Patient Group Direction For The Supply Of Hydrocortisone 1% Cream For Mild Inflammatory Skin Conditions By Banff Area Community Pharmacists Working Within NHS Grampian (Pilot Project)

<table>
<thead>
<tr>
<th>Lead Author:</th>
<th>Consultation Group:</th>
<th>Approver:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aberdeenshire H&amp;SCP Primary Care Clinical Pharmacist</td>
<td>See relevant page in the PGD</td>
<td>NHSG Medicines Guidelines and Policies Group</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Signature:</th>
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<tbody>
<tr>
<td>M. Elaine McCall</td>
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<thead>
<tr>
<th>Identifier:</th>
<th>Review Date:</th>
<th>Date Approved:</th>
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<tbody>
<tr>
<td>NHSG/PGD/Hydro/MGPG950</td>
<td>June 2020</td>
<td>June 2018</td>
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NHS Grampian have authorised this Patient Group Direction to help patients by providing them with more convenient access to an efficient and clearly defined service within the NHS Board. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 1
Revision History:

<table>
<thead>
<tr>
<th>Date of change</th>
<th>Approval date of PGD that is being superseded</th>
<th>Summary of Changes</th>
<th>Section heading</th>
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</thead>
<tbody>
<tr>
<td>March 2018</td>
<td>NA</td>
<td>New PGD.</td>
<td></td>
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<tr>
<td>April 2018</td>
<td>NA</td>
<td>Statement added from SmPC.</td>
<td>Identifying and managing possible adverse reactions.</td>
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</table>

NHS Grampian Identifier: NHSG/PGD/Hydro/MGPG950
Replaces: New PGD
Keyword(s): PGD Patient Group Direction Hydrocortisone community pharmacist skin

Policy Statement: It is the responsibility of individual community pharmacist and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect patient, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of patient safety. The expiry date should not be more than 3 years from the date the PGD was authorised.

Document: Drafted: March 2018
Completed: June 2018
Approved: June 2018 (published – August 2020)
Patient Group Direction For Use Within NHS Grampian

Organisational Authorisation

This PGD is not legally valid until it has had organisational authorisation

<table>
<thead>
<tr>
<th>NHS Grampian</th>
<th>Name</th>
<th>Signature</th>
<th>Date Signed</th>
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<tbody>
<tr>
<td>Medical Director</td>
<td>Nick Fluck</td>
<td></td>
<td>August 2018</td>
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<tr>
<td>Director of Pharmacy</td>
<td>David Pfleger</td>
<td></td>
<td>August 2018</td>
</tr>
<tr>
<td>Acting Director of Nursing, Midwifery and Allied Healthcare Professionals</td>
<td>Caroline Hiscox</td>
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<td>August 2018</td>
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Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction

**Name:**
- Elaine McDermott
- Debbie Smith
- Dr Iain Brooker
- Frances Adamson
- Elaine Neil

**Title:**
- Lead Author: Primary Care Clinical Pharmacist Banff
- Pharmacist: Community Pharmacist Portsoy
- Medical Practitioner: GP Macduff Practice
- Medicines Management Specialist Nurse
- Lead Pharmacist Aberdeenshire H&SCP
Clinical indication to which this PGD applies

<table>
<thead>
<tr>
<th>Definition of situation/condition</th>
<th>This Patient Group Direction (PGD) will authorise community pharmacists to supply hydrocortisone 1% cream for mild inflammatory skin conditions to patients from 2 years of age. This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC) and individual Summary of Product Characteristics (SmPC).</th>
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<tr>
<td>Inclusion criteria</td>
<td>Adults and children aged 2 years or older presenting with: • acute dermatitis • acute mild eczema • insect bite reactions.</td>
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<tr>
<td>Exclusion criteria</td>
<td>• Children under the age of 2 years • Skin lesions caused by bacterial, fungal or viral skin infections, e.g. cold sores, impetigo, chickenpox, acne, athlete’s foot or ringworm • Infected eczema (weeping, rapidly worsening rash, fever) • Patients with existing eczema currently prescribed medications where usual treatment is not working • Allergy to any component of the cream • Application to ano-genital region • Patients who are feeling generally unwell • Patients who have suffered any trauma to the area - scratch, graze or bite (animal or human) • Patients who have already tried topical corticosteroid unsuccessfully • Pregnancy.</td>
</tr>
<tr>
<td>Precautions and special warnings</td>
<td>As with all corticosteroids, prolonged application to the face is undesirable.</td>
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<tr>
<td>Referral criteria</td>
<td>Patients who fall into the categories detailed in the exclusion criteria should be referred to their General Practitioner (GP).</td>
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<td>------------------------------------------------------------------------------------------------------------------------</td>
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</table>
| Action if excluded from treatment | Medical advice should be sought – refer to GP or Out of Hours Service.  
The reason why the patient was excluded under the PGD will be documented in the patient’s assessment form and recorded in Pharmacy Care Record (PCR) as an SBAR.  
If urgent referral is required, refer to GP or use direct referral process contained within Unscheduled Care Folder during out of hour’s period. |
| Action if patient declines treatment | Patient should be advised of the risks and consequences of not receiving treatment.  
Record outcome in PCR and provide worsening statement and advise patient to contact their GP or NHS 24. |
| Consent | Prior to the supply of the drug, valid consent must be obtained. Consent must be in line with current NHSG consent policy. |

