Patient Group Direction

Supply of Prednisolone by Community Pharmacists to Patients with an Exacerbation of COPD
Protocol Number 301 Version 8

Date protocol prepared: **October 2022**

Date protocol due for review: **October 2024**

Expiry date: **October 2025**

This patient group direction must be signed by all health care professionals involved in its use. NHS Forth Valley should hold the original signed copy. The PGD must be easily accessible in the clinical setting.

Organisation	NHS Forth Valley

Job Title	**Name**	**Signature**	**Date**
Director of Nursing	Frances Dodd	Signed by Frances Dodd	20/4/23
Medical Director	Andrew Murray	Signed by Andrew Murray	2/4/23
Director of Pharmacy	Laura Byrne	Signed by Laura Byrne	21/4/23

This document authorises the supply of **prednisolone** by appropriate practitioners to patients who meet the criteria for inclusion under the terms of the document.

Practitioners seeking to supply **prednisolone** must ensure that they assess all clients to make sure they meet the criteria before supplying the product.

The purpose of this Patient Group Direction is to help patients by ensuring that they have ready access to a quality assured service which provides a timely, consistent and appropriate supply of **prednisolone** for **an exacerbation of COPD.**

Signatures of those developing the Patient Group Direction

Job Title	Name	Signature	Date
Doctor	Scott Williams	**Signed by Scott Williams**	15/3/23
Pharmacist	Hollie Houghton	**Signed by Hollie Houghton**	29/12/22
Nurse			
Microbiologist (if appropriate)			
Paediatrician (if appropriate)			

Approval from Patient Group Directions Group

Group	Chair	Signed on behalf of group	Date
Patient Group Directions Group	Laura Byrne	**Signed by Laura Byrne**	21/4/23

Lead Author responsible for updating change history:

Change history

Version	Date	Summary of changes
7	31/10/2022	Exclusion criteria updated to include ocular herpes simplex, galactose intolerance, frequency of supply, include increased breathing rate and signs of systemic inflammatory response
7	31/10/2022	Dosage reduced to 30mg for 5 days.
7	31/01/2022	References updated to most recent versions

The following Patient Group Direction for Supply of Prednisolone by Community Pharmacists to Patients with an Exacerbation of COPD may be used from the following business/practice:

Name:

Address:

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

CLINICAL CONDITION

Indication	To allow Community Pharmacists to supply prednisolone to patients with an infective exacerbation of Chronic Obstructive Pulmonary Disease (COPD)
Inclusion Criteria	Definite diagnosis of COPD Exacerbation characterised by **two** or more of the following • development or increase in sputum purulence • increase in shortness of breath • increase in sputum volume Patient has Forth Valley COPD "self-management plan" agreed with GP which allows for treatment from Community Pharmacist
Exclusion Criteria	• Active peptic ulceration • Pregnancy • Breastfeeding • Untreated known tuberculosis • Occular herpes simplex because of possible perforation • Previous steroid psychosis • Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. • More than 2 supplies by community pharmacist in any 3 month period or 3 supplies in 12months from any prescriber/route • Exposure to chickenpox in patients with no definite history of chickenpox or shingles • Patients on cyclosporin or methotrexate • Increased breathing rate ≥20 breaths/min • Systemic inflammatory response syndrome criteria e.g. temperature greater than >38°C, heart rate >90 beats per minute and other symptoms • Patient does not have Forth Valley COPD "self-management plan" at time of presentation

Caution/ Need for further advice	In patients with **diabetes** – advise patient to monitor blood sugar closely (e.g. daily in patients with Type II DM and four times daily in patients with Type I DM) **Hypertension** – patients should be advised to have their blood pressure checked if having repeated courses **Congestive heart failure** – worsening fluid retention – if worsening of breathlessness, advise patient to seek advice from GP or NHS 24. **Osteoporosis** – patients on repeated course of oral steroids or maintenance steroids may be at risk of osteoporosis. These patients should be advised to make a routine appointment with their GP to discuss this. **Long term steroids** or repeated courses in past year (more than 4 courses in 12 months)– advise patient to speak to their GP / Practice Nurse before current course ends for further advice on tapering dose. Ensure patient has Steroid Warning Card supplied. Prednisolone may exacerbate **epilepsy.** Patients with epilepsy should be asked if their epilepsy control has been upset by steroids in the past. If so, they should be referred to GP or contact the Out of Hours Service via Professional to Professional Line and no supply made **Patients on drugs which induce hepatic microsaomal enzymes -**cytochrome P-450 (CYP) isoenzyme 3A4 such as phenobarbital, phenytoin, rifampicin, rifabutin, carbamazepine, primidone and aminoglutethimide may reduce the therapeutic efficacy of corticosteroids by increasing the rate of metabolism. Advise patients to see their GP or to contact NHS 24 if they do not feel they are improving or they are getting worse. **Patients taking Non-steroidal anti-inflammatory drugs.**. Advise patients experiencing symptoms of GI upset to see their GP. **Patients on warfarin -** Advise patient to contact GP Practice as soon as practical to arrange to have INR checked
Action if Patient declines or is excluded	Refer patient to GP practice or Out of Hours via Professional to Professional Line

