

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 erythromycin tablets/oral suspension/oral solution for the treatment of widespread non-bullous impetigo in pregnant individuals (aged 16 years and over) 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	Removal of:	

Version: 1.1



### **ORGANISATIONAL AUTHORISATIONS**

Name	Job title and organisation	Signature	Date
Senior doctor	Prof. Sir Stephen Powis National Medical Director	St. 76.	29.04.25
Senior pharmacist	David Webb Chief Pharmaceutical Officer	TAMO	29.04.25
Specialist in microbiology	Prof. Mark Wilcox National Clinical Director, IPC/AMR	Orte list.	29/04/25
Person signing on behalf of authorising body	David Webb Chief Pharmaceutical Officer	TAMO	29.04.25

Version: 1.1



### 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-	Lead Pharmacist, HCAI, Fungal, AMR, AMU & Sepsis Division, UK
Oredope	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
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	Security Agency
Jo Jenkins	Lead Pharmacist Patient Group Directions and Medicines
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Liz Cross	Advanced Nurse Practitioner QN
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Dr Michelle Toleman	Consultant Microbiologist
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Kieran Reynolds (SLWG	Specialist Pharmacist – Medicines Governance, Medicines Use
co-ordinator)	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

Version: 1.1



### **Characteristics of staff**

Qualifications and professional registration	Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.
Initial training	<ul> <li>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.</li> <li>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.</li> <li>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.</li> </ul>
Competency assessment	<ul> <li>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).</li> <li>Individuals operating under this PGD are advised to review their competency using the NICE Competency Framework for health professionals using patient group directions.</li> </ul>
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.	

Version: 1.1



### Clinical condition or situation to which this PGD applies

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Clinical condition or situation to which this PGD applies	Widespread non-bullous impetigo in young people and adults aged 16 years and over who are pregnant, or where pregnancy is suspected and where flucloxacillin is not appropriate due to hypersensitivity.
Criteria for inclusion	<ul> <li>Informed consent</li> <li>Individuals aged 16 years and over</li> <li>Signs and symptoms of impetigo using the appropriate diagnostic (NICE CKS) guidance.</li> <li>Widespread (4 or more lesions/clusters present) non-bullous impetigo</li> <li>Pregnancy or suspected pregnancy</li> <li>Known hypersensitivity to flucloxacillin, any penicillin or any of the components within the formulation flucloxacillin formulations - see Summary of Product Characteristics. Acceptable sources of allergy information include individual/carer/parent/guardian or National Care Record OR</li> <li>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</li> </ul>
Criteria for exclusion	<ul> <li>Consent refused and documented in the individual's clinical notes</li> <li>Individuals under 16 years of age</li> <li>Currently breastfeeding with impetigo lesion(s) on the breast(s) (see Cautions for advice when treating impetigo lesion(s) not on the breast(s) in breastfeeding individuals)</li> <li>Severely immunosuppressed individuals as defined in Chapter 28a Green book):         Individuals with primary or acquired immunodeficiency states due to conditions including:         <ul> <li>acute and chronic leukaemias, and clinically aggressive lymphomas (including Hodgkin's lymphoma) who are less than 12 months since achieving cure</li> <li>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)             </li> <li>immunosuppression due to HIV/AIDS with a current CD4 count of below 200 cells/µl.</li> <li>primary or acquired cellular and combined immune deficiencies – those with lymphopaenia (&lt;1,000 lymphocytes/ul) or with a functional lymphocyte disorder</li> <li>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</li> <li>those who have received a stem cell transplant more than 24 months ago but have ongoing immunosuppression or graft versus host disease (GVHD)</li> </ul> </li> <li>Individuals on immunosuppressive or immunomodulating therapy including:</li> </ul>

Version: 1.1



- 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.

