Torbay and South Devon NHS
NHS Foundation Trust

Patient Group Direction 1594 version 5.0
Supply of Co-Amoxiclav by Registered Practitioners employed by Torbay and South Devon NHS Foundation Trust

Date of Introduction: August 2019
Review Date: July 2021

Developed By	Name	Signature	Date
Physician	Emergency Department Consultant		
Pharmacist	Antimicrobial Pharmacist		
Lead Professional	Senior Manager MIU Services / Nurse Consultant Emergency Care Unit		

Note: The Lead Professional is responsible for ensuring the co-ordination, composition, consultation, revision and distribution of the PGD to practitioners who will be using the PGD as well as ensuring that the PGD is no longer used if becomes out of date and once it has expired.

The Clinical Effectiveness Department will write to the Lead Professional approximately 4 months before the review date as a reminder that a review is required.

Ratified on behalf of: TORBAY AND SOUTH DEVON NHS FOUNDATION TRUST	
Medicines Management Committee Chair	
Signed:	
Name:	Clinical Director – Pharmacy and Prescribing
Date:	
Lead Officer	
Signed:	
Name:	Medical Director
Date:	

Patient Group Direction 1594 version 5.0
Supply of Co-Amoxiclav by Registered Practitioners employed by Torbay and South Devon NHS Foundation Trust

Objective	To enable emergency nurse practitioners (including paramedics) in ED and in MIUs to provide effective management of human or cat bites to any part of the body or other animal bites to the head, hands and bites involving joints To enable effective management of traumatic wounds including open fractures To enable effective treatment of acute pyelonephritis.

1. Clinical Condition

Definition of condition/situation	Where the need for an antibiotic is justified, in the following conditions / situations, according to the relevant Trust protocol: 1st line antimicrobial choice for the treatment of animal and human bites. 1st line antimicrobial choice for the management of traumatic wounds, including puncture wounds and open fractures. Acute pyelonephritis in children ≥ 16 and adults.
Facilities required	TTA pack of 21 x co-amoxiclav tablets TTA pack of 70ml co-amoxiclav 400/57 suspension
Criteria for inclusion	▪ The bite is of a minor nature and referral to a doctor is not required ▪ Adults and children over 2 years presenting with a human or animal bite, according to the relevant Trust protocol ▪ Adults and children over 2 with traumatic wounds, including puncture wounds and open fractures according to the relevant Trust protocol ▪ Acute pyelonephritis (1o care guideline) in children ≥ 16 and adults
Criteria for exclusion	▪ Hypersensitivity to penicillins, or other beta-lactam antibiotics, including cephalosporins ▪ Hypersensitivity to any of the ingredients of the co-amoxiclav product to be administered / supplied ▪ Children under 2 years old ▪ Any bites from exotic pets e.g. Terrapin, snakes- contact microbiologist for advice. ▪ If there is any possibility of rabies – refer to the emergency department ▪ Any patient with suspected injury to tendons, ligaments or bones– refer to the emergency department ▪ Pregnancy – refer to a doctor; increased risk of necrotizing entercolitis in the newborn. ▪ Breast feeding ▪ For cellulitis and lymphangitis – patient unwell & systemic symptoms observed e.g. pyrexia – check vital signs and refer to emergency services ▪ Infection with glandular fever, human immunodeficiency virus or cytomegalovirus ▪ Acute or chronic lymphocytic leukaemia ▪ History of penicillin or co-amoxiclav associated hepatic dysfunction ▪ Currently taking methotrexate ▪ Currently taking probenecid
Action if excluded	▪ Refer to medical practitioner **(or non-medical prescriber if appropriate)** or alternative action as indicated by related protocol and document in patient's records

Action if patient refuses medication	▪ Document informed refusal in patient's records and action taken: a) Referral to protocol b) Referral to appropriate medical practitioner

