Minor Ailment Scheme (MAS) Patient Group Direction 05 version 2.1

The Administration / Supply of Hydrocortisone 1% cream or ointment by Community Pharmacists in NHS Devon Integrated Care Board

Authorised for use in NHS Devon Integrated Care Board

NameSmith Penny**.....**

Chief Nursing Officer or their nominated deputy in NHS Devon ICB

(Acting as Clinical Governance Lead for NHS Devon ICB)

Signed .....

Date07/02/2024**……...**

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The Administration / Supply of Hydrocortisone 1% cream or ointment for the treatment of mild skin conditions (including insect bites) by Community Pharmacists in NHS Devon Integrated Care Board

Staff involved in the development of this PGD:

	Name	Signature	Date
Physician	Dr Glen Allaway	Glen Allaway Glen Allaway (Feb 7, 2024 09:47 GMT)	07/02/2024
Pharmacist	Emma Tresidder	E.Tresidder E.Tresidder (Feb 7, 2024 09:37 GMT)	07/02/2024

Date of Implementation: 1st April 2024 **Expiry Date: 31st March 2026**

Pharmacy Authorisation (Lead Pharmacist for the location named below):

I have read and approved this PGD for use by appropriate named registered pharmacists employed at ……. Pharmacy and certify that this pharmacy is registered to provide the Pharmacy First Service. I understand that I am responsible for ensuring that my staff have adequate training in providing the Pharmacy First Services to patients in strict accordance with this PGD.

Signed…….. **Dated……**

Print Name: ……

As part of the development of this PGD we have taken into account all equality and diversity issues. Patients are only excluded from this PGD in line with national guidance or for safety reasons.

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Date of Implementation: 1st April 2024 Expiry Date: 31st March 2026

The Community Pharmacists named below, based at _____Pharmacy are authorised to supply Hydrocortisone 1% cream or ointment for the treatment of mild skin conditions (including insect bites) as specified under this Patient Group Direction

In signing this document, I confirm the following:

- I have read and understood the above mentioned PGD.
- I agree to practice only within the bounds of my own competence and in accordance with my Code of Professional Conduct.
- I have the qualifications required under the staff characteristics detailed in the PGD.
- I am competent to operate under this PGD and able to evidence this.
- I agree to administer/supply the above preparations in accordance with this PGD.

NAME *(Please print)*	TITLE	SIGNATURE	AUTHORISING MANAGER *(Please print)*	MANAGER'S SIGNATURE	DATE

NAME *(Please print)*	TITLE	SIGNATURE	AUTHORISING MANAGER *(Please print)*	MANAGER'S SIGNATURE	DATE

- **Complete additional pages as necessary.**
- **Retain all original signed pages with authorising manager.**

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1. Clinical Condition

Definition of condition/situation	Mild inflammatory skin conditions
Criteria for inclusion	Where patient/parent/guardian consent has been given for patients presenting **at the** Community Pharmacy: • Adults and children 10 years or over for use on the face (use on other areas should be purchased over the counter) presenting with acute dermatitis, mild eczema, or insect bite reactions. • Children aged 1 to 9 years presenting with acute dermatitis or mild eczema or insect bite reactions (including on the face for these indications) NB: Other appropriate medicines licensed for Pharmacy / OTC sale (and not part of this service) should be considered as an alternative or in addition to administration / supply under this PGD
Criteria for exclusion	• Where patient/parent/guardian consent has NOT been given. • Children under 1 year of age. • Adults and children aged 10 years and over where licensed OTC treatments are available. • Skin lesions caused by bacterial, fungal, or viral skin infections e.g., cold sores, impetigo, chickenpox, rosacea, acne, athlete's foot, or ringworm. • Infected eczema (including cellulitis or suspected cellulitis, weeping, rapidly worsening rash, fever). • Psoriasis. • Application to the periorbital area (including eyelids). • Allergy to any component of the cream / ointment. • Patients who have suffered any trauma to the area e.g., scratch, graze, or bite (human or animal). • Patients who have already tried topical corticosteroid unsuccessfully or where PGD supply will extend any existing topical corticosteroid therapy beyond a 7-day period. • Application to the ano-genital region. • Perioral dermatitis (persistent redness or small bumps (papules) and pustules primarily around the mouth but may affect the nose and eye area). British Association of Dermatologists (bad.org.uk) • Pregnancy.
Caution	• There are no known drug interactions. As with all corticosteroids, prolonged application to the face is undesirable. There is no evidence against use in lactating women. However, caution should be exercised when Hydrocortisone cream/ointment is administered to nursing mothers. In this event, the product should not be applied to the chest area.

