Patient Group Direction
for Community Pharmacists and Registered Addictions Service Nurses
to Supply
Co-Amoxiclav 625mg (500/125 tablet or 10ml of 250/62.5mg in 5ml suspension)
to patients 18 years of age and older
for the treatment of Skin Infections associated with injection site complications

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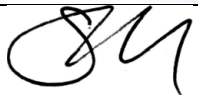
Sarah Macfarlane	Specialist Pharmacist in Substance Misuse, NHS Fife		27.04.22
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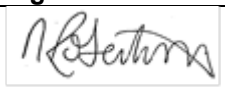
Nicola Robertson	Associate Director of Nursing NHS Fife		17.05.22
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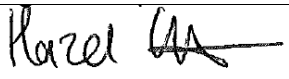
Hazel Close	Lead Pharmacist, Public Health & Community Pharmacy NHS Fife		17.05.22

1. Clinical condition to which the patient group direction applies

Indication	• Patients presenting in community pharmacy or under the care of Addictions Service with skin infections associated with injection site complications such as cellulitis and wound infections.
Inclusion criteria	• Patient aged 18 years or older • Valid consent to treatment according to NHS Fife policy • Patient requires treatment with Co-amoxiclav as specified by relevant algorithm see Appendix 1
Exclusion criteria	• Patient under 18 years old • If the area is purulent (immediate referral to medical staff is necessary) • Hypersensitivity to the active substances, to any of the penicillins or to any of the excipients. (see SPC and PIL for details) • History of a severe immediate hypersensitivity reaction (e.g. anaphylaxis) to another beta-lactam agent (e.g. a cephalosporin, carbapenem or monobactam) • History of jaundice/hepatic impairment due to amoxicillin/clavulanic acid • Severe hepatic disease • Renal impairment • Acute sore throat/tonsillitis • Current treatment with methotrexate, oral typhoid vaccine, probenecid. **N.B. This list is not exhaustive.** Please check the BNF and refer to a doctor if necessary • No valid consent to treatment according to NHS Fife policy
Cautions / Circumstances when further advice should be sought from a doctor	• Abnormal prolongation of prothrombin time (increased INR) has been reported rarely in patients receiving co amoxiclav and oral anticoagulants. **Appropriate monitoring should be undertaken when anticoagulants are prescribed concomitantly**. • In patients with reduced urine output, crystalluria has been observed very rarely, predominantly with parenteral therapy. During the administration of high doses of co amoxiclav, it is advisable to maintain adequate fluid intake and urinary output in order to reduce the possibility of crystalluria • The product should only be used during pregnancy where potential benefits outweigh the potential risks associated with treatment • The product should only be used while breastfeeding where potential benefits outweigh the potential risks associated with treatment • Patients already taking a prescribed antibiotic • Current diarrhoea or history of *Clostridium Difficile* infection • Hepatically impaired patients should be dosed with caution and hepatic function monitored at regular intervals • 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 • Convulsions may occur in patients with impaired renal function or in those receiving high doses • Concomitant use of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions • Hepatic events have been reported predominantly in males and elderly patients and may be associated with prolonged treatment. • The presence of Clavulanic acid in Co-amoxiclav may cause a non-

	specific binding of IgG and albumin by red cell membranes leading to a false positive Coombs test. • It is the responsibility of the designated, authorised staff using this PGD to ensure that treatment with the drug detailed in this direction is appropriate. If in any doubt, advice should be sought and recorded before the drug is administered / supplied.
Action if excluded	• Do not use the PGD • The patient must be referred to a doctor (Addictions Service, GP or OOH). • The reason for referral should be documented
Action if patient declines treatment	• The patient must be referred to a doctor (Addictions Service, GP or OOH). • The reason for refusal should be documented • Ensure awareness of implications of declining treatment and encourage early treatment where appropriate.

