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 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 (PGD)

supply of

clarithromycin tablets/oral suspension/oral solution

for the treatment of infected insect bite(s) and sting(s) and/or skin and soft tissue infections and wounds

by registered nurses, paramedics or physiotherapists

to

Adults and Children aged over 1 year and weighing at least 8kg

in Powys Teaching Health Board (PTHB) Minor Injury Units (MIUs)

Version number: PGD 0204A

Reference Number: PGD 0204A
Valid from: 16/03/2026
Review date: 31/08/2026
Expiry date: 28/02/2027

Change history		
Version number	**Change details**	**Date**
PGD 0204	Initial issue	25/04/2023
PGD 0204A	Review issue. All clinical content updated due to adoption of SPS template version 1.1 (PGD for the supply of clarithromycin tablets/oral suspension/oral solution for the treatment of infected insect bite(s) and sting(s)), which has been adapted for use in Powys Teaching Health Board (PTHB). The PTHB PGD also includes the treatment of skin and soft tissue infection and wounds. Treatment duration amended in line with SPS PGD template, following advice from the antimicrobial pharmacist. PTHB PGD amended to allow treatment of individuals aged over 1 year (if they are over 8kg). PGD amended to allow supply only (not administration) following confirmation at the PGD subgroup that the first dose would not be administered in MIUs. Removal of Clarithromycin 250mg/5mL oral suspension (or oral solution) from the PGD, following confirmation that this strength is not stocked in PTHB MIUs. Training requirements amended as recommended by the antimicrobial pharmacist.	16/03/2026

This Powys Teaching Health Board (PTHB) PGD is based on the PGD template 'supply of clarithromycin for the treatment of infected insect bite(s) and sting(s)' template v1.1 developed on behalf of the Specialist Pharmacy Service (SPS). The SPS PGD template has been peer reviewed by the national skin antimicrobial PGD Short Life Working Group in accordance with their Terms of Reference. It has been approved by The Advisory Committee on Antimicrobial Prescribing, Resistance and Healthcare Associated Infection (APRHAI) to the Department of Health and Social Care (England) in November 2023. The template has been adapted for use in PTHB, with an additional clinical condition (treatment of skin and soft tissue infections and wounds).

Developed by the following health professionals on behalf of the SPS:

Name	Designation
Dr Diane Ashiru-Oredope	Lead Pharmacist, HCAI, Fungal, AMR, AMU & Sepsis Division, UK Health Security Agency
Dr Imran Jawaid	GP and RCGP AMR representative
Dr Jeeves Wijesuriya	GP and Clinical Advisor to NHS England Primary Care Team and Vaccination and Screening Team
Dr Naomi Fleming*	NHS England Regional Antimicrobial Stewardship lead for the East of England region
Jackie Lamberty	Medicines Governance Consultant Lead Pharmacist, UK Health Security Agency
Jo Jenkins	Lead Pharmacist Patient Group Directions and Medicines Mechanisms, Medicines Use and Safety Division, Specialist Pharmacy Service
Liz Cross	Advanced Nurse Practitioner QN
Dr Martin Williams	Consultant in Microbiology and Infectious Diseases
Dr Matthew Scorer	Consultant Dermatologist
Dr Michelle Toleman	Consultant Microbiologist
Temitope Odetunde	Head of Medicines Management
Kieran Reynolds (SLWG co-ordinator)*	Specialist Pharmacist – Medicines Governance, Medicines Use and Safety Division, Specialist Pharmacy Service
Nigel Gooding	Consultant Paediatric Pharmacist. Neonatal and Paediatric Pharmacist Group (NPPG) representative.
Dr Stephanie Gallard	GP (Dermatology Special Interest)
Rob Hebdon	National Pharmacy Integration Lead Primary Care, Community Services and Strategy Directorate, NHS England

*Core group members

PGD authorisation

Name	Job title and organisation	Signature	Date
Senior doctor **Dr Kate Wright**	Lead doctor for PTHB	DocuSigned by: Kate Wright 1F267952823F473...	3/30/2026
Chief Pharmacist **Jonathan Boyd**	Chief Pharmacist for PTHB	Signed by: Jon Boyd 6D8ECFE8C9EB423...	3/31/2026
Senior representative of professional group using the PGD **Paul Hooton**	Executive Director of Nursing and Midwifery for PTHB	Signed by: Paul Hooton EEABC83AC83F4B9...	3/30/2026
Clinical Governance Lead **Dr Amanda Edwards**	Clinical Governance Lead for PTHB – Assistant Director for Innovation and Improvement	Signed by: Lucie Cornish on behalf of Amanda Edwards 48844B7FC02A448... Director of Improvement & Transformation	4/20/2026

The PGD is not legally valid until it has had the relevant organisational authorisations.

It is the responsibility of the provider organisation to ensure that all legal and governance requirements for using the PGD are met.

Appendix A provides a staff accreditation sheet. Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

The final authorised copy of this PGD should be kept by PTHB for 25 years after the PGD expires.