- Immunosuppressed individuals: individuals who are immunosuppressed or are currently taking immunosuppressants (including systemic corticosteroids\*) or immune modulators, but who do not meet the definition of severe immunosuppression (see above).
   [For equivalent doses in children, see Chapter 6 Green Book]
  - \* does not include:
  - o replacement corticosteroids for individuals with adrenal insufficiency
  - o corticosteroid inhalers or corticosteroids applied topically (e.g. to the skin, ears, eyes, nasal cavity)
  - o intra-articular, -bursal or -tendon corticosteroid injections.
- Known hypersensitivity to erythromycin, a macrolide or any of the components within the formulation see <a href="Summary of Product Characteristics">Summary of Product Characteristics</a>. 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. tablets or oral suspension (or oral solution))
- Current long-term use of erythromycin or another macrolide antibiotic (e.g. erythromycin for prophylaxis in asplenia, azithromycin for prophylaxis in individuals with COPD or bronchiectasis etc.)
- Individuals following a <u>ketogenic diet</u>
- Failed previous oral antimicrobial treatment for this episode of impetigo
- Recurrent impetigo (defined as 2 or more episodes in the same year)
- Currently active underlying skin condition (e.g. currently uncontrolled episode of eczema (atopic dermatitis) or contact dermatitis, or current



- episode of scabies, chickenpox or eczema herpeticum)
- Localised (3 or fewer lesions/clusters present) non-bullous impetigo: consider topical treatment
- Bullous impetigo (characterised by flaccid fluid-filled vesicles and blisters (often with a diameter of 1-2cm) which can persist for 2-3 days. Lesions rupture, leaving a thin, flat, yellow-brown crust)
- Systemically unwell
- Signs/symptoms of a more serious condition/illness (e.g, swelling, large blisters, pain, pus or spreading redness)
- Any individual identified with symptoms of <a href="severe/life-threatening">severe/life-threatening</a> infection or systemic sepsis: refer urgently via ambulance
- Previous or current known met(h)icillin-resistant *Staphylococcus* aureus (MRSA) colonisation or infection
- Known myasthenia gravis
- Known history of QT prolongation (congenital or acquired), or ventricular cardiac arrhythmia, including torsades de pointe
- Concomitant use of another medication known to cause QT prolongation (e.g. see <u>Drug interactions</u> section for further information or recommended resources include: <u>CredibleMeds</u>; registration required, or <u>Sudden arrhythmic death syndrome (SADS) Drugs to avoid</u>)
- Known electrolyte disturbances (hypokalaemia or hypomagnesaemia)
- Known Chronic Kidney Disease (CKD) stage 5 (eGFR <15mL/min/1.73m<sup>2</sup>)
- · Known or suspected liver disease
- Concomitant use with a potentially hepatotoxic medicine (use information from the <u>SPC</u> or individual monograph on <u>LiverTox</u> to determine if concomitant medicines(s) are hepatotoxic)
- Known heart disease (e.g. coronary artery disease, severe cardiac insufficiency, conduction disturbances, bradycardia < 50 beats per minute)
- Known porphyria
- Less than 3 days before receiving, or within 3 days after receiving, oral typhoid vaccine
- Concurrent use of any interacting medicine as listed in <u>Drug</u> <u>Interactions</u> section of this PGD

### Cautions including any relevant action to be taken

- Breastfeeding individuals: avoid direct contact between infant and impetigo lesion(s). erythromycin can be used in breastfeeding individuals: monitor nursing infant for gastro-intestinal disturbances, oral candida infection, rashes, drowsiness, irritability, sweating and loss of appetite.
- Caution should be exercised when supplying erythromycin tablets or oral suspension (or oral solution) to individuals who should avoid the following excipients:
  - Lactose, sucrose, fructose and sorbitol: Individuals with rare hereditary problems of galactosaemia, galactose intolerance, total lactase deficiency, glucose-galactose malabsorption, sucrase-isomaltase deficiency, fructose-1,6-bisphosphatase deficiency (also known as hereditary fructose intolerance): check the individual list of excipients available in the <a href="SPC">SPC</a> before supplying.



