Patient Group Direction

Supply of Co-Amoxiclav to patients 18 years of age and older By Community Pharmacists for the Management of Skin Infections associated with injection site complications Protocol number 663 Version 1

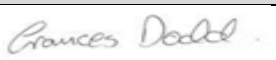
Date protocol prepared: **1 May 2025**

Date protocol due for review: **31 May 2027**

Expiry Date: **31 May 2028**

This patient group direction must be signed by all health care professionals involved in its use. The NHS organisation should hold the original signed copy. The PGD must be easily accessible in the clinical setting.

Organisation	NHS Forth Valley

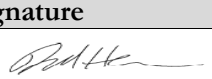
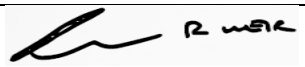
Job Title	Name	Signature	Date
Director of Nursing	Frances Dodd		30/4/25
Medical Director	Andrew Murray		8/4/25
Director of Pharmacy	Laura Byrne		1/5/25

This document authorises the supply of co-amoxiclav by appropriate practitioners to patients who meet the criteria for inclusion under the terms of the document.

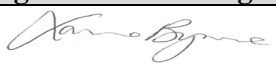
Practitioners seeking to supply co-amoxiclav must ensure that they assess all clients to make sure they meet the criteria before supplying the product.

The purpose of this Patient Group Direction is to help patients by ensuring that they have ready access to a quality assured service which provides a timely, consistent and appropriate treatment.

Signatures of those developing the Patient Group Direction

Job Title	Name	Signature	Date
Doctor	David Herron		24/2/25
Pharmacist	Hollie Houghton Euan Proud		26/2/25 2/4/25
Nurse			
Microbiologist (if appropriate)	Robbie Weir		24/2/25
Paediatrician (if appropriate)			

Approval from Patient Group Directions Group

	Chair	Signed on behalf of group	Date
Patient Group Directions Group	Laura Byrne		1/5/25

Lead Author responsible for updating change history:

Change history

Version	Date	Summary of changes
1	20/8/24	Version 1

The following Patient Group Direction for Supply of co-amoxiclav by Community Pharmacists for the Management of skin infections associated with injection site complications. Patients may be used from the following business/practice:

Name:

Address:

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

CLINICAL CONDITION

Indication	Patients presenting in community pharmacy 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 • 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 GP Practice or OOH service) • Known hypersensitivity to beta-lactam antibiotics (penicillins or cephalosporins) or to any of the excipients within the capsules. • Face or peri-orbital swelling • History of jaundice/hepatic impairment due to amoxicillin/clavulanic acid • 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 • Immunocompromised patients • No valid consent to treatment
Caution/ Need for further advice	• Please see appendix 1 for further considerations • 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 • Convulsions may occur in patients with impaired renal function or in 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.
Action if Patient declines or is excluded	Refer patient to GP / OOH for review.

DRUG DETAILS

Name, form & strength of medicine	• Co-amoxiclav tablets 625mg (500/125mg) **Or for those unable to swallow tablets** • 10ml Co-Amoxiclav 250/62.5mg suspension. Reconstitute according to manufacturer's instructions
Legal Status	POM
Route/ Method	Oral
Dosage	ONE tablet or 10mls
Frequency	THREE times daily (8 hourly)
Duration of treatment	7 days
Maximum or minimum treatment period	7 days
Quantity to Supply/ administer	7 day course • 21 tablets or • 3 x 100ml bottles of suspension 250/62.5 in 5ml
Side Effects	**Common Side Effects :** • Nausea • Vomiting • Diarrhoea • Thrush • Rash **Uncommon Side Effects :** • Headache/Dizziness • Indigestion • Skin Disorders • Anaphylaxis For a full list of side effects – refer to the marketing authorisation holder's Summary of Product Characteristics (SPC). A copy of the SPC must be available to the health professional administering medication under this Patient Group Direction. This can be accessed on www.medicines.org.uk

	Patients should be informed who to contact should they experience an adverse drug reaction All adverse reactions that are serious or result in harm should be reported to the MHRA through the Yellow Card Scheme https://yellowcard.mhra.gov.uk
Advice to patient/carer	Ensure patient is aware that if symptoms worsen or the patient becomes systemically unwell they should seek medical advice that day. If symptoms have not improved after 7 days treatment, then patients should be advised to seek further medical advice. Inform patient of possible side effects and their management and who to contact should they be troublesome. Advise patient of the importance of taking co-amoxiclav regularly and completing the course. The Manufacturer Patient Information Leaflet should be given. Patients should be informed who to contact should they experience an adverse drug reaction.
Follow up	Advise patient to seek medical advice should symptoms worsen or not improve