DRUG DETAILS

Name, form & strength of medicine	Prednisolone 5mg tablets/ Prednisolone 5mg e.c. tablets
Legal Status	POM
Route/ Method	Oral
Dosage	30mg

Frequency	Once daily in the morning with or after food
Duration of treatment	5 days
Maximum or minimum treatment period	5 days
Quantity to Supply/ administer	42 x 5mg plain tablets/e.c. tablets
Side Effects	The incidence of predictable undesirable effects, including hypothalamic-pituitary adrenal suppression correlates with the relative potency of the drug, dosage, timing of administration and the duration of treatment. It should be remembered that this PGD is for the supply of a short course. For a full list of side effects – refer to the marketing authorisation holder's Summary of Product Characteristics (SPC). A copy of the SPC must be available to the health professional administering medication under this Patient Group Direction. This can be accessed on www.medicines.org.uk Patients experiencing any adverse effects should discuss this with their GP or Community Pharmacist. All adverse reactions that are serious or result in harm should be reported to the MHRA through the Yellow Card Scheme http://yellowcard.mhra.gov.uk/
Advice to patient/carer	In patients with **diabetes** – advise patient to monitor blood sugar closely (e.g daily in patients with Type II DM and four times daily in patients with Type I DM) **Hypertension** – patients should be advised to have their blood pressure checked if having repeated courses **Congestive heart failure** – worsening fluid retention – if worsening of breathlessness, advise patient to seek advice from GP or NHS 24. **Osteoporosis** – patients on repeated course of oral steroids or maintenance steroids may be at risk of osteoporosis. These patients should be advised to make a routine appointment with their GP to discuss this. **Long term steroids** or repeated courses in past year (more than 4 courses in 12 months)– advise patient to speak to their GP / Practice Nurse before current course ends for further advice on tapering dose. Ensure patient has Steroid Warning Card supplied. Prednisolone may exacerbate **epilepsy.** Patients with epilepsy should be asked if their epilepsy control has been upset by steroids in the past. If so, they should be referred to GP practice or contact the Out of Hours Service via Professional to Professional Line and no supply made **Patients on drugs which induce hepatic microsaomal enzymes -** cytochrome P-450 (CYP) isoenzyme 3A4 such as phenobarbital, phenytoin, rifampicin, rifabutin, carbamazepine, primidone and

	aminoglutethimide may reduce the therapeutic efficacy of corticosteroids by increasing the rate of metabolism. Advise patients to see their GP or to contact NHS 24 if they do not feel they are improving or they are getting worse. **Patients taking Non-steroidal anti-inflammatory drugs.**. Advise patients experiencing symptoms of GI upset to see their GP. **Patients on warfarin -** Advise patient to contact GP Practice as soon as practical to arrange to have INR checked Inform patient of possible side effects and their management. The Manufacturer Patient Information Leaflet should be given. See also Cautions/Need for further advice section Ensure patient is aware that if symptoms worsen or becomes systemically unwell, then they should seek medical advice that day. If symptoms have not improved after 5 days treatment, then patients should be advised to seek further medical advice. Inform patient of possible side effects and their management and who to contact should they be troublesome. Advise patient of the importance of taking regularly and completing the course. Patients should be informed who to contact should they experience an adverse drug reaction.
Follow up	Patients not improving after a few days of starting the course or if any deterioration should be advised to contact GP practice or NHS 24 out of hours.

STAFF CHARACTERISTICS

Qualifications	Pharmacist currently on the practising section of pharmaceutical register held by the General Pharmaceutical Council.
Specialist competencies or Qualifications	Pharmacists must have the necessary competencies and training to use the PGD and be authorised to use the PGD by their Lead Pharmacist. Under PGD legislation there can be no delegation. Administration of Prednisolone has to be by the same practitioner who has assessed the patient under the PGD.
Continuing Training & Education	Up to date knowledge in therapeutic area evidenced through ongoing CPD. Other necessary training: Attendance at local training events on COPD.