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	Aspartame: Individuals with <u>phenylketonuria</u> (PKU) must not
	use medicines containing aspartame. Check the individual list
	of excipients available in the <u>SPC</u> before supplying.
Specific information	Provide information on impetigo (British Association of Dermatologists)
for suspected	Provide information on impetigo (NHS)
infection to be	
provided	
Action to be taken if	Record reasons for exclusion in the appropriate clinical record
the individual is	то от то от о
excluded	Individuals where treatment is not indicated:
OXOIGGG	Advise individual/carer/parent/guardian of alternative non antibiotic
	treatment if antibiotic not indicated and provide information on impetigo
	and safety netting advice.
	Advise individual/carer/parent guardian to seek medical advice if:
	<ul> <li>symptoms worsen rapidly or</li> </ul>
	<ul> <li>symptoms worsen significantly</li> </ul>
	Refer to a local health protection team (or a consultant in
	Communicable Disease Control) for further assessment if:
	Suspect a significant local outbreak (e.g. in a nursing home, crèche,
	school etc.)
	Refer urgently to a prescriber for further assessment if:
	Bullous impetigo (characterised by flaccid fluid-filled vesicles and
	blisters (often with a diameter of 1-2cm) which can persist for 2-3 days.
	Lesions rupture, leaving a thin, flat, yellow-brown crust)
	<ul> <li>Individual is systemically unwell, but not showing signs or symptoms of</li> </ul>
	sepsis
	Individuals considered to be clinically at high risk of complications (e.g.
	severely immunosuppressed or immunosuppressed and infection is
	localised)
	Recurrent impetigo (defined as 2 or more episodes in the same year)
	Individuals where treatment under this PGD is not indicated/permitted
	but dermatological symptoms are present and require further
	assessment
	Defendance which a AOT for forther access with
	Refer urgently to A&E for further assessment if:
	Individual is severely immunosuppressed or immunosuppressed and infection is widespread.
	<ul><li>infection is widespread</li><li>Signs/symptoms of a more serious condition/illness (e.g, swelling,</li></ul>
	<ul> <li>Signs/symptoms of a more serious condition/illness (e.g, swelling, large blisters, pain, pus or spreading redness) are present and</li> </ul>
	complications of impetigo (e.g. cellulitis, Staphylococcal scalded skin
	syndrome, or other deep soft tissue infection) are suspected.
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	If sepsis is suspected refer the individual urgently to A&E
Action to be taken if	Document advice given
the	Provide safety netting advice and advise
individual/carer/pare	individual/carer/parent/guardian of alternative treatment available using
nt/guardian declines	information on impetigo.
treatment	Refer to a prescriber if appropriate
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Version: 1.1



Arrangements for Refer to the appropriate medical practitioner in the care pathway
referral for medical advice

### **Description of treatment**

Route / method of administration  Tablets should be swallowed whole.  Temperature variations  Medicines should be stored according to the conditions de Storage section below. However, in the event of an inadve unavoidable deviation of these conditions the pharmacist is medicine remains pharmaceutically stable and appropriate be issued.  Where medicines have been assessed by a pharmacist in national or specific product recommendations/manufacture appropriate for continued use this would constitute off-label under this PGD.  The responsibility for the decision to release the affected relies with the pharmacist.  Manipulating solid dosage forms	
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In the event of an individual being unable to swallow solid formulations, and alternate liquid formulations not being reprovide advice on how to give doses by dispersing or crust in this way may be outside the product licence and is thus  Dispersing or crushing  The film-coated tablets can be crushed and mixed with liquid Crushing tablets should not be undertaken by anyone with vicinity of someone with a macrolide allergy. Enteric coate not be crushed and will not disperse in water.  Dispersing tablets  To disperse the tablet:  Place the tablet in the barrel of a 10mL oral syringer.	ertent or must ensure the erfor use if it is to accordance with er advice as el administration medicines for use oral dosage eadily available hing tablets. Use off-label.

