Chief Medical Officer Directorate
Pharmacy and Medicines Division

Scottish Government
Riaghaltas na h-Alba
gov.scot

4 August 2023

Addresses

For action

Chief Executives, NHS Boards

For information

NHS Directors of Pharmacy
Director of Practitioner Services, NHS NSS

Enquiries to:

Pharmacy & Medicines Division
1st Floor East Rear
St Andrew's House
EDINBURGH
EH1 3DG
Email:
PharmacyTeam@gov.scot

www.gov.scot

Dear Colleague

ADDITIONAL PHARMACEUTICAL SERVICES NHS PHARMACY FIRST SCOTLAND – ADDITION OF COMMON CLINICAL CONDITION (HAY FEVER)

Summary

1. This Circular advises Health Boards and community pharmacy contractors of new Patient Group Directions (PGDs) that are to be added to the NHS Pharmacy First Scotland service for the treatment of seasonal allergic rhinitis (hay fever).

Background

2. NHS Circular PCA (P)(2020) 13, issued on 1 July 2020, enclosed Directions for the Health Board Additional Pharmaceutical Services (NHS Pharmacy First Scotland) Directions 2020 which came into force as of 29 July 2020.

3. Four common clinical conditions, supported by PGDs, are currently included in the NHS Pharmacy First Scotland service: uncomplicated UTIs, impetigo, shingles and skin conditions.

Detail

4. The new hay fever PGDs have been signed off by NHS 24 for use in all Health Boards.

5. Health Boards are responsible for local governance processes to approve, sign and publish these PGDs. Boards are asked to complete this as soon as they can do so and by 31 August 2023 at the latest.

6. Community pharmacy contractors and pharmacy teams should ensure they are familiar with the new arrangements as detailed below.

Patient Group Directions

7. Four PGDs have been developed nationally for NHS Pharmacy First Scotland for the treatment of seasonal allergic rhinitis (hay fever). These PGDs expand the treatments available to people with hay fever symptoms when presenting at a community pharmacy and can be used when current standard treatments have failed to control a person's symptoms. Each PGD allows for a supply of up to six months and pharmacists should consider choosing the most cost effective product that is clinically appropriate. The PGDs are for the following products:

- Beclometasone diproprionate 50micrograms/actuation nasal spray
- Fexofenadine 120mg tablets
- Mometasone furoate 50micrograms/actuation nasal spray, suspension
- Olopatadine 1mg/ml eye drops

8. The attachment to this circular provides copies of the specimen PGDs which have been approved by NHS 24 to allow pharmacists as much time as possible to familiarise themselves with the relevant details. In the meantime, as local governance procedures must be followed even when a PGD is agreed nationally, Health Boards will each approve, sign and publish these PGDs through the appropriate channels.

9. Individual authorisation forms should be completed by pharmacists delivering NHS Pharmacy First Scotland and submitted to each Health Board area that they work in according to the usual process.

Training

10. Community pharmacy contractors should ensure that pharmacists complete the e-learning module for seasonal allergic rhinitis (hay fever), now available on the NES TURAS Learn website at:

https://learn.nes.nhs.scot/67704/pharmacy/cpd-resources/seasonal-allergic-rhinitis-hay-fever-for-nhs-pharmacy-first-scotland

IT update

11. All Patient Medication Record (PMR) suppliers have confirmed that pharmacy IT software, updated to support pharmacy teams to deliver the new common clinical condition, is now visible on PMR systems. However, pharmacy teams should only begin to submit claims once the PGDs have been implemented in their local area and they have signed and submitted the authorisation form.

12. Claims should only be submitted through the PGD option on UCF if the person has been assessed for potential supply of a PGD hay fever product. All other claims relating to consultations for hay fever should be submitted as a standard PFS claim.

13. The content of this Circular has been agreed with Community Pharmacy Scotland.

Action

14. Health Boards are asked to note the contents of this Circular and to bring it to the attention of community pharmacy contractors on their Pharmaceutical Lists, GPs, Health and Social Care Partnerships and Area Pharmaceutical Committees.

