

Patient Group Direction (PGD)
Supply of Flucloxacillin for Impetigo in patients aged one year and over
(Stoke on Trent and Staffordshire Pharmacies Only)

Version Control

This document is only valid on the day it was printed

The current version of this document will be found within the PharmOutcomes module – Pharmacy First PGD Service 2018 Impetigo

Revision History


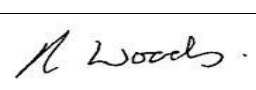
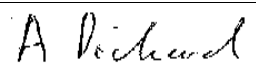
Date of this revision: 1st July 2018

Date of next revision: Before 31st March 2020 (or in response to new local/national guidelines)

Version	Date	Author	Change description
6.0 / 2018	June 2018	Andrew Pickard	Review of date expired PGD (V5)

Authorisation

This document requires authorisation by the following individuals:

Management			
PGD Author	Andrew Pickard, Pharmacy Advisor - NHS England North Midlands Staffordshire and Shropshire		
Authorisation			
Name and Designation	Organisation	Signature	Date
Dr Ken Deacon – Medical Director	NHS England North Midlands		30/07/2018
Rebecca Woods – Head of Primary Care	NHS England North Midlands		30/07/2018
Andrew Pickard - Pharmacy Advisor	NHS England North Midlands		30/07/2018

CLINICAL CONTENT OF PATIENT GROUP DIRECTION
Supply of Flucloxacillin for Impetigo in patients aged one year and over
(Stoke on Trent and Staffordshire Pharmacies Only)

Staff Characteristics	
1. Professional qualifications to be held by staff undertaking PGD	<ul style="list-style-type: none"> • Community pharmacists accredited by NHS England North Midlands to provide the Pharmacy First PGD Service
2. Competencies required to be held by staff undertaking this PGD	<ul style="list-style-type: none"> • Has a clear understanding of the legal requirements to operate a PGD. • Competent to follow and administer PGD showing clear understanding of indications for treatment (and subsequent actions to be taken), and the treatment itself. • Has a clear understanding of the drug to be administered including side effects and contraindications. • All clinicians operating within the PGD have a personal responsibility to ensure their on-going competency by continually updating their knowledge and skills.
3. Specialist qualifications, training, experience and competence considered relevant to the clinical condition treated under this PGD	<ul style="list-style-type: none"> • The community pharmacist must be registered with the General Pharmaceutical Council. • The community pharmacist must provide the service in accordance with the requirements of the associated Service Specification – Pharmacy First PGD Service 2018

Clinical Details	
Indication	<p>Impetigo (non-bullous infection).</p> <p>The use of oral antibiotics is considered as second-line therapy for localised lesions associated with impetigo.</p>
Inclusion Criteria	<p>Treat patients presenting with superficial infection of the skin with the following symptoms that are indicative of impetigo;</p> <ul style="list-style-type: none"> • Lesions that begin as vesicles or pustules, that rapidly evolve into gold-crusted plaques (typically up to 2cm in diameter) • Generally painless, but sometimes itchy • Affecting areas of the face, typically around the mouth and nose
Exclusion Criteria	<ul style="list-style-type: none"> • Bullous impetigo • Patients aged under one year • Systemic illness • Significant inflammation around lesions – consider cellulitis and refer • Lesions that are painful • Recurrent impetigo infection treated within previous 4 weeks • More than two episodes of impetigo treated under this PGD within previous 12 months • Pregnancy and breastfeeding • Moderate to severe renal and/or hepatic impairment • Allergy/hypersensitivity to penicillins – consider clarithromycin if oral antibiotic required • Concomitant use of medication that has a clinically significant interaction with flucloxacillin. The following list is not exhaustive; <ul style="list-style-type: none"> - Anticoagulants - Methotrexate - Probenecid <p>For a comprehensive list of interactions, please refer to SPC or BNF</p>
Management of excluded clients	<ul style="list-style-type: none"> • If patient meets exclusion criteria, refer to a medical practitioner. The urgency with which a referral needs to be made is based on the presenting symptoms following clinical examination. • If cellulitis suspected, or if patient presents with severe infection (including systemic symptoms) urgent referral to seek medical advice is required • Record the reason for exclusion and any action taken on PharmOutcomes.

