NHS England
Drug v

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.

PATIENT GROUP DIRECTION (PGD)

Supply of flucloxacillin capsules/oral solution/oral suspension for the treatment of infected insect bite(s) and sting(s) under the NHS England commissioned Pharmacy First service

Version Number 1.1

Change History	
Version and Date	**Change details**
Version 1.0 January 2024	New template
Version 1.1 January 2025	• 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" • Voriconazole added to list of contraindicated concomitant medicines in "Drug Interactions" section

ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Senior doctor	Prof. Sir Stephen Powis National Medical Director		29.04.25
Senior pharmacist	David Webb Chief Pharmaceutical Officer		29.04.25
Specialist in microbiology	Prof. Mark Wilcox National Clinical Director, IPC/AMR		29/04/25
Person signing on behalf of authorising body	David Webb Chief Pharmaceutical Officer		29.04.25

PGD DEVELOPMENT GROUP

Date PGD comes into effect:	31/01/2024
Review date	30/07/2026
Expiry date:	30/01/2027

This PGD has been peer reviewed by the skin antimicrobial national PGD Short Life Working Group in accordance with their Terms of Reference. It has been reviewed 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.

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

Characteristics of staff

Qualifications and professional registration	Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.
Initial training	• The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and be competent to undertake clinical assessment of patients ensuring safe provision of the medicines listed in accordance with the specification. • To deliver this service, the registered healthcare professional should have evidence of competence in the clinical skills and knowledge covered in the Centre for Pharmacy Postgraduate Education (CPPE) Pharmacy First Service self-assessment framework. • Before commencement of the service, the pharmacy contractor must ensure that pharmacists and pharmacy staff providing the service are competent to do so and be familiar with the clinical pathways, clinical protocol and PGDs. This may involve completion of training.
Competency assessment	• Individuals operating under this PGD must be assessed as competent or complete a self-declaration of competence to operate under this PGD (see an example authorisation record sheet in Appendix A). • Individuals operating under this PGD are advised to review their competency using the NICE Competency Framework for health professionals using patient group directions.
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.
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	Infected insect† bite(s) and sting(s) in children aged 1 year and over and adults. † 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).

Criteria for inclusion	• Informed consent
	• Individuals aged 1 year and over
	• Diagnosis of infected insect bite or sting using the appropriate diagnostic (NICE CKS) guidance.
	• 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)

Criteria for exclusion	• Consent refused and documented in the individual's medical notes
	• Individuals under 1 year 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. **Acceptable sources of allergy information include individual/carer/parent/guardian or National Care 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 or National Care Record**. • 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 • Any individual suspected of having a systemic reaction to an insect bite or sting i.e. angio-oedema or anaphylaxis • Previous systemic allergic reaction to the same type of bite or sting • 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 (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 • Insect sting/bite in the mouth or throat, or around the eyes • Puncture wound contaminated with freshwater or sea water, soil or manure. May require alternative antibiotics or further management such as tetanus prophylaxis. • Bite or sting 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 • Any individual identified with symptoms of severe/life-threatening infection or systemic sepsis: refer urgently via ambulance • 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. • 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
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 supplying flucloxacillin to individuals taking **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 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 supplying. ○ **Aspartame:** Individuals with phenylketonuria (PKU) must not use medicines containing aspartame. Check the individual list of excipients available in the SPC before supplying.
Specific information for suspected infection to be provided	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	• 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 to Community Pharmacy for pharmacist reassessment if: ○ Symptoms worsen at any time **OR** ○ Do not improve after 3 days of 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 • Severe pain out of proportion to the wound • Individual has significant collection of fluid or pus at site of infection • Animal bite or scratch • Human bite • Evidence of erythema migrans (bullseye rash, which may appear as a bruise on brown or black skin) • Bite or sting that occurred while travelling outside of the UK with concern of insect borne disease e.g. malaria • 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 • 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 **If sepsis is suspected refer the individual urgently to A&E**
Action to be taken if the individual/carer/parent/ guardian declines treatment	• Document advice given • Provide safety netting advice and advise individual/carer/parent/guardian of alternative treatment available using 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.
Arrangements for referral for medical advice	Refer to a prescriber if antibiotic appropriate but falls outside of this PGD.

