GIG CYMRU NHS WALES
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. Health professionals should always access the PGD via the PTHB internet to ensure that they are always working to the most up to date version

PATIENT GROUP DIRECTION (PGD)

for the administration/supply of

flucloxacillin capsules/oral solution/oral suspension

by registered nurses

to individuals aged over 2 years

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

in Powys Teaching Health Board Minor Injury Units

Version number: PGD 0188B

Reference Number: PGD0188B
Valid from: 26/02/2025
Review Date: 31/08/26
Expiry Date: 28/02/27

Change History

Version number	Change details	Date
PGD0188	Initial Issue	11/03/2022
PGD0188-A	Review issue, updated clinical content. Use of SPS template version 1.0	10/11/2024
PGD0188-B	Review issue. Use of SPS template version 1.1. (PGD for the supply of flucloxacillin capsules/oral solution/oral suspension for the treatment of infected insect bite(s) and sting(s)) • Definition of insect included in Clinical condition or situation to which this PGD applies: "† 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)." • Exclusion criterion amended from "Bite or sting occurred while travelling outside the UK" to "Bite or sting occurred while travelling outside the UK with concern of insect borne disease e.g. malaria, tick borne encephalitis". Tick borne encephalitis added to section "Action to be taken if the individual is excluded" • Voriconazole added to list of contraindicated concomitant medicines in "Drug Interactions" and "Exclusions" sections.	26/02/2025

This Powys Teaching Health Board (PTHB) PGD is based on the flucloxacillin SPS PGD template v1.1 for the treatment of infected insect bite(s) and sting(s).

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 the addition of the clinical condition of the 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...	3/3/2025
Senior pharmacist **Jayne Price**	Head of Community Services Medicines Management/Pharmacy	DocuSigned by: Jayne Price A9AFDC3B15294CC...	2/27/2025
Clinical Governance Lead **Amanda Edwards**	Clinical Governance Lead for PTHB Assistant Director for Innovation and Improvement	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	3/11/2025
Senior representative of professional group using the PGD **Claire Roche**	Executive Director of Nursing and Midwifery for PTHB	DocuSigned by: Claire Roche F07413E114E04B1...	3/3/2025

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

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

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. 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.**

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation for 25 years after the PGD expires.
Practitioners and organisations must check that they are using the current version of the PGD.

[1] This includes any relevant amendments to legislation

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 nurse currently registered with the Nursing and Midwifery Council (NMC). Practitioners must also have a current contract of employment with PTHB and be working in a Powys Minor Injury Unit. 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 administration and supply of flucloxacillin and knowledge of its uses, contraindications and adverse effects.
	
	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:
	  ○ NICE CKS Insect bites and stings resources
	  ○ An understanding of NICE Guideline 141 on Cellulitis and erysipelas: antimicrobial prescribing – see Appendix B: visual summary
	  ○ Safe and accurate reconstitution of the powder – refer to section below: Instructions for reconstitution
	• 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.
	• Undertaken appropriate training and successfully achieved competency for the identification of sepsis which includes:
	  ○ mandatory sepsis training: 000 NHS Wales RRAILS eLearning programme (acute deterioration)– PTHB staff to access via ESR.
	• Undertaken appropriate training for working under PGDs for the supply and administration of medicines. Must have completed Patient Group

	Directions training (available via eLfH PGD eLearning programme. PTHB staff to access via ESR). 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. • 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 and have up to date Intermediate Life Support skills • should fulfil any additional requirements defined by local policy **The individual practitioner must be authorised by name, 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) and 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. • Staff operating under this PGD should review their competency using the NICE Competency Framework for health professionals using patient group directions • Evidence of training in ILS, anaphylaxis and safeguarding.