Version: 1.1



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	<ul> <li>Replace the plunger</li> <li>Draw up approximately 5mL of water and 2mL of air</li> <li>Shake well and allow to disperse (this may take up to 10 minutes)</li> <li>Ensure all contents of the oral syringe are given in the mouth</li> </ul> Alternatively, the tablet may be mixed with 5 to 10mL of water in small glass or medicine cup and stirred well.
	Masking the taste
	The crushed tablet will taste bitter so it can be helpful to use a strongly flavoured drink (e.g. blackcurrant cordial) or food (e.g. jam, apple sauce, yoghurt) that the individual likes:
	<ul> <li>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</li> <li>It might be helpful to use an oral syringe for liquids</li> <li>After mixing the crushed tablet with food or drink, give it straight away</li> </ul>
	Note: some generic products advise to give one hour before food, however this is not necessary and is not practical in this situation.
	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	Young people and adults aged 16 years and over: 500mg four times daily
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.
	Young people and adults aged 16 years and over: Appropriately labelled pack of 20 x 500mg tablets <b>OR</b> appropriately labelled pack of 40 x 250mg tablets <b>OR</b> appropriately labelled pack of 2 x 100mL x 250mg/5mL oral suspension (or oral solution) <b>OR</b> appropriately labelled pack of 4 x 100mL x 125mg/5mL oral suspension (or oral solution)
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: <a href="www.medicines.org.uk">www.medicines.org.uk</a>
Drug interactions	Where it is known an individual is concurrently taking one of the following medicines, erythromycin must not be supplied under this PGD and the individual referred to a prescriber:
	<ul><li>Simvastatin</li><li>Tolterodine</li></ul>

Version: 1.1



- Amisulpride
- Astemizole, *cisapride\**, *mizolastine\**, domperidone, pimozide, *terfenadine\**.
- Ergotamine or dihydroergotamine
- Chloroquine or hydroxychloroquine
- Colchicine
- Lomitapide
- Typhoid vaccine (oral): see Criteria for exclusion
- Medicines where concomitant use with a moderate CYP 3A4 inhibitor (i.e. erythromycin) is contraindicated (e.g.
  - o Lercanidipine
  - Ivabradine
  - Quetiapine)
- Any medicine known to cause QT prolongation. For further information recommended resources include: <u>CredibleMeds</u>; registration required, or <u>Sudden arrhythmic death syndrome (SADS)</u> - <u>Drugs to avoid</u>)
- Medicines that are strong inducers of cytochrome P450 (CYP) and may reduce the efficacy of erythromycin (e.g.
  - o Rifampicin, rifabutin,
  - o Phenytoin, carbamazepine, phenobarbital,
  - St. John's wort.
  - o For further information recommended resources include:
    - Indiana University School of Medicine Drug Interactions
       Flockhart Table™
    - Mayo Clinic Labs Pharmacogenomic Association Table)
- Any other medicine where concomitant use with erythromycin is contraindicated

\*May not be readily available in the UK

Where it is known an individual is concurrently taking one of the following medicines, that are known or suspected to be affected by erythromycin, erythromycin must not be supplied under this PGD and the individual referred to a prescriber:

- Direct oral anticoagulants (DOACs) (e.g. apixaban, dabigatran, edoxaban, rivaroxaban) (see: MHRA/CHM advice).
- Statins
- Calcium channel blockers (amlodipine, diltiazem, felodipine, lercanidipine, nifedipine or verapamil)
- Digoxin
- Medicines known to cause hypokalaemia (e.g. diuretics, corticosteroids, xanthines).

See **BNF** for all drugs that can interact with erythromycin.

A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: <a href="https://www.medicines.org.uk">www.medicines.org.uk</a>

# Identification & management of

A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: <a href="https://www.medicines.org.uk">www.medicines.org.uk</a> and BNF <a href="https://www.bnf.org">www.bnf.org</a>