STAFF CHARACTERISTICS

Qualifications	Pharmacist currently on the practising section of pharmaceutical register held by the General Pharmaceutical Council.
Specialist competencies or Qualifications	Pharmacists must have the necessary competencies and training to use the PGD and be authorised to use the PGD by their Lead Pharmacist. Under PGD legislation there can be no delegation. Administration of co-amoxiclav has to be by the same practitioner who has assessed the patient under the PGD. Adhere to the GPhC Standards for Pharmacy Professionals May 2017 and subsequent updates.
Continuing Training & Education	Professional must: • Have up to date knowledge of 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. • Have undertaken appropriate training to carry out clinical assessment of patient leading to treatment according to the

	indications listed in this PGD • Be able to assess the person's capacity to understand the nature and purpose of the medication in order to give or refuse consent

REFERRAL ARRANGEMENTS & AUDIT TRAIL

Referral arrangements	Ensure patient is aware that if symptoms worsen or becomes systemically unwell then they should seek medical advice that day either from their GP or through OOH centre. If symptoms have not improved after 7 days treatment, then patients should be advised to seek further medical advice.
Records/audit trail	A record of supply should be made on PMR which includes Name, strength, form and pack size of medicine supplied Dose and route of administration Date of supply and name of person making supply The medicine must be labelled in accordance with requirements detailed in the current version of Medicines, Ethics and Practice. The patient's GP must be notified that a supply has taken place. The patient's GP must be informed if the patient experiences an adverse drug reaction. A computer or manual record of all individuals receiving a supply under this PGD should also be kept for audit purposes. Record "supplied via Patient Group Direction (PGD)" Any adverse events/incidents should be reported to the PGD group in addition to any existing pharmacy processes Records of supply should be kept for 8 years. List of any other records to be kept.
Reference sources and comments	BNF / BNFc latest edition available at www.medicinescomplete.com Summary of Product Characteristics Co-amoxiclav available at www.medicines.org.uk Best Use of Medicines in Pregnancy (Bumps) Co-amoxiclav

PATIENT GROUP DIRECTION AUTHORISATION DOCUMENT

Supply of co-amoxiclav to patients over 18 years of age by Community Pharmacists for the management of skin infections associated with injection site complications working in Forth Valley Community Pharmacies

Protocol Number 663 Version1

Individual Authorisation

This PGD does not remove inherent professional obligations or accountability

I_____ (please print in capitals), 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 the supply of the medicine will take place and agree to provide this medicine only in accordance with this PGD.

I understand that it is the responsibility of the pharmacist to act in accordance with the Code of Ethics for Pharmacists and to keep an up to date record of training and competency. I understand it is also my responsibility to ensure that all consultations with patients occur within a private and confidential area of the pharmacy.

I have read and fully understand the Patient Group Direction for the supply of co-amoxiclav and agree to provide this medicine only in accordance with this PGD in NHS Forth Valley Community Pharmacies.

Name of Pharmacist (in block capitals)_____

GPhC Number _____ Employee ☐ Locum ☐ Relief Pharmacist ☐

If you are a locum please provide a contact email address: _____

Normal NHS Forth Valley Pharmacy Location
(Please state contractor code)

_____

Signature _____

Date _____

Note :
A copy of this agreement must be signed by each pharmacy practitioner who wishes to be authorised to use the PGD for Supply of co-amoxiclav by Community Pharmacists working in Forth Valley Pharmacies.

Please return this page either by mail to Community Pharmacy Development Team, NHS Forth Valley Royal Hospital, Stirling Road, Larbert, FK5 4WR **OR** by email to FV-UHB.communitypharmacysupport@nhs.net attaching a scanned / photographed image. A copy should be retained in each pharmacy premises you provide the service in.

PATIENT GROUP DIRECTION AUTHORISATION DOCUMENT

Patient Group Direction for Supply of co amoxiclav to patients over 18 years by Community Pharmacists to Patients with skin infections associated with injection site complications Protocol Number 663 Version 1

Name of Premises & Contractor Code_____

Address of Premises_____

PROFESSIONAL AGREEMENT

I have read and confirm that I have understood the above named patient group direction. **The people below have been authorised to use this protocol.** I confirm that it is my professional responsibility to ensure all those signed below have had their professional registration confirmed as per normal company processes and have signed the necessary PGD paperwork* to enable them to work within the confines of this PGD.
*The professional signing the PGD paperwork accepts personal responsibility for having undertaken all the mandatory training requirements for the PGD.

Signature of **Lead Pharmacist** for the contractor code

Name (in block capitals)	Signature	Date

Name of Professional (IN BLOCK CAPITALS)	Registration Number	Signature	Date

Appendix 1

Cellulitis and Skin infections (aged>18years)