Patient Group Direction For The Administration Of Cyclopentolate 1% Eye Drops By Orthoptists Working Within The Children’s Eye Clinic, RACH

<table>
<thead>
<tr>
<th>Lead Author:</th>
<th>Consultation Group:</th>
<th>Approver:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Pharmacist, RACH</td>
<td>See relevant page in the PGD</td>
<td>Medicine Guidelines and Policies Group</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Signature:</th>
<th>Signature:</th>
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<tbody>
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<table>
<thead>
<tr>
<th>Identifier:</th>
<th>Review Date:</th>
<th>Date Approved:</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHSG/PGD/Cyclopentolate/MGPG849</td>
<td>November 2018</td>
<td>November 2016</td>
</tr>
<tr>
<td></td>
<td>Expiry Date:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>November 2019</td>
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</tbody>
</table>

A Patient Group Direction is a specific written instruction for the supply or administration of named medicines in an identified clinical situation. It is drawn up locally by Doctors, Pharmacists and other appropriate professionals, approved by the employer and advised by the relevant professional advisory committees. In most cases, appropriate clinical care is provided on an individual basis by a specific prescriber to a specific individual patient. Patient Group Directions should only be considered where they offer a benefit to patient care without compromising patient safety in any way.

Uncontrolled when printed

Version 5
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Approval date of PGD that is being superseded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>
</tr>
</thead>
<tbody>
<tr>
<td>September 2016</td>
<td>September 2016</td>
<td>2 yearly update to new PGD template.</td>
<td></td>
</tr>
<tr>
<td>September 2016</td>
<td>September 2016</td>
<td>Additional information regarding systemic absorption added.</td>
<td>Identifying and managing possible adverse reactions.</td>
</tr>
</tbody>
</table>

**Subject:** Patient Group Direction  
**Identifier:** NHSG/PGD/Cyclopentolate/MGPG849  
**Replaces:** NHSG/PGD/cyclo_orthop/MGPG676, Version 4  
**Keyword(s):** PGD patient group direction minimizes cyclopentolate orthoptic children

**Policy Statement:** It is the responsibility of individual orthoptists 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: July 2006  
Completed: December 2006  
Patient Group Direction For The Administration Of Cyclopentolate 1% Eye Drops By Orthoptists Working Within The Children’s Eye Clinic, RACH

Clinical indication to which this PGD applies

| Definition of situation/condition | This patient group direction (PGD) will authorise orthoptists to administer cyclopentolate 1% eye drops to individuals aged 3 months and over for the routine refraction and fundus examination of children attending the Children’s Eye Clinic, Royal Aberdeen Children’s Hospital (RACH).

This PGD should be used in conjunction with the recommendations in the current British National Formulary for Children (BNFC) and individual Summary of Product Characteristics (SPC). |
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Inclusion criteria</td>
<td>Any child three months old to 12 years of age who has subnormal vision, subnormal binocular function, a squint, or who requires an optic fundus examination.</td>
</tr>
<tr>
<td>Exclusion criteria</td>
<td>• They are under 3 months of age.&lt;br&gt;• They are over the age of 12 years.&lt;br&gt;• They have had significant local or general allergic reaction to a previous administration of cyclopentolate; a doctor should be consulted.&lt;br&gt;• They have a history of hypersensitivity to any of the components.&lt;br&gt;• The patient has confirmed or suspected narrow-angle glaucoma as an acute attack may be precipitated.</td>
</tr>
<tr>
<td>Precautions and special warnings</td>
<td>Patients will stay in the care of the hospital for at least 45 minutes after instillation of the eye drops to allow monitoring and management of any adverse effects if they occur.</td>
</tr>
<tr>
<td>Referral criteria</td>
<td>Patients who fall into the categories detailed in the exclusion criteria.</td>
</tr>
</tbody>
</table>
**Action if excluded from treatment**

Medical advice should be sought – refer to General Practitioner/Consultant (relevant medical practitioner).

The reason why the patient was excluded under the PGD will be documented in the patient’s medical notes.

**Action if patient declines treatment**

Patient/carer/guardian should be advised of the risks and consequences of not receiving treatment.

Record outcome in Patient Medication Record if appropriate and refer the patient to their General Practitioner/Consultant (relevant medical practitioner).

