University Hospitals of Derby and Burton NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Supply/Administration of Co-Amoxiclav Tablets and Suspension By Registered Nurses, Emergency Nurse Practitioners(ENP), Emergency Care Practitioners(ECP) and Emergency Physiotherapy Practitioners (EPP) In the Emergency Department and Ambulatory care at Queens Hospital, Burton and Minor Injuries departments at Samuel Johnson and Sir Robert Peel community hospitals

Documentation details

Reference no:	UHDB195
Version no:	2
Valid from:	10/01/2025
Review date:	10/07/2026
Expiry date:	10/01/2027

Change history

Version number	Change details	Date
v2	Planned review – realigned to UHDB antibiotic guidelines	Oct 2024

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
Dr Venkata Thungala	Consultant Emergency Medicine
Nida Halim	Pharmacist
Nadine Watson	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
Ellie Birnie	Antimicrobial Pharmacist	September 2024

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
Authorised for use in the following departments at UHDB: • Minor injury units at SRP and SJCH • Areas of QHB ED which do not have prescribers (e.g. triage/pitstop, or minors areas without prescriber cover) • Same Day Emergency Care (SDEC) at QHB
Limitations to authorisation
Nil

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medication Safety Officer *Pharmacist: Medicines Safety Officer, Chief Pharmacist or assigned deputies)*	James Hooley	**Signed copy held by Pharmacy**	**10/01/2025**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Pharmacist *Clinical Pharmacist from PGD working group*	**Ellie Birnie**	**Signed copy held by Pharmacy**	**10/12/2024**
Lead ED Consultant *Doctor*	**Dr Venkata Thungala**	**Signed copy held by Pharmacy**	**03/01/2025**
Senior ENP *Registered Professional representing users of the PGD*	**Nadine Watson**	**Signed copy held by Pharmacy**	**03/01/2025**

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	• NMC Registered Nurse with current professional registration operating within their usual scope of practice *or* • HCPC Registered Paramedic *or* • Completion of either University accredited module in minor illness or injury. • Must be a profession permitted by current legislation to practice under a patient group direction.
Initial training	• Completion of all Essential-to-role training as outlined in the UHDB PGD policy including core PGD training. • Individual has read and understood full content of this PGD and signed authorisation (section 7) • Completion of Medicines Management Drug Assessment
Competency assessment	• Once staff have completed all training, they will have their Meditech account adjusted to enable them to document administration/supply of the medication. • 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 the either authorising manager (section 7) or the manager within the PGD working group (section 1) so that further training can be provided as required.
On-going training and competency	• Annual Medicines Safety Training (essential to role) • Organisation PGD eLearning • Review/repeat initial training above when this PGD is revised • Up to date mandatory training including anaphylaxis/CPR. • Any staff found to be using this PGD incorrectly will need to re-attend the above training. • 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	Patients presenting with a wound as a result of a human or animal (cat or dog) bite **NB.** Thorough cleansing of the wound is essential I.e. thorough surgical toilet Practitioner must also consider / assess patient for • Tetanus / rabies risk • HIV, hepatitis B and C
Criteria for inclusion	• Age over 1 month • Bite involving hand, foot, face, joint, tendon, ligament • Puncture wound caused by animal or human bite breaking the skin • Patient is immunocompromised, diabetic, elderly, asplenic or has a prosthetic valve or joint • Signs of local or systemic infection • Consent gained – if under 16 consider requirements for consent See the following local polices: • Superficial, Soft Tissue Infection associated with Human Bites UHDB antibiotic guidelines uploaded to KOHA 14/03/23 • Superficial, Soft Tissue Infection associated with Cat or Dog UHDB guidelines uploaded to KOHA 14/03/24
Criteria for exclusion	• Lacerations or wounds not caused by bite • Consent not gained • Patient under 1 month old • Known or suspected allergy to penicillin • History of severe, acute allergic reaction to any other beta-lactam active substances e.g. cephalosporin, monobactam or carbapenem • Hypersensitivity to any of the ingredients in the product. See Home - electronic medicines compendium (emc) for specific product details • History of penicillin or co-amoxiclav associated jaundice / hepatic dysfunction • Previous acute generalised exanthemous pustulosis following amoxicillin or co-amoxiclav use If any of the above exclusions apply refer to a prescriber
Cautions including any relevant action to be taken	If any of the following apply - seek further advice from a prescriber (decision to use PGD remains with the practitioner working under this framework; refer for prescription if uncertain to proceed) • Complex laceration caused by a bite • Animal or human bite to the face • Suspected infection extending into deep tissues should be discussed with surgical team/microbiology