REFERRAL ARRANGEMENTS & AUDIT TRAIL

Referral arrangements	Patients who are not improving or feel their condition is getting worse should seek urgent treatment from their GP or through NHS 24 out of hours Ensure patient is aware that if symptoms worsen or the patient becomes systemically unwell, then they should seek medical advice that day either from their GP practice or through OOH centre. If symptoms have not improved after 5 days treatment, then patients should be advised to seek further medical advice.
Records/audit trail	A record of supply should be made on PMR and in the patient's self-management card. which includes • Name, strength, form and pack size of medicine supplied • Dose and route of administration • Date of supply and name of person making supply • Advice given re side effects and follow up. • Criteria satisfied for supply i.e. presenting symptoms. The medicine must be labelled in accordance with requirements detailed in the current version of Medicines, Ethics and Practice. The patient's GP must be notified that a supply has taken place within 72 hours of supply being made. The patient's GP must be informed if the patient experiences an adverse drug reaction. A computer or manual record of all individuals receiving a supply under this PGD should also be kept for audit purposes. Record "supplied via Patient Group Direction (PGD)" Any adverse events/incidents should be reported to the PGD group in addition to any existing pharmacy processes Records of supply should be kept for 8 years.
Reference sources and comments	1. Chronic Obstructive Pulmonary Disease. National clinical guideline on management of chronic obstructive pulmonary disease in over 16s: diagnosis and management. NG115. July 2019 2. Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for Diagnosis, Management and Prevention of COPD. 2022 (www.goldcopd.com) 3. BNF – Current Edition 4. Summary of product characteristics

PATIENT GROUP DIRECTION AUTHORISATION DOCUMENT

Supply of Prednisolone by Community Pharmacists for the management of COPD working in Forth Valley Community Pharmacies

Protocol Number 301 Version 7

Individual Authorisation

This PGD does not remove inherent professional obligations or accountability

I_____ (please print in capitals), confirm that I have read and understood the above Patient Group Direction. I confirm that I have the necessary professional registration, competence, and knowledge to apply the Patient Group Direction. I will ensure my competence is updated as necessary. I will have ready access to a copy of the Patient Group Direction in the clinical setting in which the supply of the medicine will take place and agree to provide this medicine only in accordance with this PGD.

I understand that it is the responsibility of the pharmacist to act in accordance with the Code of Ethics for Pharmacists and to keep an up to date record of training and competency. I understand it is also my responsibility to ensure that all consultations with patients occur within a private and confidential area of the pharmacy.

I have read and fully understand the Patient Group Direction for the supply of Prednisolone and agree to provide this medicine only in accordance with this PGD in NHS Forth Valley Community Pharmacies.

Name of Pharmacist (in block capitals)_____

GPhC Number _____ Employee ☐ Locum ☐ Relief Pharmacist ☐

If you are a locum please provide a contact email address: _____

Normal NHS Forth Valley Pharmacy Location
(Please state contractor code)

_____

Signature _____

Date _____

Note :
A copy of this agreement must be signed by each pharmacy practitioner who wishes to be authorised to use the PGD for Supply of Prednisolone by Community Pharmacists working in Forth Valley Pharmacies.
Please return this page either by mail to Community Pharmacy Development Team, NHS Forth Valley Royal Hospital, Stirling Road, Larbert, FK5 4WR **OR** by email to fv.communitypharmacysupport@nhs.scot attaching a scanned / photographed image. A copy should be retained in each pharmacy premises you provide the service in.

PATIENT GROUP DIRECTION AUTHORISATION DOCUMENT

Patient Group Direction for Supply of Prednisolone by Community Pharmacists to Patients with an exacerbation of COPD Protocol Number 301 Version 7

Name of Premises & Contractor Code_____

Address of Premises_____

PROFESSIONAL AGREEMENT

I have read and confirm that I have understood the above named patient group direction. **The people below have been authorised to use this protocol.** I confirm that it is my professional responsibility to ensure all those signed below have had their professional registration confirmed as per normal company processes and have signed the necessary PGD paperwork* to enable them to work within the confines of this PGD.
*The professional signing the PGD paperwork accepts personal responsibility for having undertaken all the mandatory training requirements for the PGD.

Signature of **Lead Pharmacist** for the contractor code

Name (in block capitals)	Signature	Date

Name of Professional (IN BLOCK CAPITALS)	Registration Number	Signature	Date