**Description of treatment available under the PGD**

<table>
<thead>
<tr>
<th>Name of medicine</th>
<th>Hydrocortisone 1% cream.</th>
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</table>
| Legal status | Hydrocortisone 1% cream is a Prescription-only Medicine (PoM).  
In accordance with the MHRA all medicines supplied under a PGD must either be from over-labelled stock, or be labelled appropriately in accordance with the regulatory body guidelines for the labelling of medicines for the professional providing the supply. |
### Form/Strength
Supply 1 x 15g tube or 1 x 30g tube 1% w/w cream. Each gram contains 10mg hydrocortisone.

See BNF/BNFC for suitable quantities of corticosteroid preparations to be prescribed for specific areas of the body.

### Route/Method of administration
Topical application to affected areas.

### Dosage/Total Dose
Apply cream sparingly once or twice daily for up to 7 days.

### Duration of treatment
Use for a maximum of 7 days.

### Storage requirements
Do not store above 25°C.

Patients should return any leftover cream to their local pharmacy for safe disposal.

### Follow-up (if applicable)
Ensure patient/carer is aware that if symptoms worsen then they should seek medical advice either from their GP or through NHS 24.

If symptoms have not improved after 7 days treatment, then patients should be advised to see their GP.

### Advice to patient (Verbal)
Advice should be given on what to expect and what to do for major and minor reactions.

Advise patient to read manufacturer’s patient information leaflet.

Advise patient to apply appropriate quantity of cream (fingertip units) thinly on the skin to cover the affected area.

Advice should be given on what to expect and what to do for major and minor adverse reactions.

If any signs of hypersensitivity appear, application should stop immediately.

Wash hands before and after applying the cream.
Do not cover the area with a dressing or plaster.

Be careful to avoid getting the cream in the eyes.

Advise patient on use of emollients if necessary and supply Diprobase cream or Doublebase cream Over The Counter or Minor Ailments Service as appropriate. Advise on continued long-term emollient use to decrease the need for future topical corticosteroids.

### Advice to patient (Written)

The Patient Information Leaflet (PIL) contained in the medicine(s) should be made accessible to the patient, parent, guardian, or person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.

Copies of PIL and SPCs for medicines can be found at [http://www.medicines.org.uk](http://www.medicines.org.uk) or [http://www.mhra.gov.uk/spc-pil/index.htm](http://www.mhra.gov.uk/spc-pil/index.htm)

### Concurrent Medications/Drug Interactions

None known.

### Identifying and managing possible adverse reactions

Hydrocortisone preparations are usually well tolerated, but if any signs of hypersensitivity appear, application should stop immediately.

Occasionally striae may occur especially in intertriginous areas. There may be spreading and worsening of untreated infection and pigmentation changes or excessive hair growth.

**This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SPC for details of all potential adverse reactions.**

**BNF/BNFC:**
[https://www.bnf.org/](https://www.bnf.org/)

**SPC/PIL and risk minimisation materials:**
[https://www.medicines.org.uk/emc/](https://www.medicines.org.uk/emc/)
[http://www.medicines.org.uk/emc/medicine/22894#rmm](http://www.medicines.org.uk/emc/medicine/22894#rmm)
If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Report the reaction to the MHRA using the Yellow Card System. [https://yellowcard.mhra.gov.uk/]

### Facilities and supplies required

The following should be available at sites where the medication is to be supplied:
- Appropriate storage facilities
- An acceptable level of privacy to respect patient’s right to confidentiality and safety
- Approved equipment for the disposal of used materials
- Clean and tidy work areas, including access to hand washing facilities
- Copies of the current PGD for the medicine specified in the PGD.