**Consent**

Prior to the administration of the drug, valid consent must be obtained. Consent must be in line with current NHSG “Staff Policy for Obtaining Consent for Clinical Procedures and Healthcare Interventions”. See link below.

http://intranet.grampian.scot.nhs.uk/ccc_nhsg/15692.html?pMenuID=460&

**Description of treatment available under the PGD**

<table>
<thead>
<tr>
<th>Name of medicine</th>
<th>Minims® Cyclopentolate 1%.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal status</td>
<td>Minims® Cyclopentolate 1% is a Prescription-only Medicine (PoM).</td>
</tr>
<tr>
<td>Form/Strength</td>
<td>Each Minims® unit consists of a sealed container which holds 0.5mL of a sterile, colourless solution of cyclopentolate 1%. Other ingredients in the formulation are purified water and hydrochloric acid.</td>
</tr>
<tr>
<td>Route/Method of administration</td>
<td>Child of 3 months old and above; One drop of cyclopentolate 1% solution to be instilled into the eye(s) 30 to 60 minutes before eye examination.</td>
</tr>
<tr>
<td>Dosage/Total Dose</td>
<td>Maximum of one drop into each eye daily as a single dose. Not to be repeated.</td>
</tr>
<tr>
<td>Duration of treatment</td>
<td>One treatment only.</td>
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<tr>
<td>-----------------------</td>
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</tr>
<tr>
<td>Storage requirements</td>
<td>The eye drops should be stored below 25°C and protected from light. Do not freeze. Each Minims® unit should be discarded after each single use.</td>
</tr>
<tr>
<td>Follow-up (if applicable)</td>
<td>Patients should not leave if they are feeling at all unwell without speaking to the orthoptists first. If necessary a doctor or the patient's GP should be contacted for advice.</td>
</tr>
<tr>
<td>Advice to patient/parent/guardian or person with parental responsibility (Verbal)</td>
<td>Advice should be given on what to expect and what to do for major and minor reactions.</td>
</tr>
<tr>
<td>Advice to patient/parent/guardian or person with parental responsibility (Written)</td>
<td>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. A leaflet entitled “After Eye Drops&quot; should be given to the patient/parent/guardian or person with parental responsibility in addition to the advice detailed above. All advice given must be documented in the patient’s case notes. Copies of PIL and SPCs for all medicines can be found at <a href="http://www.medicines.org/emc">http://www.medicines.org/emc</a> or <a href="http://www.mhra.gov.uk/spc-pil/index.htm">http://www.mhra.gov.uk/spc-pil/index.htm</a></td>
</tr>
<tr>
<td>Concurrent Medications/Drug Interactions</td>
<td>No known interaction with other medicaments.</td>
</tr>
<tr>
<td>Identifying and managing possible adverse reactions</td>
<td>Local: Transient stinging and blurring of vision may occur following administration of this product.</td>
</tr>
</tbody>
</table>
Systemic: Systemic absorption may be reduced by compressing the lacrimal sac at the medial canthus for a minute during and following the instillation of drops. It is especially advisable in children.

If any of the following side effects do occur they should be documented in the patient’s case notes to avoid unnecessary repeated application:

- Swelling and redness of the eyelids and conjunctiva with lacrimation.
- Pain due to raised intraocular pressure.
- Contact dermatitis, i.e. conjunctivitis.

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

BNFC: [https://www.medicinescomplete.com/mc/bnfc/current/](https://www.medicinescomplete.com/mc/bnfc/current/)


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/](https://yellowcard.mhra.gov.uk/)

Medical advice in cases of anaphylaxis

Injections of IM adrenaline/epinephrine 1:1000 must be available to treat an anaphylactic reaction should this occur. Medical advice must be sought as soon as possible from a doctor if any patient develops any signs of hypersensitivity. If there is a delay in medical support arriving and the condition of the patient is deteriorating then an emergency ambulance must be called on 999 or direct via ambulance control or dial 2222 (hospital internal) according to local procedure, or seek urgent medical advice. (Refer to Patient Group Direction for the administration of adrenaline (epinephrine) in cases of suspected anaphylactic reactions by qualified health professionals) [http://www.nhsgrampian.com/grampianfoi/files/PGD_Adrenaline.pdf](http://www.nhsgrampian.com/grampianfoi/files/PGD_Adrenaline.pdf).
Facilities and supplies required
The following should be available at sites where the medication is to be administered:

- Appropriate storage facilities.
- An acceptable level of privacy to respect patient’s right to confidentiality and safety.
- Resuscitation equipment.
- Access to medical support (this may be via the telephone).
- 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.
- PGD for the administration of Adrenaline (epinephrine) in cases of suspected anaphylactic reactions by qualified health professionals.