2. Characteristics of Staff

Qualifications required	▪ Minor Injury Practitioner (nurse or paramedic) working in community MIU. ▪ Emergency Nurse Practitioners (or paramedic) in ED
Additional requirements	▪ Working knowledge of relevant Organisation Policies, including Medicines Policy and associated Standard Operating Procedures, Anaphylaxis Policy and Consent Policy and associated risk assessments where appropriate. ▪ Working knowledge of relevant Organisation protocols ▪ Evidence of continuing professional development, and any training and competence relevant to this PGD Working knowledge of the NMC Standards for Medicines Management 2007, (updated 2010) www.nmc-uk.org and other relevant codes of professional practice. ▪ Working knowledge of the NMC Standards of Proficiency for Paramedics (September 2014), http://www.hpc-uk.org/assets/documents/1000051C Standards of Proficiency paramedics.pdf and other relevant codes of professional practice.

3. Description of Treatment

Name of Medicine Supplied	Co-amoxiclav tablets 500mg/125mg: containing amoxicillin 500mg and clavulanic acid 125mg Co-amoxiclav oral suspension 400/57: containing amoxicillin trihydrate 400mg and potassium clavulanate 57mg, per 5ml of reconstituted suspension, as a powder for reconstitution to form a suspension
Legal Class	POM (Prescription Only Medicine)
Storage	Store below 25°C in original package Reconstituted suspension: Patients to store in a fridge between +2ºC and +8ºC, for up to seven days. Do not freeze.

Dose to be used (including criteria for use of differing doses)	**Adults and children over 12years (>40kg):** Using tablets: One tablet three times a day for 7 days Using suspension: 10ml twice a day for 7 days **Child aged 7-12 years (22-40kg):** Using suspension: 5ml twice a day for 7 days **Child aged 2-6 years (13-21kg):** Using suspension: 2.5ml twice a day for 7 days For pyelonephritis in children ≥ 16 years supply 10 days and adults supply 14 days.
Method or route of administration	Oral
Total dose and number of times drug to be given. Details of supply (if supply made)	**For adults and children over 12years (>40kg):** Using tablets: One tablet three times a day for 7 days • Supply 21 x 625mg tablets Using suspension: 10ml twice a day for 7 days • Supply 2 x 70ml reconstituted co-amoxiclav 400/57mg suspension **Child aged 7-12 years (22-40kg):** 5ml suspension twice a day for 7 days • Supply 1 x 70ml reconstituted co-amoxiclav 400/57mg suspension **Child aged 2-6 years (13-21kg):** 2.5ml suspension twice a day for 7 days • Supply 1 x 70ml reconstituted co-amoxiclav 400/57mg suspension For pyelonephritis in children ≥ 16 years supply 10 days and for adults supply 14 days. **When liquid dose forms are supplied check the shelf life of reconstituted suspension If shelf life is less than required length of treatment, only reconstitute ONE bottle. Make appropriate arrangements for supplying the balance of the course. Liquid dose forms must include expiry date of reconstituted suspension**
Contra-indications	See exclusion criteria