Action if excluded	• Refer to medical practitioner / prescriber (e.g., GP or Out of Hours or NHS111) if further action / advice is needed. • Document reason for exclusion and any action(s) taken. • Give safety-netting advice. • Provide advice on alternative treatments (as appropriate) .
Action if patient refuses medication	• Document advice given and the decision reached. • Advise patient on alternative treatment if appropriate. • Refer to a prescriber if appropriate. • Give safety-netting advice.
Qualifications required	Pharmacist currently registered with the General Pharmaceutical Council.
Additional requirements	**General Requirements** • The community pharmacist authorised to operate under this PGD must have undertaken appropriate education and training and declared themselves competent to undertake clinical assessment of the patient leading to diagnosis of the conditions listed in this PGD. • Must be competent in the use of PGDs (see NICE competency framework for health professionals using PGDs). • Must have access to the PGD and associated resources relating to the use of the PGD. • Staff operating under this PGD are encouraged to attend specific commissioner organised events (when available) relating to the use of the PGD. • References included in this PGD, whilst not exhaustive, may be helpful to support competency. **Declaration of Competence** • Individuals operating under this PGD must have completed the CPPE declaration of competence (cppe.ac.uk) in minor ailments with particular reference to the treatment of mild skin conditions (including insect bites). This should be updated in line with the "keeping up to date" section in the declaration of competence. • Individuals operating under this PGD should be familiar with the national guidance for public health treatment of mild skin conditions (including insect bites) in the UK. • Individuals operating under this PGD are personally and professionally responsible for ensuring they remain up to date with the use of all medicines included in the PGD. **Continuing Professional Development and Competence** • Practitioners must ensure they are up to date with relevant issues and clinical skills relating to the treatment of mild skin conditions (including insect bites), with evidence of appropriate continued professional development (CPD). The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.

3. Description of Treatment

Name of Medicine	Hydrocortisone 1% cream Hydrocortisone 1% ointment
Legal Class	POM (Prescription Only Medicine) • NB: Supply a product (and PIL) with a license which is appropriate for both the patient age and site of administration.
Storage	• Stock must be stored in conditions in line with SPC, which is available from the electronic Medicines Compendium website: https://www.medicines.org.uk/ • Do not store above 25°C
Dose to be used (including criteria for use of differing doses)	Adults and children: Apply cream / ointment sparingly once or twice a day up to a maximum of 7 days
Method or route of administration	Topical application to affected areas
Total dose and number of times drug to be given. Details of supply (if supply made)	Supply 1 x15g tube. See 'dose to be used'

Advice and information to patient/carer including follow-up	• Explain treatment, course of action and potential side-effects. • Advise the patient/carer to read the manufacturer's patient information leaflet. • Advise the patient/carer to apply an appropriate quantity of cream or ointment (fingertip units) thinly on the skin to cover the affected area. Details can be found in the Patient Information Leaflet. • Topical hydrocortisone preparations are usually well tolerated, but if any signs of hypersensitivity occur, application should stop immediately. • The individual/carer should be advised to seek medical advice in the event of an adverse reaction. • Wash hands before and after using the cream/ointment. • Do not cover the area with a dressing or plaster. • Be careful to avoid getting the cream or ointment in the eyes. • Advise patients on emollients if necessary (which the patient may purchase over the counter). Advise on continued long term emollient use where appropriate to decrease the need for future topical corticosteroids. • Where patients are co-administering emollients, advise to apply emollient first, wait 10-15 minutes prior to applying hydrocortisone 1%. • Advise patients not to smoke or go near naked flames due to the potential flammable nature of these products causing risk of severe burns (wash clothing, bedding etc that may have come into contact). This may also apply to emollients being used. Refer to PIL for further information. • Striae (stretch marks) may occur especially in intertriginous areas (skin folds). There may be spreading and worsening of untreated infection and pigmentation changes or excessive hair growth. These effects are rare with intermittent use but should be referred to the GP if they occur. • 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 listed in the references section of this PGD. • Give marketing authorisation holder's patient information leaflet (PIL) provided with the product. • All patients/carers must be given appropriate safety netting advice. Advise patient to refer to their GP practice, if symptoms persist or there is no improvement following completion of the 7-day treatment or if condition worsens.
Specify method of recording supply /administration including audit trail	The following will be recorded in the patient's clinical records: **Record Keeping** • Valid informed consent has been obtained. • Name of individual, address, date of birth and Medical Practitioner / Prescriber with whom the individual is registered. • Any known medication allergies. • Name of registered health professional operating under the PGD. • Name of medication administered/supplied. • Batch number and expiry date. • Date / time of administration/supply. • Dose, form, and route of administration. • Quantity administered/supplied. • Advice given, including advice given if excluded or declined treatment. • Referral arrangements (including self-care). • Details of any adverse drug reactions and actions taken. • Label with "supplied via Patient Group Direction (PGD)". • Records should be signed, name printed, dated, and securely kept. Password controlled e-records can be used. • All records should be clear, legible, and contemporaneous. • A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy. • Completion of Patient Medication Record.

