University Hospitals of Derby and Burton NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Supply of Prednisolone 5mg tablets for Acute Exacerbation of COPD or Asthma
By Impact+ Outreach Service

Documentation details

Reference no:	UHDB003
Version no:	3.0
Valid from:	25/9/2024
Review date:	08/11/2026
Expiry date:	08/05/2027

Change history

Version number	Change details	Date
V2.0	Updated to cover asthma & COPD.	August 2021
V3.0	No Clinical Change. Updated 'Records' and 'initial training' sections to reflect standard UHDB policy/template wording.	September 2024

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
Kerie Hale	Lead Respiratory Nurse Specialist (ImpACT+
Hester Smail	Divisional Lead Pharmacist for Specialist 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
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
Impact+ Service
Limitations to authorisation

Organisational approval (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer	James Hooley	**Signed copy held by Pharmacy**	**25/09/2024**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Clinical Lead	Dr Deepak Subramanian	**Signed copy held by Pharmacy**	10/09/2024
Clinical Service Manager	Robin Evans	**Signed copy held by Pharmacy**	04/09/2024
Divisional Pharmacist	Hester Smail	**Signed copy held by Pharmacy**	19/09/2024

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

Qualifications and professional registration	This PGD will apply to all Specialist Nurses, Physiotherapists and Occupational Therapists in the ImpACT+ team and the Asthma specialist nurses at Royal Derby Hospital.
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 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.
Competency 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 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	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	For administration by a patient during an exacerbation of COPD or asthma following assessment by ImpACT+ outreach team or asthma specialist nurses at Royal Derby Hospital in either a community or outpatient setting.
Criteria for inclusion	Patients 16 years and over presenting in the above clinical situation □ Adult with a history of COPD or Asthma □ 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 □ Access to telephone □ Support available at home (preferably living with another person) For patients with asthma the management should follow patient's personalised asthma action plan [PAAP] (attached). Steroids are indicated when the peak flow is 70% or less than their best.
Criteria for exclusion	• Patients under 16 years old • Cannot swallow, are nil by mouth, or having difficulty swallowing food or drink. • Pregnancy and breastfeeding • Systemic infection unless specific anti-infective therapy is employed. • Hypersensitivity to the active substance or to any of the ingredients it contains. • Ocular herpes simplex because of possible perforation.
Cautions including any relevant action to be taken	• May reduce effects of anticoagulants • May enhance effects of anticoagulants • May worsen control of diabetes or impaired glucose tolerance • May worsen hypertension or congestive heart failure • Active peptic ulcer. • Known renal or hepatic impairment • Pregnancy and breastfeeding A detailed list of cautions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
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, Dr W Chang

	Out of Hours/Weekend: Respiratory Consultant on Call (via switchboard)

5. Description of treatment

Name, strength & formulation of drug	Prednisolone 5mg tablets
Legal category	POM
Route / method of administration	Oral
Dose and frequency of administration	30mg once daily for an exacerbation of COPD 40mg once daily for an exacerbation of Asthma
Duration of treatment	5 days
Quantity to be supplied	2 x 28 prednisolone 5mg tablets
Storage	Store below 25 °C. Store in the original packaging.
Drug interactions	**The following interactions have been identified and should be considered where it is known a patient is on the following medicines:** The absorption of prednisolone may be reduced by large doses of some antacids such as magnesium trisilicate or aluminium hydroxide. Response to anticoagulants may be reduced or, less often, enhanced by corticosteroids. Close monitoring of the INR or prothrombin time is required to avoid spontaneous bleeding. Glucocorticoids may increase blood glucose levels. Patients with diabetes mellitus receiving concurrent insulin and/or oral hypoglycemic agents may require dosage adjustments of such therapy. Carbamazepine, phenobarbital, phenytoin, and primidone accelerate metabolism of corticosteroids and may reduce their effect. Risk of hypokalaemia may be increased with amphotericin, therefore concomitant use with corticosteroids should be avoided unless corticosteroids are required to control reactions; ketoconazole inhibits metabolism of methylprednisolone and possibly other corticosteroids. Increased toxicity of digoxin if hypokalaemia occurs with corticosteroids. Increased risk of hypokalaemia if high doses of corticosteroids given with high doses of bambuterol, fenoteral, formoteral, ritodrine, salbutamol, salmeterol and terbutaline. A detailed list of drug interactions is available in the SPC, which is

	available from the electronic Medicines Compendium website: www.medicines.org.uk
Identification & management of adverse reactions	**The following adverse reactions have been observed in patients receiving prednisolone:** Adrenal suppression, cushingoid faces, impaired carbohydrate tolerance with increased requirement for antidiabetic therapy, manifestation of latent diabetes mellitus. Sodium and water retention, hypokalaemic alkalosis, potassium loss, negative nitrogen and calcium balance, glucose intolerance and protein catabolism. Increase both high and low density lipoprotein cholesterol concentration in the blood. Increased appetite. Weight gain, obesity, hyperglycaemia, dyslipidaemia. Irritability, depressed and labile mood, suicidal thoughts, psychotic reactions, mania, delusions, hallucinations, and aggravation of schizophrenia. Behavioural disturbances, irritability, anxiety, sleep disturbances, and cognitive dysfunction including confusion, restlessness, nervousness and amnesia. Euphoria, depression, insomnia, dizziness, headache, vertigo. Raised intracranial pressure with papilloedema (pseudotumor cerebri). Aggravation of epilepsy, epidural lipomatosis. vertebrobasilar stroke Glaucoma, papilloedema, posterior subcapsular cataracts, nuclear cataracts (particularly in children), exophthalmos, corneal or scleral thinning, exacerbation of ophthalmic viral or fungal disease. Severe exacerbation of bullous exudative retinal detachment; lasting visual loss in some patients with idiopathic central serous chorioretinopathy. Vertigo. Dyspepsia, nausea, peptic ulceration with perforation and haemorrhage, abdominal distension, abdominal pain, diarrhoea, oesophageal ulceration, acute pancreatitis. Fatigue, malaise, impaired healing Increased intra-ocular pressure, may suppress reactions to skin tests. **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.

	• 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	Give marketing authorisation holder's patient information leaflet (PIL) provided with the product.
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	The record of administration must be documented in the ePMA system or medicines chart used in your area. This may include SystmOne for Impact+ services. 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	• 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] Prednisolone 5mg tablets for Impact+ Service [v3.0]
PGD ref: UHDB 003

Valid from: 25/09/2024 Expiry date: 08/05/2027

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 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.