University Hosp
Derby and

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PATIENT GROUP DIRECTION (PGD)

Supply of Amoxicillin 500mg capsules
By Impact+ Outreach Service

Documentation details

Reference no:	UHDB 002
Version no:	2.0
Valid from:	11/02/2021
Review date:	10/11/2023
Expiry date:	10/02/2024

Change history

Version number	Change details	Date
2.0	Expiry date and review date updated to reflect 3 year validity. Removal of provision as rescue pack.	21/12/2020

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
Kate Coulthard	Lead Respiratory Nurse Specialist (impact+)
James Kerr	Divisional Pharmacist for 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 Consulted
Dr Julia Lacey	Lead Antimicrobial Pharmacist	26/03/2020

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 version held in pharmacy**	**11/2/21**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Clinical Lead	Deepak Subramanian	**Signed version held in pharmacy**	**21/1/21**
Clinical Service Manager	Robin Evans	**Signed version held in pharmacy**	**21/1/21**
Divisional Pharmacist	James Kerr	**Signed version held in pharmacy**	**11/2/21**

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	Impact+ outreach team. Registered professional with current professional registration operating within their usual scope of practice
Initial training	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. Has undertaken appropriate training for working under Patient Group Directions for the supply and administration of medicines
Competency assessment	Approved drug 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 the senior individual responsible for authorising individuals to act under the PGD and further training 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 supply to a patient during an infective exacerbation of COPD (as per Guidelines for empirical antibiotics for exacerbation of COPD) following assessment by ImpACT+ outreach team. Patients who are unable to take doxycycline capsules.
Criteria for inclusion Use BNF/BNFC/SPC. Take into account any clinical guidelines or policies that are available locally or nationally, e.g. BASHH/NICE/JCVI	Patients 16 years and over presenting with the above clinical situation • Contraindication to doxycycline treatment • Adult with a history of COPD • 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) Refer to UHDB guidelines: Infective Exacerbation of Chronic Obstructive Pulmonary Disease
Criteria for exclusion	• Patients under 16 years old • Hypersensitivity or known allergy to amoxicillin, to any of the penicillins or to any of the ingredients contained in the product • Recent previous culture and sensitivity results which indicate that amoxicillin is not an appropriate antibiotic choice • History of a severe immediate hypersensitivity reaction (e.g. anaphylaxis) to another beta-lactam agent (e.g. a cephalosporin, carbapenem or monobactam). • Cannot swallow, are nil by mouth, or having difficulty swallowing food or drink. • Pregnancy and breastfeeding • Immunocompromised patients • Patients already taking a prescribed antibiotic • Patients taking warfarin, allopurinol or methotrexate • Patients with known cholestatic jaundice or previous antibiotic-associated jaundice/hepatic dysfunction • Patients with glandular fever
Cautions including any relevant action to be taken	Hypersensitivity reactions Before initiating therapy with amoxicillin, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other beta-lactam agents Convulsions may occur in patients with impaired renal function or in those receiving high doses or in patients with predisposing factors (e.g. history of seizures, treated epilepsy or meningeal disorders) The occurrence at the treatment initiation of a feverish generalised

	erythema associated with pustula may be a symptom of acute generalised exanthemous pustulosis. This reaction requires amoxicillin discontinuation and contra-indicates any subsequent administration. Antibiotic-associated colitis has been reported with nearly all antibacterial agents and may range in severity from mild to life threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhoea during, or subsequent to, the administration of any antibiotics. Should antibiotic-associated colitis occur, amoxicillin should immediately be discontinued, a physician consulted and an appropriate therapy initiated. Anti-peristaltic medicinal products are contra-indicated in this situation. In patients with reduced urine output, crystalluria has been observed very rarely, predominantly with parenteral therapy. During the administration of high doses of amoxicillin, it is advisable to maintain adequate fluid intake and urinary output in order to minimize the possibility of amoxicillin crystalluria. In patients with bladder catheters, a regular check of patency should be maintained. Severe renal impairment (CrCl <15ml/min)
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 Out of Hours/Weekend: Respiratory Consultant on Call (via switchboard)

5. Description of treatment

Name, strength & formulation of drug	Amoxicillin 500mg Capsules
Legal category	POM
Route / method of administration	Oral
Dose and frequency of administration	1000mg three times a day
Duration of treatment	5 days
Quantity to be supplied	2 packs of 15 x 500mg amoxicillin capsules
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: Concomitant use of probenecid is not recommended. Probenecid decreases the renal tubular secretion of amoxicillin. Concomitant use of probenecid may result in increased and prolonged blood levels of amoxicillin. Concurrent administration of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions. Tetracyclines and other bacteriostatic drugs may interfere with the bactericidal effects of amoxicillin. Oral anticoagulants and penicillin antibiotics have been widely used in practice without reports of interaction. However, in the literature there are cases of increased international normalised ratio in patients maintained on acenocoumarol or warfarin and prescribed a course of amoxicillin. If co-administration is necessary, the prothrombin time or international normalised ratio should be carefully monitored with the addition or withdrawal of amoxicillin. Moreover, adjustments in the dose of oral anticoagulants may be necessary. Penicillins may reduce the excretion of methotrexate causing a potential increase in toxicity.
Identification & management of adverse reactions	• Nausea and vomiting • Diarrhoea • Rashes • Hypersensitivity reactions • Rarely antibiotic associated colitis 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. • Report via Datix
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	Nursing documentation and back of treatment card. State 'administered under PGD' with name and signature of authorised nurse. For EPMA:

	Document the utilisation of the medicine under PGD by ordering the appropriate drug order item against the correct patient record. Complete all mandated fields on the prescription form, identified by a blue star. Document the administration of the medicine. Document in SystmOne.

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]: **Supply of Amoxicillin 500mg capsules By Impact+ Outreach Service [v2.0]**
PGD ref: UHDB 002
Valid from: 11/02/2021 **Expiry date: 10**/02/2024

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.