North East Essex
Clinical Commissioning Group

This Patient Group Direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent signed final version of the PGD should be used as indicated by the validity dates below.

Patient Group Direction

For the supply of:

Doxycycline Capsules 100mg

By registered Pharmacists working in participating North East Essex community pharmacies

Condition/situation/patient group:

For treatment of infective exacerbations of Chronic Obstructive Pulmonary Disease (COPD) in accordance with the NEECCG patient pathway

Version number: 1

Valid from: 1st February 2018

Expiry date: 31st August 2018

Change history

Version number	Change details	Date
1	Original document	23.1.18

PGD authorisation

Name	Job title and organisation	Signature	Date
Doctor Dr Hasan Chowan	North East Essex CCG Chairman		6.2.18
Carol Sampson	North East Essex CCG Senior Pharmacist		6.2.18.
CCG Clinical Governance Lisa Llewelyn	Director of Nursing & Clinical Quality		6/2/18

Training and competency of registered health professionals

	Requirements of registered health professionals working under the PGD
Qualifications and professional registration	Registered with General Pharmaceutical Council (GPhC)
Competency assessment	Has a current, valid Centre for Pharmacy Postgraduate Education (CPPE) Declaration of Competence in working with PGDs.
Ongoing training and competency	• Attended Anaphylaxis and Basic Life Support training yearly • Attended a PGD training session and 3 yearly update • Trained and assessed in using the local antibiotic guidelines

Clinical condition or situation to which this PGD applies	Acute exacerbation of COPD defined as; Two or more of the following three symptoms- increased sputum, increased breathlessness, increased purulence AND patient recognises the symptoms of an acute exacerbation of COPD
Inclusion criteria	• Patients over 18 years old • Confirmed diagnosis of COPD, with a written management plan available to the community pharmacist, which includes antibiotic therapy to manage exacerbations. • Confirmed diagnosis of COPD, with no written management plan available to the community pharmacist, but a supply of a rescue pack made in the preceding six months • Patient allergic to penicillins, cephalosporins or carbapenems • Valid consent obtained and documented • No current supply of Doxycline available to the patient • Confirmation of previous prescription is confirmed by the pharmacy Patient Medication Record, the Summary Care Record or other legitimate access to prescribing records.
Exclusion criteria – refer as per pathway Version number: 1 ~~Valid from: 1st February 2018~~	• COPD diagnosis uncertain • Management plan does not allow the use of a rescue pack • Management plan not in place and the patient has not had a supply of a rescue pack in the last three months • More than TWO supplies in the previous TWELVE months, or last supply less than FOUR weeks ago • Patient currently ill, and symptoms are not typical of COPD exacerbation. • Hypersensitivity to Doxycycline or other Tetracyclines. • Hypersensitivity to any excipients • Pregnancy or breast feeding mothers • Patients already receiving antibiotics, Ciclosporin, oral retinoids • Myasthenia Gravis • Systemic Lupus Erythematosus (SLE) • Significant and unstable co-morbidities • Patients with hereditary problems of galactose intolerance, the Lapp lactase deficiency or

	glucose-galactose malabsorption • Immunocompromised patients • No valid consent
Cautions (including any relevant action to be taken)	• Warfarin; There have been reports of prolonged prothrombin time in patients taking doxycycline. Patients should be advised to contact their practice as soon as possible for INR monitoring • Photosensitivity; Patients should be advised to avoid prolonged exposure to bright light (sunlight or sun lamps) while taking these drugs. • Where appropriate and if the patient meets the criteria prednisolone may be supplied under the current PGD
Arrangements for referral for medical advice	• Patient has symptoms of an exacerbation; refer to ACE community COPD team if patient is known to this service or to their GP/OOH provider if patient not known to the COPD team. The patient should be advised to contact the COPD team/GP whilst still in the pharmacy so input can be given as necessary. • Where the patient is in acute respiratory distress and treatment is urgently required refer to A&E via 999 • If patient is not currently unwell and does not have a management plan suggest this is discussed with their GP/respiratory specialist nurse at their next review. • Should there be any concerns relating to vulnerable adults, adhere to Safeguarding Adults Policy and Procedure. • Should there be any concerns regarding safeguarding consult a member of the organisations safeguarding team to discuss
Action to be taken if patient excluded	• Document in patient's record the reason for the exclusion and any further advice given
Action to be taken if patient declines treatment	• Advise patient about the implications of declining treatment. • Advise patient to seek advice from GP or alternative e.g. ACE community COPD team if appropriate • Document in patient's record reasons for patient declining treatment and advice given • Mental Capacity Act - should the healthcare

	professional think that the patient, parent/legal guardian who is giving consent, is unable to deliberate sufficiently with regard to the information they have been given, then the Mental Capacity Act should be followed(Mental Capacity Act 2005 code of practice

Name, form and strength of medicine	Doxycycline 100mg capsules
Legal category	POM
Indicate any off-label use (if relevant)	The recommended doses and periods of treatment are as specified in current NEE CCG antibiotic guidelines based on HPA advice and may be at variance from the manufacturer's SPC
Route/method of administration	Oral
Dose and frequency	Doxycycline Caps 100mg; Take TWO capsules on day one then ONE a day for FOUR further days (FIVE day course in total)
Quantity to be supplied	SIX Capsules to be supplied labelled with patient name, date of supply, full directions for use and cautionary labels as appropriate
Adverse effects	• Allergy/Anaphylaxis • Abdominal pain • Nausea • Vomiting • Diarrhoea • Rashes • Headache • Joint pain • Muscle pain • Tinnitus A full list of potential adverse effects is provided in the patient information leaflet Report adverse reactions to the MHRA using the Yellow Card system found at: https://yellowcard.mhra.gov.uk

Records to be kept	Record in patients' record on PharmOutcomes date and time of supply and/or administration • patient details, such as name, date of birth, allergies, previous adverse events and how the patient met the criteria of the PGD • details of medicine, such as name, strength, dose, frequency, quantity, route of administration; • a statement that supply or administration is by using a PGD • name of the health professional administering or supplying the medicine • relevant information that was provided to the patient or their carer • whether patient consent to treatment was obtained
Patient information	
Written information to be given to patient or carer	• Ensure that the Manufacturer's patient information leaflet is available & offered
Follow-up advice to be given to patient or carer	• Explain treatment, side effects, course of treatment • Take at regular intervals and complete course. • Capsules should be swallowed whole and taken during meals with plenty of fluid whilst sitting upright or standing. • The absorption of doxycycline may be impaired by concurrently administered antacids containing aluminium, calcium, magnesium or other drugs containing these cations; oral zinc, iron salts or bismuth preparations. Dosages should be maximally separated. • Seek further medical advice if side effects occur (nausea and vomiting, severe diarrhoea) • Seek further medical advice if symptoms do not improve within 72 hours • If rash develops, discontinue treatment and seek further medical advice. • Patient or carer to be advised to discard any residual medication

Appendix A Key references

1.Summary of Product Characteristics, online access

https://www.medicines.org.uk/emc/product/5778

Please note that various manufacturers have their SPCs for each preparation which may vary slightly from the example linked

2. North East Essex CCG Management of infections in primary care, online access
http://www.neessexccg.nhs.uk/uploads/files/Infection%20management%20for%20primary%20care%20Oct%202017%20updating%20for%20chairperson%20action.pdf

3. Current BNF

Appendix B Health professionals' agreement to practise

I have read and understood the Patient Group Direction and agree to supply and/or administer this medicine only in accordance with this PGD.

Name of health professional	Signature	Date

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