University Hospitals of Derby and Burton NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Supply/Administration of Amoxicillin By Registered Nurses, Emergency Nurse Practitioners (ENP) and Emergency Care Practitioners (ECP) In Emergency Department and Ambulatory care at Queens Hospital, Burton and Minor Injury departments at Samuel Johnson and Sir Robert Peel Community Hospitals

Documentation details

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Change history

Version number	Change details	Date
1	New UHDB Format	21/09/2023

Glossary

Abbreviation	Definition

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

Aron Fudger	Emergency Nurse Practitioner
Venkat Thungala	ED Consultant
Angelina Dyche	Antimicrobial Pharmacist
Mohima Akhtar	BAMBU Pharmacist
Aron Fudger	Emergency Nurse Practitioner

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 Reviewed
Angelina Dyche	Antimicrobial Pharmacist	21/09/2023

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
In Emergency Department and Ambulatory care at Queens Hospital, Burton and Minor Injury departments at Samuel Johnson and Sir Robert Peel community hospitals.
Limitations to authorisation
Only ENPs can follow this PGD within ED and ambulatory care at QHB. All suitably trained staff meeting the requirements of section 3 may be trained to perform this role within MIUs at Sir Robert Peel and Samuel Johnson community hospitals.

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medication Safety Officer	James Hooley	**Signed copy held by Pharmacy**	**05/10/2023**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Antimicrobial Pharmacist	Angelina Dyche	**Signed copy held by Pharmacy**	25/09/2023
ED Consultant	Venkat Thungala	**Signed copy held by Pharmacy**	25/09/2023
Emergency Nurse Practitioner	Aron Fudger	**Signed copy held by Pharmacy**	25/09/2023

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	Qualified Emergency Nurse Practitioners with current Nursing & Midwifery Council (NMC) or Emergency Care Practitioners from one of the professions listed in legislation who can perform under PGD. Also for community hospital MIUs only: NMC registered nurses who have received adequate training.
Initial training	- Completion of all Essential-to-role training as outlined in the UHDB PGD policy. - Individual has read and understood full content of this PGD and signed authorisation (section 7) - Completion of Medicines Management Drug Assessment - Deemed competent by their line manager to undertake the clinical assessment of a patient leading to a diagnosis that requires treatment according to the indications listed in this PGD and Trust clinical guidelines
Competency assessment	Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions 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 either authorising manager (section 7) or the manager within the PGD working group (section 1) so that further training can be provided as required.
Ongoing training and competency	• Annual Medicines Safety Training (essential to role) • Review/repeat initial training above when this PGD is revised • The registered healthcare practitioner will ensure. • Anaphylaxis/CPR training is kept updated yearly. • The registered healthcare professional must actively take part in CPD and annual individual performance reviews. • Regular training and updating in safeguarding children and vulnerable adults as per trust policy.
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	Otitis Media – middle ear infection Before using antibiotics discuss with patients and carer and explain the benefits and drawbacks of antibiotic use. Many are viral. Resolves in 80% without antibiotics. Points to highlight include: • Antibiotics are rarely indicated as most cases are viral. • Antibiotics do not reduce pain in the 1st 24 hours, subsequent attacks or deafness. • Poor outcome is unlikely if there is no vomiting or temperature at less than 38.5°C. • The main benefit to antibiotics is that they can reduce the duration and severity of symptoms. • The drawback is they may promote antibiotic resistance in the individual and the community and may cause adverse effects • The specialist advisory committee on antimicrobial resistance concluded that antibiotics are probably unnecessary in acute otitis media. Reassurance, time and adequate pain relief is required. Self-care options include, analgesia (used for pain) and decongestants/steam may relieve symptoms.
Criteria for inclusion	Oral antibiotics can be considered if one or more of the following conditions apply: • Consent gained. • Earache/pain lasting 72 hours that has not responded to analgesia – however consider earlier treatment if systemically unwell or there is a considerable risk of complications. • Perforated ear drum with otorrhea. • Under 2 years with an infection in both ears.
Criteria for exclusion	• Known allergy/hypersensitivity to amoxicillin/penicillin. • Known allergy/hypersensitivity to any of the ingredients or excipients. • Consent not gained. • Taking allopurinol, acenocoumarol, warfarin or methotrexate. • Renal impairment. • Recent treatment within 1 month for the same condition. • History of trauma to the ear. • Concurrent throat infections. • Those where hearing loss if the only symptom. • Analgesia only used for the first 24-48 hours.

Cautions including any relevant action to be taken	• Hepatic impairment - manufacturer advises caution
Action to be taken if the patient is excluded	• Record reasons for exclusion in patient notes • Advise patient on alternative treatment. • Discuss with Nonmedical prescriber. • Contact/refer to patients GP.
Action to be taken if the patient or carer declines treatment	• Document advice given. • Advise patient on alternative treatment.
tArrangements for referral for medical advice	Patient should consult their own GP if there is no improvement in 72 hours. Despite commencing antibiotic treatment or sooner if condition deteriorates.

5. Description of treatment

Name, strength & formulation of drug	Amoxicillin, 500mg Capsules Amoxicillin, 250mg Capsules Amoxicillin, 125mg/5ml Suspension Amoxicillin, 250mg/5ml Suspension
Legal category	Prescription only medication (POM)
Route / method of administration	Oral Capsules – swallow whole with water. Suspension – Reconstitute as directed on bottle with potable water.
Indicate any off-label use (if relevant)	N/A
Dose and frequency of administration	Age: 1 month – 11months — Dose: 125mg three times a day Age: 1 year – 4 years — Dose: 250mg three times a day Age: 5 years – 17 years — Dose: 500mg three times a day Age: Adult — Dose: 500mg three times a day
Duration of treatment	Three times a day for 5 days
Quantity to be supplied (leave blank if PGD is administration ONLY)	Supply sufficient quantity to complete the 5 day course. If the quantity of suspension in one bottle exceeds the amount required for

	5-7 days' supply the full bottle but if there is any leftover advise patient to dispose of it safely Preparations available for supply: - 250mg & 500mg capsules - 125mg/5ml suspension - 250mg/5ml suspension Each box/bottle must be appropriately labelled with: - Patients name - Drug name - Strength and form - Clear dosage instructions - Date of supply - Name and address of supplying unit 1 prescription charge per item should be levied if the patient normally pays for prescriptions.
Storage	Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below:
Drug interactions	*The following interactions have been identified and should be considered where it is known a patient is on the following medicines:* • **Allopurinol** • **Warfarin** • **Methotrexate** • **Acenocoumarol** A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Adverse reactions	The following side effects are common: • ***Nausea*** • ***Vomiting*** • ***Diarrhoea*** • ***Skin reactions*** • ***Thrombocytopenia*** The following side effects are uncommon: • **Antibiotic associated colitis** • **Arthralgia** 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. • Serious adverse reactions (moderate harm or above as per NRLS definition) should be reported via trust incident management system (e.g. Datix) to ensure duty of candour and learning from harm during clinical use.
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 Capsules: - Swallow whole with water. - Store in original packaging. - Take at regular intervals. - Complete the prescribed course. Suspension: - May need to store in fridge (please check packaging) - Shake well before each use. - Take at regular intervals. - Complete the prescribed course. - If there are any left please take to local pharmacy for safe disposal. - Supply a 5ml syringe and instruct on usage. General: - Analgesia can be used when using antibiotics. - Steam may reduce symptoms. Interactions **Oral contraceptives** Amoxicillin is not an enzyme producing antibiotics; latest recommendations are that no additional contraception's are required unless diarrhoea or vomiting occurs. Women should be advised about the correct contraceptive practice during periods of illness.
Records	Either the system holding the record, or the healthcare practitioner working under the PGD, must capture/document all the following: • name of individual, address, date of birth and GP with whom the individual is registered (if relevant) • name of registered health professional • name of medication supplied/administered • date of supply/administration • dose, form and route of supply/administration

	• quantity supplied/administered. • batch number and expiry date (if applicable e.g. injections and implants) • advice given, including advice given if excluded or declines treatment • details of any adverse drug reactions and actions taken • Confirm whether supplied and/or administered and that this was done via Patient Group Direction (PGD) Records should be signed and dated (or a password controlled e-records). All records should be clear, legible and contemporaneous. If you are not recording in ePMA (or other electronic system which has ability to generate audit reports) then a record of all individuals receiving treatment under this PGD should also be in the clinical area for audit purposes as per UHDB PGD policy.

6. Key references

Key references	*BNF 84: September 2022 - March 2023* *BNF for children 2022-2023* *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* *NICE guideline (NG91) Otitis media (acute): antimicrobial prescribing*

7. Registered health professional authorisation sheet

PGD Name [version]: QHB/SJH/SRP - Emergency Department, Ambulatory Care and Minor Injuries Unit – Amoxicillin [v1]
PGD ref: UHDB280
Valid from: 05/10/2023 Expiry date: 04/10/2025

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 any core PGD e-Learning or training records on My Learning Passport or within your department.
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 must be retained by a manager 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.