	• Practitioners must be competent, recognise their own limitations and personal accountability and act accordingly. • 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 – see Appendix B: 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. Updating at least every 2 years or earlier in response to new local/national guidance on the administration/supply of flucloxacillin and the treatment of insect bites/stings and the treatment of skin and soft tissue infection and wounds. Practitioners must ensure they are up to date with relevant issues and clinical skills and management of anaphylaxis, ILS, with evidence of appropriate Continued Professional Development (CPD). Evidence of appropriate Continued Professional Development (CPD) must be retained and made available on request. Compliance with all mandatory NHS training including safeguarding at the level relevant to the role. Evidence of ongoing / refresher training to be submitted to line manager annually. **It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.** **The decision to administer or supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.**

Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Treatment of skin and soft tissue infection and wounds in individuals aged 2 years and over (including following insect† bite(s) and sting(s)) where a 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). Flucloxacillin at high doses is active against the large majority of staphylococcal and streptococcal species that cause cellulitis therefore is recommended by NICE Guidelines on Management of acute cellulitis as empirical treatment. **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 risk of 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 administered/supplied via this PGD if appropriate based on inclusion/exclusion criteria however the individual must be informed that treatment may change once 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/administering healthcare professional to ensure that the patient is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the treatment.**

	If there is any reason for concern, seek medical advice.
Criteria for inclusion	• 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 • Medical and drug history taken, no reason for exclusion • Individuals aged 2 years and over • Diagnosis of infected insect bite or sting using the appropriate diagnostic (NICE CKS) guidance or infection of skin or soft tissues or wounds. • **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 pustular discharge at site of bite(s) or sting(s) • **Infection of skin or soft tissues/Infected wounds** ○ Symptoms or signs of infection are increased pain, inflammation, fever, discharge or an unpleasant smell
Criteria for exclusion	• Conditions outside of the clinical situations criteria • Individuals who have not given valid consent (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005, has not been obtained). Several resources are available to inform consent (see written information to be given to individual, parent or carer section). This must be documented in the individual's medical notes. • Individuals under 2 years of age

	• Pregnancy or suspected pregnancy in individuals under 16 years of age • 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 flucloxacillin, any penicillin or any of the components within the formulation of flucloxacillin – see Summary of Product Characteristics. **OR** • History of severe immediate hypersensitivity reaction (e.g. anaphylaxis) to another beta-lactam antibiotic (e.g. cephalosporin, carbapenem or monobactam). • Inability to absorb oral medications and/or inability to swallow oral dosage formulations (i.e. capsules or oral solution (or oral suspension)) • Individuals following a ketogenic diet • Failed previous antibiotic for this episode of infected insect bite or sting or spreading infection not responding to oral antibiotics

	• Any individual suspected of having a systemic reaction to an insect bite or sting or tissue infection e.g. 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) • Significant collection of fluid or pus at site of infection (for incision and drainage, where appropriate) • 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. Patients with Class III and IV cellulitis – require urgent hospital admission

	• Previous or current known met(h)icillin-resistant *Staphylococcus aureus* (MRSA) colonisation or infection • Individuals with previous or current history of liver disease • Individuals with a previous history of flucloxacillin associated jaundice/liver dysfunction • Known Chronic Kidney Disease (CKD) stage 5 (eGFR <15ml/min/1.73m²) • Individuals at risk of high anion gap metabolic acidosis (HAGMA) (e.g. malnutrition, sepsis, renal impairment) who are recently or currently taking paracetamol. • Individuals with symptoms or signs suggesting a more serious illness or condition, e.g. orbital cellulitis, osteomyelitis, septic arthritis, necrotising fasciitis or sepsis • Individual with lymphangitis • Less than 3 days before receiving, or within 3 days after receiving, oral typhoid vaccine • Less than 14 days before receiving, or within 10 days after receiving live cholera vaccine Concurrent use of any interacting medicine as listed in Drug Interactions section of this PGD • Methotrexate • Probenecid • Voriconazole • Typhoid vaccine (oral) • Live cholera vaccine: see above • Paracetamol: recent or current use in individuals at risk of HAGMA with other risk factors (e.g. malnutrition, sepsis, renal impairment). *Paracetamol can be taken concomitantly with flucloxacillin in patients without these risk factors.* Refer to sections action to be taken if the individual is excluded and action to be taken if the individual/carer/parent/guardian declines treatment. **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:** Flucloxacillin can be used in breastfeeding individuals: monitor nursing infant for gastro-intestinal disturbances, oral candida infection, hypersensitivity and rash. **********

	Caution should be exercised when administering/supplying flucloxacillin to individuals taking the following medicine(s): **Coumarin anticoagulants (e.g. warfarin, acenocoumarol, phenindione):** rises in INR reported. Individuals should be advised to have their INR monitored while on treatment with flucloxacillin and should be counselled re: seeking medical attention if any episode of bleeding develops while taking. ********** Caution should be exercised when administering/supplying flucloxacillin capsules or oral solution (or oral suspension) 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 administering/supplying. **Aspartame:** Individuals with phenylketonuria (PKU) must not use medicines containing aspartame. Check the individual list of excipients available in the SPC before administering/supplying. ********** When managing cellulitis or erysipelas, refer patient to their GP to manage underlying conditions such as diabetes, venous insufficiency, eczema and oedema. Check for any other medications that the patient is taking, including topical or inhaled products, food supplements and herbal or homeopathic products. (Refer to BNF/SPC for full list) 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 the 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	• Explain reason to individual /carer /parent /guardian • Record reasons for exclusion in the appropriate clinical record **Individuals where treatment is not indicated:** • As appropriate, 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 to NHS website for insect bites and stings). **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 • Severe pain out of proportion to the wound • Individual has significant collection of fluid or pus at site of infection • 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 or sting 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 with symptoms or signs suggesting a more serious illness or condition, e.g. orbital cellulitis, osteomyelitis, septic arthritis, necrotising fasciitis or sepsis • 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 Consider referring people with cellulitis or erysipelas to hospital, or seek specialist advice, if they: ○ have infection near the eyes or nose (including periorbital cellulitis) or ○ could have uncommon pathogens, for example, after a penetrating injury, exposure to water-borne organisms, or an infection acquired outside the UK

	○ have lymphangitis • 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. • Contact GP or microbiologist for advice or refer to DGH if applicable. Document advice given. **NB If sepsis is suspected refer the individual urgently to A&E**
Action to be taken if the individual/carer/ parent/guardian declines treatment	Informed consent from the individual, or a person legally able to act on the individual's behalf, must be obtained for each supply/administration and recorded appropriately. The patient information leaflet should be available to inform consent. Document advice given. Complete a Discharge Against Advice Form if appropriate. Explain consequences of refusing treatment. • 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. Where appropriate, complete the letter on the WPAS system and send to the GP.

Arrangements for referral for medical advice	Refer to a prescriber if antibiotic appropriate but falls outside of this PGD. Document any advice given.

Description of treatment

Name, strength and formulation of drug	Flucloxacillin 500mg capsules Flucloxacillin 250mg/5mL oral solution (or oral suspension) x 100mL Flucloxacillin 250mg/5mL sugar free oral solution (or oral suspension) x 100mL **Note** • Capsules should not be issued to children under 12 years old
Legal category	Prescription Only Medicine (POM)
Black triangle▼	No
Off-label use	The doses used are off-label for all age groups. Use of high doses of oral flucloxacillin is well established and common practice. These doses provide optimal cover against both Staph aureus and group A Streptococci as per NICE Guidelines on Management of acute cellulitis. The healthcare professional should follow relevant professional guidance, taking full responsibility for the decision. Consider informing the individual / carer that it is being offered in accordance with best clinical practice but that this is outside the product license. Informed consent should be obtained and documented. **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 a pharmacy professional must ensure the medicine remains pharmaceutically stable and appropriate for use if it is to be issued. Where medicines have been assessed by a pharmacy professional in accordance with national or specific product recommendations/manufacturer advice as

	appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected medicines for use lies with the 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 opening capsules. Use in this way may be outside the product licence and is thus off-label. **Opening and dispersing** Flucloxacillin capsules can be opened and the contents tipped out and mixed with liquid or soft food. However, this **should not** be performed by anyone with, or in the vicinity of someone with a penicillin allergy. **Masking the taste** The capsule contents 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 powder with food or drink, give it straight away Although flucloxacillin is generally given on an empty stomach, evidence suggests that there is no difference in absorption when flucloxacillin is given with or without food. 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.
Route and method of administration	Orally 1 hour before or 2 hours after food. Capsules should be swallowed whole.

<table>
<tr><td></td><td>Note: Flucloxacillin sugar free oral solution (or oral suspension) may have a poor taste potentially leading to reduced compliance.
After discussion with individual/carer/parent/guardian consider sugar-containing preparation if available.

