Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

This Patient Group Direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used. Health professionals should always access the PGD via the PTHB internet to ensure that they are always working to the most up to date version

Patient Group Direction

for the administration and supply of

Co-amoxiclav oral preparations

by registered nurses

following an animal or human bite to

Adults and Children aged 2 years and over

in Powys Teaching Health Board Minor Injury Units

Version number: PGD0028E

Reference Number: PGD0028E
Valid from: 12/06/2024
Review date: 12/06/2026
Expiry date: 11/06/2027

Change history

Version number	Change details	Date
PGD0028	Initial issue	09/03/2006
PGD0028_A	Review issue	01/12/2010
PGD0028_B	Review issue- inclusion of 625mg tablet, change to interaction information with combined oral contraceptives	26/04/2013
PGD0028_C	Review issue- in line with NICE guidance July 2015 (Bites-human and animal)	03/05/2018
PGD0028_D	Review issue, new PTHB template, NICE guidelines update and SPC update	09/09/2021
PGD 0028 E	Review in line with current reference sources. Minor changes to format to promote consistency with other PTHB PGDs Removal of table containing reconstitution volumes for different brands of suspensions Adult dose standardised in line with AWMSG Primary Care antimicrobial guidelines and microbiologist advice. PGD amended to adults and children over 2 years	12/06/2024

PGD authorisation

Name	Job title and organisation	Signature	Date
Senior doctor **Dr Kate Wright**	Lead doctor for PTHB	DocuSigned by: Kate Wright 1F267952823F473...	6/18/2024
Chief Pharmacist **Jacqui Seaton**	Chief Pharmacist for PTHB	DocuSigned by: Jacqui Seaton 71E8089DE3634C4...	6/11/2024
Senior representative of professional group using the PGD **Claire Roche**	Executive Director of Nursing and Midwifery for PTHB	DocuSigned by: Claire Roche F07413E114E04B1...	6/11/2024
Clinical Governance Lead **Amanda Edwards**	Clinical Governance Lead for PTHB – Assistant Director for Innovation and Improvement	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	7/9/2024

Appendix A provides a staff accreditation sheet. Individual practitioners must be authorised by name to work to this PGD.

Those using this PGD must ensure that it is organisationally authorised and signed by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **The PGD is not legal or valid without signed authorisation in accordance with** HMR2012 Schedule 16 Part 2**.**

The final authorised copy of this PGD should be kept by PTHB for 25 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for 25 years after the PGD expires.

[1] This includes any relevant amendments to legislation.

Training and competency of registered health professionals

	Requirements of registered health professionals working under the PGD
Qualifications and professional registration	Practitioners must only work under this PGD where they are competent to do so. Practitioners must also be a registered professional with the following body: • Nurses currently registered with the Nursing and Midwifery Council (NMC) and working in a Minor Injury Unit in PTHB The NMC registered nurse should have a current contract of employment with PTHB. Practitioners must also fulfil the additional requirements listed below. Check Appendix A – Staff Accredited to use this Patient Group Direction to confirm whether all the registered practitioners listed above have organisational authorisation to work under this PGD.
Initial training	• The administration and supply of co-amoxiclav tablets and suspension and knowledge of its uses, contraindications and adverse effects Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for administration and supply of medicines. Recommended training eLfH PGD eLearning programme. PTHB staff to access via ESR. • must be competent in the use of PGDs (see NICE Competency framework for health professionals using patient group directions) • must have completed locally required training (including updates) in safeguarding children and vulnerable adults or a minimum of level 2 safeguarding or the equivalent. • must be familiar with the product and alert to changes in the BNF and Summary of Product Characteristics • must have undertaken training appropriate to this PGD as required by local policy

	• must have an understanding of NICE CKS- Bites- human and animal • must be able to safely and accurately reconstitute the powder – refer to section below: Instruction for reconstitution • must have received training and be competent in the recognition, management of, and reporting of recognised adverse reactions, including anaphylaxis. • must be competent in the administration of adrenaline and have up to date Intermediate Life Support (ILS) skills. • must have access to the Patient Group Direction and associated online resources **THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.**
Competency assessment	• Evidence of ongoing PGD training to be submitted to Line Manager annually– this should include an annual completion certificate of PGD e-learning or a dated screenshot of the PGD e-learning assessment results as proof of completion. • Practitioners must be competent, recognise their own limitations and personal accountability and act accordingly • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions • Individuals operating under this PGD must be assessed as competent (see Appendix A) and complete a self-declaration of competency in their Personal Appraisal and Development Review (PADR). The **personal development plan** (yellow) section of the PADR booklet should be used to record completion of Statutory and Mandatory training, including annual PGD e-learning. • Evidence of training in ILS, anaphylaxis and safeguarding.