Yours sincerely

Alison Strath
Chief Pharmaceutical Officer
Pharmacy & Medicines Division

Patient Group Directions for treatment of Seasonal Allergic Rhinitis (Hay fever)

Patient assessment form

Patient name and address (including postcode):	Click or tap here to enter text.	**Date of Birth /CHI:**	Click or tap here to enter text.	
		Sex	M ☐ F ☐	
Date of assessment:	Click or tap to enter a date.	**Patient is aware that GP practice will be informed:**	YES ☐	NO ☐

Patient clinical picture and related appropriate actions

Clinical features/symptom assessment	**Yes**	**No**	**Actions**
Is patient presenting with typical clinical features of **SEASONAL** allergic rhinitis and alternative causes have been explored and are less likely: (e.g., Sneezing, nasal discharge, nasal itching, nasal congestion – bilateral symptoms typically developing within minutes following allergen exposure. Additional symptoms such as postnasal drip, itching of palate and cough; and features suggestive of chronic nasal congestion such as snoring, mouth breathing and halitosis. Associated eye symptoms such as bilateral itching, redness and tearing)	☐	☐	If **NO**, consider alternative diagnosis and appropriate treatment or refer if required
Is the patient pregnant?	☐	☐	If **YES** to any, do not treat with PGDs, consider alternative treatment or refer if required
Is the patient breastfeeding?	☐	☐	
Does patient have hypersensitivity to any of active ingredients or excipients of medications available under these PGDs?	☐	☐	
Other criteria specific to individual medications			
Beclometasone 50microgram nasal spray	**Yes**	**No**	**Actions**
Is the patient 6 years of age or over?	☐	☐	If **NO**, do not treat with this PGD, consider mometasone nasal spray PGD
Does the patient have single sided prolonged discharge, or nasal blockage in the absence of rhinorrhoea, nasal itching and sneezing?	☐	☐	If **YES** to any, do not treat with this PGD, consider alternative treatment or refer if required
Has the patient experienced recent trauma or surgery to nose where healing is not complete, or has untreated localised nasal infection?	☐	☐	
Does the patient have symptoms associated with acute bacterial sinusitis e.g., fever, severe pain, purulent nasal discharge?	☐	☐	
Fexofenadine 120mg tablets	**Yes**	**No**	**Actions**
Is the patient 12 years of age or over?	☐	☐	If **NO**, do not treat with this PGD, consider alternative treatment or refer if required
Has the patient had treatment failure or remained symptomatic despite using at least two other allergy products available over the counter in the last six months?	☐	☐	If **NO**, do not treat with this PGD, consider alternative treatment
Mometasone 50microgram nasal spray	**Yes**	**No**	**Actions**
Is the patient 3 years of age or over?	☐	☐	If **NO**, do not treat with this PGD, consider alternative treatment or refer if required

Has the patient had treatment failure or remained symptomatic despite using at least two other allergy products available over the counter in the last six months?	☐	☐	If **NO**, do not treat with this PGD, consider alternative treatment
Does the patient have single sided prolonged discharge, or nasal blockage in the absence of rhinorrhoea, nasal itching and sneezing?	☐	☐	If **YES** to any, do not treat with this PGD, consider alternative treatment or refer if required
Has the patient experienced recent trauma or surgery to nose where healing is not complete, or has untreated localised nasal infection?	☐	☐	
Does the patient have symptoms associated with acute bacterial sinusitis e.g., fever, severe pain, purulent nasal discharge?	☐	☐	
Olopatadine 1mg/ml eye drops	**Yes**	**No**	**Actions**
Has the patient has been diagnosed with allergic conjunctivitis?	☐	☐	If **NO**, refer to optometrist for diagnosis
Is the patient 3 years of age or over?	☐	☐	If **NO** to any, do not treat with this PGD, consider alternative treatment or refer to optometrist if required
If patient is not pregnant, are they using effective contraception? (Where applicable)	☐	☐	
Has the patient had treatment failure or remained symptomatic despite using at least one other allergy treatment for ocular symptoms available over the counter?	☐	☐	
Has the patient been using olopatadine for 4 months or longer?	☐	☐	If **YES**, do not treat with this PGD, consider alternative treatment or refer to optometrist if required
Patient (or legal representative) has given informed consent to treatment with appropriate product?	☐	☐	If **NO**, patient is unable to receive treatment

Preparation options and supply method

Medicine and strength	Regime	Supply method
Beclometasone 50microgram nasal spray	*Adults and children over 6 years:* TWO puffs in each nostril TWICE daily until symptoms controlled (can then be reduced to ONE puff in each nostril TWICE daily, return to higher dose if symptoms recur). The minimum dose should be used at which effective control of symptoms is maintained. Total daily administration should not normally exceed EIGHT sprays.	PGD via UCF
Fexofenadine 120mg tablets	*Adults and children over 12 years:* ONE tablet daily	
Mometasone furoate 50microgram nasal spray	*Adults and children over 12 years:* TWO sprays in each nostril ONCE daily until symptoms controlled (can then be reduced to ONE spray in each nostril ONCE daily for maintenance. If symptoms remain inadequately controlled, dose may be increased to FOUR sprays per nostril ONCE daily – dose reduction recommended following control of symptoms) *Children between 3 and 11 years:* ONE spray in each nostril ONCE daily	
Olopatadine 1mg/ml eye drops	*Adults and children over 3 years:* Instil ONE drop in each eye TWICE daily.	