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adverse reactions	The following side effects are listed in the product SPC/BNF as very common or common with erythromycin (but may not reflect all reported side effects):  • Gastrointestinal discomfort; including diarrhoea, nausea and vomiting, pancreatitis  • Decreased appetite  • Dizziness  • Headache  • Hearing impairment  • Insomnia  • Skin rashes/reactions, paresthesia  • Taste altered  • Vasodilation  • Vision disorders
	Severe adverse reactions are rare, but <u>anaphylaxis</u> (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	<ul> <li>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: <a href="https://yellowcard.mhra.gov.uk">https://yellowcard.mhra.gov.uk</a></li> <li>Record all adverse drug reactions (ADRs) in the individual's clinical record.</li> <li>Report and document in accordance with organisation incident policy.</li> <li>It is considered good practice to notify the individual's GP in the event of an adverse reaction.</li> </ul>
Written information to be given to individual/carer/ parent/guardian	<ul> <li>Provide marketing authorisation holder's information leaflet (PIL) provided with the product.</li> <li><u>Signpost</u> individual/carer/parent/guardian to information re: transmission and the importance of good hygiene to prevent onward transmission.</li> <li>Utilise <u>TARGET antibiotic checklist</u> for counselling individuals/carers/parents/guardians.</li> <li>Give any additional information in accordance with the service specification.</li> </ul>
Individual advice / follow up treatment	<ul> <li>Explain the dose, frequency and method of administration.</li> <li>The individual/carer/parent/guardian should be advised to read the PIL.</li> <li>Store reconstituted oral suspension (or oral solution) in accordance with the conditions as outlined in the individual product SPC (storage recommendations may vary between different reconstituted oral suspension (or oral solution) products).</li> <li>Advise individual/carer/parent/guardian to seek medical advice if symptoms worsen rapidly or significantly at any time.</li> <li>Advise individual/carer/parent/guardian to seek immediate medical attention (by calling 999 or going to A&amp;E) if the individual develops signs or symptoms of sepsis.</li> <li>Inform individual/carer/parent/guardian of possible side effects and</li> </ul>

Version: 1.1



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- Advise individual/carer/parent/guardian to take/give the medication at regular intervals and to finish the course.
- If the individual is affected by dizziness or drowsiness advise them not to drive or operate machinery.
- 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.
- Individual/carer/parent/guardian should be advised of the following:
  - Impetigo is contagious and transmission occurs directly through close contact with an infected individual or indirectly via contaminated objects (e.g. toys, clothing, or towels).
  - Individuals, and if appropriate their family and carers/guardians, should be advised on good hygiene measures to reduce the spread of impetigo to other body areas and to other people.
  - To help stop impetigo spreading or getting worse (while it's still contagious), the following advice can be given to affected individuals:
    - Stay away from school or work (inform school or nursery of infection) until the individual is no longer contagious. Individuals are no longer contagious 48 hours after treatment has started OR when the lesions are healed, dry and crusted if no treatment is provided.
    - Food handlers are required by law to inform employers immediately if they have impetigo
    - Wash hands with soap and warm water before and after applying the cream
    - Wash flannels, sheets and towels at a high temperature
    - Wash or wipe down toys with detergent and warm water.
- If a dose is missed advise to refer to PIL supplied with the product
- Advise individual/carer/parent/guardian to complete the full course even if symptoms improve.
- Advise individual/carer/parent/guardian to return any unused medicines to a pharmacy for disposal: do not dispose of medicines in the bin, down the sink or toilet.

#### 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 <u>national guidance</u>. This includes individual data, master copies of the PGD and lists of authorised practitioners.

Records must be signed and dated (or a password controlled erecords).

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.

Version: 1.1



### **Key references**

# Key references (last accessed November 2023)

- British Association of Dermatologists. Impetigo Patient Information Leaflet (PIL). <a href="https://www.bad.org.uk/pils/impetigo/">https://www.bad.org.uk/pils/impetigo/</a>
- Electronic Medicines Compendium <a href="http://www.medicines.org.uk/">http://www.medicines.org.uk/</a>
- Electronic BNF https://bnf.nice.org.uk/
- Reference guide to consent for examination or treatment
   <a href="https://assets.publishing.service.gov.uk/government/uploads/system/uploads/">https://assets.publishing.service.gov.uk/government/uploads/system/uploads/</a>
   attachment data/file/138296/dh 103653 1 .pdf
- NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2
- NHS Specialist Pharmacy Service. Using solid oral dosage form antibiotics in children <a href="https://www.sps.nhs.uk/articles/using-solid-oral-dosage-form-antibiotics-in-children/">https://www.sps.nhs.uk/articles/using-solid-oral-dosage-form-antibiotics-in-children/</a>
- UK Sepsis Trust. Sepsis e-learning resources. https://sepsistrust.org/professional-resources/sepsis-e-learning/
- National Health Service. Impetigo. <a href="https://www.nhs.uk/conditions/impetigo/">https://www.nhs.uk/conditions/impetigo/</a>
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Version: 1.1



# 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.

Version: 1.1