

**Patient Group Direction 1594** version 4.0

**Supply of Co-Amoxiclav by Registered Practitioners employed by Torbay and South Devon NHS Foundation Trust**

**Date of Introduction: December 2017**

**Review Date: November 2019**

Developed By	Name	Signature	Date
Physician	Emergency Department Consultant		
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of the PGD to practitioners who will be using the PGD as well as ensuring that the PGD is no longer used if becomes out of date and once it has expired.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.

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

# Supply of Co-Amoxiclav by Registered Practitioners employed by Torbay and South Devon NHS Foundation Trust

<b>Objective</b>	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.
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## 1. Clinical Condition

<b>Definition of condition/situation</b>	Where the need for an antibiotic is justified, in the following conditions / situations, according to the relevant Trust protocol: 1 <sup>st</sup> line antimicrobial choice for the treatment of animal and human bites. 1 <sup>st</sup> line antimicrobial choice for the management of traumatic wounds, including puncture wounds and open fractures. Acute pyelonephritis in children $\geq 16$ and adults.
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<b>Facilities required</b>	TTA pack of 21 x co-amoxiclav tablets TTA pack of 70ml co-amoxiclav 400/57 suspension
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<b>Criteria for inclusion</b>	<ul style="list-style-type: none"><li>▪ The bite is of a minor nature and referral to a doctor is not required</li><li>▪ Adults and children over 2 years presenting with a human or animal bite, according to the relevant Trust protocol</li><li>▪ Adults and children over 2 with traumatic wounds, including puncture wounds and open fractures according to the relevant Trust protocol</li><li>▪ Acute pyelonephritis (1<sup>o</sup> care guideline) in children <math>\geq 16</math> and adults</li></ul>
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<b>Criteria for exclusion</b>	<ul style="list-style-type: none"><li>▪ Hypersensitivity to penicillins, or other beta-lactam antibiotics, including cephalosporins</li><li>▪ Hypersensitivity to any of the ingredients of the co-amoxiclav product to be administered / supplied</li><li>▪ Children under 2 years old</li><li>▪ Any bites from exotic pets e.g. Terrapin, snakes- contact microbiologist for advice.</li><li>▪ If there is any possibility of rabies – refer to the emergency department</li><li>▪ Any patient with suspected injury to tendons, ligaments or bones– refer to the emergency department</li><li>▪ Pregnancy – refer to a doctor; increased risk of necrotizing enterocolitis in the newborn.</li><li>▪ Breast feeding</li><li>▪ For cellulitis and lymphangitis – patient unwell &amp; systemic symptoms observed e.g. pyrexia – check vital signs and refer to emergency services</li><li>▪ Infection with glandular fever, human immunodeficiency virus or cytomegalovirus</li><li>▪ Acute or chronic lymphocytic leukaemia</li><li>▪ History of penicillin or co-amoxiclav associated hepatic dysfunction</li><li>▪ Currently taking warfarin</li><li>▪ Currently taking methotrexate</li><li>▪ Currently taking probenecid</li></ul>
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<b>Action if excluded</b>	<ul style="list-style-type: none"> <li>▪ Refer to medical practitioner (<b>or non-medical prescriber if appropriate</b>) or alternative action as indicated by related protocol and document in patient's records</li> </ul>
<b>Action if patient refuses medication</b>	<ul style="list-style-type: none"> <li>▪ Document informed refusal in patient's records and action taken:             <ul style="list-style-type: none"> <li>a) Referral to protocol</li> <li>b) Referral to appropriate medical practitioner</li> </ul> </li> </ul>

## 2. Characteristics of Staff

<b>Qualifications required</b>	<ul style="list-style-type: none"> <li>▪ Minor Injury Practitioner (nurse or paramedic) working in community MIU.</li> <li>▪ Emergency Nurse Practitioners (or paramedic ) in ED</li> </ul>
<b>Additional requirements</b>	<ul style="list-style-type: none"> <li>▪ 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.</li> <li>▪ Working knowledge of relevant Organisation protocols</li> <li>▪ 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) <a href="http://www.nmc-uk.org">www.nmc-uk.org</a> and other relevant codes of professional practice.</li> <li>▪ Working knowledge of the NMC Standards of Proficiency for Paramedics (September 2014), <a href="http://www.hpc-uk.org/assets/documents/1000051C%20Standards%20of%20Proficiency%20paramedics.pdf">http://www.hpc-uk.org/assets/documents/1000051C Standards of Proficiency paramedics.pdf</a> and other relevant codes of professional practice.</li> </ul>

