Supply of Prednisolone by Community Pharmacists to Patients with an Exacerbation of COPD

Protocol Number 301 Version 6

Date protocol prepared: March 2016

Date protocol due for review: March 2018

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	Angela Wallace	Signed by Angela Wallace	9/5/16
Medical Director	Tracey Gillies	Signed by Tracey Gillies	9/5/16
Director of Pharmacy	Gail Caldwell	Signed by Gail Caldwell	10/5/16

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	Dr. William Newman	**Signed by William Newman**	20/4/16
Pharmacist	Clare Colligan	**Signed by Clare Colligan**	15/4/16
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	Gail Caldwell	**Signed by Gail Caldwell**	10/5/16

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	1. Active peptic ulceration 2. Pregnancy 3. Breastfeeding 4. Untreated Tuberculosis 5. Previous steroid psychosis 6. More than 2 supplies by community pharmacist in any 3 month period. 7. Exposure to chickenpox in patients with no definite history of chickenpox or shingles 8. Patients on ciclosporin or methotrexate 9. Patient does not have Forth Valley COPD "self-management plan" at time of presentation
Caution/ Need for further advice	1. 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) 2. **Hypertension** – patients should be advised to have their blood pressure checked if having repeated courses 3. **Congestive heart failure** – worsening fluid retention – if worsening of breathlessness, advise patient to seek advice from GP or NHS 24. 4**. 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.5. **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. 6. 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 **7. 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. **8 Patients taking Non-steroidal anti-inflammatory drugs.**. Advise patients experiencing symptoms of GI upset to see their GP. **9. 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	1 – 9. Refer patient to GP 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	40mg
Frequency	Once daily in the morning with after food
Duration of treatment	7days
Maximum or minimum treatment period	
Quantity to Supply/ administer	56 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. **Body as a Whole** Leucocytosis, hypersensitivity including anaphylaxis, thromboembolism, fatigue, malaise. **Cardiovascular** Congestive heart failure in susceptible patients, hypertension

	Gastro-intestinal Dyspepsia, nausea, peptic ulceration with perforation and haemorrhage, abdominal distension, abdominal pain, increased appetite which may result in weight gain, diarrhoea, oesophageal ulceration, oesophageal candidiasis, acute pancreatitis. **Musculo-skeletal** Proximal myopathy, osteoporosis, vertebral and long bone fractures, avascular osteonecrosis, tendon rupture, myalgia. **Metabolic/Nutritional** Sodium and water retention, hypokalaemic alkalosis, potassium loss, negative nitrogen and calcium balance. **Skin/Appendages** Impaired healing, hirsutism, skin atrophy, bruising, striae, telangiectasia, acne, increased sweating, may suppress reactions to skin tests, pruritis, rash, urticaria. **Endocrine** Suppression of the hypothalamo-pituitary adrenal axis particularly in times of stress, as in trauma, surgery or illness, growth suppression in infancy, childhood and adolescence, menstrual irregularity and amenorrhoea. Cushingoid facies, weight gain, impaired carbohydrate tolerance with increased requirement for antidiabetic therapy, manifestation of latent diabetes mellitus, Increased appetite. **Central and Peripheral Nervous System** Euphoria, psychological dependence, depression, insomnia, dizziness, headache, vertigo. Raised intracranial pressure with papilloedema (pseudotumor cerebri) in children, usually after treatment withdrawal. Aggravation of schizophrenia. Aggravation of epilepsy. **Vision** Increased intra-ocular pressure, glaucoma, papilloedema, posterior subcapsular cataracts, exophthalmos, corneal or scleral thinning, exacerbation of ophthalmic viral or fungal disease. **Anti-inflammatory and immunosuppressive effects** Increases susceptibility to, and severity of infections with suppression of clinical symptoms and signs, opportunistic infections, recurrence of dormant tuberculosis. **Withdrawal symptoms** Too rapid a reduction of corticosteroid dosage following prolonged treatment can lead to acute adrenal insufficiency, hypotension and death A steroid "withdrawal syndrome" seemingly unrelated to adrenocortical insufficiency may also occur following abrupt discontinuance of glucocorticoids. This syndrome includes symptoms such as: anorexia, nausea, vomiting, lethargy, headache, fever, joint pain, desquamation, myalgia, arthralgia, rhinitis, conjunctivitis, painful itchy skin nodules weight

	loss, and/or hypotension. These effects are thought to be due to the sudden change in glucocorticoid concentration rather than to low corticosteroid levels. For a full list of side effects – refer to Summary of Product Characteristics. A copy of this must be available to the health professional administering medication under this Patient Group Direction This can be accessed at 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.
Advice to patient/carer	Inform patient of possible side effects and their management. The Drug Manufacturer Patient Information Leaflet should be given. See also Cautions / Need for further advice section
Follow up	**Patients not improving after a few days of starting the course or if any deterioration should be advised to contact GP or OOH service.**

STAFF CHARACTERISTICS

Qualifications	Pharmacist whose name is currently on the practising section of the pharmaceutical register held by The General Pharmaceutical Council
Specialist competencies or Qualifications	Attendance at local training events on COPD. Completion of NES COPD interactive resource – via NES Portal http://www.nes.scot.nhs.uk/education-and-training/by-discipline/pharmacy/about-nes-pharmacy/educational-resources/resources-by-topic/respiratory-disease/chronic-respiratory-disease/copd/chronic-obstructive-pulmonary-disease.aspx
Continuing Training & Education	Up to date knowledge in therapeutic area

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
Records/audit trail	Record of supply must be made on PMR and in the patient's self-management card. This should include the date of supply, the dosing instructions and the advice given re side effects and follow up. The record on the PMR should include the name of the pharmacist

	making the supply and criteria satisfied for supply i.e. presenting symptoms A computer or manual record of all patients receiving prednisolone through this PGD must be kept for audit purposes. The patient's GP must be made aware of the supply within 72 hours of supply being made.
Reference sources and comments	1. Chronic Obstructive Pulmonary Disease. National clinical guideline on management of chronic obstructive pulmonary disease in adults in primary and secondary care. CG101. June 2010 2. Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for Diagnosis, Management and Prevention of COPD. 2015 (www.goldcopd.com) 3. BNF – Current Edition 4. Summary of product characteristics

PATIENT GROUP DIRECTION AUTHORISATION DOCUMENT

Supply of Prednisolone tablets by Community Pharmacists to Patients with an Exacerbation of COPD Protocol Number 301 version 6

Individual Authorisation

This PGD does not remove inherent professional obligations or accountability

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct. It is also your 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 tablets and agree to provide this medicine only in accordance with this PGD in NHS Forth Valley Community Pharmacies.

Name of Pharmacist _____

GPhC Number_____

Normal Pharmacy Location (including contractor code) _____

Signature _____

Date _____

The above person has been authorised to use this protocol

Signature of Authorising Pharmacist on behalf of Employing Organisation

Name	Signature	Date

Note :
A copy of this agreement must be signed by each pharmacist who wishes to be authorised to use the PGD for Supply of Prednisolone tablets by Community Pharmacists working in Forth Valley Pharmacies. Please return this form (page 9) to Pharmacy Services, Falkirk Community Hospital, Westburn Avenue, Falkirk. FK1 5QE Fax. 01324 673616 and retain a copy in each pharmacy premises they wish to provide the medicine from. A copy of the PGD must also be available in the pharmacy for reference.

Each authorised pharmacy practitioner should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.