Torbay and South Devon NHS
NHS Foundation Trust

Patient Group Direction 2196 version 1.0
Administration / Supply of Amoxicillin in Patients presenting with Acute Severe Sinusitis / Acute Otitis Media by Registered Practitioners employed by Torbay and South Devon NHS Foundation Trust

Date of Introduction: September 2017
Review Date: August 2019

Developed By	Name	Signature	Date
Physician	Nick Mathieu Emergency Department Consultant		
Pharmacist	Kate Wormald		
Lead Professional	Deirdre Molloy 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of the PGD to practitioners who will be using the PGD as well as ensuring that the PGD is no longer used if becomes out of date and once it has expired.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:	Paul Foster, Clinical Director – Pharmacy and Prescribing
Date:	
Lead Officer	
Signed:	
Name:	Dr Rob Dyer, Medical Director
Date:	

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Administration / Supply of Amoxicillin in Patients presenting with Acute Severe Sinusitis / Acute Otitis Media 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 acute severe sinusitis / acute otitis media in patients presenting to the Emergency Department or MIUs.

1. Clinical Condition

Definition of condition/situation	▪ Acute severe sinusitis - 1st line antimicrobial choice for the management of according to local protocol. ▪ Acute otitis media - 1st line antimicrobial choice for the management of according to local protocol.
Facilities required	TTA packs of 21 x amoxicillin 500mg capsules TTA packs of 21 x amoxicillin 250mg capsules TTA packs of 100ml amoxicillin 250mg / 5ml suspension
Criteria for inclusion	**For sinusitis:** ▪ Patients **aged 12 years and over** presenting with severe sinusitis where the need for an antibiotic is justified, according to the relevant Trust protocol. **For acute otitis media:** ▪ Patients **aged 1 year and over** presenting with acute otitis media where the need for an antibiotic is justified, according to the relevant Trust protocol.
Criteria for exclusion	▪ Hypersensitivity to penicillins, or other beta-lactam antibiotics, including cephalosporins ▪ Hypersensitivity to any ingredient of the amoxicillin product to be administered / supplied ▪ Infection with glandular fever, human immunodeficiency virus or cytomegalovirus ▪ Acute or chronic lymphocytic leukaemia ▪ Concurrent methotrexate therapy ▪ Fructose intolerance patients are excluded from having oral suspension as contains sorbitol. **For sinusitis only:** ▪ Exclude children under the age of 12 years **For acute otitis media only:** ▪ Exclude children under the age of 1 year
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	If the patient does not wish to receive treatment, or is non-compliant, then the following action will be taken: ▪ Document in patient's notes and refer to medical practitioner (or non-medical prescriber if appropriate).

2. Characteristics of Staff

Qualifications required	▪ Minor Injury Practitioner (nurse or paramedic) working in community MIU. ▪ Emergency Practitioner (nurse or paramedic) working in ED
Additional requirements	▪ Working knowledge of relevant Organisation Policies, including Medicines Policy and associated Standard Operating Procedures, Anaphylaxis Policy, Consent Policy ▪ 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 / Administered	Amoxicillin 250mg capsules Amoxicillin 500mg capsules Amoxicillin 250mg / 5ml suspension
Legal Class	POM (Prescription Only Medicine)
Storage	**Capsules:** Do not store above 25°C. Store in the original pack **Dry powder:** Do not store above 25°C. Store in the original container in order to protect from light and moisture. Once reconstituted, store in a fridge between +2ºC and +8ºC. Do not freeze.
Dose to be used (including criteria for use of differing doses)	**For sinusitis:** ▪ Adults and children aged 12 years and over: 500mg **For acute otitis media:** ▪ Children aged 1-4 years: 250mg ▪ Adults and children aged 5 years and over: 500mg
Method or route of administration	Oral

Total dose and number of times drug to be given. Details of supply (if supply made)	**For sinusitis:** ▪ Adults and children aged 12 years and over: 500mg three times a day for seven days Supply **either** 1 or 2 pack(s) of amoxicillin 250mg **or** 500mg capsules as appropriate **For acute otitis media:** ▪ Children aged 1-4 years: 250mg three times a day for five days 1 x 100ml of reconstituted amoxicillin 250mg/5ml suspension as appropriate ▪ Adults and children aged 5 years and over: 500mg three times a day for five days Supply 1 or 2 pack(s) of amoxicillin 250mg or 500mg capsules **or** 2 x 100ml of reconstituted amoxicillin 250mg/5ml suspension as appropriate All supplies must be appropriately labelled with patient's name, drug name, strength and form, clear dosage instructions, the date of supply and name and address of supplying center. **Label to include expiry date of reconstituted suspension**
Contra-indications	▪ See exclusion criteria
Cautions	▪ Oral suspension has a high sodium content, therefore use with caution in patients on sodium-restricted diets. ▪ **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 (DMARDs**) – see patient advice ▪ Patients taking **methotrexate** - advise them 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).
Interactions	▪ If patient is taking any other medications consult BNF Appendix 1 for any potential interactions.