2. Medication details

Name strength & formulation of drug	• Co-amoxiclav tablets 625mg (500/125mg) (amoxicillin 500mg, clavulanic acid 125mg) **Or for those unable to swallow tablets (Community Pharmacy Only)** • 10ml Co-Amoxiclav 250/62.5mg suspension. Reconstitute according to manufacturer's instructions.
Route of administration	• Oral
Dosage	• ONE tablet **or** • 10ml suspension Community Pharmacy)
Frequency of administration	• THREE times a day
Duration of treatment	• 7 days
Quantity to be supplied	• **7 day course** - 21 tablets **or** • 3 x 100ml bottles of suspension 250/62.5 in 5ml (Community Pharmacy)
Patient advice verbal and written	• The patient information leaflet should be given. • Take at regular intervals and complete the course unless otherwise directed. • For best results take at the start of a meal. • Tablets should be swallowed whole. Do not crush or chew them. • Seek further medical advice if condition worsens or fails to improve with treatment.
Legal category	• POM
Use outwith SPC	• No
Storage requirements	• Store in a dry place under 25°C. • Once reconstituted the suspension has 7 days shelf life if stored in a fridge between 2 – 8°C • Ensure within expiry date
Identification and management of adverse reactions	• May cause nausea, vomiting, diarrhoea and indigestion • May cause rash The occurrence at the treatment initiation of a feverish generalised erythema associated with pustula may be a symptom of acute generalised exanthemous pustulosis (AGEP). This reaction requires Co-amoxiclav discontinuation and contra-indicates any subsequent administration of amoxicillin

	• Hepatic events have been reported predominantly in males and elderly patients and may be associated with prolonged treatment. These events have been very rarely reported in children. In all populations, signs and symptoms usually occur during or shortly after treatment but in some cases may not become apparent until several weeks after treatment has ceased. These are usually reversible. Hepatic events may be severe and, in extremely rare circumstances, deaths have been reported. These have almost always occurred in patients with serious underlying disease or taking concomitant medications known to have the potential for hepatic effects • May cause cholestatic jaundice • 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 • Should antibiotic-associated colitis occur, amoxicillin/clavulanic acid should immediately be discontinued, a physician be consulted and an appropriate therapy initiated. • Any suspected adverse drug reactions should be reported to the doctor and documented in patient's medical case notes. • In the case of anaphylaxis, treat according to NHS Fife Operational Procedure for the Management of Anaphylaxis and refer immediately for medical attention. • Advise patient to seek medical advice for significant side effects or if concerned. • All suspected serious reactions should be reported directly to the MHRA/Commission on Human Medicines through the Yellow Card scheme and recorded in the patient's medical notes. Reports should be made online at https://yellowcard.mhra.gov.uk
Additional facilities/ supplies required	• Ensure immediate access to anaphylaxis medication as appropriate to current NHS Fife procedure for the Management of Anaphylaxis. • Immediate telephone access to a doctor • Access to a BNF • NHS Fife Safe and Secure Use of Medicines Policy and Procedures (SSUMPP) should be followed • Adhere to hand decontamination policy
Follow up – appointment with or notification to GP required?	• Ask the patient to return for review at 7 days, if symptoms recur then refer to Addictions Service doctor, OOH or GP. • In the best interest to the patient, carry out a review even if they return after 7 days and refer if necessary.
Disposal	• Complete course, return any unused medication to pharmacy.

3. Staff characteristics

Professional qualifications	• GPhC Registered Pharmacists working in community pharmacy within NHS Fife • Registered Nurses with current NMC registration working in Addiction Services
Specialist competencies or qualifications	**For all staff:** • **PGD Practitioner** who is competent to undertake supply and administration of medicines under Patient Group Directions. • Has undertaken appropriate training to carry out clinical assessment of