### Characteristics of staff authorised to supply medicine under PGD

<table>
<thead>
<tr>
<th>Professional qualifications</th>
<th>Pharmacists whose name is currently on the register held by the General Pharmaceutical Council (GPhC).</th>
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</table>
| Specialist competencies    | Approved by the organisation as:  
  - Competent to assess the patient’s capacity to understand the nature and purpose of the supply in order for the patient to give or refuse consent  
  - Having undertaken appropriate training to carry out clinical assessment of patients leading to a diagnosis that requires treatment according to the indications listed in the PGD  
  - Aware of current treatment recommendations and be competent to discuss issues about the drug with the patient. |
| Ongoing training and competency | All professionals working under this PGD must:  
  - Maintain their skills, knowledge and their own professional level of competence in this area according to their Code of Professional Conduct  
  - Must be familiar with the SPC for all medicines supplied in accordance with this PGD  
  - Undertake the NES distance learning pack “Common Clinical Conditions and Minor Ailments” and NES e-learning Pharmacy First module. |
### Professional managers/Lead Nurses will be responsible for:

- Ensuring that the current PGD is available to staff providing care under this direction.
- Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.
- Maintain up to date record of all staff authorised to supply drug specified in PGD.

### Documentation

#### Authorisation of supply

Community pharmacists working within NHS Grampian (specific community pharmacists only) can be authorised to supply the drug specified in this PGD by their Director of Pharmacy.

All authorised staff are required to read the PGD and sign the Agreement to Supply Medicines Under PGD ([Appendix 1](#)). This should be held in the individual practitioners records, or as agreed locally.

A Certificate of Authorisation ([Appendix 2](#)) signed by the authorising doctor/manager and staff working to the PGD, should be held as agreed locally.

#### Record of supply

An electronic or paper record for recording the screening of patients and the subsequent supply of the drug specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum:

- Name and address of patient
- Patient CHI No and date of birth
- Details of parent/guardian, or person with parental responsibility where applicable
- General Practitioner details
- Risk group, if appropriate
- Findings of physical examination, if appropriate
- Exclusion criteria, record why the drug was not supplied.
- Reason for giving
- Consent to the supply (if not obtained elsewhere)
- Signature and name in capital letters of practitioner who supplied the drug
- Date drug given
- Record of any adverse effects (advise patient’s doctor)
• The patient’s GP must be notified on the same or next working day that a supply has taken place
• Electronic claims form should be completed.

These records should be retained:

**For children and young people**, retain until the patient's 25th birthday or 26th if the young person was 17 at the conclusion of treatment.

**For 17 years and over** retain for 6 years after last date of entry, for 3 years after death, or in accordance with local policy, where this is greater than above.

**Audit**

All records of the drug(s) specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each H&SCP/practice/service will be responsible for auditing completion of drug forms and collation of data.

**References**

Electronic Medicines Compendium
[http://www.medicines.org.uk](http://www.medicines.org.uk) Hydrocortisone 1% w/w Cream (Pinewood Healthcare) – Date of revision of text 03/03/17, accessed 23/03/18


National Institute for Health and Care Excellence, Clinical Knowledge Summary Dermatitis – contact [https://cks.nice.org.uk/dermatitis-contact](https://cks.nice.org.uk/dermatitis-contact)


Common clinical conditions and minor ailments – NES distance learning resource pack.

Health Care Professional Agreement to Supply Medicines Under Patient Group Direction

I: _______________________________ (Insert name)

Working within: _______________________________ e.g. H&SCP, Practice

Agree to supply medicines under the direction contained within the following Patient Group Direction

Patient Group Direction For The Supply Of Hydrocortisone 1% Cream For Mild Inflammatory Skin Conditions By Banff Area Community Pharmacists Working Within NHS Grampian (Pilot Project)

I have completed the appropriate training to my professional standards enabling me to supply medicines under the above Patient Group Direction. I agree not to act beyond my professional competence nor out with the recommendations of the Patient Group Direction.

Signed: ______________________________________

Print Name: ______________________________________

Date: ______________________________________

Professional Registration No: _______________________________
# Appendix 2

Health Professionals Authorisation to Administer Medicines Under Patient Group Direction

<table>
<thead>
<tr>
<th>Name of Healthcare Professional</th>
<th>Signature</th>
<th>Date</th>
<th>Name of Manager</th>
<th>Signature</th>
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The lead nurse/professional of each clinical area is responsible for maintaining records of their clinical area where this PGD is in use, and to whom it has been disseminated.

The manager who approves a healthcare professional to supply medicines under the patient group direction, is responsible for ensuring that he or she is competent, qualified and trained to do so and for maintaining an up-to-date record of such approved persons in conjunction with the Head of Profession.

The healthcare professional who is approved to supply medicines under the direction is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that supply is carried out within the terms of the direction, and according to his or her code of professional practice and conduct.

**Patient Group Direction For The Supply Of Hydrocortisone 1% Cream For Mild Inflammatory Skin Conditions By Banff Area Community Pharmacists Working Within NHS Grampian (Pilot Project)**

Local clinical area(s) where these healthcare professionals will operate under this PGD:
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