



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

This Patient Group Direction (PGD) must only be used by registered healthcare 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. Healthcare 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/or supply of

Co-trimoxazole 40 mg/200 mg per 5 ml oral paediatric suspension

by registered nurses

following an animal or human bite to

Children aged between 2 years and 12 years

in Powys Teaching Health Board Minor Injury Units

Version number: PGD 0180A

Change history

Version number	Change details	Date
PGD 0180	Initial issue	25/10/2021
PGD 0180A	Review in line with current reference sources. Minor changes to format to promote consistency with other PTHB PGDs PGD amended to children over 2 years Dosage section amended to incorporate microbiology advice	07/10/2024

PGD authorisation

Name	Job title and organisation	Signature	Date
Senior doctor Dr Kate Wright	Lead doctor for PTHB	DocuSigned by: <i>Kate Wright</i> 1F267952823F473...	9/19/2024
Chief Pharmacist Jacqui Seaton	Chief Pharmacist for PTHB	Signed by: <i>Jacqui Seaton</i> 71E8089DE3634C4...	9/19/2024
Senior representative of professional group using the PGD Claire Roche	Executive Director of Nursing and Midwifery for PTHB	DocuSigned by: <i>Claire Roche</i> F07413E114E04B1...	9/19/2024
Clinical Governance Lead Amanda Edwards	Clinical Governance Lead for PTHB – Assistant Director for Innovation and Improvement	DocuSigned by: <i>Amanda Edwards</i> 74A4E51A42E9473...	9/23/2024

[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.

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	<p>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:</p> <ul style="list-style-type: none"> • Nurses currently registered with the Nursing and Midwifery Council (NMC) and working in a Minor Injury Unit (MIU) in Powys Teaching Health Board (PTHB) <p>The NMC registered nurse should have a current contract of employment with PTHB.</p> <p>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.</p>

Initial training

- The administration and supply of co-trimoxazole paediatric 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, young people 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 have completed mandatory sepsis training: 000 NHS Wales RRAILS eLearning programme (acute deterioration).
- 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.

<p>Competency assessment</p>	<ul style="list-style-type: none"> • 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.
<p>Ongoing training and competency</p>	<ul style="list-style-type: none"> • 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 discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required. • Update at least every 2 years, or earlier in response to new local/national guidance, on the use of PGDs and co-trimoxazole 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. <p>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.</p>

Clinical condition

Reference Number: PGD 0180A
Valid from: 07/10/2024
Review date: 07/10/2026
Expiry date: 06/10/2027

<p>Clinical condition or situation to which this PGD applies</p>	<p>Prevention and treatment of infection in children aged between 2 years and 12 years, presenting with an animal (cat, dog or other traditional pet bite) or human bite, AND child is allergic to penicillin or if co-amoxiclav is unsuitable, in accordance with NICE guidance -see Appendix B.</p> <p>Co-trimoxazole is the alternative first-choice oral antibiotic, for children under 12 years if allergic to penicillin or if co-amoxiclav is unsuitable.</p> <p>Notes:</p> <ul style="list-style-type: none"> • 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.
<p>Inclusion criteria</p>	<p>Children aged between 2 years and 12 years with:</p> <ul style="list-style-type: none"> • Known allergy to penicillin or co-amoxiclav is unsuitable • 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: <ul style="list-style-type: none"> ○ that has broken the skin and drawn blood ○ 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 ○ 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: <ul style="list-style-type: none"> ○ that has broken the skin and drawn blood ○ 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): <ul style="list-style-type: none"> ▪ that has broken skin and drawn blood and has penetrated bone, joint, tendon or vascular structures or