	• Hypersensitivity to cephalosporins and no previous experience of penicillins • Patients who are systemically unwell, including pyrexia • Patients with hepatic dysfunction or at risk of hepatic dysfunction (>50 years with serious underlying disease) • Pregnancy or breast-feeding • Moderate renal impairment (eGFR < 30ml/min) - increased risk of convulsions • Current treatment with mycophenolate for prevention of transplant rejection • Patients with glandular fever, leukaemia or cytomegalovirus
Action to be taken if the patient is excluded	• Discuss with ED Doctor and consider prescribing an alternative medication. • Discuss with the patient and advise alternative treatment. • Document in patient's notes the reason for exclusion, and actions taken.
Action to be taken if the patient or carer declines treatment	• Explain to the patient the importance of treatment. • Offer alternative intervention/treatment. • Document in medical notes the reason for refusal, action taken, advice given. • Escalate to ED doctor and consider prescribing an alternative medication/treatment if needed.
Arrangements for referral for medical advice	Refer to the appropriate medical practitioner in the care pathway.

5. Description of treatment

Name, strength & formulation of drug	**Co-amoxiclav tablets 500mg/125mg** **Co-amoxiclav oral suspension 250mg/62mg in 5ml**
Legal category	Prescription-only Medicine (POM)
Route / method of administration	Oral
Indicate any off-label use (if relevant)	Only to be used within the licensed indications
Dose and frequency of administration	**<u>Oral suspension 250mg/62mg in 5ml</u>** 1 month – 11 months 0.125ml/kg THREE times a day 1 year to 5 years 2.5ml THREE times a day 6 – 11 years 5ml THREE times a day **<u>Tablet 500mg/125mg</u>** 12 years and over 1 tablet THREE times day NB. BNF and BNFc quote doses for children under the age of 5 years using the 125/31oral suspension. The ratio of

	amoxicillin:clavulanic acid is the same in both strengths of suspension – with 250/62 being twice the strength of the 125/31. Therefore, it is acceptable to use the stronger suspension (250/62) for children under 5 years of age, as long as the dose volume is corrected (use half the volume of the stronger suspension). The dosage above reflects this.
Duration of treatment	**Prophylaxis:** If there are no symptoms, signs, or investigative findings of soft tissue infection, but there is a skin breach/breakage give co amoxiclav prophylaxis for 3 days **Treatment:** If there are symptoms, signs or investigative findings of soft tissue infection give treatment – 5 - 7 days
Quantity to be supplied (leave blank if PGD is administration ONLY)	Supply sufficient to complete the full course. If the quantity in the bottle or box exceeds the amount required, supply the full bottle or box and advise patient /carer to return any excess medicines to their local pharmacy on completion of the course. **Oral suspension 250/62 in 5ml TTO pack** Reconstitute with potable water according to the packaging prior to administration or supply. • 1 bottle is sufficient for a dose of 5ml TDS for 7 days • 2 bottles are required for a dose of 10ml TDS for 7 days Ensure a medicine spoon or appropriately sized oral syringe is also provided. If a 3 day prophylactic course is prescribed inform patient to discard remaining solution after 3 days. **Tablets 500mg/125mg TTO packs** • Supply 2 box of 15 tablets if a 7 days course is required - advise patient to return excess tablets to any pharmacy for destruction • Supply 1 box of 15 tablets if a 5 day course is required • Supply 1 box of 15 tablets if a 3 day prophylaxis course is required – advise patient to return excess tablets to any pharmacy for destruction Labelling must meet the requirements outlined in Trust PGD Policy and associated training. The pharmacy department supply overlabelled or ready-labelled packs to meet the legal requirements for supply. If you do not hold these appropriately labelled packs in stock, then a supply to patients is not appropriate. The following information **must** be added to the ready-labelled TTO packs before supply if it is not already printed on the label • Patient name • Date of supply • The dose required (in mls or number of tablets) • The duration of treatment • Name of the department issuing the TTO pack

