder, constipation **OCCULAR** There have been isolated reports of ocular complications (i.e. mydriasis, increased intra-ocular pressure, narrow-angle

	glaucoma, eye pain) when aerosolised ipratropium has come into contact with the eyes during nebuliser therapy. 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. 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 (see cautions) A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: https://www.medicines.org.uk/emc/product/7467
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.
Written information to be given to patient or carer	None routinely required for administration in department. May give copy of marketing authorisation holder's patient information leaflet (PIL) which can be obtained from www.medicines.org.uk if required https://www.medicines.org.uk/emc/files/pil.7467.pdf
Patient advice / follow up treatment	Advised to seek medical advice in the event of an adverse reaction.
Records	For inpatients, the record of administration must be documented in the ePMA system or medicines chart used in your area. For other areas, an ePMA system should be used if in-use in your area as this will ensure all legal criteria are fulfilled and auditable. Otherwise, records can be made in the medical notes or within the patient pathway (e.g. in daycase or triage where a pathway booklet is in use) but must include the legal requirements below. 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 supplied and/or administered 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	*UHDB. Asthma - Management of Acute Exacerbations in Adults – Full Clinical Guideline* *Electronic Medicines Compendium http://www.medicines.org.uk/* *Electronic BNF https://bnf.nice.org.uk/* NICE https://cks.nice.org.uk/topics/asthma/management/acute-exacerbation-of-asthma/ BTS/SIGN GUIDELINES available at https://www.sign.ac.uk/media/1383/qrg158.pdf

7. Registered health professional authorisation sheet

PGD Name [version]: Ipratropium Nebules for adults [v1.0] PGD ref: UHDB192

Valid from: 12/07/2022 Expiry date: 11/07/2025

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.