Cautions	**If patient is taking any other medications consult BNF Appendix 1 for any potential interactions.** ▪ **Patients taking anticoagulants requiring INR monitoring (warfarin, acenocoumarol or phenindione):** Due to concerns of altered international normalized ratio (INR), the risk/benefit of the use of this antibiotic in patients taking anticoagulation therapy should be carefully considered and advice sought as necessary. Where a decision to treat is made, the patient should be warned of the possibility that the anticoagulant effect may be altered – see patient advice ▪ **Immunocompromised patients** – see patient advice ▪ **Patients taking immunosuppressant or disease-modifying anti-rheumatic drugs (DMARD**s) – see patient advice ▪ Patients taking **methotrexate** - Advise patient to see their GP for a full blood count check and liver function test ▪ Patients taking **allopurinol –** advise that this may increase the occurrence of rash ▪ Breastfeeding – trace amounts excreted in breast milk (only significant if infant is sensitized/ hypersensitive to penicillins or cephalosporins) ▪ Known hepatic impairment / dysfunction (including hepatitis & jaundice). Committee on Safety of Medicines (CSM) has advised that cholestatic jaundice can occur during or shortly after use of co-amoxiclav. ▪ Severe renal impairment – risk of crystalluria with high doses - maintain adequate fluid intake & convulsions ▪ Amoxicillin/clavulanic acid should be avoided if infectious mononucleosis is suspected since the occurrence of a morbilliform rash has been associated with this condition following the use of amoxicillin. ▪ Antibiotic-associated colitis has been reported with nearly all antibacterial agents including amoxicillin and may range in severity from mild to life threatening. Should antibiotic-associated colitis occur, co-amoxiclav should immediately be discontinued, a physician be consulted and an appropriate therapy initiated. ▪ Increased risk of erythematous rash in patients with cytomegalovirus infection and acute / chronic lymphocytic leukaemia. ▪ Currently taking warfarin. Refer back to GP for INR check.
Interactions	▪ If patient is taking any other medications consult BNF Appendix 1 for any potential interactions. **Oral anticoagulants** and penicillin antibiotics have been widely used in practice without reports of interaction. However, in the literature there are cases of increased INR in patients maintained on acenocoumarol or warfarin and prescribed a course of amoxicillin. If co-administration is necessary, the prothrombin time or INR should be carefully monitored with the addition or withdrawal of amoxicillin. Moreover, adjustments in the dose of oral anticoagulants may be necessary. **Methotrexate**: Penicillins may reduce the excretion of methotrexate causing a potential increase in toxicity. **Probenecid:** 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 but not of clavulanic acid. **Mycophenolate mofetil**: In patients receiving mycophenolate mofetil, reduction in pre-dose concentration of the active metabolite mycophenolic acid (MPA) of approximately 50% has been reported following commencement of oral amoxicillin plus clavulanic acid. The change in pre-dose level may not accurately represent changes in overall MPA exposure. Therefore, a change in the dose of mycophenolate mofetil should not normally be necessary in the absence of clinical evidence of graft dysfunction. However, close clinical monitoring should be performed during the combination and shortly after antibiotic treatment.

Potential side-effects and adverse reactions	**Infections**: Mucocutaneous candidosis, overgrowth of non-susceptible organisms **Blood and lymphatic system disorders**: Reversible leucopenia (including neutropenia), thrombocytopenia, reversible agranulocytosis, haemolytic anaemia, prolongation of bleeding time and prothrombin time. **Immune system disorders**: Angioneurotic oedema, anaphylaxis, serum sickness-like syndrome, hypersensitivity vasculitis. **Nervous system disorders**: Dizziness, headache, reversible hyperactivity, convulsions, aseptic meningitis. **Gastrointestinal disorders**: Diarrhoea, nausea, vomiting, indigestion, antibiotic-associated colitis, black hairy tongue. **Hepatobiliary disorders**: Rises in AST and/or ALT, hepatitis, cholestatic jaundice. **Skin and subcutaneous tissue disorders**: Skin rash, pruritus, urticarial, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous exfoliative-dermatitis, acute generalised exanthemous pustulosis (AGEP)9 **Renal and urinary disorders**: Interstitial nephritis, crystalluria. Unusual or life threatening reactions require immediate medical attention.
Management of potential side-effects and adverse reactions	Unusual or life threatening reactions require immediate medical attention. ▪ Document adverse reaction in the patients notes. ▪ Notify the doctor responsible for assessing the patient immediately. ▪ Nurse to seek medical advice. ▪ Advise patient to seek medical advice.