	patient leading to diagnosis that requires treatment according to the indications listed in the PGD, using NHS Fife approved diagnostic algorithm/guidelines • Able to assess the patient's capacity to understand the nature and purpose of the treatment in order to give informed consent. **For Nurses only: (As per NHS Fife requirements)** • Has undertaken NHS Fife approved anaphylaxis management training. • Has undertaken NHS Fife training in adult basic life support • It is essential that the NHS Fife approved PGD e-learning programme is accessed and completed.
Continued training requirements	**For all staff:** • It is the responsibility of the designated, authorised staff using this PGD to keep up-to-date with information on contraindications, cautions and interactions for Co-amoxiclav from the BNF, SPC and PIL and ensure that treatment with the drug detailed in this direction is appropriate. If in any doubt, advice should be sought and recorded before the product is supplied. • Maintain own professional level of competence and knowledge in this area. • A 2 yearly update of the PGD e-learning programme is essential **For Nurses only: (As per NHS Fife requirements)** • Annual update of anaphylaxis management according to NHS Fife Policy • Annual update of training in adult basic life support

4. Referral arrangements/Audit trail

Arrangements for referral to medical advice	• The patient may be referred to a doctor at any stage, if this is necessary, in the professional opinion of the *Pharmacist or Nurse*. • Patients should be referred to the doctor if treatment proves to be ineffective in relieving the symptoms
Records/Audit trail	• Enter in record - date - name of patient - date of birth/ CHI no - name of medicine - batch number and manufacturer - expiry date - dose/volume - quantity administered - route and site of administration - name of clinician providing treatment - signature / individual log-on details of clinician providing treatment • Record on appropriate form. • Record medical history taken, diagnosis and the advice given to the patient/carer
References/ Resources & comments	• BNF / BNFc latest edition available at www.medicinescomplete.com • NHS Fife Consent Policy • NHS Fife Procedure for the Management of Anaphylaxis • NHS Fife Resuscitation Guidelines • NMC/RPS Administration of Medicines Guidance Jan 2019 • NHS Fife Safe and Secure Use of Medicines Policy and Procedures (SSUMPP) • Summary of Product Characteristics Co-amoxiclav available at www.medicines.org.uk

This Patient Group Direction has been assessed for Equality and Diversity Impact

5. Management and monitoring of patient group direction

PATIENT GROUP DIRECTION FOR COMMUNITY PHARMACISTS
and Registered Addictions Service Nurses
to Supply **Co-Amoxiclav 625mg (500/125 tablet or 10ml of 250/62.5mg in 5ml suspension)**
to patients 18 years of age and older
for the treatment of Skin Infections associated with injection site complications

This patient group direction is to be read, agreed to, and signed by all *healthcare professionals* it applies to. One signed copy is to be given to each clinician with the original being kept on file by the line manager. One signed copy should be forwarded to the appropriate lead nurse / lead clinician where applicable.

Pharmacist/Nurse Agreement

I _____, confirm that I have read and understood the above Patient Group

Direction. I confirm that I have the necessary professional registration, competence, and knowledge to apply the Patient Group Direction. I will ensure my competence is updated as necessary. I will have ready access to a copy of the Patient Group Direction in the clinical setting in which supply or administration of the medicine will take place.

I understand that it is the responsibility of the healthcare professional to act in accordance with the GPhC/ NMC Guidelines for Professional Practice and Guidelines for the Administration (or Supply) of Medicines and to keep an up to date record of training and competency.

Name of clinician----------

Professional Category----------

Registration No.----------

Is authorised to give **Co-Amoxiclav 625mg tablets**
or 10ml of 250/62.5mg in 5ml suspension (community pharmacy only)
under this patient group direction