Ongoing training and competency	• Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training provided as required. • Updating at least every 2 years, or earlier in response to new local/national guidance, on the use of PGDs and co-amoxiclav and the treatment of human and animal bites. • Practitioners must ensure they are up to date with relevant issues and clinical skills and management of anaphylaxis, ILS, with evidence of appropriate Continued Professional Development (CPD). • Evidence of appropriate Continued Professional Development (CPD) must be retained and made available on request. • Compliance with all mandatory NHS training including safeguarding at the level relevant to the role. • Evidence of ongoing / refresher training to be submitted to line manager annually.
	It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD. The decision to administer or supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.

Clinical condition

Clinical condition or situation to which this PGD applies	Prevention and treatment of infection in patients aged from 2 years presenting with an animal (cat, dog or other traditional pet bite) or human bite in accordance with NICE guidance – see Appendix B. Co-amoxiclav is the first-choice oral antibiotic for all people with a human or animal bite (cat, dog or other traditional pet bite) as it has good activity against the relevant range of likely pathogens. **Notes:** • For all bites assess the risk of tetanus, rabies or a bloodborne viral infection and take appropriate action, following MIU guidelines. • If there is discharge (purulent or non-purulent), before cleaning, send a pus or a deep wound swab for

	culture, state on the form that the swab is from an infected human/animal bite as appropriate. • Topical cleaning, thorough irrigation and debridement should be completed as necessary- follow MIU Guidelines.
Inclusion criteria	• Adults and Children aged from 2 years old with: • **An infected human or animal bite** (traditional pet including cats and dogs) if there are symptoms or signs of infection, such as increased pain, inflammation, fever, discharge or an unpleasant smell • **An uninfected human bite**: o that has broken the skin and drawn blood o that has broken the skin but not drawn blood in a person at risk of a serious wound infection because of a co-morbidity such as diabetes, immunosuppression, asplenia or decompensated liver disease o that has broken the skin but not drawn blood if it is in a high-risk area (includes the hands, feet, face, genitals, skin overlying cartilaginous structures or an area of poor circulation) • **An uninfected cat bite**: o that has broken the skin and drawn blood o that has broken the skin but not drawn blood if the wound could be deep • **An uninfected dog bite or other uninfected traditional pet bite (excluding cat)**: o that has broken skin and drawn blood and ▪ has penetrated bone, joint, tendon or vascular structures or ▪ is deep, is a puncture or crush wound, or has caused significant tissue damage or ▪ is visibly contaminated (for example, if there is dirt or a tooth in the wound) or

	▪ is a bite in a high-risk area (e.g. hand, feet, face, genitals, skin overlying cartilaginous structures or near prosthetic joints, or an area of poor circulation) or the patient is considered at high risk of a serious wound infection or systemic infection because of a co-morbidity such as diabetes mellitus, asplenia, immunosuppression, decompensated liver disease, or they have a prosthetic heart valve, or if they are at extremes of age **NB**. If there is a discharge (purulent or non-purulent) from the area of bite, take a swab for microbiological testing. Co-amoxiclav may be administered/supplied via this PGD if appropriate based on inclusion/exclusion criteria however the patient must be informed that treatment may change once the results are received, refer for medical advice. • Medical and drug history taken, no reason for exclusion. **Refer to exclusion criteria for wounds that must be referred to hospital.** In case of any doubt, contact medical team or emergency services. • Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained prior to administration/supply and recorded appropriately. Refer to PTHB Consent to Treatment and Examination Policy. Any vulnerable adult or child protection concerns should be referred to Safeguarding and the PTHB safeguarding policies followed. Consider discussing with GP. **It is the responsibility of the administering/ supplying healthcare professional to ensure that the patient is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the treatment. If there is any reason for concern, seek medical advice.**

Exclusion criteria (Exclusion under this Patient Group Direction does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required)	• Conditions outside of the clinical situations criteria • No valid consent, patient/representative refuses treatment, or a 'best-interests' decision, in accordance with the Mental Capacity Act 2005, has not been obtained or received. Refer to sections "Action to be taken if patient is excluded or "Action to be taken if patient declines treatment". • Children aged under 2 years- refer to a prescriber. • Known hypersensitivity to the active substances, to any of the penicillins or other beta-lactam antibiotics such as cephalosporins or to any of the excipients in the medicinal product(s)- see relevant SPC. • Renal impairment where eGFR or creatinine clearance is 30ml/min or less (convulsions may occur in patients with impaired renal function). • History of penicillin/clavulanic acid associated jaundice or hepatic dysfunction. • Patient who has developed symptoms or signs of infection after taking prophylactic antibiotics- refer to a prescriber • Patients who cannot swallow or take oral antibiotics- refer to a prescriber. • Bites from a wild or exotic animal (including birds and non-traditional pets) unfamiliar domestic or farm animal because the spectrum of bacteria involved may be different and there may be a risk of other serious non-bacterial infections- seek advice from a microbiologist. • Bites from bats- Urgent treatment required. All patients should be referred to A&E and Public Health Wales Health protection team or the duty virologist (University Hospital of Wales) contacted. Please see PHE guidance (for advice on Rabies) and refer to patients to PHE PIL • Bites with signs suggesting a more serious illness or condition (such as severe cellulitis, abscess, lymphangitis, osteomyelitis, septic arthritis, necrotising fasciitis or sepsis), bites to the eye or orbit, or severe bite injuries with heavy bleeding causing haemodynamic instability, or a penetrating wound involving arteries, joints, nerves, muscles, tendons, bones or the central nervous system. **NB these patients must be referred to hospital**. • A systemically unwell patient or patient is at risk of a serious wound infection because of a pre-existing medical condition- **refer to hospital**.