Potential side-effects and adverse reactions	▪ **Infections:** candidiasis ▪ **Blood and lymphatic system:** Eosinophilia, haemolytic anaemia, leucopenia, neutropenia, granulocytopenia, thrombocytopenia, pancytopenia, anaemia, myelosuppression, agranulocytosis, prolongation of bleeding an dprothrombin time ▪ **Immune system:** laryngeal oedema, serum sickness, allergic vasculitis, anaphylaxis ▪ **Nervous system:** hyperkinesia, dizziness and convulsions ▪ **Gastrointestinal:** gastric complaints, nausea, loss of appetite, vomiting, flatulence, soft stools, diarrhoea, enanthemas, dry mouth, taste disturbances, dicolouration of the teeth and very rarely pseudomembranous colitis, black tongue ▪ **Hepato-biliary:** elevated liver enzymes, rarely hepatitis and cholestatic jaundice ▪ **Skin and subcutaneous tissue:** exanthema, pruritis, urticarial (discontinue if occurs at start of treatment), angtioneurotic oedema, erythema multiforme exsudativum, acute generalised pustulosis, Lell's syndrome, Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous and exfoliative dermatitis. ▪ **Renal:** acute interstitial nephritis, crystalluria ▪ **Others:** drug fever. Unusual or life threatening reactions require immediate medical attention. Indicate other issues for patients / carers to consider e.g. drug – food interactions, likelihood to effect ability to drive / work etc.
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

Advice and information to patient/carer including follow-up	Unusual or life threatening reactions require immediate medical attention. ▪ 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 them to see their GP for a full blood count check and liver function test – increased risk of toxicity ▪ 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 ▪ Rash ▪ Advise patient to seek urgent medical attention if they experience persistent or severe diarrhoea. ▪ Advise patients to complete the course of antibiotics ▪ Advise patient to seek further medical advice if symptoms do not improve or if symptoms worsen. ▪ 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) if available. ▪ 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 amoxicillin. 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, who should be advised that guidance in the Patient Information Leaflet may differ. ▪ **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 documents: - 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:	▪ Follow up as required for presenting complaint, if no improvement or deterioration to be advised to consult a medical practitioner.
Arrangements for medicine supply:	TTA pack and 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:	▪ NICE guidance ▪ National Institute for Health and Care Excellence, 2013, NICE medicines practice guidelines [MPG2] Patient Group Directions | Guidance and guidelines | NICE ▪ Trust Protocols and Documents ▪ BNF& cBNFaccessed via www.bnf.org Aug 2017 ▪ Summary of Product Characteristics: Amoxicillin 250mg & 500mg capsules https://www.medicines.org.uk/emc/medicine/26188 https://www.medicines.org.uk/emc/medicine/26178 Accessed 02.08.17 ▪ Summary of Product Characteristics: Amoxicillin 125mg/5ml oral suspension https://www.medicines.org.uk/emc/medicine/24923 Accessed 02.08.17 ▪ Summary of Product Characteristics: Amoxicillin 250mg/5ml oral suspension https://www.medicines.org.uk/emc/medicine/31831 Accessed 02.08.17 ▪ South and West Devon Formulary Accessed Aug 2017 http://www.southwest.devonformularyguidance.nhs.uk / South Devon Joint Formulary and South Devon Healthcare NHS Foundation Trust Adult Empirical Antimicrobial Guidelines. ▪ 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
Audit details	Periodic audit of compliance. Case note review of identified patients. We will ask nurses to identify patients they have given medication to against PGD and review the appropriateness and documentation against the critieria.
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 September 2017 and expires end of August 2019

Version History

Version	Date	Brief Summary of Change	Owner's Name
v 1.0	August 2017	Two year review of PGDs. Content transferred to the Trust's new PGD template.	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	**September 2017**
Reference	PGD 2196 v 1.0 Amoxicillin for Sinusitis & Otitis Media
Path	V:Medicines Governance/PGDs/MIUs/PGD 2196 v 1.0 Amoxicillin for Sinusitis & Otitis Media Sept17 – Aug19

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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

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Ref No:	2196		
Document title:	Amoxicillin for Severe Sinusitis and Acute Severe Sinusitis / Acute Otitis Media		
Purpose of document:	Patient Group Direction		
Date of issue:	2 October 2017	**Next review date:**	31 August 2019
Version:	1	**Last review date:**	
Author:	Emergency Department Consultant Pharmacist Senior Manager MIU Services / Nurse Consultant Emergency Care Unit		
Directorate:	Medical Services		
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:	19 September 2017		
Links or overlaps with other policies:	All TSDFT Trust Strategies, policies and procedure documents		

	Please select	
	Yes	*No*
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:
2 October 2017	1	New	Chair, Trust Medicines Management Committee Medical Director