Protocol for the supply of topical hydrogen peroxide 1% cream (e.g. Crystacide® 1% cream) for the treatment of localised non-bullous impetigo under the NHS England commissioned Pharmacy First service

Version Number 1.0

Change History	
Version and Date	**Change details**
Version 1 January 2024	New template

Version: 1.0
Reference Number: 3a
Valid from: 31/01/2024
Review date: 30/07/2026
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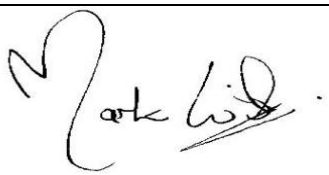
ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Senior doctor ***Professor Sir Stephen Powis***	National Medical Director, NHS England		11.12.23
Senior pharmacist ***David Webb***	Chief Pharmaceutical Officer, NHS England		08.12.23
Specialist in microbiology ***Professor Mark Wilcox***	National Clinical Director for AMR & IPC, NHS England		11.12.23
Person signing on behalf of authorising body ***David Webb***	Chief Pharmaceutical Officer, NHS England		08.12.23

Protocol DEVELOPMENT GROUP

This protocol has been developed by the national skin antimicrobial 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.
Training and competency requirements	**Initial training:** • The registered healthcare professional authorised to operate under this protocol 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 protocol must be assessed as competent or complete a self-declaration of competence to operate under this protocol (see an example authorisation record sheet in Appendix A). **Ongoing training and competency:** Individuals operating under this protocol are personally responsible for ensuring they remain up to date with the use of all medicines and guidance included in the protocol - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the protocol and further training provided as required.
The decision to supply any medication rests with the individual registered health professional who must abide by the protocol and any associated organisational policies.	

Clinical condition or situation to which this protocol applies	
Clinical condition or situation to which this protocol applies	Localised non-bullous impetigo in children over 1 year and adults who are systemically well and not at high risk of complications.
Criteria for inclusion	• Informed consent • Individuals aged 1 year and over • Signs and symptoms of impetigo using the appropriate diagnostic (NICE CKS) guidance. • Localised (3 or fewer lesions/clusters present) non-bullous impetigo
Criteria for exclusion	• Consent refused and documented in the individual's clinical notes • Individuals under 1 year of age • Pregnancy or suspected pregnancy in individuals under 16 years of age • Currently breastfeeding with impetigo lesion(s) present on the breast (see Cautions for advice when treating impetigo lesion(s) not on the breast(s) in breastfeeding individuals) • 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.*** • 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: • replacement corticosteroids for individuals with adrenal insufficiency • corticosteroid inhalers or corticosteroids applied topically (e.g. to the skin, ears, eyes, nasal cavity) • intra-articular, -bursal or -tendon corticosteroid injections. • Hypersensitivity to hydrogen peroxide or any of the components within the formulation - see Summary of Product Characteristics. **Acceptable sources of allergy information include individual/carer/parent/guardian or National Care Record**. • Failed previous topical or oral treatment (including antimicrobials) 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) • Any open wounds affecting the application area or the immediate vicinity • Widespread (4 or more lesions/clusters present) non-bullous

	impetigo • 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 severe/life-threatening infection or systemic sepsis: refer urgently via ambulance • Impetigo near the eyes: hydrogen peroxide can be irritant • Individuals using topical iodine, permanganates or other strong oxidising agents.
Cautions including any relevant action to be taken	• Breastfeeding individuals: avoid direct contact between infant and impetigo lesion(s). Wash hands after applying hydrogen peroxide 1% cream and before touching the infant. • Hydrogen peroxide cream can be irritant. A mild sensation of burning may be experienced for a short time after application and this is normal.
Specific information for suspected infection to be provided	Provide information on impetigo (British Association of Dermatologists) Provide information on impetigo (NHS)

Action to be taken if the individual is excluded	• Record reasons for exclusion in the appropriate clinical record
	
	Individuals where treatment is not indicated:
	• Provide individual/carer/parent/guardian with information on impetigo and safety netting advice.
	• Advise individual/carer/parent guardian to seek medical advice if:
	  ○ Symptoms worsen rapidly or
	  ○ Symptoms worsen significantly
	
	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)
	• Individual is systemically unwell, but not showing signs or symptoms of 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 protocol is not indicated/permitted but dermatological symptoms are present

	and require further assessment **Refer urgently to A&E for further assessment if:** • Individual is severely immunosuppressed or immunosuppressed and infection is widespread • Signs/symptoms of a more serious condition/illness (e.g, swelling, large blisters, pain, pus or spreading redness) are present and complications of impetigo (e.g. cellulitis, Staphylococcal scalded skin syndrome, or other deep soft tissue infection) are suspected. **If sepsis is suspected refer the individual urgently to A&E**
Action to be taken if individual/carer/ parent/guardian declines treatment	• Document advice given. • Provide safety netting advice and advise individual/carer/parent/guardian on alternative treatment available using information on impetigo. • Refer to a prescriber if appropriate.
Arrangements for referral for medical advice	• Refer to the appropriate medical practitioner in the care pathway

