

Patient Group Direction

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

Protocol Number 476 Version 3.1

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
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Job Title	Name	Signature	Date
Director of Nursing	Frances Dodd	Signed by Frances Dodd	28/7/23
Medical Director	Andrew Murray	Signed by Andrew Murray	12/6/23
Director of Pharmacy	Laura Byrne	Signed by Laura Byrne	1/8/23

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

Practitioners seeking to supply **doxycycline** 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 **doxycycline** for **an infective exacerbation of COPD**.

Signatures of those developing the Patient Group Direction

Job Title	Name	Signature	Date
Doctor	Scott Williams	Signed by Scott Williams	9/6/23
Pharmacist	Hollie Houghton	Signed by Hollie Houghton	11/5/23
Nurse			
Microbiologist (if appropriate)	Dr. Robbie Weir	Signed by Robbie Weir	16/5/23
Paediatrician (if appropriate)	NA		

Approval from Patient Group Directions Group

	Chair	Signed on behalf of group	Date
Patient Group Directions Group	Laura Byrne	Signed by Laura Byrne	1/8/23

Lead Author responsible for updating change history:

Change history

Version	Date	Summary of changes
3	31/10/2022	Exclusion section updated to include increased breathing rate, signs of systemic inflammatory response, long-term use of Azithromycin, symptoms of a severe exacerbation and interacting medication. Supply information updated.
3	31/10/2022	Caution/need for further advice section updated to include information on alcohol dependence and photosensitivity.
3	31/10/2022	Advice to patient/carer updated to include visual disturbances
3	31/10/2022	References updated to most recent versions
3.1	9/5/2023	Exclusion criteria updated with temperature of 38.

The following Patient Group Direction for Supply of Doxycycline 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 doxycycline to patients with an infective exacerbation of Chronic Obstructive Pulmonary Disease (COPD) who have an allergy to penicillin.
Inclusion Criteria	<p>Definite diagnosis of COPD</p> <p>Infective exacerbation characterised by development or increase in sputum purulence and one or more of the following</p> <ul style="list-style-type: none"> - increase in shortness of breath - increase in sputum volume <p>Patient has Forth Valley COPD “self-management plan” agreed with GP which allows for treatment from Community Pharmacist</p>
Exclusion Criteria	<ul style="list-style-type: none"> • Known allergy to doxycycline, tetracyclines or any other excipients • Pregnancy • Breast Feeding • Signs and symptoms of a severe exacerbation (e.g. new/worsening confusion, marked breathlessness/tachypnoea, new onset cyanosis/peripheral oedema, rapid symptom onset) • Increased breathing rate ≥ 20 breaths/min • Systemic inflammatory response syndrome criteria e.g. temperature greater than $>38^{\circ}\text{C}$, heart rate >90 beats per minute and other symptoms. • Patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrose-isomaltase insufficiency. • Myasthenia gravis • Systemic lupus erythematosus (SLE) • Patients receiving the following medications; methotrexate, oral cyclosporin, oral retinoids, penicillins, lithium, oral typhoid vaccine. • Patients taking ergotamine or methysergide • Patient taking long term course of azithromycin • Patients taking drugs known to increase the metabolism of

	<p>doxycycline (e.g. phenytoin, barbiturates, primidone, carbamazepine, rifampicin)</p> <ul style="list-style-type: none"> • Course of antibiotics within the last month with no resolution of symptoms • More than 2 supplies by community pharmacist in any 3 month period as part of the COPD rescue meds service or 3 supplies in 12months from any prescriber/route • Patient does not have Forth Valley COPD “self-management plan” at time of presentation
Caution/ Need for further advice	<ul style="list-style-type: none"> • The absorption of doxycycline may be impaired by concurrently administered antacids containing aluminium, calcium, magnesium or other drugs containing these cautions; oral zinc, iron salts or bismuth preparations. Dosages should be maximally separated by at least 2-3 hours. • For patients taking warfarin - advise patient to contact GP Practice as soon as practical to arrange to have INR checked. • Use in caution with patients who have alcohol dependence or who are receiving potentially hepatotoxic drugs.(See BNF) • Use in caution with patients who have photosensitivity. Avoid exposure to sunlight or sun lamp
Action if Patient declines or is excluded	Refer patient to GP or Out of Hours via Professional to Professional Line