Characteristics of staff

Qualifications and professional registration	Practitioners must only work under this PGD where they are competent to do so. Practitioners working under this PGD must also be a registered healthcare professional listed in the legislation as able to practice under Patient Group Directions, with one of the following bodies: • Nurses currently registered with the Nursing and Midwifery Council (NMC) and working in a Minor Injury Unit (MIU) in PTHB. • Paramedics or physiotherapists, currently registered with the Health and Care Professions Council (HCPC) and working in a Minor Injury Unit (MIU) in PTHB. 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 practitioners listed above have organisational authorisation to work under this PGD.
Initial training	The supply of clarithromycin tablets/oral suspension/oral solution and knowledge of its uses, contraindications and adverse effects. Safe and accurate reconstitution of the granules – refer to section below: Instruction for reconstitution The registered healthcare professional authorised to operate under this PGD must have: • Undertaken appropriate training and successfully achieved competency to undertake clinical assessment of individuals leading to diagnosis of the conditions listed. • Recommended training includes: o An understanding of NICE Guideline 141 on Cellulitis and erysipelas: antimicrobial prescribing and Cellulitis and erysipelas- Visual Summary o NICE CKS Insect bites and stings resources o An understanding of NICE Guidelines 182 on Insect bites and stings o An understanding of Cellulitis Guidelines for People with Lymphoedema/Chronic Oedema in NHS Wales • Individuals operating under this PGD must be familiar with the product and alert to changes in the Summary of Product Characteristics (SPC).

	• Individuals operating under this PGD must have access to the PGD and associated online resources.
	• Antimicrobial stewardship awareness: initially completion of HEIW Antimicrobial Stewardship followed by 3-yearly update session delivered locally
	• Undertaken appropriate training and successfully achieved competency for the identification of sepsis which includes:
	  ○ NEWS2 training
	  ○ ILS
	  ○ Use of the sepsis detection tool (found in CDP 004 resus training policy)
	  ○ Awareness of NICE guidance on sepsis
	  ○ Any further updated training on sepsis as recommended by PTHB
	• Undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - eLfH PGD elearning programme- PTHB staff to access via ESR.
	• Completed locally required training (including updates) in safeguarding vulnerable adults and children or a minimum of level 2 safeguarding or the equivalent
	
	Additionally, practitioners:
	• must be competent in the recognition, management and reporting of recognised adverse reactions, including anaphylaxis. Must be competent in the administration of adrenaline 1 in 1000 and have up to date Intermediate Life Support (ILS) skills.
	
	THE PRACTITIONER MUST BE AUTHORISED BY NAME, AS AN APPROVED PRACTITIONER UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.

Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix A). The individual must complete a self-declaration of competence to operate under this PGD 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 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. • Evidence of training in ILS, anaphylaxis and safeguarding. • Staff operating under this PGD should review their competency using the NICE Competency Framework for health professionals using patient group directions • Individuals operating under this PGD should follow the national guidance for the diagnosis (NICE CKS) and management (NICE) of infected insect bites and stings in the UK and NICE Guidelines on Cellulitis and erysipelas: antimicrobial prescribing and Cellulitis and erysipelas- Visual Summary
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 discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required. • Annual PGD training- 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. • Update at least every 2 years, or earlier in response to new local/national guidance, on the use of clarithromycin and the treatment of insect bites/stings and the treatment of skin and soft tissue infection and wounds. • 3-yearly antimicrobial stewardship update session delivered locally by the antimicrobial pharmacist.

	• 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), which must be retained and made available on request. • Compliance with all mandatory NHS training including safeguarding at the level relevant to the role. **It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.**
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Treatment of skin and soft tissue infection including wounds (including infected insect† bite(s) and sting(s)) in individuals aged 1 year and over, where individual is excluded from PGD 0188 Flucloxacillin due to hypersensitivity (or otherwise unsuitable) and hospital admission is not required in accordance with NICE guidance. † As per NICE and NICE CKS guidance, the term "insect" includes those with six legs (e.g. mosquitoes, gnats and flies) and those with eight legs (e.g. spiders, mites and ticks). **Note:** For all wounds and bites assess the risk of tetanus, rabies or a bloodborne viral infection and take appropriate action, following MIU Guidelines. NB: If the wound is infected, the skin is broken and there is risk of an uncommon pathogen, before cleaning, send a pus or a deep wound swab for culture. State on the form that the swab is from an infected bite/wound as appropriate. Antibiotics may be supplied via this PGD if appropriate based on inclusion/exclusion criteria however the individual must be informed that treatment may change when the results are received - refer for medical advice. Topical cleaning, thorough irrigation and debridement should be completed as necessary- follow MIU Guidelines. NB. For cellulitis and erysipelas, consider marking extent of infection with a single-use surgical marker pen.

	It is the responsibility of the 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.

Criteria for inclusion	• Informed consent, from the individual or a person legally able to act on the individual's behalf, must be obtained prior to supply and recorded appropriately. Refer to PTHB Consent to Treatment and Examination Policy.
	• Medical and drug history taken, no reason for exclusion
	• Individuals aged 1 year and over and weighing at least 8kg
	• Diagnosis of infected insect bite or sting using the appropriate diagnostic (NICE CKS) guidance or infection of skin or soft tissues or wounds
	  ○ For **INSECT BITE(S) OR STING(s)-** Clear evidence of infection that is present or worsening at least 48 hours after the initial bite(s) or sting(s) with 3 or more of the following symptoms:
	  ▪ Redness of the skin (erythema may be more difficult to distinguish on darker skin tones)
	  ▪ Pain or tenderness to the area
	  ▪ Swelling of the skin
	  ▪ Skin surrounding the bite(s) or sting(s) feels hot to touch
	  AND any of the following:
	  ▪ Redness or swelling of the skin surrounding the bite(s) or sting(s) is spreading
	  ▪ Evidence of purulent discharge at site of bite(s) or sting(s)
	  ○ For **INFECTION OF SKIN OR SOFT TISSUES/ INFECTED WOUNDS** -Symptoms or signs of infection are pain in affected area, inflammation, fever, discharge or an unpleasant smell.
	