	<ul style="list-style-type: none"> ▪ 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 individual 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. <p>NB. If there is a discharge (purulent or non-purulent) from the area of bite, take a swab for microbiological testing. Antibiotics may be administered/supplied via this PGD if appropriate based on inclusion/exclusion criteria however the individual/carer must be informed that treatment may change once the results are received, refer for medical advice.</p> <ul style="list-style-type: none"> • Medical and drug history taken, no reason for exclusion <p>Refer to exclusion criteria for wounds that must be referred to hospital.</p> <p>In case of any doubt, contact medical team or emergency services.</p> <ul style="list-style-type: none"> • 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. <p>Any vulnerable adult or child protection concerns should be referred to Safeguarding and the PTHB safeguarding policies followed. Consider discussing with GP.</p> <p>It is the responsibility of the administering/supplying healthcare professional to ensure that the individual 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.</p>
<p>Exclusion criteria (Exclusion under this Patient Group Direction does not</p>	<ul style="list-style-type: none"> • Conditions outside of the clinical situations criteria • No valid consent, individual/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 individual

necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required)

[is excluded](#)" or "[Action to be taken if individual declines treatment](#)".

- Children under 2 years old - refer to a prescriber
- Individual 12 years and over -refer to [PGDs 0029](#) and [0031](#) or a prescriber
- Known hypersensitivity to sulphonamides, trimethoprim, or co-trimoxazole or to any of the excipients in the medicinal product(s)- see relevant SPC.
- Individual with previous Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) or drug reaction with eosinophilia and systemic symptoms (DRESS) with the use of co-trimoxazole.
- Individual with previous thrombocytopenia.
- Individuals who are not allergic to penicillin and no reason why co-amoxiclav is unable to be taken. Refer to [co-amoxiclav PGD 0028](#)
- Individuals with severe liver disease or severe parenchymal hepatic disease
- Individuals with severe renal impairment- [refer to a prescriber](#)
- Pregnant/breastfeeding
- Individual who has developed symptoms or signs of infection after taking prophylactic antibiotics- [refer to a prescriber](#)
- Individuals 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 individuals 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 individuals 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 individuals must be [referred to hospital.](#)**
- A systemically unwell child or child who is at risk of a serious wound infection because of a pre-existing medical condition- [refer to hospital.](#)
- Any individual identified with symptoms of [severe/life-threatening infection or systemic sepsis](#): refer urgently via ambulance.

	<ul style="list-style-type: none"> • Infected bite that is not responding to oral antibiotics within 24 hours to 48 hours of starting treatment- refer to a prescriber • For those who require INR monitoring due to their anticoagulant, the practitioner must check that the individual’s latest International Normalised Ratio (INR) is up to date and within the target range as stated in the individual’s yellow anti-coagulant record book. An individual 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. • Individuals who were bitten in a fight – refer to DGH for exploration/irrigation/IV antibiotics • Individual with acute porphyria or known or suspected to be at risk of porphyria or other blood disorders- refer to a prescriber • Individual with known glucose-6-phosphate dehydrogenase (G6PD) deficiency (risk of haemolytic anaemia)– refer to a prescriber • Individual with known rare hereditary problems of fructose intolerance- refer to a prescriber • Individuals taking (refer to Drug Interaction section): <ul style="list-style-type: none"> • Azathioprine • Cyclosporin • Folinic acid • Lamivudine • Methotrexate • Phenytoin • Pyrimethamine • Zidovudine
<p>Cautions /reasons for seeking further advice from a prescriber</p>	<ul style="list-style-type: none"> • Seek further advice from a prescriber for the following individuals: <ul style="list-style-type: none"> ○ with asthma or severe atopy ○ with a predisposition to folate deficiency ○ with a predisposition to hyperkalaemia and/or hyponatraemia as monitoring will be required ○ with phenylketonuria who are not on a special diet to help their condition ○ who are underweight or malnourished ○ with ulcers in the mouth, throat, nose, genitals, or conjunctivitis (red and swollen eyes) • An adequate urinary output should be maintained at all times. Evidence of crystalluria <i>in vivo</i> is rare, although sulphonamide crystals have been noted in cooled urine from treated individuals. In individuals suffering from malnutrition the risk may be increased. • Consider referral or seeking specialist advice if the bite is in an area of poor circulation