Management of patients requiring referral	<p>If patient declines treatment or advice, ensure the following details are recorded on PharmOutcomes;</p> <ul style="list-style-type: none"> • The advice given by the clinician • Details of any referral made • The intended actions of the patient (including parent or guardian).
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Drug Details	
Name, form & strength of medicine	<ul style="list-style-type: none"> • Flucloxacillin 250mg and 500mg capsules • Flucloxacillin 125mg/5ml and 250mg/5ml oral solution (Sugar and Sugar Free formulations)
Legal classification	Prescription Only Medicine (POM)
Route/Method	Oral
Dosage/Frequency/ Duration of Treatment	<p>Dosage is dependent on age, weight and severity of infection. Refer to cBNF and BNF</p> <p>Usual children's dosage;</p> <ul style="list-style-type: none"> • Aged 1-2 years; 62.5mg–125mg four times a day* • Aged 2-9 years; 125mg - 250mg four times a day* • Aged 10-12 years; 250mg-500mg four times a day* <p>Usual adult dosage (12 yrs+); 500mg four times a day</p> <p>Duration of treatment is for 5 days</p> <p>Doses should be administered on an empty stomach at least half to one hour before meals</p> <p>* Use the higher dosage in each age range unless judged necessary to use lower cBNF dose</p> <p>Note: In children, sugar-free versions of Flucloxacillin suspension may have a poor taste leading to reduced compliance. In discussion with parent/guardian consider sugar-containing preparation.</p>
Quantity to supply/administer	<p>20 x 500mg capsules (or 40 capsules if the 250mg capsule is supplied)</p> <p>Oral suspension in multiples of 100ml to provide 5 days of treatment</p>
Storage	Capsules – Store in a dry place below 25°C

	<p>Unconstituted powder: Store in a dry place below 25°C. Protect from light</p> <p>Reconstituted oral suspension: Store for 7 days in a refrigerator.</p>
<p>Cautions</p>	<ul style="list-style-type: none"> • Pseudomembranous colitis has been reported with nearly all antibacterial agents, including flucloxacillin, and may range in severity from mild to life-threatening. • <i>Clostridium difficile</i>-associated diarrhoea (CDAD) has been reported with use of nearly all antibacterial agents including flucloxacillin, and may range in severity from mild diarrhoea to fatal colitis. CDAD must be considered in all patients who present with diarrhoea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents • Caution is advised when flucloxacillin is administered concomitantly with paracetamol due to the increased risk of high anion gap metabolic acidosis (HAGMA). Patients at high risk for HAGMA are in particular those with severe renal impairment, sepsis or malnutrition especially if the maximum daily doses of paracetamol are used. <p>Please refer to current BNF http://bnf.org/bnf/ and SPC for full details http://www.medicines.org.uk/emc/</p>
<p>Side Effects</p>	<p>Common side effects;</p> <ul style="list-style-type: none"> • Diarrhoea • Nausea • Vomiting • Skin rash <p>Severe adverse reactions are rare, but anaphylaxis (delayed or immediate) has been reported and requires immediate medical treatment.</p> <p>Please refer to SPC for uncommon and rare side effects</p> <p>Use the Yellow Card System to report adverse drug reactions directly to the MHRA. http://yellowcard.mhra.gov.uk/</p>
<p>Drug interactions</p>	<ul style="list-style-type: none"> • Probenecid and sulfapyrazone slow down the excretion of flucloxacillin by decreasing tubular secretion. • Oral typhoid vaccine may be inactivated by flucloxacillin.

	<ul style="list-style-type: none"> • Flucloxacillin reduces the excretion of methotrexate which can cause methotrexate toxicity. • There are rare cases of altered international normalised ratio (INR) in patients taking warfarin and prescribed a course of flucloxacillin. • Concomitant use with paracetamol has been associated with high anion gap metabolic acidosis, especially in patients with risk factors <p>Please refer to current BNF http://bnf.org/bnf and SPC www.medicines.org.uk/emc for full details</p>
<p>Advice to patients</p>	<p>Provide the patient with the manufacturer’s Patient Information Leaflet and discuss as necessary.</p> <ul style="list-style-type: none"> • Take doses at regular six hourly intervals if possible, on an empty stomach, and complete the course • Reassure the patient that impetigo usually heals completely without scarring, and that serious complications are rare • If symptoms have not improved after 5 days, advise patient to contact their GP • Hygiene measures are important to aid healing and stop infection spreading to other parts of the body and to other people. It is recommended that the patient; <ul style="list-style-type: none"> - washes the affected areas with soapy water - washes hands after touching a patch of impetigo - avoids scratching affected areas, and keeps fingernails clean and cut short - avoids sharing towels, flannels, clothing and bathwater until infection has cleared • Children and adults should stay away from school or work until the lesions are dry and scabbed over, or, if the lesions are still crusted or weeping, for 48 hours after antibiotic treatment has started. • It is no longer necessary to use an extra method of contraception with the pill, patch or vaginal ring when taking flucloxacillin unless the patient experiences diarrhoea and vomiting. This change in advice comes because to date there is no evidence to prove that antibiotics (other than rifampicin or rifabutin) affect these contraceptives. This is the latest guidance from the Faculty of Sexual & Reproductive Healthcare. <p>Please refer to current BNF http://bnf.org/bnf/ or SPC for full details http://www.medicines.org.uk/emc/</p>