	• Infected bite that is not responding to oral antibiotics within 24 hours to 48 hours of starting treatment- refer to a prescriber • Patients receiving methotrexate. Penicillins may reduce the excretion of methotrexate and may cause toxicity. • For those patients who require INR monitoring due to their anticoagulant, the practitioner must check that the patients latest International Normalised Ratio (INR) is up to date and within the target range as stated in the patient's yellow anti-coagulant record book. A patient with an out of date INR, or whose most recent INR is out of range or unknown is excluded from this PGD and must be referred to a prescriber. • Patients with acute or chronic lymphocytic leukaemia, cytomegalovirus infection or glandular fever due to increased risk of erythematous rashes- refer to prescriber • Patients who are pregnant or breastfeeding- refer to a prescriber for a suitable alternative. • Patients who were bitten in a fight – refer to DGH for exploration/irrigation/IV antibiotics • Patients with known hepatic dysfunction (monitoring of hepatic function may be required)- refer to prescriber. • Patients taking allopurinol – increased risk of allergic skin reaction such as rashes • Patients taking probenecid – excretion of penicillin is reduced causing increased plasma concentration. • Refer to a prescriber if the patient is receiving mycophenolate mofetil (for advice on close clinical monitoring – see Drug Interactions).
Cautions /reasons for seeking further advice from a prescriber	• Children with phenylketonuria should be discussed with a prescriber, as co-amoxiclav suspension may contain aspartame, a source of phenylalanine (refer to SPC). • Refer to a prescriber if a child has a rare glucose-galactose malabsorption or hereditary problems of fructose intolerance as suspension may not be suitable (refer to SPC). • Consider referral or seeking specialist advice if the bite is in an area of poor circulation • Check for any other medications that the patient is taking, including topical or inhaled products, food supplements and herbal or homeopathic products.

	• For those patients who require INR monitoring due to their anticoagulant, the practitioner must check the patients latest International Normalised Ratio (INR)– see Drug Interaction section. If the latest INR is up to date and within the target range (as stated in their yellow anti-coagulant record book) then the patient may be supplied with co-amoxiclav **but must** be advised to contact their usual anti-coagulant clinic to inform them that they have been prescribed a course of antibiotics. • Discuss with appropriate medical/ independent non-medical prescriber if the individual has multiple allergies, or any medical condition or medication of which the healthcare professional is unsure or uncertain. • Patients with facial dog bites should be referred to MaxFax at DGH • May interfere with some diagnostic tests – see SPC for further details • See NICE CKS for patients that should be referred to secondary care (urgency depending on clinical judgement) Refer to BNF/SPC for full list of cautions. Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and PTHB safeguarding policies followed. Consider discussing with GP. Any safeguarding concerns need to be directed to Safeguarding Hub: • To generic email address: PowysTHB.Safeguarding@wales.nhs.uk And • Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847 Advice can also be sought from local Safeguarding leads

Action to be taken if patient excluded	• If there is a penicillin allergy, or co-amoxiclav is unsuitable, the alternative first-choice oral antibiotics for
	  ○ adults and young people aged 12 years and over are doxycycline (PGD0029) with metronidazole (PGD0031)
	  ○ children under 12 years is co-trimoxazole (PGD0180)
	due to good activity against the range of likely pathogens.
	• Record reason and seek medical advice.
	• Explain reason to patient / carer.
	• If appropriate refer to GP / DGH / out of hours service, offer alternative management if appropriate.
	• Bites from bats- Urgent treatment required. All patients should be referred to A&E and Public Health Wales Health protection team or the duty virologist (University Hospital of Wales) contacted. Please see PHE guidance (for advice on Rabies) and refer to patients to PHE PIL

Action to be taken if patient declines treatment	Explain consequences of refusing treatment. Make patient or their representative aware of alternative sources of treatment (DGH or GP as appropriate). Offer alternative management if appropriate. Document refusal and any advice given. Complete a Discharge Against Advice Form if appropriate. Inform or refer to GP/follow local procedures as appropriate. Where appropriate, complete the letter on the WPAS system and send to the GP.
Arrangements for referral for medical advice	Contact GP or microbiologist for advice or refer to DGH if applicable. Document advice given.
Details of the medicine	
Name, form and strength of medicine	Co-amoxiclav • 500mg/125mg tablets or • powder for oral suspension 125/31.25mg in 5ml (or 125/31 mg in 5ml) or • powder for oral suspension 250/62.5mg in 5ml (or 250/62 mg in 5ml) **Note** that the proportion of amoxicillin and clavulanic acid vary between the suspension and tablet formulations so they are not interchangeable: • Suspensions must not be issued to adults and children aged 12 years and over Tablets must not be issued to children under 12