	• Individual is excluded from PGD 0188 Flucloxacillin due to:
	  ○ Known hypersensitivity to flucloxacillin, any penicillin or any of the components within the formulation of flucloxacillin – see Summary of Product Characteristics, or if flucloxacillin is otherwise unsuitable. **Acceptable sources of allergy information include individual/carer/parent/guardian/Welsh Clinical Portal or GP record**
	  OR
	  ○ History of severe immediate hypersensitivity reaction (e.g. anaphylaxis) to another beta-lactam antibiotic (e.g. cephalosporin, carbapenem or monobactam).

	Acceptable sources of allergy information include individual/carer/parent/guardian/Welsh Clinical Portal or GP record • Individual has no contraindications to clarithromycin **NB. Refer to exclusion criteria and action to be taken if the individual is excluded for wounds that must be referred to hospital.** In case of any doubt, contact medical team or emergency services. Any vulnerable adult or child protection concerns should be referred to Safeguarding and PTHB safeguarding policies followed. Where there are safeguarding concerns (Child Protection or Protection of Vulnerable Adults, POVA) advice from the local Safeguarding team should be sought (see below).

Criteria for exclusion	• Conditions outside of the clinical situations criteria
	• **Any cause for clinical concern- refer to a prescriber/ A&E as appropriate**
	• Individuals not excluded from PGD 0188 flucloxacillin
	• Consent refused and documented in the individual's medical notes. Refer to section "Action to be taken if the individual/carer/parent/guardian declines treatment".
	• Individuals under 1 year of age
	• Individuals weighing less than 8kg
	• Pregnancy or suspected pregnancy
	• Severely immunosuppressed individuals as defined in Chapter 28a Green book:
	Individuals with primary or acquired immunodeficiency states due to conditions including:
	  • acute and chronic leukaemias, and clinically aggressive lymphomas (including Hodgkin's lymphoma) who are less than 12 months since achieving cure
	  • individuals under follow up for a chronic lymphoproliferative disorders including haematological malignancies such as indolent lymphoma, chronic lymphoid leukaemia, myeloma, Waldenstrom's macroglobulinemia and other plasma cell dyscrasias (N.B: this list not exhaustive)
	  • immunosuppression due to HIV/AIDS with a current CD4 count of below 200 cells/µl.
	  • primary or acquired cellular and combined immune deficiencies – those with lymphopaenia (<1,000

	lymphocytes/ul) or with a functional lymphocyte disorder • those who have received an allogeneic (cells from a donor) or an autologous (using their own cells) stem cell transplant in the previous 24 months • those who have received a stem cell transplant more than 24 months ago but have ongoing immunosuppression or graft versus host disease (GVHD) **Individuals on immunosuppressive or immunomodulating therapy including:** • those who are receiving or have received in the past 6 months immunosuppressive chemotherapy or radiotherapy for any indication • those who are receiving or have received in the previous 6 months immunosuppressive therapy for a solid organ transplant • those who are receiving or have received in the previous 3 months targeted therapy for autoimmune disease, such as JAK inhibitors or biologic immune modulators including B-cell targeted therapies (including rituximab but for which a 6 month period should be considered immunosuppressive), monoclonal tumor necrosis factor inhibitors (TNFi), T-cell co-stimulation modulators, soluble TNF receptors, interleukin (IL)-6 receptor inhibitors., IL-17 inhibitors, IL 12/23 inhibitors, IL 23 inhibitors (N.B: this list is not exhaustive) **Individuals with chronic immune mediated inflammatory disease who are receiving or have received immunosuppressive therapy** • moderate to high dose corticosteroids (equivalent ≥20mg prednisolone per day) for more than 10 days in the previous month • long term moderate dose corticosteroids (equivalent to ≥10mg prednisolone per day for more than 4 weeks) in the previous 3 months • any non-biological oral immune modulating drugs e.g. methotrexate >20mg per week (oral and subcutaneous), azathioprine >3.0mg/kg/day; 6-mercaptopurine >1.5mg/kg/day, mycophenolate >1g/day) in the previous 3 months • certain combination therapies at individual doses lower than stated above, including those on ≥7.5mg prednisolone per day in combination with other immunosuppressants (other than hydroxychloroquine or sulfasalazine) and those receiving methotrexate (any dose) with leflunomide in the previous 3 months

	Individuals who have received a short course of high dose steroids (equivalent >40mg prednisolone per day for more than a week) for any reason in the previous month. • Known hypersensitivity to clarithromycin, any macrolide or any of the components within the formulation - see Summary of Product Characteristics. **Acceptable sources of allergy information include individual/carer/parent/guardian/Welsh Clinical Portal or GP record** • Inability to absorb oral medications and/or inability to swallow oral dosage formulations (i.e. tablets or oral suspension (or oral solution)) • Current long-term use of clarithromycin or another macrolide antibiotic (e.g. erythromycin for prophylaxis in asplenia, azithromycin for prophylaxis in individuals with COPD or bronchiectasis etc.) • Individuals following a ketogenic diet • Failed previous antibiotic for this episode of infected insect bite or sting or skin and soft tissue infections/wounds • Spreading infection not responding to oral antibiotics • Any individual suspected of having a systemic reaction to an insect bite or sting or tissue infection i.e. angio-oedema or anaphylaxis • Previous systemic allergic reaction to the same type of bite or sting (if relevant) • Known comorbidity which may complicate or delay resolution of infection (for example peripheral arterial disease, chronic venous insufficiency, lymphoedema or morbid obesity). • Severe pain out of proportion to the wound (may indicate presence of toxin-producing bacteria) • Numbness or tingling of the affected area • No clear evidence of infection (If relevant, initial inflammation around the site of the bite should be managed in accordance with self-care advice; including analgesia, oral antihistamines and topical steroids (over the counter)) • Human bite or animal bite or scratch. NB refer to relevant PGDs in first instance. • Insect sting/bite in the mouth or throat, or around the eyes • Facial cellulitis • Puncture wound contaminated with freshwater or sea water, soil or manure. May require alternative antibiotics or further management such as tetanus prophylaxis. • Bite, sting, or infection occurred while travelling outside the UK with concern of insect borne disease e.g. malaria, tick borne encephalitis • Bite or sting caused by an unusual or exotic insect