Patient advice checklist

Advice	Provided (Tick as appropriate)
General	
Explain mode of action, benefits of the medicine, possible side effects and their management	☐
Give general advice for managing high pollen count	☐
If symptoms do not improve or worsening symptoms, advise to seek advice initially from the pharmacy	☐
Advise to seek immediate medical advice in event of severe adverse reaction	☐
Patient information leaflet relating to medication(s) is/are given to patient	☐
Beclometasone or mometasone nasal sprays	☐
Explain initial priming, how to spray into nostril	☐
Advise that it may take 1 -2 weeks of treatment to obtain maximum effect	☐
Explain how to increase/reduce dose according to symptom control	☐
Olopatadine eye drops	
Demonstrate instillation technique	☐
Advise on use with contact lenses/other eye drops	☐
Advise that care required if blurred vision occurs	☐
Advise that maximum treatment period of 28 days per bottle, and **FOUR** months in total	☐
Advise that if patient of child-bearing potential, effective contraception is required whilst using olopatadine	☐
Advise that benzalkonium chloride may cause irritation to eyes	☐
Fexofenadine tablets	☐
Advise to take tablet before a meal	☐
If taking aluminium or magnesium containing antacids – advise to leave at least 2 hours between administration of fexofenadine and these medicines.	☐

Communication

Contact made with	Details (include time and method of communication)
Patient's General Practice (details)	Click or tap here to enter text.

Details of medication supplied and pharmacist supplying under the PGD

Medication supplied	Click or tap here to enter text.	Batch number and expiry	Click or tap here to enter text.

Additional medication supplied (if applicable)

Medication supplied	Click or tap here to enter text.	Batch number and expiry	Click or tap here to enter text.
Medication supplied	Click or tap here to enter text.	Batch number and expiry	Click or tap here to enter text.

Print name of pharmacist	Click or tap here to enter text.	GPhC Registration number	Click or tap here to enter text.
Signature of pharmacist			

Patient Group Directions for treatment Seasonal Allergic Rhinitis (Hay fever)

Notification of supply from community pharmacy

CONFIDENTIAL WHEN COMPLETED

Data protection confidentiality note: this message is intended only for the use of the individual or entity to whom it is addressed and may contain information that is privileged, confidential and exempt from disclosure under law. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited.

GP name	Click or tap here to enter text.
GP practice address	Click or tap here to enter text. Click or tap here to enter text.
The following patient has attended this pharmacy for assessment and potential treatment of Seasonal Allergic Rhinitis (Hay fever):	
Patient name	Click or tap here to enter text.
Date of birth/CHI	Click or tap here to enter text.
Patient address	Click or tap here to enter text. Click or tap here to enter text.
Postcode	Click or tap here to enter text.

Pharmacy Stamp/Address details
Pharmacist name Click or tap here to enter text.
GPhC number Click or tap here to enter text.
Date Click or tap to enter a date.

Following assessment (Tick as appropriate)

Presenting condition: Seasonal Allergic Rhinitis (Hay fever)			
Sneezing ☐	Nasal discharge ☐	Nasal itching ☐	Nasal congestion ☐
Itchy eyes ☐	Redness of eyes ☐	Watery eyes ☐	
The patient has been given:			
Beclometasone 50mcg nasal spray (200 doses) ☐		Mometasone 50mcg nasal spray (140 doses) ☐	
Fexofenadine 120mg tablets (30 tablets) ☐ (60 tablets) ☐		Olopatadine 1mg/ml eye drops (5ml) ☐	
The patient has been given self-care advice only			☐
The patient is unsuitable for treatment via PGD for the following reasons and has been referred: Click or tap here to enter text.			☐

You may wish to include this information in your patient records.

Patient consent: I can confirm that the information is a true reflection of my individual circumstances and I give my consent to allow a pharmacist working under the terms of NHS Pharmacy First Scotland to provide the most appropriate advice and/or treatment for me. I also give my permission to allow the pharmacist to pass, to my own GP, details of this consultation and any advice given, or treatment provided. I have been advised that some of the information may be used to assess the uptake of the service, but this will be totally anonymous and not be attributable to any individual patient.	Consent received ☐

This form should now be sent to the patient's GP and a copy retained in the pharmacy.