	<ul style="list-style-type: none"> • Co-Trimoxazole has been associated with metabolic acidosis when other possible underlying causes have been excluded. Close monitoring is always advisable when metabolic acidosis is suspected. • 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. • Check for any other medications that the individual is taking, including topical or inhaled products, food supplements and herbal or homeopathic products. Check these against the Drug Interactions section. • For those who require INR monitoring due to their anticoagulant, the practitioner must check the individuals 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 individual may be administered/supplied with co-trimoxazole but the individual or their carer must be advised to contact their usual anti-coagulant clinic to inform them that the individual has been prescribed a course of antibiotics. • Individuals with facial dog bites should be referred to MaxFax at DGH • See NICE CKS for individuals that should be referred to secondary care (urgency depending on clinical judgement) Refer to BNF/SPC for full list of cautions. <p>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.</p> <p>Any safeguarding concerns need to be directed to Safeguarding Hub:</p> <ul style="list-style-type: none"> • to generic email address: PowysTHB.Safeguarding@wales.nhs.uk <p>and</p> <ul style="list-style-type: none"> • Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847 <p>Advice can also be sought from local Safeguarding leads</p>
<p>Action to be taken if the individual is excluded</p>	<ul style="list-style-type: none"> • If individual is not allergic to penicillin and co-amoxiclav is available and suitable, refer to co-amoxiclav PGD0028 • Co-trimoxazole is the alternative first-choice oral antibiotic, for children under 12 years if allergic to penicillin or if co-amoxiclav is unsuitable. If the individual is excluded from the use of co-trimoxazole, refer to microbiologist.

	<ul style="list-style-type: none"> Record reason and seek medical advice. <p>Refer urgently to a prescriber for further assessment if:</p> <ul style="list-style-type: none"> Individual is severely immunosuppressed or immunosuppressed Individual is systemically unwell, but not showing signs or symptoms of sepsis <p>Refer urgently to A&E for further assessment if:</p> <ul style="list-style-type: none"> Signs of a more serious illness or condition Signs of intracranial complications such as swelling over the frontal bone, symptoms or signs of meningitis, severe frontal headache or focal neurological signs. <p>If sepsis is suspected refer the individual urgently to A&E</p> <ul style="list-style-type: none"> If appropriate refer to refer to GP / DGH / out of hours service / microbiologist, offer alternative management if appropriate. Explain reason to individual/ carer. Bites from bats- Urgent treatment required. All individuals 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 individual/carers to PHE PIL.
<p>Action to be taken if individual declines treatment</p>	<p>Explain consequences of refusing treatment.</p> <p>Make individual or their representative aware of alternative sources of treatment (DGH or GP as appropriate). Offer alternative management if appropriate.</p> <p>Document refusal and any advice given. Complete a Discharge Against Advice Form if appropriate.</p> <p>Inform or refer to GP/follow local procedures as appropriate.</p> <p>Where appropriate, complete the letter on the WPAS system and send to the GP.</p>
<p>Arrangements for referral for medical advice</p>	<ul style="list-style-type: none"> Refer to the appropriate medical practitioner in the care pathway - contact GP or microbiologist for advice or refer to out of hours service/ DGH if applicable. Document advice given.

Details of the medicine

Name, form and strength of medicine	<p>Co-trimoxazole 40 mg/200 mg per 5 ml Oral Paediatric Suspension</p> <p>Each 5 ml contains 40 mg Trimethoprim and 200 mg Sulfamethoxazole</p> <p>Note: the higher concentration suspension (80/400mg per 5 mL) is not licensed to be used in children under 12 years old and is NOT included in this PGD.</p>
Legal category	POM
Indicate any off-label use	<p>In children:</p> <p>Co-trimoxazole may be used as detailed in this PGD (in line with NICE and AWMSC primary care antimicrobial guidelines), although these situations are considered unlicensed:</p> <ul style="list-style-type: none"> • prophylaxis and treatment of infection due to human bites • prophylaxis and treatment of infection due to animal bites <p>Where treatment is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the treatment is being offered in accordance with national guidance but that this is outside the product licence. Informed consent should be obtained and documented.</p> <p>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.</p>
Route/method of administration	<p>Oral.</p> <p>The suspension is ready-made, no preparation is required.</p> <p>It may be preferable for co-trimoxazole to be taken with some food or drink to minimise the possibility of gastrointestinal disturbances.</p>