Characteristics of staff authorised to supply/administer medicine under PGD

<table>
<thead>
<tr>
<th>Professional qualifications</th>
<th>Orthoptists with a Degree or Diploma in Orthoptics, and registered with the Health Professions Council.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialist competencies</td>
<td>Be competent to assess the patient’s capacity to understand the nature and purpose of the administration in order for the patient to give or refuse consent.</td>
</tr>
<tr>
<td></td>
<td>Has 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.</td>
</tr>
<tr>
<td></td>
<td>Be aware of current treatment recommendations and be competent to discuss issues about the drug with the patient.</td>
</tr>
<tr>
<td></td>
<td>Is competent in the administration of the drug.</td>
</tr>
<tr>
<td></td>
<td>Orthoptists are professionals trained to assess children’s visual development, binocular status, and identify and treat amblyopia and squints. They are best placed to decide if and when a child needs refracted, and also ideally placed to ensure the smooth running of the children’s eye clinic, and to order the instillation of and instil the cyclopentolate eye drops.</td>
</tr>
</tbody>
</table>
| **Ongoing training and competency** | Have attended basic life support training which is required to be updated annually.  
Have undertaken the NHS e-anaphylaxis training session (and annual updates) which covers all aspects of the identification and management of anaphylaxis. This can be accessed via eKSF, or the AT Learning tool.  
Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct.  
The orthoptist must be familiar with the SPC for all medicines supplied in accordance with this PGD. |
| **Professional managers 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 administer drug specified in PGD. |

**Documentation**

| **Authorisation of administration** | Orthoptists working within RACH in NHS Grampian can be authorised to administer the drug specified in this PGD by their Professional Manager or Consultant.  
All authorised staff are required to read the PGD and sign the Agreement to administer Medicines under PGD ([Appendix 1](#)).  
A certificate of authorisation ([Appendix 2](#)) signed by the authorising doctor/manager should be supplied. This should be held in the individual practitioners records, or as agreed locally. |
| **Record of administration/supply** | An electronic or paper record for recording the screening of patients and the subsequent administration of the drug specified in this PGD must be completed in order to allow audit of practice. This should include:  
• Name and address of patient |
- Patient CHI No and date of birth
- Details of parent/guardian, or person with parental responsibility where applicable
- Consultant/General Practitioner details
- Risk group, if appropriate
- Findings of physical examination, if appropriate
- Exclusion criteria, record why the drug was not administered
- Reason for giving
- Consent to the administration (if not obtained elsewhere)
- Drug manufacturer, batch number, expiry date
- Site where drug administered, dose and route of administration
- Signature and name in capital letters of practitioner who administered the drug
- Date drug given
- Record of any adverse effects (advise patient's doctor).

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.

## Audit
All records of the drug 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  

British National Formulary for Children  
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

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frances Adamson</td>
<td>Medicines Management Specialist Nurse</td>
</tr>
<tr>
<td>Jenny Mosley</td>
<td>Pharmacist: Paediatric Pharmacist</td>
</tr>
<tr>
<td>Nicola Nicolson</td>
<td>Highly Specialist Orthoptist</td>
</tr>
<tr>
<td>Victoria Nicol</td>
<td>Lead Author: Pharmacist</td>
</tr>
<tr>
<td>Mr Christopher Scott</td>
<td>Medical Professional: Consultant Paediatric Ophthalmologist</td>
</tr>
</tbody>
</table>

Authorising Managers

Dr Nick Fluck  
Medical Director, NHS Grampian

Mr David Pfleger  
Director of Pharmacy and Medicines Management, NHS Grampian

Professor Amanda Croft  
Director of Nursing, Midwifery and AHPs, NHS Grampian
Appendix 1

Health Care Professional Agreement to Administer Medicines Under Patient Group Direction

I:  ___________________________________________  (Insert name)

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

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

Patient Group Direction For The Administration Of Cyclopentolate 1% Eye Drops By Orthoptists Working Within The Children’s Eye Clinic, RACH

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

Signed: _______________________________________

Print Name: ____________________________________

Date: _________________________________________

Professional Registration No: _____________________
Appendix 2

Certificate Of Authorisation To Administer Medicines Under Patient Group Direction

This authorises: __________________________________________

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

To administer medicines under the following Patient Group Direction

Patient Group Direction For The Administration Of Cyclopentolate 1% Eye Drops By Orthoptists Working Within The Children’s Eye Clinic, RACH

The above named person has satisfied the training requirements and is authorised to administer medicines under the above Patient Group Direction. The above named person has agreed not to act beyond their professional competence nor outwith the recommendations of the Patient Group Direction

Signed: __________________________________________ Authorising Manager/Doctor

Print Name: __________________________________________

Date: __________________________________________