Description of treatment	
Name, strength & formulation of drug	Hydrogen peroxide 1% (10mg/1g) cream (e.g. Crystacide® 1% cream)
Legal category	P
Route/method of administration	Topical (cutaneous application) to the affected area(s) of the skin.
Dose and frequency of administration	**Children 1 year and over and adults:** Apply a thin layer to the affected area(s) up to 3 times a day Use enough of the cream to cover the lesion(s) with a thin layer of cream. A dry film will appear on the skin after each application, this can be washed off with water. Hands should be washed after this also.
Duration of treatment	5 days **Treatment should be started immediately and 5 days of treatment completed.**
Quantity to be supplied	**Children 1 year and over and adults:** Appropriately labelled tube of 25g cream. (The 40g tube may be supplied, only if the 25g tube is unavailable).
Storage	Stock must be securely stored according to organisation medicines policy and in conditions in line with SPC, which is available from the MHRA website: https://products.mhra.gov.uk/
Drug interactions	Hydrogen peroxide 1% cream is incompatible with topical iodine, permanganates and other stronger oxidising agents.

	Due to the external administration of the product and application of the active ingredients at a low dose, systemic absorption is very unlikely. Therefore, no clinically significant interactions are expected.
Identification & management of adverse reactions	A detailed list of adverse reactions is available in the SPC, which is available from the MHRA website: https://products.mhra.gov.uk/ The following side effect is listed in the product SPC for topical hydrogen peroxide cream (but may not reflect all reported side effects): ○ Paraesthesia (mild sensation of burning), which may be experienced for a short time after application. See Cautions for further information. 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: http://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the individual's medical record/medical notes. • If documenting an ADR in the individual's past mediation record (PMR), the individual's GP should be notified also. • Report via organization incident policy.
Written information to be given to individual/carer/parent/guardian	• Provide marketing authorisation holder's information leaflet (PIL) provided with the product (there is also a useful patient information leaflet provided by PrescQIPP: registration required). • Signpost individual/carer/parent/guardian to information re: transmission and the importance of good hygiene to prevent onward transmission • Give any additional information in accordance with the service specification.
Individual advice / follow up treatment	• Explain the dose, frequency and method of administration. • The individual/carer/parent/guardian should be advised to read the PIL (there is also a useful patient information leaflet provided by PrescQIPP: registration required). • Avoid contact with eyes: wash immediately with plenty of clean, cold water if comes into contact with eyes. • Hydrogen peroxide cream contains potential skin irritants: ○ Salicylic acid: a mild irritant which can cause dermatitis, ○ Propylene glycol: can also cause skin irritation. • Hydrogen peroxide cream can bleach fabric. Avoid contact with fabric. • Only apply to the affected area(s) and do not apply to large or deep wounds or to healthy skin. • Advise individual/carer/parent/guardian to seek medical advice if

	their impetigo has not improved after completion of treatment course or is getting worse (e.g. is becoming more widespread), or symptoms worsen rapidly or significantly at any time.
	• 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.
	• Inform individual/carer/parent/guardian of possible side effects and their management. A mild sensation of burning may be experienced for a short time after application and this is normal.
	• Advise individual/carer/parent/guardian to apply the medication at regular intervals and to finish the course.
	• 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 people:
	  ▪ 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 an application is missed, apply as soon as remembered.
	• Advise individual/carer/parent/guardian to complete the full course even if symptoms improve.
	• Dispose of tube 28 days after opening. Return to pharmacy for safe 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 protocol
• Specify how the individual has/has not met the criteria of the protocol
• 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 protocol
• 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 protocol 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 protocol must also be kept for audit purposes in accordance with the service specification.

Key references (last accessed November 2023)

- British Association of Dermatologists. Impetigo Patient Information Leaflet (PIL). https://www.bad.org.uk/pils/impetigo/
- Medicines and Healthcare products Regulatory Agency https://products.mhra.gov.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
- Reig Jofre UK Limited. Crystacide 1% cream. Summary of Product Characteristics. Medicines and Healthcare products Regulatory Agency. https://mhraproductsprod.blob.core.windows.net/docs-20200302/1604b32f4102b7c93966dea922fd4f77b1e8fdfc Accessed: 28th June 2023
- NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2
- National Health Service. Impetigo. https://www.nhs.uk/conditions/impetigo/
- National Institute of Health and Clinical Excellence Clinical Knowledge Summary. Impetigo. https://cks.nice.org.uk/topics/impetigo/
- National Institute of Health and Clinical Excellence guideline 153 (NG153). Impetigo: antimicrobial prescribing, https://www.nice.org.uk/guidance/ng153
- UK Sepsis Trust. Sepsis e-learning resources. https://sepsistrust.org/professional-resources/sepsis-e-learning/
- Loadsman MEN, Verheji TJM, van der Velden AW. (Aug 2019) Impetigo incidence and treatment: a retrospective study of Dutch routine primary care data*. Family Practice.* Vol 36: 4: 410–16. https://doi.org/10.1093/fampra/cmy104

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

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

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

Registered health professional

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

Protocols 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 protocol 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 protocol. I give authorisation on behalf of insert name of organisation for the above named health care professionals who have signed the protocol 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 protocol.

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