Legal category	POM
Indicate any off-label use	Medicines should be stored according to the conditions detailed in the Storage section in this document. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where drugs have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with pharmacy/Medicines Management. Where a product is recommended off-label consider, as part of the consent process, informing the individual or their carer that the product is being offered in accordance with national guidance, but this is outside the product license.
Route/method of administration	Oral
Instructions for reconstitution for suspension preparations	**NB** Suspension must not be reconstituted by any nurse who has a history of severe penicillin allergy/anaphylaxis. For suspension preparations follow the reconstitution instructions on the packaging. Follow directions for shaking the bottle and adding the correct volume of potable water recommended on the bottle by the manufacturer. - NB. The volume may vary between different brands. Ensure that the bottle cap or seal is intact before using- do not use if not intact. The cap ring-seal is broken once the cap is opened. Alternatively, if a foil-backed seal on the mouth of the bottle is present, this should be removed at the time of preparation. Only use the reconstituted suspension if the colour is white to off-white. Ensure that either the expiry date or the date of reconstitution is marked clearly on the label.

<table>
<tr><td rowspan="3">Dose and frequency</td><td>Children aged 2 -5 years</td><td>Children aged 6 – 11 years</td><td>Adults and children aged over 12</td></tr>
<tr><td>1 x 5mL spoonful (or 5ml as indicated on the oral syringe) of co-amoxiclav 125/31.25 (or 125/31) suspension</td><td>1 x 5mL spoonful (or 5ml as indicated on the oral syringe) of co-amoxiclav 250/62.5 (or 250/62) suspension</td><td>One tablet of 500/125mg</td></tr>
<tr><td colspan="3">Three times a day, ideally at eight-hour intervals. There must be at least 4 hours between doses.

To reduce gastro-intestinal side effects from the tablets, patient may be advised to take at the start of a meal.</td></tr>
<tr><td>Quantity to be administered and/or supplied</td><td colspan="3">One pre-labelled pack of:
• 21 tablets (500/125mg)
or
• 100mL oral suspension with a 5mL medicine spoon and / or a 5mL oral syringe</td></tr>
<tr><td>Maximum or minimum treatment period</td><td colspan="3">• treatment of infected bite for 5 days in both adults and children
• prophylaxis of infection for 3 days in both adults and children</td></tr>
<tr><td>Storage</td><td colspan="3">Tablets:
• Store in the original package to protect from light/moisture.
• Do not store above 25°C.
• Tablets in desiccated pouch packs should be used within 30 days of opening.

Powder for oral suspension:
• Store the dry powder in the original container.
• Do not store above 25°C.
• Keep the container tightly closed in order to protect from moisture

Reconstituted suspension:
• Reconstituted suspensions should be stored at 2°C - 8°C (but not frozen) for up to 7 days. Keep the container tightly closed</td></tr>
</table>

Drug interactions	All concomitant medications should be checked for interactions. • Anti-coagulants such as warfarin, acenocoumarol (nicoumalone) or phenindione: co-amoxiclav may affect the INR. The prothrombin time or international normalised ratio (INR) should be monitored more closely with the addition or withdrawal of a penicillin. Adjustment of the anticoagulant dose may be necessary- see cautions and exclusions • Allopurinol – increased risk of allergic skin reaction such as rashes- see exclusion criteria • Probenecid – excretion of amoxicillin is reduced causing increased plasma concentration- see exclusion criteria • Methotrexate – increased risk of methotrexate toxicity- see exclusion criteria • Mycophenolate mofetil - reduction in pre-dose concentration of the active metabolite mycophenolic acid; close clinical monitoring should be performed during the combination and shortly after antibiotic treatment – seek advice from a prescriber - see exclusion criteria. **NB.** This list is not exhaustive. A detailed list of drug interactions is available in the BNF https://bnf.nice.org.uk and SPC http://www.medicines.org.uk Refer to a prescriber if any concern of a clinically significant drug interaction and document advice given.
Identification, management and reporting of adverse effects	A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF https://bnf.nice.org.uk. The following side effects are listed in the product SPC or BNF as **common or very common** (but may not reflect all reported side effects)**:** • Thrush / Mucocutaneous candidosis / increased risk of infection • Diarrhoea • Hypersensitivity • Nausea – this may be reduced by taking the medication with a meal • Skin reactions • Vomiting • Thrombocytopenia