- Recording of any prescription charges / exemptions (the current prescription charge is to be levied to those who are not exempt from prescription fees).

Audit trail

- PMR entry.
- The hydrocortisone cream / ointment must be labelled with the directions and the words "supplied under Patient Group Direction".
- All PGD documentation for adults must be kept for 8 years and for children until the child is 25 years old, or for 8 years after a child's death.
- Patient's medical practitioner/prescriber to be notified within 48 hours of supply for inclusion in the patient's notes.
- Electronic claims to be made in line with local arrangements.
- Adherence to this PGD must be audited at least annually and audit records retained to satisfy internal Community Pharmacy governance arrangements and inspection by the commissioner of service.

Reporting procedure for adverse reactions

- Adverse drug reactions must be clearly documented and, where appropriate, reported to the Medicines and Healthcare products Regulatory Agency (MHRA) using the yellow card scheme http://yellowcard.mhra.gov.uk
    - Record all ADRs in the patient's medical record.
    - Report via organisation incident policy.

Confidentiality

- All pharmacists and their supporting staff must respect their duty of confidentiality and information should not be disclosed to any third party without the patient's consent. Practitioners should be aware of their obligations under their appropriate Code of Conduct/Ethics.
- The patient/parent/guardian must be asked for consent for their Medical Practitioner / Prescriber to be informed.

References used in the development of this PGD:	**Specific Guidance** • Summary of Product Characteristics accessed via Electronic Medicines Compendium https://www.medicines.org.uk/emc/ • Hydrocortisone 1% ointment / Efcortelan 1% ointment, accessed 09/11/2023 https://www.medicines.org.uk/emc/product/12909 • Hydrocortisone 1% cream / Efcortelan 1% cream, accessed 09/11/2023 https://www.medicines.org.uk/emc/product/12908 • British National Formulary (online) accessed 09/11/2023 https://bnf.nice.org.uk/drug/hydrocortisone.html • NICE Clinical Knowledge Summaries, Insect Bites and Stings, accessed 09/11/2023 https://cks.nice.org.uk/topics/insect-bites-stings/ • NICE Clinical Knowledge Summaries, Mild Eczema, accessed 09/11/2023 https://cks.nice.org.uk/topics/eczema-atopic/management/mild-eczema/ • British Association of Dermatologists (bad.org.uk), accessed 09/11/2023 **General Guidance** • Current Devon Joint Formularies, accessed 09/11/2023 https://southwest.devonformularyguidance.nhs.uk/formulary/chapters/13-skin/13-4-topical-corticosteroidsand https://northeast.devonformularyguidance.nhs.uk/formulary/chapters/13-skin/13-4-topical-corticosteroids • MHRA, yellow card, making medicines and medical devices safer: http://yellowcard.mhra.gov.uk • Specialist Pharmacy Service, PGD Resource page https://www.sps.nhs.uk/home/guidance/patient-group-directions/

Please refer to the summary of product characteristics for full information

This Patient Group Direction is operational from 1st April 2024 and expires 31st March 2026

Version History

Version	Date	Brief Summary of Change	Owner's Name
0.1	25/11/21	Initial draft of PGD. Utilised existing drafts of peer reviewed PGDs from Bristol, North Somerset and South Gloucestershire CCG and Kernow CCG	Paul Humphriss, Medicines Optimisation Pharmacist
0.2	29/12/21	Minor alterations following Consultation Process:	Paul Humphriss
0.3	14/01/2022	Minor alterations following second consultation period: From CCG Medicines Optimisation, Devon LPC and Bristol, North Somerset and South Gloucestershire CCG	Paul Humphriss
1.0	27/01/2022	Ratification of PGD by NHS Devon PGD VRP Group	Paul Humphriss
2.0	10/10/2023	Review of PGD by Emma Tresidder. References to CCG changed to ICB. ICB format introduced, e.g., sections including "characteristics of staff" and "record keeping/audit trail". Reference section updated.	Emma Tresidder Medicines Optimisation Pharmacist
2.1	10/01/2024	Minor changes made following consultation process	Emma Tresidder Medicines Optimisation Pharmacist

PGD MAS 5 Hydrocortisone 1% Topical v2.1

Final Audit Report 2024-02-07

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"PGD MAS 5 Hydrocortisone 1% Topical v2.1" History

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