	• Insect bites caused by ticks (where tick present or presentation indicative of tick bite): due to risk of Lyme disease
	• Evidence of erythema migrans (bullseye rash, which may appear as a bruise on brown or black skin) on examination: due to risk of Lyme disease
	• Systemically unwell or are at risk of a serious wound infection because of a pre-existing medical condition
	• Any individual identified with symptoms of severe/life-threatening infection or systemic sepsis: refer urgently via ambulance. NB. Individuals with Class III and IV cellulitis – require urgent hospital admission
	• Individuals presenting with cellulitis who also have symptoms of the following complications must be referred urgently to A&E:
	  ○ Deep vein thrombosis
	  ○ Tissue necrosis
	• Previous or current known met(h)icillin-resistant Staphylococcus aureus (MRSA) colonisation or infection
	• Known myasthenia gravis
	• Known history of QT prolongation (congenital or acquired), or ventricular cardiac arrhythmia, including torsades de pointe
	• Concomitant use of another medication known to cause QT prolongation (e.g. haloperidol, sotalol, terfenadine, pimozide) (For further information recommended resources include: CredibleMeds; registration required, or Sudden arrhythmic death syndrome (SADS) - Drugs to avoid)
	• Known electrolyte disturbances (hypokalaemia or hypomagnesaemia)
	• Known Chronic Kidney Disease (CKD) stages 4 or 5 (eGFR <30mL/min/1.73m^2)
	• Previous history of macrolide-associated jaundice/hepatic dysfunction
	• Known or suspected severe liver disease
	• Known heart disease (e.g. coronary artery disease, severe cardiac insufficiency, bradycardia < 50 beats per minute)
	• Less than 3 days before receiving, or within 3 days after receiving, oral typhoid vaccine
	• Concurrent use of any interacting medicine as listed in Drug Interactions section of this PGD
	• Individual with lymphangitis
	• Individual has porphyria
	• If the individual has symptoms of diarrhoea and they have received an antibiotic within the previous 3 months
	
	Refer to section 'Action to be taken if the individual is excluded'.

	NB- Individuals with bites or wounds with signs of a serious illness must be referred to hospital.
Cautions including any relevant action to be taken	**Breastfeeding individuals:** Clarithromycin can be used in breastfeeding individuals (as per UKDILAS advice): monitor nursing infant for gastro-intestinal disturbances, oral candida infection, rashes, drowsiness, irritability, sweating and loss of appetite. ********** Check for any other medications that the individual is taking, including topical or inhaled products, food supplements and herbal or homeopathic products. Caution should be exercised when supplying clarithromycin, a strong cytochrome P450 (CYP) 3A4 inhibitor to individuals taking the following medicine(s), that are known or suspected to be affected by clarithromycin: **Coumarin anticoagulants (e.g. warfarin, acenocoumarol, phenindione):** rises in INR reported. Individuals should be advised to have their INR monitored while on treatment with clarithromycin and should be counselled re: seeking medical attention if any episode of bleeding develops while taking. In PTHB, individuals must be advised to arrange review with the clinic responsible for INR monitoring within 3 days of starting clarithromycin treatment. **Direct oral anticoagulants (DOACs)** (e.g. apixaban, dabigatran, edoxaban, rivaroxaban) Increased risk of bleeding when given with clarithromycin. Individuals should be advised to seek medical attention if any episode of bleeding develops while taking. **Statins:** simvastatin use is contraindicated with clarithromycin. Counsel individuals taking other statins of the risk of rhabdomyolysis while taking clarithromycin and to seek medical attention if muscle pain develops. Consider withholding statin while taking clarithromycin to reduce risk of rhabdomyolysis. **Calcium channel blockers:** lercanidipine use is contraindicated with clarithromycin. Risk of hypotension (low blood pressure) when taking clarithromycin with amlodipine, diltiazem, felodipine, nifedipine or verapamil. Counsel individuals of the risk and advise to avoid driving/operating machinery if light headed/dizzy.

	Oral hypoglycaemic agents (e.g. sulphonylureas)/insulin: Use with clarithromycin can cause low blood glucose levels (hypoglycaemia). Advise individuals to monitor blood glucose levels more regularly while taking. **Digoxin**: Concomitant use with clarithromycin can increase digoxin levels. Advise individuals of symptoms of digoxin toxicity (change in vision e.g. blurred vision, diarrhoea, confusion, dizziness, nausea, vomiting, skin rash) and to seek medical attention if any of these develop. Caution should be exercised when supplying clarithromycin to individuals taking the following medicine(s): **Medicines known to cause hypokalaemia** (e.g. diuretics, corticosteroids, xanthines): may cause electrolyte disturbances – monitoring may be indicated. Advise individuals to contact their prescriber to discuss need. This list is not exhaustive and a detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk ********** Caution should be exercised when supplying clarithromycin tablets or oral suspension (or oral solution) to individuals who should avoid the following excipients: **Lactose, sucrose, fructose and sorbitol:** Individuals with rare hereditary problems of galactosaemia, galactose intolerance, total lactase deficiency, glucose-galactose malabsorption, sucrase-isomaltase deficiency, fructose-1,6-bisphosphatase deficiency (also known as hereditary fructose intolerance): check the individual list of excipients available in the SPC before supplying. **Aspartame:** Individuals with phenylketonuria (PKU) must not use medicines containing aspartame. Check the individual list of excipients available in the SPC before supplying. ********** • Refer to the SPC for clarithromycin for full details of special warnings and precautions for use • Consider referring people with cellulitis or erysipelas to hospital, or seek specialist advice, if they could have

	uncommon pathogens, for example, after a penetrating injury, exposure to water-borne organisms, or an infection acquired outside the UK. NB Refer to exclusions • Consider taking a swab or take a pus sample into a universal container, if possible, for microbiological testing from people with cellulitis or erysipelas to guide treatment, but only if the skin is broken and: ○ there is a penetrating injury or ○ there has been exposure to water-borne organisms or ○ the infection was acquired outside the UK NB Refer to exclusions • When managing cellulitis or erysipelas, refer individual to their GP to manage underlying conditions/risk factors such as diabetes, venous insufficiency, eczema, leg ulcer, tinea pedis and oedema/lymphoedema. **NB If there is any doubt about the supply of the medication or the individual's fitness or suitability to receive the medication, a prescriber should be consulted.** 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.
Specific information for suspected infection to be provided	As appropriate: Provide TARGET self-care leaflet Provide information on insect bites and stings: • NHS Website - Insect bites and stings And, where relevant, provide the following information: • UKHSA - Tick Awareness

	• The Anaphylaxis Campaign - Insect sting allergy – the facts.

Action to be taken if the individual is excluded	• Refer to PGD 0188 flucloxacillin if appropriate
	• Explain reasons for exclusion to individual/carer/parent/guardian
	• Record reasons for exclusion in the appropriate clinical record
	
	Individuals where treatment is not indicated:
	• Advise individual/carer/parent/guardian of alternative non antibiotic treatment if antibiotic not indicated and provide TARGET self-care leaflet and safety netting advice.
	• Some individuals may wish to consider oral antihistamines to help relieve itching, even though there is uncertainty about their effectiveness.
	• Ask the individual to draw a line around the border of erythema (or take clear photos of the area) and to return for reassessment, as per local service specification if:
	  ○ Symptoms worsen at any time **OR**
	  ○ Do not improve after self-care.
	
	Refer urgently to a prescriber for further assessment if:
	• Individual is systemically unwell, but not showing signs or symptoms of sepsis
	• Individual is systemically well but with a comorbidity (for example peripheral arterial disease, chronic venous insufficiency, or morbid obesity) which may complicate or delay resolution of infection
	• Failed previous antibiotic for this episode of infected insect bite or sting or skin and soft tissue infections/wounds
	• Spreading infection not responding to oral antibiotics
	• Severe pain out of proportion to the wound
	• Animal bite or scratch – NB refer to relevant PGDs in first instance
	• Human bite – NB refer to relevant PGDs in first instance
	• Evidence of erythema migrans (bullseye rash, which may appear as a bruise on brown or black skin)
	• Bite, sting or wound occurred while travelling outside of the UK with concern of insect borne disease e.g. malaria, tick borne encephalitis
	• Bite or sting caused by an unusual or exotic insect
	• Individuals where treatment under this PGD is not indicated/permitted but dermatological symptoms are present and require further assessment
	
	Refer urgently to A&E for further assessment if:
	• Any individual suspected of having a systemic reaction to

	an insect bite or sting i.e. angio-oedema or anaphylaxis, or individuals with symptoms or signs suggesting a more serious illness or condition, e.g. lymphangitis, orbital cellulitis, osteomyelitis, septic arthritis, necrotising fasciitis or sepsis
	• Any individual identified with symptoms of severe/life-threatening infection or systemic sepsis: refer urgently via ambulance. NB. Individuals with Class III and IV cellulitis – require urgent hospital admission
	• Previous systemic allergic reaction (e.g. angio-oedema or anaphylaxis) to the same type of bite or sting
	• Individual is severely immunosuppressed and has signs or symptoms of infection
	• Has been stung on the mouth, throat or tongue and is at risk of airway obstruction
	• Has been stung around the eyes and is at risk of compromised vision
	• Individual presents with cellulitis and also has symptoms of the following complications:
	  ○ Deep vein thrombosis
	  ○ Tissue necrosis
	
	Contact the Lymphoedema Service if the patient has oedema or associated skin changes: LymphoedemaNetworkWales@wales.nhs.uk
	
	Consider referring people with cellulitis or erysipelas to hospital, or seek specialist advice, if they:
	• have infection near the eyes or nose or
	• could have uncommon pathogens, for example, after a penetrating injury, exposure to water-borne organisms, or an infection acquired outside the UK
	
	Contact GP or microbiologist for advice or refer to DGH, A&E or NHS 111 if applicable. Offer alternative management if appropriate. Document advice given.
	
	If sepsis is suspected refer the individual urgently to A&E
	
	NB Individuals excluded from this PGD due to identification of clinical red flags or any clinical concern must be referred to hospital urgently.