## 3. Description of Treatment

<b>Name of Medicine Supplied</b>	<p>Co-amoxiclav tablets 500mg/125mg: containing amoxicillin 500mg and clavulanic acid 125mg</p> <p>Co-amoxiclav oral suspension 400/52: containing amoxicillin trihydrate 400mg and potassium clavulanate 52mg as a powder for reconstitution to form a suspension</p>
<b>Legal Class</b>	POM (Prescription Only Medicine)
<b>Storage</b>	<p>Store below 25°C in original package</p> <p>Reconstituted suspension: Patients to store in a fridge between +2°C and +8°C, for up to seven days. Do not freeze.</p>
<b>Dose to be used (including criteria for use of differing doses)</b>	<p><b>Adults and children over 12years (&gt;40kg):</b> 625mg tablet three times a day for 7 days or 10ml (800/114mg) suspension twice a day for 7 days</p> <p><b>Child aged 7-12 years (22-40kg):</b> 5ml (400/57mg) suspension twice a day for 7 days</p> <p><b>Child aged 2-6 years (13-21kg):</b> 2.5ml (200/28.5mg) suspension twice a day for 7 days</p> <p>For pyelonephritis in children <math>\geq</math> 16 years supply 10 days and adults supply 14 days.</p>

<b>Method or route of administration</b>	Oral
<b>Total dose and number of times drug to be given. Details of supply (if supply made)</b>	<p><b>For adults and children over 12years (&gt;40kg):</b> 625mg 3 times a day for 7 days</p> <ul style="list-style-type: none"> <li>▪ Supply 21 x co-amoxiclav 500/125mg tablets</li> </ul> <p><b>Child aged 7-12 years (22-40kg):</b> 5ml (400/57mg) suspension twice a day for 7 days</p> <ul style="list-style-type: none"> <li>▪ Supply 1 x 70ml reconstituted co-amoxiclav 400/57mg suspension</li> </ul> <p><b>Child aged 2-6 years (13-21kg):</b> 2.5ml (200/28.5mg) suspension twice a day for 7 days</p> <ul style="list-style-type: none"> <li>▪ Supply 1 x 70ml reconstituted co-amoxiclav 400/57mg suspension</li> </ul> <p>For pyelonephritis in children ≥ 16 years supply 10 days and adults supply 14 days.</p> <p>Supply sufficient quantity of appropriate dose form in each case to complete the course.</p> <p><b>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</b></p>
<b>Contra-indications</b>	See exclusion criteria
<b>Cautions</b>	<p><b>If patient is taking any other medications consult BNF Appendix 1 for any potential interactions.</b></p> <ul style="list-style-type: none"> <li>▪ <b>Patients taking anticoagulants requiring INR monitoring (warfarin, acenocoumarol or phenindione):</b> 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</li> <li>▪ <b>Immunocompromised patients</b> – see patient advice</li> <li>▪ <b>Patients taking immunosuppressant or disease-modifying anti-rheumatic drugs (DMARDs)</b> – see patient advice</li> <li>▪ Patients taking <b>methotrexate</b> - Advise patient to see their GP for a full blood count check and liver function test</li> <li>▪ Patients taking <b>allopurinol</b> – advise that this may increase the occurrence of rash</li> <li>▪ Breastfeeding – trace amounts excreted in breast milk (only significant if infant is sensitized/hypersensitive to penicillins or cephalosporins)</li> <li>▪ Known hepatic impairment / dysfunction (including hepatitis &amp; jaundice). Committee on Safety of Medicines (CSM) has advised that cholestatic jaundice can occur during or shortly after use of co-amoxiclav.</li> <li>▪ Severe renal impairment – risk of crystalluria with high doses - maintain adequate fluid intake &amp; convulsions</li> <li>▪ 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.</li> <li>▪ 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.</li> <li>▪ Increased risk of erythematous rash in patients with cytomegalovirus infection and acute / chronic lymphocytic leukaemia.</li> </ul>

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## 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.