	Severe adverse reactions are rare, but anaphylaxis (delayed or immediate) has been reported and requires immediate medical treatment. In the event of a severe adverse reaction, the individual must be advised to stop treatment immediately and seek urgent medical advice. NB. The most important side effect of penicillins is hypersensitivity which causes rashes and anaphylaxis and can be fatal. Hypersensitivity reactions can also progress to Kounis syndrome, a serious allergic reaction that can result in myocardial infarction. Drug-induced enterocolitis syndrome (DIES) has been reported mainly in children receiving amoxicillin/clavulanic acid. DIES is an allergic reaction with the leading symptom of protracted vomiting (1-4 hours after drug administration) in the absence of allergic skin or respiratory symptoms. Further symptoms could comprise abdominal pain, diarrhoea, hypotension or leucocytosis with neutrophilia. There have been severe cases including progression to shock. If an allergic reaction occurs, amoxicillin/clavulanic acid therapy must be discontinued and appropriate alternative therapy instituted. In the case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use: Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a working telephone must be available. In case of anaphylaxis: • Refer to adrenaline PGD 0017 and anaphylaxis policy • Request medical assistance urgently. If the GP is not immediately available, dial 999 to transfer to A&E • Ensure reaction is fully documented in patient notes • Ensure all patient records are marked allergic to Co-amoxiclav (amoxicillin/clavulanic acid) • The patient may be advised to wear a Medic Alert or similar device to alert other healthcare providers Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. For established medicines, serious adverse events in adults or all suspected

	adverse reactions in children that may be attributable to the medication should be reported. Guidance on the yellow card system is available at the back of the BNF, or using the above link. Record all adverse drug reactions (ADRs) in the patient's medical record and the individual's GP should be informed. All significant adverse drug reactions should be reported via the Once for Wales Reporting System.
Records to be kept	Record consultation details as required by local procedures. In addition, record: • That valid informed patient consent to treatment was obtained. Record name of representative who gave consent if appropriate. • If the patient has refused treatment, and any advice given in this circumstance. • Name of individual, address, date of birth • GP contact details where appropriate • Relevant past and present medical and drug history taken, including any allergies and previous adverse events • Any reasons for exclusion or referral, including actions taken, referral arrangements made and advice given. • Any advice received from medical cover and advice given to patient / carer. • Examination or microbiology finding/s where relevant. • Printed name and signature of registered health professional responsible for administration/ supply For administration, record: • Date and time of administration • Name, form, strength and dose of drug administered • Route of administration • Expiry date(s) • Details of any adverse reactions and actions taken For supply, record: • Date and time of supply • Name, form, strength, route, dose, frequency and quantity of medication supplied • Expiry date of medicine supplied • Advice given about the medication including side effects, benefits, and when and what to do if any concerns

	Record that medication was administered/supplied via Patient Group Direction (PGD), record PGD version number. The record must include the printed name and signature (or a password controlled e-records) of the healthcare professional responsible for administration/supply. The record must be kept securely for a defined period in line with local policy. All records should be clear, legible and contemporaneous. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

Patient information

Written/verbal information to be given to patient or carer	Supply a single pre-labelled MIU pack of 21 tablets or 100mL oral suspension. As the full pre-labelled pack is supplied, advise that the remainder of the tablets/ suspension must be returned to a pharmacy or GP for safe disposal. Provide patient information leaflet. Draw the patients/carers attention to the label and patient information leaflet. Where applicable, inform the individual or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed in the product's SPC. Write the patients name and the date of supply onto the label. Advise: • Take regularly at the recommended intervals and complete the course, even if the wound looks better • Take the medicines at the start of a meal. This gives good absorption and decreases the risk of gastric side effects • Indications, contra-indications and cautions • Appropriate storage conditions for the medicine supplied • About appropriate oral pain relief • Regarding possible adverse effects and to seek medical advice if side effects or overdose occur

	• Patient to discontinue medication and seek urgent medical attention (go to hospital urgently/call 999) if there are signs of an allergic reaction: o collapse o swelling of face, lips, throat, or difficulty breathing o skin rash, blistering, peeling skin, red or purple raised spots. o fever, joint pain, swollen glands in the neck, armpit or groin o chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction o signs of meningitis or flu-like symptoms. • Patient to stop taking the medication, and seek urgent medical attention (go to hospital urgently/call 999) if they experience the following: o Protracted vomiting (1-4 hours after drug intake) or further symptoms such as abdominal pain, lethargy, diarrhoea, low blood pressure- could indicate DIES which has been reported mainly in children receiving amoxicillin/clavulanic acid o Inflammation of the large intestine, causing watery diarrhoea usually with blood and mucus, stomach pain and/or fever as patient should be assessed for antibiotic associated colitis. Should antibiotic-associated colitis occur, amoxicillin/clavulanic acid should immediately be discontinued, a physician be consulted and an appropriate therapy initiated. NB. The patient may experience mild gastro-intestinal side-effects, especially diarrhoea during or subsequent to the administration of any antibiotic o Ongoing pain in the stomach area- could be a sign of acute pancreatitis o Black tongue which looks hairy o Jaundice, which may make the skin and whites of eyes appear yellow. Hepatic events (eg. Cholestatic jaundice) are reported more frequently in males and in the elderly; they have very rarely been reported in children. They usually occur during or shortly after treatment, but can occur several weeks after treatment has ended. They are usually reversible but may be severe, in extremely rare circumstances deaths have been reported. o Blood takes longer to clot o Hyperactivity or convulsions