Action to be taken if the individual/carer/ parent /guardian declines treatment	• The patient information leaflet should be available to inform consent • Explain consequences of refusing treatment • Document refusal and complete a Discharge Against Advice Form if appropriate • Inform or refer to GP/follow local procedures as appropriate • Make individual or their representative aware of alternative sources of treatment (DGH, A&E or GP as appropriate). Offer alternative management if appropriate. • Where appropriate, complete the letter on the WPAS system and send to the GP • Document advice given • Provide safety netting advice and advise individual/carer/parent/guardian of alternative treatment available using TARGET self-care leaflet as appropriate. Provide information on insect bites and stings if relevant: • NHS Website – Insect bites and stings And, where relevant, provide the following information: • UKHSA — Tick Awareness • The Anaphylaxis Campaign — Insect sting allergy – the facts.
Arrangements for referral for medical advice	Refer to a prescriber if antibiotic appropriate but falls outside of this PGD (contact GP/microbiologist or refer to DGH/A&E if applicable). Document advice given.
Name, strength and formulation of drug	Clarithromycin 250mg tablets Clarithromycin 500mg tablets Clarithromycin 125mg/5mL oral suspension (or oral solution) x 70mL **NOTE:** Tablets must not be issued to children under 12 years old
Legal category	POM
Route/Method of Administration	Orally, tablets swallowed whole with water (taken with or without food) *Note: Clarithromycin oral suspension (or oral solution) can cause a bitter after-taste. This can be avoided by drinking juice or water soon after intake of the oral suspension (or oral solution).*

Description of treatment

	Instructions for reconstitution of oral suspension (or oral solution) • Follow reconstitution instructions on the packaging. • Ensure that the label is completed to indicate the date when the medicine must be discarded/expires. Children over 12 years should be encouraged (where possible) to swallow tablets: • Medicines for Children has useful guides on how to give medicines, including giving tablets • KidzMed is an eLfH resource for healthcare professionals teaching children to swallow pills.
Indicate any off-label use (if relevant)	**Temperature variations** Medicines should be stored according to the conditions detailed in the storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions, the local Medicines Management team must be consulted to ensure the medicine remains pharmaceutically stable and appropriate for use if it is to be issued. Where medicines have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations/manufacturer advice as appropriate for continued use this would constitute off-label supply under this PGD. The responsibility for the decision to release the affected medicines for use lies with the registered pharmacy professional. Manipulating solid dosage forms In the event of an individual being unable to swallow solid oral dosage formulations, and alternate liquid formulations not being readily available provide advice on how to give doses by dispersing or crushing the tablets. Use in this way may be outside the product licence and is thus off-label. **Dispersing or crushing** Clarithromycin tablets are film-coated and can be crushed and mixed with liquid or soft food. Crushing tablets **should not** be undertaken by anyone with, or in the vicinity of someone with a macrolide allergy.

	Dispersing tablets To disperse the tablet: • Place the tablet in the barrel of a 10mL oral syringe • Replace the plunger • Draw up approximately 5mL of water and 2mL of air • Shake well and allow to disperse (this may take up to 10 minutes) • Ensure all contents of the oral syringe are given in the mouth Alternatively, the tablet may be mixed with 5 to 10mL of water in small glass or medicine cup and stirred well. **Masking the taste** The crushed tablet will taste bitter so it can be helpful to use a strongly flavoured drink (e.g. blackcurrant cordial) or food (e.g. jam, apple sauce, yoghurt) that the individual likes: • Use a small amount of food or drink (e.g. a teaspoonful) so you can be sure the individual eats it all and swallows the whole dose • It might be helpful to use an oral syringe for liquids • After mixing the crushed tablet with food or drink, give it straight away. Where a drug is recommended off-label consider, as part of the consent process, informing the individual/carer/parent/guardian that the drug is being offered in accordance with national guidance but that this is outside the product licence.
Dose and frequency of administration	**Children 1-11 years:** Body-weight: • **up to 8 kg: excluded from PGD** – refer to a prescriber • **8–11 kg: 62.5mg** (2.5ml of clarithromycin 125mg/5ml suspension (or oral solution)) **twice daily** (every 12 hours) • **12–19 kg: 125mg** (5ml of clarithromycin 125mg/5ml suspension (or oral solution)) **twice daily** (every 12 hours) • **20–29 kg: 187.5mg** (7.5ml of clarithromycin 125mg/5ml suspension (or oral solution)) **twice daily** (every 12 hours)

	• **30–40 kg: 250mg** (10ml of clarithromycin 125mg/5ml suspension (or oral solution)) **twice daily** (every 12 hours) **Children 12–17 years and adults:** **500mg twice daily** (every 12 hours)
Duration of treatment	5 days **Treatment should be started immediately and 5 days of treatment completed**
Quantity to be supplied	**Children 1-11 years:** Body-weight: • up to 8 kg: **excluded from PGD** – refer to a prescriber • 8–11 kg: appropriately labelled pack of 1 x 70mL x 125mg/5mL oral suspension (or oral solution) • 12–19 kg: appropriately labelled pack of 1 x 70mL x 125mg/5mL oral suspension (or oral solution) • 20**–**29 kg: appropriately labelled pack of 2 x 70mL x 125mg/5mL oral suspension (or oral solution) • 30–40 kg: Appropriately labelled pack of 2 x 70mL x 125mg/5mL oral suspension (or oral solution) **Children 12–17 years and adults:** Appropriately labelled pack of 14 x 500mg tablets **OR** appropriately labelled pack of 2 x 14 x 250mg tablets **OR** appropriately labelled pack of 3 x 70mL x 125mg/5mL oral suspension (or oral solution) NB. A 5ml medicine spoon or oral syringe must be provided with oral solution (or oral suspension). Advise to return any unused medicine to a pharmacy at the end of the course of treatment.
Storage	Stock must be securely stored according to organisation medicines policy and in conditions in line with SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Drug interactions	Where it is known an individual is concurrently taking one of the following medicines, clarithromycin must not be supplied under this PGD and the individual referred to a prescriber: • Simvastatin, *lovastatin** • Astemizole, *cisapride**, domperidone, pimozide, *terfenadine**