Advice and information to patient/carer including follow-up	Unusual or life threatening reactions require immediate medical attention. ▪ Co-amoxiclav is a penicillin based antibiotic to prevent skin/wound infection at bite site. ▪ Advise patient to seek further medical advice if no improvement in symptoms within 5 – 7 days ▪ **Immunocompromised patients** – seek urgent medical attention for full blood count and liver function tests if systemically unwell ▪ **Patients taking immunosuppressant or disease-modifying anti-rheumatic drugs (DMARDs)** – seek urgent medical attention for full blood count and liver function tests if systemically unwell ▪ Patients taking **methotrexate** - Advise patient to see their GP for a full blood count check and liver function test ▪ Inform patient of possible side effects and appropriate management. Possible mild & transitory side effects include; ▪ Gastro-intestinal upset; diarrhoea, indigestion, nausea and vomiting ▪ Mucocutaneous candidiasis, including vaginal candidiasis ▪ Rash ▪ Advise patient of symptoms of cholestatic jaundice and to seek medical advice if jaundice develops during or shortly after completing treatment. (May be up to 2 weeks after the course of co-amoxiclav). ▪ Advise patient to seek urgent medical attention if they experience persistent or severe diahorrea. ▪ Advise patients to complete the course of antibiotics ▪ Reconstituted oral suspension to be refrigerated and not used after 7 days. Any remainder should be taken to a community pharmacy for safe disposal on completion of course. Instructions must be given for making up the further bottles of antibiotic suspension if required. ▪ Provide manufacturers patient information leaflet (PIL). ▪ Advise on symptom relief, including appropriate OTC analgesia ▪ **Patients taking combined oral contraceptives (COCs):** Additional contraceptive precautions are **not required** during or after a course of co-amoxiclav. Women should be advised that if the antibiotics (and/or illness) cause vomiting or diarrhoea, then the usual additional precautions relating to these conditions should be observed. Women should also be advised about the importance of correct contraceptive practice during periods of illness. These recommendations should be discussed with the woman. ▪ **Patients taking anticoagulants requiring INR monitoring (warfarin, acenocoumarol or phenindione):** Warn patient that antibiotics may alter the anticoagulant effect. Advise them to tell the clinic responsible for monitoring their anticoagulant dose that they are taking antibiotics. **Provide patient / carer with a copy of anticoagulation and antibiotics patient information leaflet.**

Specify method of recording supply /administration including audit trail	Document allergies and other adverse drug reactions clearly in patient records and inform the GP and other relevant practitioners/patient/carer for further reporting and action if required. Report any adverse drug reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) through the yellow card reporting system (www.mhra.gov.uk). **In MIUs** the following will be recorded in the patient's records: ▪ The diagnosis and treatment ▪ The dose administered and/or the quantity supplied ▪ The route of administration and site of administration where appropriate ▪ The frequency of administration and duration of treatment ▪ The time and date of supply/administration ▪ The signature and name of the person supplying/administering the medication or if documenting in Symphony, an electronic signature recorded by the system is acceptable. ▪ Whether the medication was witnessed as taken within the department & endorse PGD **In ED** a yellow ED prescription should be completed and include the particulars (see appendix A): - Patient addressograph (including name, hospital number and date of birth) - Drug name, formulation, strength, dose, frequency and quantity / duration - Signature and name printed of nurse - Endorsement 'PGD' - Date of supply Administration is documented on the front page of the patients drug chart under 'once only drugs'. Details which must be documented: - Patient name - Patient hospital number - Drug name - Drug dose - Route - Date and time of administration - Registered nurse signature and phrase 'PGD' Administration and supply should also be documented on Symphony to facilitate coding (note: this is not an electronic prescribing system).

4. Other Information

Follow up treatment:	Advise patient to seek further medical advice if no improvement in symptoms within 5 – 7 days
Arrangements for medicine supply:	TTA pack stock available in MIUs, ED minors and paediatrics
Arrangements for medical referral:	Medical referral should be made as detailed in the protocol

Lines of accountability:	▪ Individual nurses are accountable for their own practice under the code of professional conduct laid down by the NMC (Nursing and Midwifery Council 2002 – section 1) ▪ Individual paramedics are accountable for their own practice under the HCPC Standards of Proficiency for Paramedics (September 2014) ▪ Minor Injury Practitioners are accountable to the senior practitioner on duty and their line manager ▪ Registered nurses are accountable to their line manager and senior nurse