	Suspension: • The suspension must be stored in a refrigerator and shaken well before each dose. • If an oral syringe has been supplied ensure that the carer is familiar with its use and draw their attention to the leaflet provided. • Advise that superficial tooth discolouration can occur very rarely, mostly with the suspension. This can usually be removed by brushing. **Tablets:** • If co-amoxiclav tablets are to be taken, they should be swallowed whole with a glass of water Additionally, if applicable: • Do not drive or operate machinery unless feeling well (consider any side effects of co-amoxiclav which may influence the ability to drive or operate machines) • Women taking oral hormonal contraception should be advised about the importance of correct contraceptive practice if they experience vomiting or diarrhoea (see the sections on vomiting or diarrhoea in the CKS topics on Contraception - combined hormonal methods and Contraception - progestogen-only methods.) • For patients taking **oral anti-coagulants** such as warfarin, acenocoumarol (nicoumalone) or phenindione, advise them to contact their usual anti-coagulant clinic to inform them that they have been prescribed a course of antibiotics. Patients should be advised to seek medical advice if they experience any bruising or bleeding All patients should be advised to seek medical review / contact their GP if: • There is no improvement in their condition within 24 to 48 hours of starting treatment • Symptoms or signs of infection develop or worsen rapidly or significantly at any time, or if the boundaries of the soft tissue infection continue to expand • The person becomes systemically unwell • There is severe pain that is out of proportion to the infection • If the condition has not completely cleared towards the end of the treatment course

Follow-up advice to be given to patient or carer	• Refer to MIU guidelines. • The patient should be advised to contact their GP if there is no improvement or if the presenting complaint/infection worsens or if they feel increasingly unwell. • If wound is infected, patient should be advised to contact their GP for review at 24 and 48 hours to ensure infection is responding to treatment. • Inform that a 5-day course is appropriate for treating infection following most human or animal bites, but course length can be increased to 7 days (with review) based on clinical assessment of the wound by a clinician. • If a swab has been taken, the patient/carer will be contacted once the results are received. The GP/prescriber will also be contacted to review the choice of antibiotic based on the swab results. • If co-amoxiclav is given for prophylaxis, advise patient/carer to check for signs of infection- if these develop advise patient to attend urgently for review. • Advise to seek medical advice immediately if they have any unexpected reaction or other cause for concern. Contact GP via surgery or emergency on call service.

Key references

- British National Formulary (BNF) and British National Formulary for Children (BNFC) - accessed 18 March 2024
- Electronic Medicines Compendium http://www.medicines.org.uk/ accessed 12/03/2024
- NICE guideline [NG184] - Human and animal bites: antimicrobial prescribing, published: 04 November 2020
- NICE CKS Prescribing information: Co-amoxiclav | Prescribing information | Bites - human and animal | CKS | NICE – accessed 05/03/2024

Appendix A Staff accredited to use this Patient Group Direction

Authorising Manager: I confirm that the practitioners named below have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Powys Teaching Health Board for the named healthcare professionals below who have signed the PGD to work under it.
The authorising manager must use the competency checklist (below).

Practitioner: By signing this PGD you are indicating that you agree to its contents and that you will work within it. PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.

Printed name of registered health professional	Signature of registered health professional	Printed name of senior representative authorising health professional	Signature of senior representative authorising health professional	Date

The authorising manager should retain a copy of the list, which will be requested for audit purposes. This list should be kept by PTHB for 25 years after the PGD expires.
The healthcare professional should retain a copy of the document after signing.

Competency check list for manager or senior team lead to use as part of the authorising process for health professionals to work to a Patient Group Direction (PGD). Review of authorisation will take place on each PGD update and at the individual's annual PADR.