	• Ergotamine or dihydroergotamine
	• Ranolazine
	• Ticagrelor
	• Chloroquine or hydroxychloroquine
	• Colchicine
	• Midazolam (oral)
	• Lomitapide
	• Ivabradine
	• Typhoid vaccine (oral): see Criteria for exclusion
	• Medicines where concomitant use with a strong CYP 3A4 inhibitor (i.e. clarithromycin) is contraindicated (e.g.
	  ○ Avanafil
	  ○ Dronedarone
	  ○ Eplerenone
	  ○ Finerenone
	  ○ Lercanidipine
	  ○ Lurasidone
	  ○ Naloxegol
	  ○ Quetiapine)
	• Any medicine known to cause QT prolongation. For further information recommended resources include: CredibleMeds; registration required, or Sudden arrhythmic death syndrome (SADS) - Drugs to avoid
	• Medicines that are strong inducers of cytochrome P450 (CYP) and may reduce the efficacy of clarithromycin (e.g.
	  ○ Efavirenz, etravirine, nevirapine,
	  ○ Rifampicin, rifabutin, rifapentine,
	  ○ Phenytoin, carbamazepine, phenobarbital,
	  ○ St. John's wort.
	  ○ For further information recommended resources include:
	  ▪ Indiana University School of Medicine Drug Interactions Flockhart Table™
	  ▪ Mayo Clinic Labs Pharmacogenomic Association Table)
	• Any other medicine where concomitant use with clarithromycin is contraindicated.
	** May not be readily available in the UK*
	
	See BNF for all drugs that can interact with clarithromycin.
	
	NB. The list is not exhaustive. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
	
	Call medical cover for advice if appropriate and document advice given.

Identification and management of adverse reactions	The following list of adverse reactions is not exhaustive. 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/BNF as **very common or common** with clarithromycin (but may not reflect all reported side effects): • Gastrointestinal discomfort; including dyspepsia, diarrhoea, nausea and vomiting, abdominal pain, pancreatitis • Abnormal liver function tests • Decreased appetite • Dizziness • Headache • Hearing impairment • Insomnia • Skin rashes/reactions, hyperhidrosis, paresthesia; • Taste altered • Vasodilation • Vision disorders 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. 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. In case of anaphylaxis: • Refer to adrenaline (epinephrine) PGD 0017 and anaphylaxis procedure • 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 CLARITHROMYCIN** and record the manufacturer. • The individual may be advised to wear a MedicAlert or similar device to alert other healthcare providers • Report via Datix Once for Wales Reporting system

Management of and reporting procedure for adverse reactions	• Healthcare professionals and individuals/carers/parent/guardians are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: https://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the individual's clinical record. Report suspected adverse reactions to a doctor. • Report via organisation incident policy. All significant adverse drug reactions must be recorded via the Datix Once for Wales Reporting system • It is considered good practice to notify the individual's GP in the event of an adverse reaction.
Additional facilities and supplies	• Access to a weighing scale suitable to weigh children

Written information to be given to individual/ carer/parent/ guardian	• Supply appropriate number of pre-labelled MIU pack(s) of clarithromycin tablets or oral suspension/oral solution.
	• Write the individual's name, date of supply, appropriate number of tablets/ml to be taken and duration (as per dosage section) on the medication label.
	• Provide marketing authorisation holder's information leaflet (PIL) provided with the product.
	• Provide safety netting advice and advise individual/carer/parent/guardian of alternative treatment available using TARGET self-care leaflet if appropriate.
	• Utilise TARGET antibiotic checklist for counselling individuals/carers/parents/guardians.
	• Give any additional information in accordance with the local service specification.
	• If relevant, provide the individual/carer/parent/guardian with appropriate information on avoidance of insect bites and stings.
	• If relevant, provide patient information on cellulitis, for example:
	  ○ The British Association of Dermatologists (BAD) leaflet Cellulitis and erysipelas.
	  ○ The Lymphoedema Support Network information About cellulitis.
	  ○ The NHS information on Cellulitis.