	A prescription charge should be levied in clinical areas who are required to issue NHS prescription charges.
Storage	Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below: **Once reconstituted, co-amoxiclav oral suspension may need to be stored in a refrigerator – ensure patient / carer is aware of this when a supply is made.** Product specific information can be found on the electronic Medicines Compendium website
Drug interactions	The following interactions have been identified and should be considered where it is known a patient is on the following medicines: **Anti-coagulants** (warfarin, phenidione) - possible INR changes – advise patient to make a note of date of starting antibiotic treatment and to share information with their INR monitoring service **Methotrexate** – increased toxicity **Probenecid** – may reduce clearance of amoxicillin but not clavulanic acid, leading to resistance **Mycophenolate** - plasma levels may be reduced (clinically significant if used for prevention of transplant rejection) **Allopurinol** – possible risk of skin rash 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: • Diarrhoea, nausea and vomiting • Mucocutaneous candidiasis (thrush) • Dizziness and headaches • Dyspepsia (indigestion) • Skin reactions The following are less common: • Blood dyscrasias • Anaphylactic reactions, including antineurotic oedema • Convulsions (especially with high doses or renal impairment) • Hepatitis and cholestatic jaundice • Erythema multiforme, Steven-johnson syndrome, toxic epidermal necrolysis, bullous exfoliative-dermatitis, acute generalised exanthemous pustulosis 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	Provide advice on wound management Take at regular intervals and complete the required course Oral suspension - store in a refrigerator, shake well before administration. If the TTO pack provided contains excess medicine for the required course length, dispose of any leftover medicine safely e.g. return to a pharmacy Inform the patient / carer of possible side effects and their management. Advise the patient / carer to seek medical advice in the event of an adverse reaction. If progression of localised symptoms (e.g. skin erythema, warmth, tenderness, swelling) - see GP as may require conversion from prophylaxis to treatment) If systemically unwell (e.g. fever, chills, sweats) after a few days of oral antibiotics, patient may require IV antibiotics - so present to hospital **Oral contraceptives** Co-amoxiclav is not an enzyme producing antibiotic; latest recommendations are that no additional contraceptives are required unless diarrhoea or vomiting occurs. Women should be advised about the correct contraceptive practice during periods of illness
Records	Record the following information on ePMA (Electronic Prescribing system) UHDB – Meditech Either the system holding the record, or the healthcare practitioner working under the PGD, must capture/document all of 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 via a 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 https://www.medicines.org.uk/emc/product/9127/smpc#about-medicine accessed online 11th April 2024. • Electronic BNF https://www.new.medicinescomplete.com/#/content/bnf/_522717287?hspl=co%20amoxiclav updated 11 November 2021 accessed online 11th April 2024. • Electronic BNF for children https://www.new.medicinescomplete.com/#/content/bnfc/_522717287?hspl=co%20amoxiclav updated 11 November 2021 accessed online 11th April 2024. • NICE Medicines practice guideline “Patient Group Directions” https://www.nice.org.uk/guidance/mpg2 • UHDB trust Guidelines https://derby.koha-ptfs.co.uk/cgi-bin/koha/opac-retrieve-file.pl?id=270dd3939453ddd3038f4aca5ef12508 uploaded to KOHA 14/03/23 Accessed online 11th April 2024 • UHDB trust Guidelines https://derby.koha-ptfs.co.uk/cgi-bin/koha/opac-retrieve-file.pl?id=6c594a4bd15727303d076f8599d07c07 uploaded to KOHA 14/03/24 Accessed online 11th April 2024

7. Registered health professional authorisation sheet

PGD Name [version]: QHB-ED/MIU/Ambulatory Care - Co-Amoxiclav Tablets and Suspension [v2] PGD ref: UHDB195
Valid from: 10/01/2025 Expiry date: 10/01/2027

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.