University Hospitals of Derby and Burton
NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

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

Documentation details

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Valid from:	22/06/2022
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Expiry date:	21/06/2024

Change history

Version number	Change details	Date
1	Convert to new format Update available TTO pack information and align doses with available TTO packs Update dose and course length in line with latest BNF / BNFc recommendations	21/10/2021

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
Alannah Davies	RGN
Julie Vanes	Pharmacist
Sarah Pearson	ED Consultant
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
Angellina Dyche	Anti-microbial pharmacist	23/12/21

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
Emergency Department and Ambulatory care at Queens Hospital, Burton and Minor Injuries departments at Samuel Johnson and Sir Robert Peel community hospitals
Limitations to authorisation
Nil

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
James Hooley *Pharmacist: Medicines Safety Officer, Chief Pharmacist or assigned deputies)*	Medicine Safety Officer	**Signed copy held by Pharmacy**	**22/06/2022**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Divisional pharmacist, Medicine *Clinical Pharmacist from PGD working group*	**James Kerr**	**Signed copy held by Pharmacy**	**22/06/2022**
Emergency Department Consultant *Doctor*	**Dr Sarah Pearson**	**Signed copy held by Pharmacy**	**21/06/2022**
Sister Minor Injuries Sir Robert Peel Hospital	**Alannah Davies**	**Signed copy held by Pharmacy**	**20/06/2022**

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	Registered professional with current professional registration operating within their usual scope of practice. 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. - 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 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.
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	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	• Patient age over 1 month • Bite involving hand, foot, face, joint, tendon, ligament • Puncture wound • 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: • *Bites - Human - Superficial, Soft Tissue Infection- Antibiotic Guideline – UHDB antibiotic guidelines uploaded to KOHA 21/12/2020* • *Bites - Cat or Dog - Superficial, Soft Tissue Infection - Antibiotic Guideline – UHDB guidelines uploaded to KOHA 21/12/2020* • *Lacteration - Antibiotic Guideline UHDB guideline uploaded to KOHA 21/12/2020*
Criteria for exclusion	• 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) • 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	• Record reasons for exclusion in patient notes • Refer to a Dr or prescriber if appropriate • If referral required but no Dr or Prescriber working within the department where the practitioner is based, advise patient to attend a department where a Dr or prescriber is available e.g. QHB ED • Advise patient on alternative treatment
Action to be taken if the patient or carer declines treatment	• Document advice given • Advise patient on alternative treatment • Refer to a Dr or prescriber if appropriate
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	POM – Prescription Only Medicine
Route / method of administration	Oral
Indicate any off-label use (if relevant)	Not applicable
Dose and frequency of administration	**Oral suspension 250mg/62mg in 5ml** **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 **Tablet 500mg/125mg** **12 years and over** 1 tablet THREE times day CO-AMOXICLAV | Drug | BNFc content published by NICE CO-AMOXICLAV | Drug | BNF content published by NICE 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 breach/breakage of the skin 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 5 ml 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 1 box of 21 tablets if a 7 days course is required Supply 1 box of 15 tablets if a 5 day course is required Supply 1 box of 9 tablets if a 3 day prophylaxis course is required. Labelling must meet the requirements outlined in Trust PGD Policy and associated training. The pharmacy department supply over-labelled 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 Home - electronic medicines

	compendium (emc)
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
Identification & management of 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 the patient becomes unwell, or symptoms do not completely resolve in 72 hours, advise that the patient should visit their GP **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 in an ePMA system if implemented in your area as this will ensure all legal criteria are fulfilled and auditable. Otherwise, records can be made in the medical notes or within the patient pathway (e.g. in daycase or triage where a pathway booklet is in use) but must include the legal requirements below. 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 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/* • *Electronic BNF https://bnf.nice.org.uk/* • *NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2* • *Bites - Human - Superficial, Soft Tissue Infection- Antibiotic Guideline – UHDB antibiotic guidelines uploaded to KOHA 21/12/2020* • *Bites - Cat or Dog - Superficial, Soft Tissue Infection - Antibiotic Guideline – UHDB guidelines uploaded to KOHA 21/12/2020* • *Lacteration - Antibiotic Guideline UHDB guideline uploaded to KOHA 21/12/2020*

7. Registered health professional authorisation sheet

PGD Name [version]: ED MIU and Ambulatory Care – Co-Amoxiclav [v1]
PGD ref: UHDB195

Valid from: 22/06/2022 Expiry date: 21/06/2024

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 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.