Dose and frequency	Children aged 2 years to 5 years	Children aged 6 years to 11 years
	240 mg: 5mL of 40mg/200mg per 5ml oral suspension (or 24 mg/kg)	480 mg: 10mL of 40mg/200mg per 5ml oral suspension (or 24 mg/kg)
	Where appropriately calibrated weighing scales are available, microbiology advise weight based dosing (24 mg/kg)	
	<p>For treatment: twice a day for 5 days. For prophylaxis: twice a day for 3 days.</p> <p>NB. Doses should be calculated to the nearest measurable graduation, and an oral syringe or spoon must be provided, as appropriate.</p>	
Quantity to be administered and/or supplied	<p>One pre-labelled bottle of 100mL oral paediatric suspension 40mg/200mg per 5 mL.</p> <p>The respective dose (to the nearest measurable graduation), individual's name and date of supply must be written on the label.</p> <p>Insert number of days treatment (see guidance below). An appropriate 5ml spoon and/or an oral syringe must be provided (an oral syringe will be required for any doses that are not 5ml or 10ml).</p>	
Maximum or minimum treatment period	<ul style="list-style-type: none"> • treatment of infected bite for 5 days • prophylaxis of infection for 3 days 	
Storage	<p>Store below 25°C. Protect from light</p>	

<p>Drug Interactions</p>	<p>All concomitant medications should be checked for interactions.</p> <p>Individuals taking the following are excluded from the PGD – see exclusion criteria (and refer to a prescriber):</p> <ul style="list-style-type: none"> • Azathioprine – there are conflicting clinical reports of interactions between azathioprine and trimethoprim-sulfamethoxazole, resulting in serious haematological abnormalities. • Cyclosporin - reversible deterioration in renal function has been observed in individuals treated with co-trimoxazole and cyclosporin following renal transplantation. • Folinic acid – folinic acid supplementation has been shown to interfere with the antimicrobial efficacy of trimethoprim-sulfamethoxazole. • Lamivudine – concomitant co-trimoxazole causes an increase in lamivudine exposure. • Methotrexate – co-trimoxazole may increase the free plasma levels of methotrexate. If co-trimoxazole is considered appropriate therapy, a folate supplement should be considered. • Phenytoin: co-trimoxazole prolongs the half-life of phenytoin and if co-administered could result in excessive phenytoin effect. Close monitoring of the individual's condition and serum phenytoin levels are advisable. • Pyrimethamine – occasional reports suggest that individuals receiving pyrimethamine at doses in excess of 25 mg weekly may develop megaloblastic anaemia should co-trimoxazole be prescribed concurrently. • Zidovudine – in some situations, concomitant treatment with zidovudine may increase the risk of haematological adverse reactions to co-trimoxazole. If concomitant treatment is necessary, consideration should be given to monitoring of haematological parameters. <p>Other interactions include:</p> <ul style="list-style-type: none"> • Warfarin and other coumarins: co-trimoxazole has been shown to potentiate the anticoagulant activity of warfarin. Careful control of the anticoagulant therapy during treatment with Co-Trimoxazole is advisable. See list of exclusions and list of cautions for further advice, which is dependent on INR result. • Drugs that can cause hyperkalaemia, eg. ACE inhibitors, angiotensin receptor blockers and potassium-sparing diuretics – caution should be exercised as concomitant use of co-trimoxazole may result in hyperkalaemia. • Sulfonylureas – interaction with co-trimoxazole is uncommon, but potentiation has been reported. • Repaglinide- trimethoprim may increase the exposure of repaglinide which may result in hypoglycaemia.
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	<ul style="list-style-type: none"> Laboratory tests: may interfere with the estimation of serum/plasma creatinine when the alkaline picrate reaction is used- see SPC for further details. <p>Also refer to cautions.</p> <p>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</p> <p>Refer to a prescriber if any concern of a clinically significant drug interaction and document advice given.</p>
<p>Identification, management and reporting of adverse effects</p>	<p>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.</p> <p>The following side effects are listed in the BNF and/or SPC as common or very common (but may not reflect all reported side effects):</p> <ul style="list-style-type: none"> diarrhoea skin reactions / rash electrolyte imbalance / hyperkalaemia fungal overgrowth headache nausea (can be reduced by taking the dose with some food or drink) <p>In the event of a severe adverse reaction, the individual/carer must be advised to stop treatment immediately and seek urgent medical advice.</p> <p>NB. Co-trimoxazole is associated with rare but serious side effects. Discontinue immediately if blood disorders (including leucopenia, thrombocytopenia, megaloblastic anaemia, eosinophilia, haemophagocytic lymphohistiocytosis) or rash/skin reactions (including Stevens-Johnson syndrome, toxic epidermal necrolysis, acute generalised exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms) develop.</p>