Place of Work----------

Signature of clinician----------

Date----------

Authorised by: **(not required for pharmacists)**

Name of authorising clinician/manager----------

Signature----------

Date----------

Pharmacists send signed copy of this page to fife.pgd@nhs.scot

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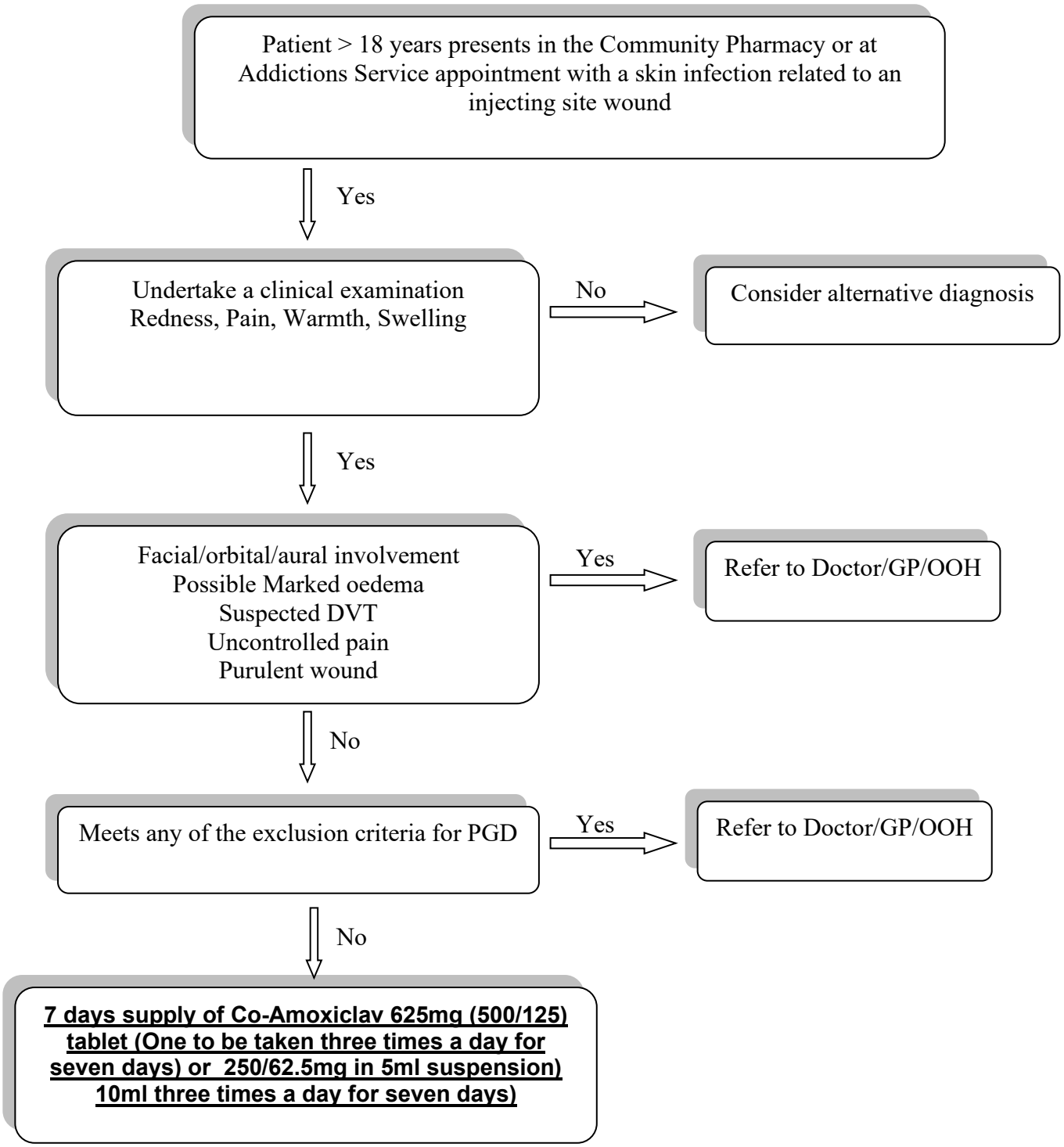
Appendix 1

Cellulitis and skin infections.
(AGED > 18 years)



If symptoms recur or increase, advise patient to contact NHS 24 Out of Hours, Addiction Services or their own GP during normal surgery opening times