5. Appendices

References used in the development of this PGD:	▪ National Institute for Health and Care Excellence, 2013, NICE medicines practice guidelines [MPG2] Patient Group Directions | Guidance and guidelines | NICE ▪ Summary of Product Characteristics (GSK) https://www.medicines.org.uk/emc/product/6530/smpc Accessed 08.01.19 ▪ British National Formulary (BNF) 74 ▪ British National Formulary for Children (2017-2018) ▪ South and West Devon Formulary; Accessed 08.01.19 via http://southwest.devonformularyguidance.nhs.uk/
Audit details	▪ Periodic audit of compliance. ▪ Case note review of identified patients. We will ask nurses to identify patients they have given medication against PGD and review the appropriateness and documentation against the criteria.
Training	▪ **Medical treatment:** As per clinical protocol ▪ **Competency assessment:** Ongoing CPD – benchmarked competency assessment in clinical protocol. ▪ **Frequency of training / review process:** Ongoing review / supervision.

Please refer to the summary of product characteristics for full information

This Patient Group Direction is operational from the start of August 2019 and expires end of July 2021

Version History

Version	Date	Brief Summary of Change	Owner's Name
V 1.0	May 2017	Two year review of PGD. Merge of MIU and Acute PGDs and content transferred to Trust's current PGD template.	Torbay and South Devon NHS Foundation Trust
V 4.0	December 2017	PGD updated to include treatment of pylonephritis	Torbay and South Devon NHS Foundation Trust
V 5.0	August 2019	Two year review. Amendment made to dosing for Child aged 2-6 years. Wafarin moved from Exclusion Criteria to Caution.	Torbay and South Devon NHS Foundation Trust

For more information on the status of this document, contact:	Medicines Governance Team Administrator Pharmacy Department Torbay Hospital tsdft.medicinesgovernance@nhs.net
Date of Issue	**August 2019**
Reference	PGD 1594 v 5.0 Co-Amoxiclav
Path	V:Medicines Governance/ PGDs/MIUandA&E/PGD 1594 v 5.0 Co-Amoxiclav Aug19 – Jul21

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Objective: To enable emergency nurse practitioners (including paramedics) in ED and in MIUs to provide effective management of human or cat bites to any part of the body or other animal bites to the head, hands or genitals.

To enable effective treatment of acute pyelonephritis.

The individual practitioners named below are authorised to operate within the above PGD, being employees of Torbay and South Devon NHS Foundation Trust

CLINICAL AREA	LOCATION / DEPARTMENT

The following list must be kept with a copy of the PGD in each clinical area using that PGD. Each practitioner will receive and sign for an individual copy of the PGD. Only fully competent, qualified and trained professionals may operate within PGDs.

I agree to administer/supply the above preparation in accordance with this Patient Group Direction and I have received an up to date copy of the ratified PGD:

NAME *(please print)*	PROFESSIONAL TITLE	SIGNATURE	AUTHORISING MANAGER *(please print)*	MANAGER'S SIGNATURE	DATE

Document Control Information

This is a controlled document and should not be altered in any way without the express permission of the author or their representative.

Please note this document is only valid from the date approved below, and checks should be made that it is the most up to date version available.

If printed, this document is only valid for the day of printing.

This guidance has been registered with the Trust. The interpretation and application of guidance will remain the responsibility of the individual clinician. If in doubt contact a senior colleague or expert. Caution is advised when using clinical guidance after the review date, or outside of the Trust.

Ref No:	1594		
Document title:	Co-Amoxiclav, Administration and supply of to adults and children presenting with human or animal bites		
Purpose of document:			
Date of issue:	6 September 2019	**Next review date:**	31 July 2021
Version:	5	**Last review date:**	
Author:	Emergency Department Consultant Antimicrobial Pharmacist Senior Manager MIU Services / Nurse Consultant Emergency Care Unit		
Directorate:	Organisation Wide		
Equality Impact:	The guidance contained in this document is intended to be inclusive for all patients within the clinical group specified, regardless of age, disability, gender, gender identity, sexual orientation, race and ethnicity & religion or belief		
Committee(s) approving the document:	Chair, Trust Medicines Management Committee Medical Director		
Date approved:	30 August 2019		
Links or overlaps with other policies:			