Fatalities, although very rare, have occurred due to severe reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), fulminant hepatic necrosis, agranulocytosis, aplastic anaemia, other blood dyscrasias and hypersensitivity of the respiratory tract.

Life-threatening cutaneous reactions SJS, TEN (e.g. progressive skin rash often with blisters or mucosal lesions), and drug reaction with eosinophilia and systemic symptoms (DRESS) (e.g. fever, eosinophilia) have been reported with the use of co-trimoxazole. Individuals/carers should be advised of the signs and symptoms and monitored closely for skin reactions- if present, co-trimoxazole should be discontinued. The highest risk for occurrence of SJS or TEN is within the first weeks of treatment. Individuals should be monitored for allergic reactions such as an itchy rash and hives.

- At the start of treatment, the occurrence of a generalised febrile erythema associated with pustules, should raise the suspicion of acute generalised exanthematous pustulosis (AGEP); it requires cessation of treatment and contraindicates any new administration of co-trimoxazole alone or in combination with other drugs.
- Cases of Haemophagocytic lymphohistiocytosis (HLH) have been reported very rarely in individuals treated with co-trimoxazole. HLH is a life-threatening syndrome of pathologic immune activation characterised by clinical signs and symptoms of an excessive systemic inflammation (e.g. fever, hepatosplenomegaly, hypertriglyceridaemia, hypofibrinogenaemia, high serum ferritin, cytopenias and haemophagocytosis). Individuals who develop early manifestations of pathologic immune activation should be evaluated immediately. If diagnosis of HLH is established, co-trimoxazole treatment should be discontinued.
- Very rare, severe cases of respiratory toxicity, sometimes progressing to Acute Respiratory Distress Syndrome (ARDS), have been reported during co-trimoxazole treatment. The onset of pulmonary signs such as cough, fever, and dyspnoea in association with radiological signs of pulmonary infiltrates, and deterioration in pulmonary function may be preliminary signs of ARDS. In such circumstances, co-trimoxazole should be discontinued and appropriate treatment given.
- Jaundice cholestatic and hepatic necrosis may be fatal.

<p>Identification, management and reporting of adverse effects (cont.)</p>	<p>Report any suspected adverse reactions to a doctor. Record all adverse drug reactions (ADRs) in the individual’s medical record and the individual’s GP should be informed.</p> <p>All significant adverse drug reactions should be reported via the Once for Wales Reporting System.</p> <p>In 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:</p> <ul style="list-style-type: none"> • 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 individual’s notes • Ensure all individual’s records are marked ALLERGIC TO Co-trimoxazole. • The individual may be advised to wear a MedicAlert or similar device to alert other healthcare providers • Report via the Once for Wales Reporting System <p>Healthcare professionals and individuals/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.</p>
<p>Records to be kept</p>	<p>Record consultation details as required by local procedures. In addition, record:</p> <ul style="list-style-type: none"> • That valid informed patient consent to treatment was obtained. Record name of representative who gave consent if appropriate. • If individual was not treated under PGD, record action taken and advice given. • Name of individual, address, date of birth • GP contact details where appropriate • If individual was not treated under PGD, record action taken and advice given. • Name of individual, address, date of birth • GP contact details where appropriate

