

This Patient Group Direction (PGD) must only be used by registered pharmacists who have been named and authorised by their organisation to practise under it. The most recent and in date final signed version of the PGD should be used.

# **Patient Group Direction**

for the supply of antibiotics

## **Flucloxacillin and Clarithromycin**

by registered pharmacists for

## **Infected Insect Bites and Stings**

in a Community Pharmacy within the East Region

Final Version

Reference Number:

Valid from: 25<sup>th</sup> August 2021

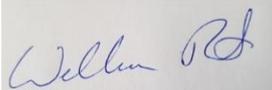
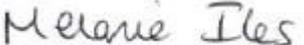
Review date: 31<sup>st</sup> August 2022

Expiry date: 31<sup>st</sup> December 2022

## PGD development

Name	Job title and organisation	Signature	Date
<b>Lead author &amp; Lead Pharmacist</b>	Pharmacist, Pharmacy LPN, East Region	Jane Newman	
<b>Lead doctor</b>	Associate Medical Director, NHS England & NHS Improvement, East of England		25/8/21
<b>Other members of the PGD working group</b>	Senior Community Pharmacy & Optometry Contract Manager	Jackie Bidgood	
	Pharmacist, Pharmacy LPN, East Region	Paul Duell	

## PGD authorisation

Name	Job title and organisation	Signature	Date
<b>Senior doctor (or dentist)</b>	Associate Medical Director, NHS England & NHS Improvement, East of England		25/8/2021
<b>Senior pharmacist &amp; Senior representative of professional group using the PGD</b>	Regional Chief Pharmacist		03/09/2021
<b>Person signing on behalf of authorising body</b>	Medical Director for System Improvement, NHS England & NHS Improvement, East of England		31/08/21

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## PGD adoption by the provider<sup>1</sup>

Name	Job title and organisation	Signature	Date
Signatures to be determined locally, if relevant			

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<sup>1</sup> Delete section if not relevant

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Training and competency of registered pharmacists	Requirements of registered pharmacists working under the PGD
<b>Qualifications and professional registration</b>	The pharmacist must be registered with the General Pharmaceutical Council.
<b>Initial training and competencies required to be held by staff undertaking this PGD</b>	<ul style="list-style-type: none"> <li>• Has a clear understanding of the legal requirements to operate a PGD.</li> <li>• Competent to follow and administer PGD showing clear understanding of indications for treatment (and subsequent actions to be taken), and the treatment itself.</li> <li>• Has a clear understanding of the drug to be administered including side effects and contra-indications.</li> <li>• Is competent in clinical assessment of the relevant conditions, aware of danger signs and symptoms and able to provide appropriate safety net advice.</li> <li>• Has read and understood the Service Level Agreement for this service.</li> </ul>
<b>Competency assessment</b>	<p>Every pharmacist signed up to the PGD must have completed the Self-Assessment Framework for Minor Ailments Declaration of Competency (DoC). Available from the Centre for Pharmacy Postgraduate Education (CPPE) website.</p> <p>The DoC system is a self-assessment and declaration process which provides pharmacy professionals with a framework to demonstrate to themselves, their employers and the service commissioners that they have the skills and knowledge necessary to provide a specific pharmacy service</p>
<b>Ongoing training and competency</b>	All clinicians operating within the PGD have a personal responsibility to ensure their on-going competency by continually updating their knowledge and skills.

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<p><b>Clinical condition or situation to which this PGD applies</b></p>	<p>Infected Insect Bites and Stings</p>
<p><b>Inclusion Criteria</b></p>	<p><b>Adults aged 18 and over</b> presenting with <b>superficial infection of the skin following an insect bite or sting</b> with symptoms that are indicative of Eron Class 1 Cellulitis. (No signs of systemic toxicity and the person has no uncontrolled co-morbidities: Refer to CKS for full details (1))</p> <p><b>Clear evidence of infection: An acute onset of red, painful, hot, swollen, and tender skin that has spread rapidly (all these features must be present).</b></p> <p>Treatment via this PGD can only be initiated where there is clear evidence of infection, indicated by cellulitis that is present or worsening at least 24 hours after the initial bite(s).</p> <p>Initial swelling/inflammation around the site of the bite should be managed in accordance with self-care guidance.</p> <p>Patient can be managed with oral antimicrobials in solid dosage form.</p>

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<p><b>Exclusion Criteria</b></p> <p><b>Patient not to be treated under PGD. Urgent referral for “red flag” symptoms</b></p>	<p>Patients who do not consent to answering the questions required, to the pharmacist verifying their registration with a GP or sharing information with their GP</p> <p><b>Red Flag:</b> Signs of systemic hypersensitivity reaction or anaphylaxis. Previous systemic allergic reaction to the same type of bite or sting.</p> <p><b>Red Flag: Signs of sepsis or systemic illness,</b> such as; patches of discoloured skin indicative of hemorrhagic (purpuric) rash; decreased urination; changes in mental ability; problems breathing; abnormal heart functions; chills due to fall in body temperature; unconsciousness; fever; headache; weakness.</p> <p><b>Red Flag: Bite or sting is in the mouth or throat or around the eyes.</b></p> <p>The bite or sting occurred whilst travelling abroad or was caused by an unusual or exotic insect.</p> <p>Uncontrolled co-morbidities</p> <p>Known allergy to both antibiotic treatment options</p> <p>Animal (dogs, cats etc.) or human bites</p> <p>If the skin appears black</p> <p>Pregnancy or breastfeeding</p> <p>More than 2 episodes of infected bites treated under this PGD within previous 12 months</p> <p>Patient aged 17 or under</p> <p>A very large area of red, inflamed skin – diameter great than 20cm</p> <p>If the area affected is causing numbness, tingling or other changes in a hand, arm, leg or foot.</p> <p>Facial cellulitis</p> <p>Moderate to severe renal impairment (CKD 4 or 5, eGFR less than 30ml/min. 1.73m<sup>2</sup>)</p> <p>Moderate to severe hepatic impairment</p>
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<p><b>Action to be taken if patient excluded</b></p>	<p>All exclusion criteria indicate the need for onward referral. Pharmacists should use their clinical judgement to determine the urgency, route and need for referral.</p> <p>Red flag symptoms need immediate medical consultation, refer to A&amp;E or call 999</p> <p>Record the reason for exclusion and any action taken</p>
<p><b>Arrangements for referral for medical advice</b></p>	<p>The spectrum of severity may range from localised erythema in a systemically well patient to the rapidly spreading erythema and fulminant sepsis seen with necrotising fasciitis. The urgency with which a referral needs to be made is based on the presenting symptoms following clinical examination.</p> <p>The options are:</p> <ul style="list-style-type: none"> <li>- Refer the patient for an urgent in-hours appointment</li> <li>- Call the NHS 111 service when the patient's own GP Practice is not available</li> <li>- Refer the patient to A&amp;E or call 999</li> </ul>
<p><b>Action to be taken if patient declines treatment</b></p>	<p>Hygiene measures are important to aid healing. It is recommended that the patient:</p> <p>Wash the affected areas with soapy water</p> <p>Keep hands clean before and after touching the skin</p> <p>Avoid scratching affected areas, and keep fingernails clean and cut short, wear cotton gloves if necessary</p> <p>Advise to seek medical help if symptoms worsen, if they become systemically unwell or show signs of anaphylaxis.</p>

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**Where treatment under PGD is indicated: Which of the following apply?**

Where patient can take penicillin? Use flucloxacillin	Penicillin allergy/sensitivity - Use clarithromycin	
Penicillin and macrolide allergy/sensitivity – refer to GP		

**Details of the medicine: Flucloxacillin supply (1<sup>st</sup> line option)**

Exclusion criteria for Flucloxacillin

Allergy/hypersensitivity to Penicillin's	
Renal or Hepatic impairment	
Taking medication with clinically significant interaction. The following list is not exhaustive. – Warfarin / Coumarin Anticoagulants - Methotrexate – Probenecid - Piperacillin.	
Check BNF and/or SPC (1)	
<b>Name, form and strength of medicine</b>	Flucloxacillin 500mg capsules or Flucloxacillin 250mg capsules
<b>Legal category</b>	POM
<b>Indicate any off-label use (if relevant)</b>	n/a
<b>Route/method of administration</b>	Oral
<b>Dose and frequency</b>	Take 500mg four times a day at regular six hourly intervals, if possible on an empty stomach. Take for 7 days.
<b>Quantity to be administered and/or supplied</b>	28 x 500mg or 56 x 250mg
<b>Maximum or minimum treatment period</b>	7 days
<b>Adverse effects</b>	The most common side effects associated with Flucloxacillin use include - Diarrhoea, Nausea, Vomiting, Skin rash. (2) FSRH no longer advises additional precautions when using Flucloxacillin with combined hormonal contraception. NB If antibiotic (+/or the condition itself) causes vomiting or diarrhoea in patient on CHC, additional precautions required.
<b>Records to be kept</b>	Counselling and advice given

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## Details of the medicine: Clarithromycin supply (2<sup>nd</sup> line treatment if Flucloxacillin is contra-indicated or excluded)