Name: **Role:**		Sign / Initial	Further training identified (Y/N) Specify in "comments"	Comments
1	The PGD sign off is for the following PGD:(document the exact title and PGD number) _____			
2	We have discussed the expiry of the PGD and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the PGD			
4	The Patient Group Direction has been read in full by the staff member			
5	The identified training has been completed as specified in the PGD and is in date			
6	We have discussed some examples of inclusion criteria and exclusion criteria			
7	The staff member is confident in the administration method and doses			

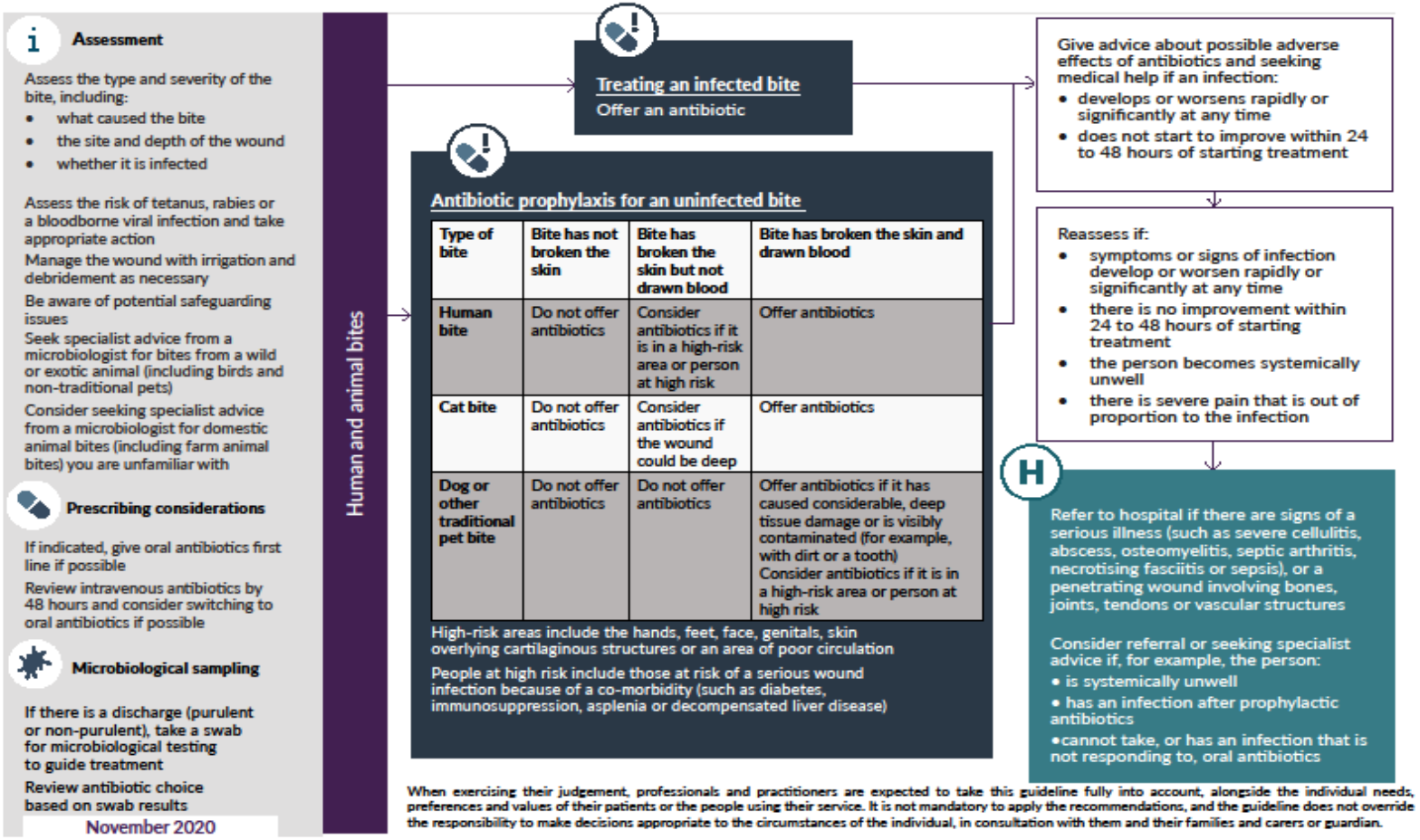
Staff member print & sign name		Date
Manager or senior team lead to print & sign name		Date

Please send a copy of this completed form to individual's line manager and to the staff member, in conjunction with the PGD Appendix A authorisation sheet. A copy of this form should also be kept by service lead in the training file.

Appendix B

Human and animal bites: antimicrobial prescribing

NICE National Institute for Health and Care Excellence



Reference Number: PGD0028E
Valid from: 12/06/2024
Review date: 12/06/2026
Expiry date: 11/06/2027

Human and animal bites: antimicrobial prescribing

Choice of antibiotic for prophylaxis and treatment: adults aged 18 years and over