	<ul style="list-style-type: none"> • Relevant past and present medical history and drug history taken, including any allergies and previous adverse events • Measure and record weight of child where appropriate and possible. • 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 individual / carer. • Examination or microbiology finding/s where relevant. <p>For <u>administration</u>, record:</p> <ul style="list-style-type: none"> • 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 <p>For <u>supply</u>, record:</p> <ul style="list-style-type: none"> • 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 <p>Record that medication was supplied/administered via Patient Group Direction (PGD) record PGD version number.</p> <p>The record must include the printed name and signature (or a password controlled e-records) of the healthcare professional responsible for administration/supply.</p> <p>The record must be kept securely for a defined period in line with local policy.</p> <p>All records should be clear, legible and contemporaneous.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p> <ul style="list-style-type: none"> • GP to be notified of administration/supply via usual communication channels
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Individual information

Written/verbal information to be given to individual or carer	<p>Supply a single pre-labelled MIU bottle of 100mL oral co-trimoxazole 40mg/200mg per 5ml paediatric suspension. Write the individuals name and the date of supply onto the label. Insert the number of ml dose and the number of days of treatment onto the label. Instruct the individual/carers about the dose and course length (i.e. 3 or 5 days, as appropriate).</p>
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Draw the individual's/carers attention to the label and provide the 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](#).

Supply a 5mL medicine spoon and / or an oral syringe. When an oral syringe is supplied ensure that the carer is familiar with its use and draw their attention to the leaflet provided.

Advise:

- Take regularly at the recommended intervals and complete the course, even if the wound looks better.
- If a dose is missed, advise to refer to PIL supplied with the product.
- The individual may experience mild gastro-intestinal side-effects- the risk may be reduced by taking the medicine at the start of a meal.
- As the full pre-labelled pack is supplied, advise that the remainder of liquid must be returned to a community Pharmacy or GP for safe disposal.
- To maintain adequate fluid intake.
- To discontinue treatment if overdose occurs and to seek medical advice.
- About appropriate oral pain relief.
- To seek urgent medical attention if the child develops an unexpected worsening of cough and shortness of breath.
- Individual/carers to discontinue medication and seek urgent medical attention (go to hospital urgently/call 999) if:
 - there are signs of an allergic reaction
 - blistering or bleeding or peeling of the skin
 - symptoms or signs of SJS, TEN or DRESS, which may appear initially as reddish target-like spots or circular patches often with central blisters on the trunk

Individual/carers to seek urgent medical attention (go to hospital urgently/call 999) if:

- the individual develops [signs or symptoms of sepsis](#).
- there are symptoms or signs of [meningitis](#) or flu like symptoms.

Explain:

- Indications, contra-indications, possible adverse effects and cautions
- Storage conditions

	<p>All individuals/carers should be advised to seek medical review /contact their GP if:</p> <ul style="list-style-type: none"> • 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 child 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 • Refer to MIU guidelines.
<p>Follow-up advice to be given to individual or carer</p>	<ul style="list-style-type: none"> • Refer to MIU guidelines. • The individual/carer should be advised to contact their GP if there is no improvement or if the presenting complaint/infection worsens or if the individual feels increasingly unwell. • If wound is infected, individual/carer should be advised to contact their GP for review at 24 and 48 hours to ensure infection is responding to treatment. • If co-trimoxazole is given for prophylaxis, advise individual/carer to check for signs of infection-if these develop advise individual to attend urgently for review. • If a swab has been taken, the individual/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. • 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. NB. the treatment beyond 5 days is not covered by this PGD and is to be supplied by GP/non-medical prescriber. • 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 for Children \(BNFC\)](#) - accessed 16/07/2024
- Electronic Medicines Compendium <http://www.medicines.org.uk/> accessed 20/08/2024
- [NICE guideline \[NG184\]](#) - Human and animal bites: antimicrobial prescribing, published: 04 November 2020
- NICE CKS Prescribing information: [Co-trimoxazole | Prescribing information | Bites - human and animal | CKS | NICE](#) – accessed 16/07/2024
- [All Wales Medicines Strategy Group Primary Care Antimicrobial Guidelines](#) March 2022 – accessed 16/07/2024

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.