Children over 12 years should be encouraged (where possible) to swallow solid oral dose forms (i.e. tablets or capsules):
<u>Medicines for Children</u>: has useful guides on how to give medicines, including <u>giving tablets</u> and <u>giving capsules</u>.
<u>KidzMed</u> is an eLfH resource for healthcare professionals teaching children to swallow pills.</td></tr>
<tr><td>Instructions for reconstitution</td><td>Follow reconstitution instructions on the packaging.

After opening of the screw cap, ensure that the bottle cap seal is intact and tightly attached to the bottle rim. Do not use if not intact.
Shake the bottle to loosen the powder.
Add volume of potable water (as per instruction on the bottle label provided by the manufacturer). Note: volume may vary between different brands.
Shake until all contents are dissolved.
Ensure that either the expiry date or the date of reconstitution is marked on the label.
NB Oral solution must not be reconstituted by any nurse who has a history of severe penicillin allergy/anaphylaxis.</td></tr>
<tr><td>Dose and frequency of administration</td><td><table>
<tr><th>Children aged 2 – 9 years</th><th>Children aged 10– 17 years</th><th>Adults</th></tr>
<tr><td>250mg of flucloxacillin:
1 x 5mL spoonful of oral solution (or oral suspension) 250mg/5mL</td><td>500mg of flucloxacillin:
• 2x5mL oral solution (or oral suspension) 250mg/5mL
or
• ONE capsule of 500mg (if over 12 years old)</td><td>1g of flucloxacillin:
TWO capsules of 500mg</td></tr>
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<table>
<tr><td></td><td>FOUR times a day, ideally at six-hour intervals for 5 to 7 days.
To be taken at least 1 hour before or 2 hours after meals.
***C**ourse length depends on the severity of the infection and is based on clinical judgement*</td></tr>
<tr><td>Duration of treatment</td><td>5 to 7 days based on clinical judgement.
Treatment should be started immediately and the course of treatment completed</td></tr>
<tr><td>Quantity to be administered/ supplied</td><td>Pre-labelled packs:
<table>
<tr><th>Children 2 - 9 years old</th><th>Children 10 - 11 years old</th><th>Children 12 – 17 years old</th><th>Adults</th></tr>
<tr><td colspan="4">5 days course*</td></tr>
<tr><td>One bottle of 100mL of 250mg/5mL oral solution (or oral suspension)</td><td>Two bottles of 100mL of 250mg/5mL oral solution (or oral suspension)</td><td>28 x 500mg capsules</td><td>56 x 500mg capsules</td></tr>
<tr><td colspan="4">7 days course *</td></tr>
<tr><td>Two bottles of 100mL of 250mg/5mL oral solution (or oral suspension)</td><td>Three bottles of 100mL of 250mg/5mL oral solution (or oral suspension)</td><td>28 x 500mg capsules</td><td>56 x 500mg capsules</td></tr>
</table>
***course length depends on the severity of the infection and is based on clinical judgement*

NB. A 5ml medicine spoon or oral syringe must be provided with oral solution (or oral suspension).

Where appropriate, individuals must be advised that they have been supplied with full packs of medication, and will have an excess quantity at the end of the course. Excess medication must be returned to a pharmacy for disposal.</td></tr>
<tr><td>Storage</td><td>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</td></tr>
</table>