NICE National Institute for Health and Care Excellence

Prophylaxis and treatment	Antibiotic, dosage and course length for prophylaxis (3 days) and treatment (5 days)
First-choice oral antibiotic	**Co-amoxiclav**: 250/125 mg or 500/125 mg three times a day
Alternative first-choice oral antibiotics for penicillin allergy or if co-amoxiclav is unsuitable	**Doxycycline**: 200 mg on first day, then 100 mg or 200 mg daily With **Metronidazole**: 400 mg three times a day
Alternative first-choice oral antibiotics in pregnancy for penicillin allergy or if co-amoxiclav is unsuitable	Seek specialist advice
First-choice intravenous antibiotic (if unable to take oral antibiotics or severely unwell)	**Co-amoxiclav**: 1.2 g three times a day
Alternative first-choice intravenous antibiotics for penicillin allergy or if co-amoxiclav is unsuitable If a cephalosporin is not appropriate, seek specialist advice	**Cefuroxime** (caution in penicillin allergy): 750 mg three times a day (increased to 750 mg four times a day or 1.5 g three or four times a day if infection is severe) With **Metronidazole**: 500 mg three times a day **Ceftriaxone** (caution in penicillin allergy) 2 g once a day With **Metronidazole**: 500 mg three times a day

See the BNF and summary of product characteristics for appropriate use and dosing in specific populations, for example, for hepatic or renal impairment, in pregnancy, when breastfeeding and when administering intravenous (or, if appropriate, intramuscular) antibiotics.

A 5-day course is appropriate for treating most human or animal bites, but course length can be increased to 7 days (with review) based on clinical assessment of the wound, for example, if there is significant tissue destruction or it has penetrated bone, joint, tendon or vascular structures.

Reference Numbe[illegible]
Valid from: 12/06/2024
Review date: 12/06/2026
Expiry date: 11/06/2027

Human and animal bites: antimicrobial prescribing

NICE National Institute for Health and Care Excellence

Choice of antibiotic for prophylaxis and treatment: children and young people under 18 years

Prophylaxis and treatment	Antibiotic, dosage and course length for prophylaxis (3 days) and treatment (5 days)
Choice for children under 1 month	Seek specialist advice
First-choice oral antibiotic for children aged 1 month and over	**Co-amoxiclav**: 1 month to 11 months: 0.25 ml/kg of 125/31 suspension three times a day 1 year to 5 years: 0.25 ml/kg or 5 ml of 125/31 suspension three times a day 6 years to 11 years: 0.15 ml/kg or 5 ml of 250/62 suspension three times a day 12 years to 17 years: 250/125 mg or 500/125 mg three times a day Co-amoxiclav 400/57 suspension may also be considered to allow for twice-daily dosing
Alternative first-choice oral antibiotic for children under 12 years for penicillin allergy or if co-amoxiclav is unsuitable	**Co-trimoxazole** (off-label use; see the BNF for Children for information on monitoring): 6 weeks to 5 months: 120 mg or 24 mg/kg twice a day 6 months to 5 years, 240 mg or 24 mg/kg twice a day 6 years to 11 years, 480 mg or 24 mg/kg twice a day For off-label use, follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's good practice in prescribing and managing medicines and devices for information.
Alternative first-choice oral antibiotics for young people aged 12 to 17 years for penicillin allergy or if co-amoxiclav is unsuitable	**Doxycycline**: 200 mg on first day, then 100 mg or 200 mg daily **With metronidazole**: 400 mg three times a day
Alternative first-choice oral antibiotics in pregnancy for penicillin allergy or if co-amoxiclav unsuitable	Seek specialist advice
First-choice intravenous antibiotic (if unable to take oral antibiotics or severely ill)	**Co-amoxiclav**: 1 month to 2 months: 30 mg/kg twice a day 3 months to 17 years: 30 mg/kg three times a day (maximum per dose 1.2g)
Alternative first-choice intravenous antibiotics for penicillin allergy or if co-amoxiclav is unsuitable If a cephalosporin is not appropriate, seek specialist advice	**Cefuroxime** (caution in penicillin allergy): 1 month to 17 years: 20 mg/kg three times a day (maximum 750 mg per dose), which can be increased to 50 mg/kg to 60 mg/kg three or four times a day (maximum per dose 1.5 g) **With metronidazole**: 1 month: loading dose 15 mg/kg, then (after 8 hours) 7.5 mg/kg three times a day 2 months to 17 years: 7.5 mg/kg three times a day (maximum per dose 500 mg) **Ceftriaxone** (caution in penicillin allergy): 1 month to 11 years (up to 50 kg): 50 mg/kg to 80 mg/kg once a day (maximum 4 g per day) 9 years to 11 years (50 kg and above) and 12 years to 17 years: 1 g to 2 g once a day **With metronidazole**: 1 month: loading dose 15 mg/kg, then (after 8 hours) 7.5 mg/kg three times a day 2 months to 17 years: 7.5 mg/kg three times a day (maximum per dose 500 mg)

See the BNF for Children and summary of product characteristics for appropriate use and dosing in specific populations, for example, for hepatic or renal impairment, in pregnancy, when breastfeeding and when administering intravenous (or, if appropriate, intramuscular) antibiotics.

A 5-day course is appropriate for treating most human or animal bites, but course length can be increased to 7 days (with review) based on clinical assessment of the wound, for example, if there is significant tissue destruction or it has penetrated bone, joint, tendon or vascular structures