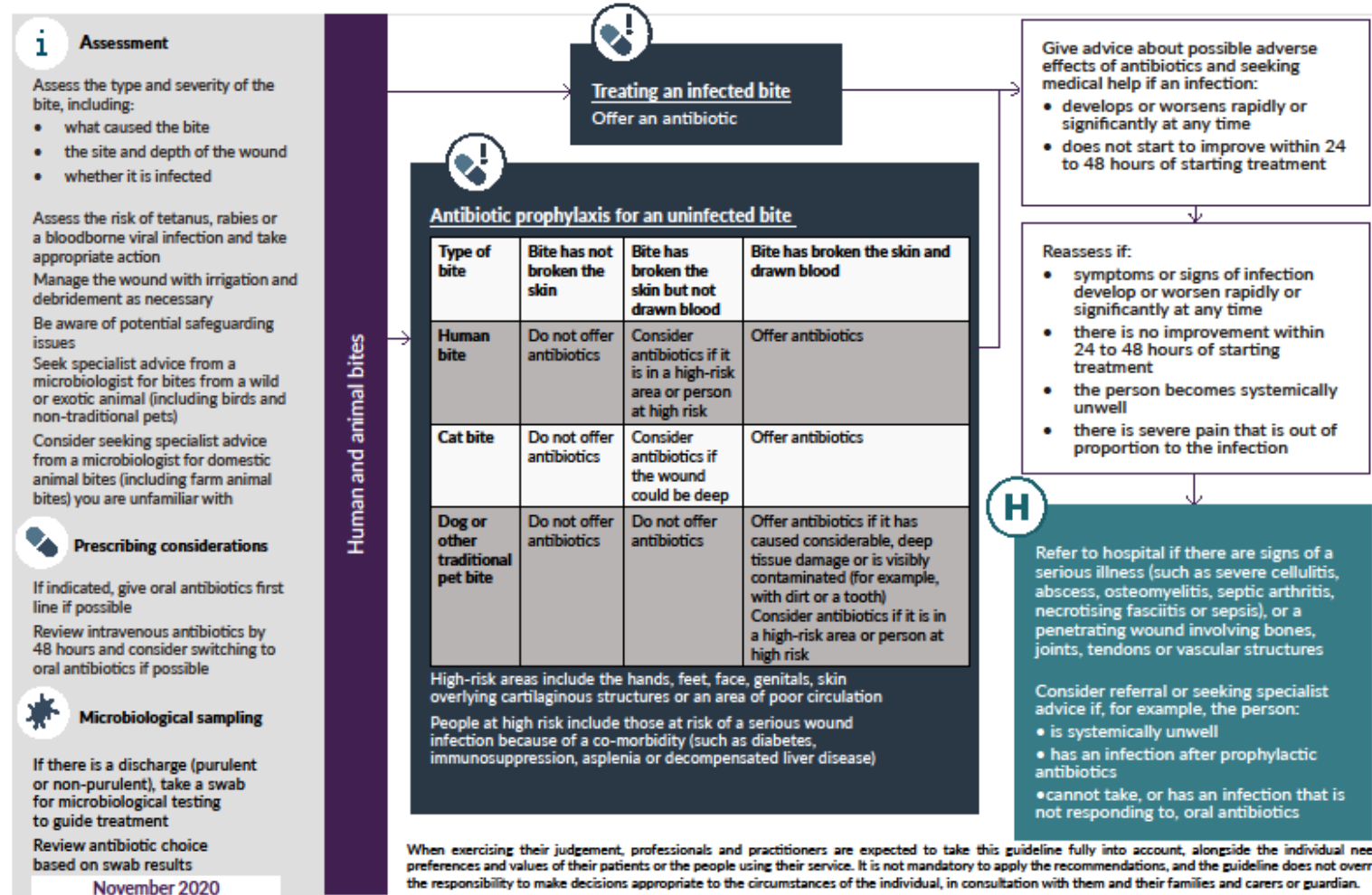
Name: Role:		Sign / Initial	Further training identified (Y/N) Specify in " comment s"	Comments
1	The PGD sign off is for the following PGD:(document the exact title and PGD number)			
2	We have discussed the expiry of the PGD and are using a version accessed electronically			
3	The member of staff has 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



When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

Human and animal bites: antimicrobial prescribing

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

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.

Human and animal bites: antimicrobial prescribing

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

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