DRUG DETAILS

Name, form & strength of medicine	Doxycycline 100mg capsules
Legal Status	POM
Route/ Method	Oral
Dosage	200mg day 1 then 100mg daily
Frequency	Daily
Duration of treatment	5 days
Maximum or minimum treatment period	
Quantity to Supply/ administer	6
Side Effects	<p>Common side effects include headache, nausea and vomiting.</p> <p>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</p>

	<p>accessed on www.medicines.org.uk</p> <p>Patients experiencing any adverse effects should discuss this with their GP or Community Pharmacist.</p> <p>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/</p>
Advice to patient/carer	<p>The Manufacturer Patient Information Leaflet should be given.</p> <p>Patients taking antacids containing aluminium, calcium, magnesium or other drugs containing these cautions; oral zinc, iron salts or bismuth preparations should be advised to avoid taking these at the same time as doxycycline.</p> <p>Patients receiving warfarin should be advised to have their INR checked.</p> <p>Ensure patient is aware that if symptoms worsen or becomes systemically unwell, then they should seek medical advice that day.</p> <p>If symptoms have not improved after 5 days treatment, then patients should be advised to seek further medical advice.</p> <p>Inform patient of possible side effects and their management and who to contact should they be troublesome. Visual disturbances such as blurring of vision may occur during treatment with doxycycline and in such cases please advise patients that they must refrain from driving or operating machinery.</p> <p>Advise patient of the importance of taking regularly and completing the course.</p> <p>The Manufacturer Patient Information Leaflet should be given.</p> <p>Patients should be informed who to contact</p>
Follow up	<p>Patients not improving after a few days of starting antibiotic course or if any deterioration should be advised to contact GP or NHS 24 out of hours service.</p>

STAFF CHARACTERISTICS

Qualifications	<p>Pharmacist currently on the practising section of pharmaceutical register held by the General Pharmaceutical Council.</p>
Specialist competencies or Qualifications	<p>Pharmacists must have the necessary competencies and training to use the PGD and be authorised to use the PGD by their Lead Pharmacist.</p>

	Under PGD legislation there can be no delegation. Administration of doxycycline has to be by the same practitioner who has assessed the patient under the PGD.
Continuing Training & Education	Pharmacists must have up to date knowledge of therapeutic area and Doxycycline evidenced through ongoing CPD. Other necessary training: Attendance at local training events on COPD.

REFERRAL ARRANGEMENTS & AUDIT TRAIL

Referral arrangements	<p>Patients who are not improving or feel their condition is getting worse should seek urgent treatment from their GP or through NHS24 out of hours.</p> <p>If symptoms have not improved after 5 days treatment, then patients should be advised to seek further medical advice.</p>
Records/audit trail	<p>A record of supply should be made on PMR and in the patient's self-management card which includes</p> <ul style="list-style-type: none"> • Name, strength, form and pack size of medicine supplied • Dose and route of administration • Date of supply and name of person making supply • Criteria satisfied for supply i.e. presenting symptoms. • Advice given re side effects and follow up. <p>The medicine must be labelled in accordance with requirements detailed in the current version of Medicines, Ethics and Practice.</p> <p>The patient's GP must be notified that a supply has taken place within 72 hours of supply being made using the agreed pro-forma. The patient's GP must be informed if the patient experiences an adverse drug reaction.</p> <p>A computer or manual record of all individuals receiving a supply under this PGD should also be kept for audit purposes.</p> <p>Record "supplied via Patient Group Direction (PGD)"</p> <p>Any adverse events/incidents should be reported to the PGD group in addition to any existing pharmacy processes</p> <p>Records of supply should be kept for 8 years.</p>
Reference sources and comments	<p>1. Chronic Obstructive Pulmonary Disease. National clinical guideline on management of chronic obstructive pulmonary disease in over 16s: diagnosis and management. NG115.</p>

	<p>July 2019</p> <ol style="list-style-type: none">2. Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for Diagnosis, Management and Prevention of COPD. 2022 (www.goldcopd.com)3. BNF – Current Edition4. Summary of product characteristics
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PATIENT GROUP DIRECTION AUTHORISATION DOCUMENT

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

Protocol Number 476 Version 3.1

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 Doxycycline 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 Doxycycline 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 Doxycycline by
Community Pharmacists to Patients with an exacerbation of
COPD
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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