Individual advice / follow up treatment	• Give appropriate advice if the medication is used off-label. • Explain the dose, frequency and method of administration. • The individual/carer/parent/guardian should be advised to read the PIL. • Store reconstituted oral suspension (or oral solution) in

	accordance with the conditions as outlined in the individual product SPC (storage recommendations may vary between different reconstituted oral suspension (or oral solution) products).
	• Initial pain and swelling should be managed with appropriate over the counter (OTC) pain relief such as paracetamol or ibuprofen (where appropriate), and the use of a cold compress (flannel or cloth cooled with cold water) over the affected area.
	• If treating insect bites and stings, oral antihistamines (e.g. chlorphenamine [sedating]) or topical corticosteroids (e.g. hydrocortisone 1%) may help reduce itching but use is off-label and good quality evidence supporting its use is lacking.
	• Seek medical attention immediately if condition deteriorates and/or individual becomes systemically unwell
	• Advise individual/carer/parent/guardian that if rash or other signs of hypersensitivity occur, stop taking the medicine and seek immediate medical advice
	• Hygiene measures are important to aid healing. It is recommended that the individual;
	  ○ Avoids scratching affected areas, and keeps fingernails clean and cut short, wear cotton gloves if necessary
	  ○ Keep hands clean before and after touching the skin
	• Advise individual/carer/parent/guardian to take the medication at regular 12 hour intervals and to finish the course.
	• If dose is missed advise to refer to the PIL supplied with the product
	• Inform individual/carer/parent/guardian of possible side effects and their management. Parents and carers should be advised to seek medical attention if vomiting or irritability with feeding occurs, due to the risk of infantile hypertrophic pyloric stenosis.
	• Advise individual/carer/parent/guardian to complete the full course even if symptoms improve.
	• If treating an infected insect sting, advise individual/carer/parent/guardian to remove visible stingers as quickly as possible by scraping sideways with a fingernail, a piece of card or a credit card.
	• Advise individual/carer/parent/guardian to seek medical attention if symptoms worsen rapidly or significantly at any time, if there is severe pain that is out of proportion to the infection, significantly worse than the appearance of the wound (may indicate the presence of toxin-producing bacteria), or if redness or swelling extends beyond the initial presentation.
	• Advise individual/carer/parent/guardian to seek medical

	attention if symptoms do not improve after completion of antibiotic treatment course (if treating infected insect bites and stings), or if symptoms do not start to improve in 2 to 3 days (if treating cellulitis and erysipelas). • Advise individual/carer/parent/guardian to seek immediate medical attention (by calling 999 or going to A&E) if the individual develops signs or symptoms of sepsis. • Advise individual/carer/parent that skin does take time to return to normal, and full resolution of skin redness and itch may take up to 10 days (if treating infected insect bites and stings). • The individual/carer/parent/guardian should be advised to seek medical advice in the event of an adverse reaction or if any other new symptoms develop. • Advise individual/carer/parent/guardian to return any unused medicines to a pharmacy for disposal: do not dispose of medicines in the bin, down the sink or toilet. • If relevant, avoid the use of compression garments during acute cellulitis • If individual is being treated for cellulitis, the affected limb may be elevated for pain relief and to reduce oedema where appropriate • If individual has cellulitis, advise on preventative measures to reduce the risk of recurrence, including weight loss (where applicable, see the CKS topic Obesity) and the use of emollients to prevent dry skin and cracking. • If individual has two or more separate episodes of cellulitis in 12 months, advise to discuss with GP (to consider routine referral to secondary care for advice on the use of prophylactic antibiotics). • If a swab has been taken, the individual/carer/parent/guardian 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.
Records	Record consultation details as required by local procedures. Appropriate records must include the following: • That valid informed consent has been given. Record name of representative who gave consent, if appropriate. • Individual's name, address, date of birth • Name of GP individual is registered with or record where an individual is not registered with a GP • Name of registered healthcare professional operating under the PGD • Specify how the individual has/has not met the criteria of the PGD • Relevant past and present medical history and medication

	history • Name/dose/form/strength/quantity of medicine supplied • Date and time of supply • Documentation of cautions as appropriate • Advice given if individual excluded or declines treatment • Details of any ADRs/allergy status and actions taken • Measure and record weight of child where appropriate • That supply was made under a PGD, record PGD title and version number • Any safety incidents, such as medication errors, near misses and suspected adverse events • Expiry date of medicine supplied • Any additional requirements in accordance with the service specification • GP to be notified of MIU attendance, any treatment and medication given via a discharge letter, which is posted the same day • All records should be kept in line with national guidance. This includes individual data, master copies of the PGD and lists of authorised practitioners. • Advice given about the medication including side effects, benefits, and when and what to do if any concerns • Any advice received from medical cover and advice given to individual/carer/parent/guardian • If a swab has been taken, document advice given, results (when available) and action taken **Records must be signed and dated (or a password controlled e-records).** **All records must 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.**

Key references (last accessed November 2023)

- Electronic Medicines Compendium http://www.medicines.org.uk/
- Electronic BNF https://bnf.nice.org.uk/
- Electronic BNF for children https://bnfc.nice.org.uk/
- Reference guide to consent for examination or treatment https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/138296/dh_103653__1_.pdf
- Medicines for Children. Clarithromycin for bacterial infections. https://www.medicinesforchildren.org.uk/medicines/clarithromycin-for-bacterial-infections/
- NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2
- NICE Clinical Guideline 182 "Insect bites and stings: antimicrobial prescribing" https://www.nice.org.uk/guidance/ng182
- NICE Clinical Guidance 141 "Cellulitis and erysipelas: antimicrobial prescribing NG141" https://www.nice.org.uk/guidance/ng141
- NICE Clinical Knowledge Summaries "Insect Bites and Stings" https://cks.nice.org.uk/topics/insect-bites-stings/
- Cellulitis Guidelines for People with Lymphoedema/Chronic Oedema in NHS Wales- v 6.0 accessed 21/01/26
- NICE Clinical Knowledge Summaries "Acute Cellulitis" https://cks.nice.org.uk/topics/cellulitis-acute/
- TARGET Self-care leaflet. Leaflets to discuss with patients: Self-care Leaflet (rcgp.org.uk)

Appendix A Staff accredited to use the 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 required 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, 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.