Description of treatment

Name, strength & formulation of drug	Flucloxacillin 250mg capsules Flucloxacillin 500mg capsules Flucloxacillin 125mg/5mL oral solution (or oral suspension) x 100mL Flucloxacillin 125mg/5mL sugar free oral solution (or oral suspension) x 100mL Flucloxacillin 250mg/5mL oral solution (or oral suspension) x 100mL Flucloxacillin 250mg/5mL sugar free oral solution (or oral suspension) x 100mL
Legal category	POM
Route / method of administration	Orally 1 hour before or 2 hours after food. Capsules should be swallowed whole. *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.*

	Children should be encouraged (where possible) to swallow solid oral dose forms (i.e. tablets or capsules): • *Medicines for Children: has useful guides on how to give medicines, including giving tablets and giving capsules.* • *KidzMed is an eLfH resource for healthcare professionals teaching children to swallow pills.*
Off-label use	**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 pharmacist must ensure the medicine remains pharmaceutically stable and appropriate for use if it is to be issued. Where medicines have been assessed by a pharmacist 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 pharmacist. 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.
Dose and frequency of administration	**Children aged 1 year and over and under 2 years of age:** 125mg four times a day **Children 2–9 years:** 250mg four times a day **Children 10–17 years and adults:** 500mg four times a day
Duration of treatment	5 days **Treatment should be started immediately and 5 days of treatment completed.**
Quantity to be supplied	In line with the Pharmacy First service specification the best value product to meet the clinical need should be supplied from those listed within this PGD. **Children aged 1 and over and under 2 years of age:** Appropriately labelled pack of 1 x 100mL x 250mg/5mL oral solution (or oral suspension) **OR** appropriately labelled pack of 1 x 100mL x 125mg/5mL oral solution (or oral suspension) **Children 2–9 years** Appropriately labelled pack of 20 x 250mg capsules **OR** appropriately labelled pack of 1 x 100mL x 250mg/5mL oral solution (or oral suspension) **OR** appropriately labelled pack of 2 x 100mL x 125mg/5mL oral solution (or oral suspension) **Children 10–17 years and adults** Appropriately labelled pack of 20 x 500mg capsules **OR** appropriately labelled pack of 40 x 250mg capsules **OR** appropriately labelled pack of 2 x 100mL x 250mg/5mL oral solution (or oral suspension) **OR** appropriately labelled pack of 4 x 100mL x 125mg/5mL oral solution (or oral suspension)
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, 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 • 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 & 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 www.bnf.org 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.
Management of and 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 • Record all adverse drug reactions (ADRs) in the individual's clinical record. • Report via organisation incident policy. • 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	• 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. • Utilise TARGET antibiotic checklist for counselling individuals/carers/parents/guardians. • Give any additional information in accordance with the service specification.
Individual advice / follow up treatment	• 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.
	• 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.
	• 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.
	• Advise individual/carer/parent/guardian to seek medical attention if symptoms do not improve after completion of antibiotic treatment course.
	• 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.
	• 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.

Records	Appropriate records must include the following:
	
	• That valid informed consent has been given
	• 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
	• Name and registration number of registered healthcare professional operating under this PGD
	• Specify how the individual has/has not met the criteria of the PGD
	• Relevant past and present medical history and medication history
	• Any known allergies and nature of reaction(s)
	• Name/dose/form/quantity of medicine supplied
	• Date and time of supply
	• Documentation of cautions as appropriate
	• Advice given, including advice given if individual excluded or declines treatment
	• Details of any adverse drug reactions and actions taken
	• Advice given about the medication including side effects, benefits, and when and what to do if any concerns.
	• Any follow up and/or referral arrangements made.
	• Any supply outside the terms of the product marketing authorisation
	• The supply must be entered in the Patient Medication Record (PMR)
	• That supply was made under a PGD
	• Any safety incidents, such as medication errors, near misses and suspected adverse events
	• Any additional requirements in accordance with the service specification:
	  • The pharmacy contractor will ensure that a notification of the provision of the service is sent to the patient's general practice on the day of provision or on the following working day. Where possible, this should be sent as a structured message in real-time via the NHS assured Pharmacy First IT system. In the absence of an automated digital solution or if there is a temporary problem with the system, this should be sent via NHSmail or hard copy.
	  • Where an action is required by the General Practice team (such as booking the patient in for a follow up or appointment) an action message or alternative form of an URGENT ACTION communication (rather than the standard post event message) must be sent to the practice.
	• 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 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 must also be kept for audit purposes in accordance with the

	service specification.

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 – example registered health professional authorisation sheet (example – local versions/electronic systems may be used)

PGD Name/Version **Valid from:** **Expiry:**

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

Registered health professional

By signing this Patient Group Direction you are indicating that you agree to its contents and that you will work within it.

Patient Group Directions 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.			
Name	**Designation**	**Signature**	**Date**

Authorising manager

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of insert name of organisation for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

Add details on how this information is to be retained according to organisation PGD policy.