Drug interactions	Where it is known an individual is concurrently taking one of the following medicines, flucloxacillin must not be supplied under this PGD and the individual referred to a prescriber: • Methotrexate • Probenecid • Voriconazole • Typhoid vaccine (oral): see Criteria for exclusion • Live cholera vaccine: see Criteria for exclusion • Paracetamol: recent or current use in individuals at risk of HAGMA with other risk factors (e.g. malnutrition, sepsis, renal impairment). *Paracetamol can be taken concomitantly with flucloxacillin in patients without these risk factors.* A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Identification and management of adverse reactions	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 (British National Formulary) | NICE The following side effects are listed in the product SPC/BNF as **very common or common** with flucloxacillin (but may not reflect all reported side effects): • Diarrhoea • Nausea • Skin rash • Hypersensitivity • Vomiting • Thrombocytopenia (low levels of platelets in the blood) 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 must be available for immediate use. 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 patient notes • Ensure all patient records are marked **ALLERGIC TO flucloxacillin** • The patient may be advised to wear a MedicAlert or similar device to alert other healthcare providers • Report via Datix Once for Wales Reporting system
Reporting procedure for adverse reactions	• Healthcare professionals and individuals/carers/parents/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 or search for MHRA Yellow Card in the Google Play or Apple App Store. For established medicines, serious adverse events in adults or all suspected adverse reactions in children that may be attributable to the medication should be reported. Guidance on the yellow card system is available at the back of the BNF, or using the above link. • Record all adverse drug reactions (ADRs) in the individual's clinical record and report any suspected adverse reactions to a doctor. • Report and document in accordance with organisation incident policy. All significant adverse drug reactions should be reported via the Once for Wales Reporting System. • It is considered good practice to notify the individual's GP in the event of an adverse reaction.
Written information to be given to individual/ carer/ parent / guardian	• Supply pre-labelled MIU pack(s) of capsules or appropriate number of bottles of 100mL oral solution (or suspension). • Write the patient's name, date of supply, appropriate number of capsules/ml to be taken, frequency 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. • Give any additional information in accordance with the local service specification.

Individual advice / follow up treatment	• Give appropriate advice if the medication is used off-label.
	• Explain dose, frequency and method of administration.
	• The individual/carer/parent/guardian should be advised to read the PIL.
	• Store reconstituted oral solution (or oral suspension) in accordance with the conditions as outlined in the individual product SPC (storage recommendations may vary between different reconstituted oral solution (or oral suspension) products).
	• Initial pain and swelling as result of an insect bite 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 infected 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 the individual becomes systemically unwell
	• Advise individual 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 that flucloxacillin is a penicillin related antibiotic

	• Advise individual/carer/parent/guardian to take the medication at regular intervals and to finish the course. • Advise to give/take the capsules or oral solution (or oral suspension) with a glass of water and not to lie down immediately after taking (to reduce the risk of oesophageal pain after taking). • Advise individual/carer/parent/guardian that flucloxacillin should be taken on an empty stomach. This means one hour before for food or two hours after food. • 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. • Advise individual/carer/parent/guardian to complete the full course even if symptoms improve. • If treating infected insect bites and stings, 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 the 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 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.
Records	Record consultation details as required by local procedures. The practitioner must ensure the following is recorded: • that valid informed consent has been given. Record name of representative who gave consent if appropriate. • Individual's name, address and date of birth • Name of GP individual is registered with or record where an individual is not registered with a GP • Specify how the individual has/has not met the criteria of the PGD • Relevant past and present medical history and drug history taken, including any allergies and previous adverse events and actions taken • Name of registered healthcare professional operating under the PGD • Name/dose/form/quantity of medicine administered/supplied • Date and time of administration/supply • Expiry date of medication administered/supplied • Documentation of cautions as appropriate • Any safety incidents, such as medication errors, near misses and suspected adverse events • Any reasons for exclusion or referral, including advice given and actions taken • Advice given, including advice given if the individual declines treatment • Details of any adverse drug reactions and actions taken • Administered/supplied via PGD, record PGD version number • If a swab has been taken, document advice given, results (when available) and action taken All records should be kept in line with national guidance. This includes individual data, master copies of the PGD and lists of authorised practitioners.

	Records should be signed and dated (or password-controlled on e-records). All records must be clear, legible and contemporaneous. Appropriate health records should be kept and the individual's GP informed. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

Key references

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 "Flucloxacillin in bacterial infections" https://www.medicinesforchildren.org.uk/medicines/flucloxacillin-for-bacterial-infections/ • NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2 • 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/ • NICE Clinical Knowledge Summaries "Acute Cellulitis" https://cks.nice.org.uk/topics/cellulitis-acute/ • Specialist Pharmacy Service: Flucloxacillin Lactation Safety Information https://www.sps.nhs.uk/medicines/flucloxacillin/ • 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 requested for audit purposes. This list should be kept by PTHB for 25 years after the PGD expires.

The healthcare professional should retain a copy of the document after signing.

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

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

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

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

Appendix B Visual Summary