Have you identified any issues on the Rapid (E)quality Impact Assessment. If so please detail on Rapid (E)QIA form.	Yes ☐	
	Please select *Yes*	*No*
Does this document have implications regarding the Care Act? *If yes please state:*	☐	☐
Does this document have training implications? *If yes please state:*	☐	☐

Does this document have financial implications? *If yes please state:*	☐	☐
Is this document a direct replacement for another? *If yes please state which documents are being replaced:*	☐	☐

Document Amendment History

Date	Version no.	Amendment summary	Ratified by:
18 October 2013	1	New	Clinical Director of Pharmacy Medical Director
5 February 2016	2	Revised	Chair, Trust Medicines Management Committee Medical Director
16 June 2017	3	Revised	Chair, Trust Medicines Management Committee Medical Director
12 January 2018	4	Revised	Chair, Trust Medicines Management Committee Medical Director
6 September 2019	5	Revised	Chair, Trust Medicines Management Committee Medical Director

The Mental Capacity Act 2005

The Mental Capacity Act provides a statutory framework for people who lack capacity to make decisions for themselves, or who have capacity and want to make preparations for a time when they lack capacity in the future. It sets out who can take decisions, in which situations, and how they should go about this. It covers a wide range of decision making from health and welfare decisions to finance and property decisions

Enshrined in the Mental Capacity Act is the principle that people must be assumed to have capacity unless it is established that they do not. This is an important aspect of law that all health and social care practitioners must implement when proposing to undertake any act in connection with care and treatment that requires consent. In circumstances where there is an element of doubt about a person's ability to make a decision due to 'an impairment of or disturbance in the functioning of the mind or brain' the practitioner must implement the Mental Capacity Act.

The legal framework provided by the Mental Capacity Act 2005 is supported by a Code of Practice, which provides guidance and information about how the Act works in practice. The Code of Practice has statutory force which means that health and social care practitioners have a legal duty to have regard to it when working with or caring for adults who may lack capacity to make decisions for themselves.

"The Act is intended to assist and support people who may lack capacity and to discourage anyone who is involved in caring for someone who lacks capacity from being overly restrictive or controlling. It aims to balance an individual's right to make decisions for themselves with their right to be protected from harm if they lack the capacity to make decisions to protect themselves". (3)

All Trust workers can access the Code of Practice, Mental Capacity Act 2005 Policy, Mental Capacity Act 2005 Practice Guidance, information booklets and all assessment, checklists and Independent Mental Capacity Advocate referral forms on iCare

http://icare/Operations/mental_capacity_act/Pages/default.aspx

Infection Control

All staff will have access to Infection Control Policies and comply with the standards within them in the work place. All staff will attend Infection Control Training annually as part of their mandatory training programme.

Clinical and Non-Clinical Policies – Data Protection

Torbay and South Devon NHS Foundation Trust (TSDFT) has a commitment to ensure that all policies and procedures developed act in accordance with all relevant data protection regulations and guidance. This policy has been designed with the EU General Data Protection Regulation (GDPR) and Data Protection Act 2018 (DPA 18) in mind, and therefore provides the reader with assurance of effective information governance practice.

The UK data protection regime intends to strengthen and unify data protection for all persons; consequently, the rights of individuals have changed. It is assured that these rights have been considered throughout the development of this policy. Furthermore, data protection legislation requires that the Trust is open and transparent with its personal identifiable processing activities and this has a considerable effect on the way TSDFT holds, uses, and shares personal identifiable data.

Does this policy impact on how personal data is used, stored, shared or processed in your department? Yes ☐ No ☐

If yes has been ticked above it is assured that you must complete a data mapping exercise and possibly a Data Protection Impact Assessment (DPIA). You can find more information on our GDPR page on ICON (intranet)

For more information:

- Contact the Data Access and Disclosure Office on dataprotection.tsdft@nhs.net,
- See TSDFT's Data Protection & Access Policy,
- Visit our Data Protection site on the public internet.