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## 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)<sup>9</sup>

**Renal and urinary disorders:** Interstitial nephritis, crystalluria.

Unusual or life threatening reactions require immediate medical attention.

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## 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 diarrhoea.
- 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](http://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).

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#### **4. Other Information**

**Follow up treatment:**

Advise patient to seek further medical advice if no improvement in symptoms within 5 – 7 days

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**Arrangements for medicine supply:**

TTA pack stock available in MIUs, ED minors and paediatrics

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**Arrangements for medical referral:**

Medical referral should be made as detailed in the protocol

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#### 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

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## 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) Augmentin & Augmentin-Duo Accessed 16.05.17 <http://www.medicines.org.uk>
- British National Formulary (BNF) 72
- British National Formulary for Children (2016-2017)
- South and West Devon Formulary; Accessed 16.05.17 via <http://southwest.devonformularyguidance.nhs.uk/>
- The Faculty of Sexual and Reproductive Healthcare Clinical Guidance: Drug Interactions with Hormonal Contraception. January 2011 (Updated January 2017). <http://www.fsrh.org/pdfs/CEUGuidanceDrugInteractionsHormonal.pdf>
- Relevant Trust Clinical Treatment Protocol/s
- Adult Empirical Antimicrobial Guidelines
- Paediatric Empirical Antimicrobial Guidelines

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#### 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.

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#### 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 December 2017 and expires end of November 2019

### 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 pyelonephritis	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 <a href="mailto:tsdft.medicinesgovernance@nhs.net">tsdft.medicinesgovernance@nhs.net</a>
<b>Date of Issue</b>	<b>December 2017</b>
Reference	PGD 1594 v 4.0 Co-Amoxiclav
Path	V:Medicines Governance/ PGDs/MIUandA&E/PGD 1594 v 4.0 Co-Amoxiclav December 2017-November 2019



## Protocols & Guidelines – Document Control

This is a controlled document. It should not be altered in any way without the express permission of the author or their representative. On receipt of a new version, please destroy all previous versions.

Ref: 1594	Title: Co-Amoxiclav, Administration and supply of to adults and children presenting with human or animal bites		
Date of Issue:	12 January 2018	Next Review Date:	30 November 2019
Version:	4		
Author:	Emergency Department Consultant Pharmacist Senior Manager MIU Services / Nurse Consultant Emergency Care Unit		
Index:	Patient Group Direction		
Classification:	Patient Group Direction		
Applicability:	As indicated		
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.		
Evidence based:	Yes		
References:	See Page 8		
Produced following audit:	See Page 8		
Audited:	See Page 8		
Approval Route:	See ratification	Date Approved:	22 December 2017
Approved By:	Chair, Trust Medicines Management Committee		
	Medical Director		
Links or overlaps with other policies:			
All TSDFT Trust strategies, policies and procedure documents.			

### PUBLICATION HISTORY:

Issue	Date	Status	Authorised
1	18 October 2013	New	Clinical Director of Pharmacy Medical Director
2	5 February 2016	Revised	Chair, Trust Medicines Management Committee Medical Director
3	16 June 2017	Revised	Chair, Trust Medicines Management Committee Medical Director
4	12 January 2018	Revised	Chair, Trust Medicines Management Committee Medical Director

## Clinical and Non-Clinical Policies – New Data Protection Regulation (NDPR)

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 New Data Protection Regulation (NDPR) in mind and therefore provides the reader with assurance of effective information governance practice.

NDPR 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, NDPR 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. The most effective way of being open is through data mapping. Data mapping for NDPR was initially undertaken in November 2017 and must be completed on a triannual (every 3 years) basis to maintain compliance. This policy supports the data mapping requirement of the NDPR.

For more information:

- Contact the Data Access and Disclosure Office on [dataprotection.tsdf@nhs.net](mailto:dataprotection.tsdf@nhs.net),
- See TSDFT's [Data Protection & Access Policy](#),
- Visit our [GDPR](#) page on ICON.