Exclusion Criteria for clarithromycin

Allergy/hypersensitivity to Clarithromycin
History of QT prolongation or ventricular cardiac arrhythmia
Pregnancy
Renal and/or hepatic impairment
Hypokalaemia
Breastfeeding
Concomitant use of medication that has a clinically significant interaction with Clarithromycin. <b>Check BNF/SPC (1)</b> This list is not comprehensive: Drugs metabolised by cytochrome P450 system - includes: oral anticoagulants, ergot alkaloids, phenytoin, ciclosporin and valproate. Also, HMG-CoA reductase inhibitors such as Simvastatin

<b>Name, form and strength of medicine</b>	Clarithromycin 500mg tablets or clarithromycin 250mg
<b>Legal category</b>	<i>POM</i>
<b>Indicate any off-label use (if relevant)</b>	<i>n/a</i>
<b>Route/method of administration</b>	Oral
<b>Dose and frequency</b>	<i>500mg twice daily (every 12 hours) for 7 days</i>
<b>Quantity to be administered and/or supplied</b>	14 x 500mg or 28 x 250mg
<b>Maximum or minimum treatment period</b>	7 days
<b>Adverse effects</b>	The most common side effects include - Diarrhoea, Nausea, Vomiting, Abdominal Pain, Metallic or bitter taste, Indigestion, Headache. (3) If person develops severe diarrhoea during or after treatment with Clarithromycin, consider pseudomembranous colitis and advise patient to immediately seek medical assistance.
<b>Records to be kept</b>	Counselling and advice given

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<p><b>Patient information</b></p> <p><b>Written information to be given to patient or carer</b></p>	<p>Provide the patient with the manufacturers Patient Information Leaflet and discuss as necessary.</p>
<p><b>Follow-up advice to be given to patient or carer</b></p>	<p><b>Pharmacist Advice to be given to all patients who receive PGD treatment:</b></p> <p>Take doses regularly and finish the course.</p> <p>Seek medical help if symptoms worsen rapidly or significantly at any time, or do not start to improve within 2 to 3 days.</p> <p>Advise the person to seek medical help if they:</p> <ul style="list-style-type: none"> <li>• Become systemically very unwell <b>or</b></li> <li>• have severe pain out of proportion to the infection <b>or</b></li> <li>• have redness or swelling spreading significantly beyond the initial presentation (taking into account that some initial spreading will occur and that redness may be less visible on darker skin tones). Note: consider recommending the patient draws with a pen around the extent of the infection at point of presentation to enable assessment of improvement or deterioration</li> </ul> <p>The skin takes some time to return to normal after the course of antibiotics has finished.</p> <p>Severe adverse reactions to antibiotics are rare, but anaphylaxis (delayed or immediate) has been reported and requires immediate medical treatment.</p> <p>Hygiene measures are important to aid healing. It is recommended that the patient:</p> <p>Wash the affected areas with soapy water</p> <p>Keep hands clean before and after touching the skin</p> <p>Avoid scratching affected areas, and keep fingernails clean and cut short, wear cotton gloves if necessary</p>

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<b>General advice</b>	Initial pain and swelling as a result of an insect bite should be managed with appropriate OTC pain relief if needed and a cold compress (flannel or cloth cooled with cold water) over the affected area.
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*Patients should be asked to report any serious adverse reaction to the pharmacist: The Pharmacist should notify patient's GP, record the information on the PMR, complete and submit a yellow card.*

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## Appendices

### Appendix A Key references

#### References

1. **NICE**. Insect bites and stings. *NICE CKS*. [Online] September 2020. <https://cks.nice.org.uk/topics/insect-bites-stings/>.
2. **BNF**. Flucloxacillin. *BNF*. [Online] <https://bnf.nice.org.uk/drug/flucloxacillin.html>.
3. —. Clarithromycin. *BNF*. [Online] <https://bnf.nice.org.uk/>.
4. **NICE**. Insect bites and stings: antimicrobial prescribing. *NICE guideline NG182*. [Online] 22 September 2020. <https://www.nice.org.uk/guidance/NG182>.
5. —. Cellulitis and erysipelas:antimicrobial prescribing. *NICE guideline NG141*. [Online] 27 September 2019. <https://www.nice.org.uk/guidance/NG141>.

#### Also refer to

[NICE guidance](#) and the [Summary of Product Characteristics](#)

### Appendix B Health professionals' agreement to practise

I have read and understood the Patient Group Direction and agree to supply and/or administer this medicine only in accordance with this PGD.

ODS Code & Pharmacy Name	Name of health professional	Signature	Senior representative authorising health professional	Date

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