Records and Follow Up	
Follow up	<ul style="list-style-type: none"> • Seek medical attention immediately if condition deteriorates and/or patient becomes systemically unwell • Advise patient that if rash or other signs of hypersensitivity occur, stop taking the medicine and contact their medical practitioner immediately • Seek medical attention if there is little improvement after 5 days of treatment
Records/audit trail	<ul style="list-style-type: none"> • In discussion with the client enter consultation details onto the relevant module within PharmOutcomes or complete the paper proforma if unable to access PharmOutcomes at the time of the consultation. All consultations must be entered onto PharmOutcomes on the day that the consultation takes place. • Details of the supply must also be made in the patients (PMR) record. • All supplies of flucloxacillin must be labelled in accordance with the labelling requirements for a dispensed medicine as stated within Schedule 5 of The Medicines (Marketing Authorisations etc) Regulations 1994. No 3144 as amended. In addition to the above, the label must also state the words “Supplied under a PGD” to help with audit purposes. • Informed verbal consent should be obtained (for clients aged under 16 years, Fraser guidelines should be followed) • Electronic patient records and/or the completed paper proforma should be retained for adults for a period of 10 years after attendance and for children until the child is 25 years old. Computerised patient medication records are recommended to be kept. • If the client is excluded, a record of the reason for exclusion must be documented within PharmOutcomes, and any specific advice that has been given. • In every case when a supply of flucloxacillin is made in accordance with this PGD, the pharmacist must inform the patients GP of the supply within two working days. This will be done through secure nhs.net email accounts via PharmOutcomes once the consultation data has been recorded within the specified module. Where no nhs.net account is available to PharmOutcomes, the pharmacist will be informed by the system and must make alternative arrangements to send the information (within two working days).

Adverse drug reactions	All serious adverse reactions must be reported to MHRA via the yellow card system www.yellowcard.gov.uk . A client presenting with a suspected serious ADR should be referred to their medical practitioner.	
Date last reviewed: June 2018	Date for next review: January 2020	
Expiry date: 31st March 2020	Version No: 6.0 / August 2018	

References	BNF – Current Version Clinical knowledge summaries – Impetigo – July 2015 Antimicrobial prescribing guidelines in general practice (Staffordshire) – 2016 Antibiotic guidance for Shropshire and Powys Primary Care – 2017 Electronic Medicines Compendium - SPC Flucloxacillin - 2018
Glossary	BNF – British National Formulary CKS – Clinical Knowledge Summaries SPC – Summary of Product Characteristics PIL – Patient Information Leaflet PGD – Patient Group Direction PMR – Patient Medication Record POM – Prescription Only Medicine MHRA – Medicines and Healthcare Products Regulatory Agency ADR – Adverse Drug Reaction LPC – Local Pharmaceutical Committee

PGD Workgroup

The following individuals have been involved with the production and review of this PGD;

Andrew Pickard MRPharmS	Pharmacy Advisor – NHS England North Midlands
Tania Cork MRPharmS	Chief Operating Officer – North Staffs and Stoke LPC
Hitesh Patel MRPharmS	Senior Pharmaceutical Advisor – Telford and Wrekin CCG

Register of practitioners qualified to supply Flucloxacillin for the treatment of Impetigo via PGD (Stoke on Trent and Staffordshire Pharmacies Only)

Operation of this PGD is the responsibility of the commissioner and service providers.

The practitioner must be authorised by name, under the current version of this PGD before working according to it.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Contractors who are commissioned to provide the service will be notified of any amendments, and provided with updated documentation for use by individual practitioners.

NHS England authorise this PGD for use by accredited community pharmacists delivering the service from community pharmacies that meet the requirements as outlined in the service specification and that have been commissioned by NHS England.

This page must be completed and retained by each individual pharmacist who intends to work in accordance with this PGD.

Professional Responsibility and Declaration

- I have successfully completed the relevant training as outlined in the Service Specification and this Patient Group Direction
- I agree to maintain my clinical knowledge appropriate to my practice in order to maintain competence to deliver this service
- I am a registered pharmacist with the General Pharmaceutical Council
- I confirm that indemnity insurance is in place to cover my scope of practice
- I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this PGD

Name of professional (please print)	Signature	Date of signing

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY