University Hospitals of Derby and Burton
NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Supply/Administration of Clarithromycin 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

Reference no:	UHDB279
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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

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

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
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	If penicillin contraindicated in adults and children over 6 months of age: - **Acute sore throa**t) - if treatment indicated as per NICE guideline for Acute Sore throat NG84 See:https://www.nice.org.uk/guidance/ng84/chapter/recommendation s for further guidance. - **Otitis media** – if treatment indicated as per NICE guideline for Otitis Media (acute) NG91 - **Cellulitis -** As per UHDB Trust antibiotic guidelines for the following conditions: • Empirical treatment of cellulitis class 1 in adult patients in line with the guideline 'Erysipelas and Cellulitis in Adults' accessed online: UHDB Erysipelas and Cellulitis in Adults (koha-ptfs.co.uk) • Empirical treatment of cellulitis class 1 in paediatric patients in line with the guideline 'Cellulitis-Paediatric Clinical Guideline' accessed online: UHDB Cellulitis -Paediatric Clinical Guidelines (koha-ptfs.co.uk) • Prevention or treatment of infection in traumatic lacerations as defined in the guideline 'Lacerations – Antibiotic Guideline'. As either: patients presenting with signs of an infected laceration with no history/evidence of contamination with high risk material or patients with clean wounds at high risk of it becoming infected. Guideline accessed online: Lacerations - Antibiotic Guideline (koha-ptfs.co.uk)
Criteria for inclusion	- Patients presenting requiring treatment for the conditions specified above - The patient must be able to take the medicine orally
Criteria for exclusion	• Allergy to any of the ingredients • Known hypersensitivity to any macrolide • Hepatic failure • Current treatment with any of the interacting drugs listed as 'not to be co-administered' in the Drug Interactions section of this PGD • Hypokalaemia or hypomagnesaemia or any other electrolyte disturbances • Pregnancy • Breastfeeding • Cellulitis of the face or around the eyes

Cautions including any relevant action to be taken	• Any of the exclusion criteria above • Hepatic impairment • Myasthenia gravis • Heart disease especially QT interval prolongation, ventricular cardiac arrhythmia including torsade de pointe • Drug interaction listed in this PGD (but note exclusions for drugs 'not to be co-administered')
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.
Arrangements for referral for medical advice	Patient should consult their own GP if there is no improvement in 72 hours 48 hours in children, despite commencing antibiotic treatment or sooner if condition deteriorates.

5. Description of treatment

Name, strength & formulation of drug	Clarithromycin 250mg tablets Clarithromycin 250mg/5ml oral suspension
Legal category	Prescription only medication (POM)
Route / method of administration	Oral Tablets 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	Adult and child 12 years and older: 500mg every 12 hours Children 1 month up to 12 years of age:

Weight	Dosage every 12 hours	Volume of 250mg/5ml susp
Under 8kg	7.5mg/kg	Calculate

	<table><tr><td>8 - 11kg</td><td>62.5mg</td><td>1.25ml</td></tr><tr><td>12 - 19kg</td><td>125mg</td><td>2.5ml</td></tr><tr><td>20 - 29kg</td><td>187.5mg</td><td>3.75ml</td></tr><tr><td>30 - 40kg</td><td>250mg</td><td>5ml</td></tr></table>
Duration of treatment	Twice a day (every12 hours) The duration of treatment is dependent on indication: Cellulitis: 5-7 days as per guideline Laceration- prophylaxis: 3 days Laceration - treatment 5-7 days Acute sore throat: 5 days Otitis media: 5-7 days
Quantity to be supplied (leave blank if PGD is administration ONLY)	Supply sufficient quantity to complete the course. If the quantity of suspension in one bottle exceeds the amount required for 7 days' supply the full bottle but if there is any leftover advised patient to dispose of it safely via a community pharmacy Preparations available for supply: - 250mg tablets - 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 levelled 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: Do not store above 25°C. Do not refrigerate or freeze. Keep the bottle tightly closed.
Drug interactions	*The following interactions have been identified and should be considered where it is known a patient is on the following medicines:* **Clarithromycin not to be administered under PGD with any of the following:** - Cisapride, pimozide, astemizole and terfenadine - domperidone - Ergotamine and dihydroergotamine - Reboxitine - Mizolastine - quetiapine

	- Eplenerone - Ivabradine - Ranolazine - Sirolimus - Ticagralor - Midazolam - Eletriptan **To be withheld whilst taking clarithromycin and restarted when course complete:** - Simvastatin or lovastatin - Colchicine **The dose of the following or dose of clarithromycin, may need adjusting if co-administered:** - Antivirals - Carbamazepine - Cilozastrol - Ivaftacor - Mirabegron - Phenytoin **Increased risk of adverse effects with:** - Antiarrhythmics - Rifabutin and rifampicin - Warfarin and acecoumarol - Calcium channel blockers - Ciclosporin - Oral chemotherapy – seen BNF - Tacrolimus 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*** • ***Taste disturbance*** • ***Dyspepsia*** • ***Headache*** • ***Insomnia*** • ***Abdominal pain*** 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	Ensure TTO pack contains patient information leaflet (PIL) and issue the Emergency Department patient leaflet on 'Antibiotics'.
Patient advice / follow up treatment	Tablets: - 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 is any left please take to local pharmacy for safe disposal - Supply a 5ml syringe and instruct on usage - - Inform the individual/carer of possible side effects and their management. - The patient/carer should be advised to seek medical advice in the event of an adverse reaction. - Patients should be advised to continue taking this medicine until they have completed the course, even if they feel better. If they stop treatment early, the infection could come back. - The patient should be advised to seek review with their own GP (General Practitioner) or review clinic arranged for follow-up accordingly as indicated by the presenting concerns. - The patient should return to the emergency department for reassessment if symptoms are not resolving or get worse despite treatment.
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	*Electronic Medicines Compendium* http://www.medicines.org.uk/clarithromycin *accessed online 5/7/23* *Electronic BNF https://bnf.nice.org.uk/ accessed on 5/7/23* *Electronic BNF https://bnfc.nice.org.uk/ accessed on 5/7/23* *NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2* UHDB guideline 'Erysipelas and Cellulitis in Adults' Erysipelas and Cellulitis in Adults UHDB guideline 'Lacerations – Antibiotic Guideline' Lacerations - Antibiotic Guideline (koha-ptfs.co.uk) UHDB guideline 'Cellulitis - Paediatric full clinical guideline' (koha-ptfs.co.uk) NICE guideline 84 Acute Sore Throat. published Jan 2018. accessed online 5/7/23 NICE guideline 91 Otitis Media last updated March 22. Accessed online 5/7/23

7. Registered health professional authorisation sheet

PGD Name [version]: QHB/SJH/SRP - Emergency Department, Ambulatory Care and Minor Injuries Unit – Clarithromycin [v1]
PGD ref: UHDB279

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.