Patient Group Direction (PGD)

This PGD authorises community pharmacists to supply beclometasone 50micrograms/actuation nasal spray to patients aged 6 years and over presenting with symptoms of seasonal allergic rhinitis with persistent congestion under NHS Pharmacy First Scotland.

Publication date: 17 May 2023

Version 1.0

NHS SCOTLAND

Most Recent Changes

Version	Date	Summary of changes
1.0	17/05/2023	• New national PGD produced.

Contents

Authorisation 4

1. Clinical situation 6

2. Description of treatment 9

3. Adverse reactions 12

4. Characteristics of staff authorised under the PGD 15

5. Audit trail 17

6. Additional references 19

7. Individual authorisation (Appendix 1) 20

8. Version history 21

Authorisation

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

PGD beclometasone 50micrograms/actuation nasal spray

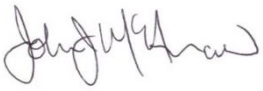
This specimen PGD template has been produced in collaboration with the Primary Care Community Pharmacy Group to assist NHS Boards in the uniform provision of services under 'NHS Pharmacy First Scotland' banner across NHS Scotland. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

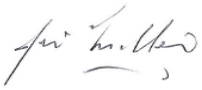
The community pharmacist who may supply beclometasone nasal spray under this PGD can do so only as a named individual. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with the General Pharmaceutical Council Standards for Pharmacy Professionals and to ensure familiarity with the manufacturer's product information/summary of product characteristics (SPC) for all medicines supplied in accordance with this PGD.

NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Supply of the medicine has to be by the same practitioner who has assessed the patient under the PGD.

This PGD has been approved on behalf of NHS Scotland by NHS 24 by:

Doctor (Name / Signature): Dr Laura Ryan 

Pharmacist (Name /Signature): Dr John McAnaw 

NHS Scotland representative (Name / Signature): Mr Jim Miller 

Approved on behalf of NHS……*insert Board*…… by:

Medical Director (Name / Signature) ……..
Director of Pharmacy/Senior Pharmacist (Name / Signature) ……
Clinical Governance Lead (Name / Signature) ……..
Date approved: ……

Effective from: *insert date*

It is the responsibility of the person using the PGD to ensure they are using the most recent issue.

Expiry date: 17 May 2026

1. Clinical situation

1.1. Indication

Relief of symptoms of seasonal allergic rhinitis.

1.2. Inclusion criteria

Patients aged 6 years and older with symptoms of seasonal allergic rhinitis.

NB: A combination of allergy treatment products may be required to obtain acceptable symptom control. However, beclometasone nasal spray should not be used together with other nasal steroid treatments.

Valid consent to receiving treatment under this PGD has been obtained.

1.3. Exclusion criteria

Patients under 6 years of age.

Hypersensitivity to beclometasone or to any of the excipients within the nasal spray.

Nasal blockage in the absence of rhinorrhoea, nasal itch and sneezing.

Unilateral discharge.

Untreated localised infection involving the nasal mucosa e.g., herpes simplex.

Patients with symptoms associated with acute bacterial sinusitis e.g., fever, severe pain, purulent nasal discharge.

Patients who have experienced recent nasal surgery or trauma where healing is not complete.

Pregnancy.

Breast Feeding.

Individuals for whom no valid consent has been received.

1.4. Cautions/need for further advice/ circumstances when further advice should be sought from a doctor

Consult **Beconase® Aqueous Nasal Spray - (SmPC)** for full list of cautions and special warnings.

- Systemic effects of nasal corticosteroids may occur, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different corticosteroid preparations.

  Potential systemic effects may include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, cataract, glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children).

- Although beclometasone aqueous nasal spray will control seasonal allergic rhinitis in most cases, an abnormally heavy challenge of summer allergens may in certain instances necessitate appropriate additional therapy particularly to control eye symptoms (consider olopatadine PGD).

- Beclometasone aqueous nasal spray contains benzalkonium chloride which may cause wheezing and breathing difficulties (bronchospasm) especially if the patient has asthma. Patient should stop using the medicine and seek further medical advice if required.

- Visual disturbance – if patient presents with visual disturbances e.g., blurred vision or other visual disturbances, referral to an ophthalmologist should be considered for evaluation of possible causes.

1.5. Action if excluded

Consider alternative NHS Pharmacy First Scotland treatments (either under PGD or otherwise).

If appropriate, refer to GP practice and document the reason for exclusion and any action taken in Patient Medication Record (PMR).

1.6. Action if patient declines

If appropriate, refer to GP practice and document the reason for declining treatment and advice given in PMR.

2. Description of treatment

2.1. Name of medicine/form/strength

Beclometasone diproprionate 50micrograms /actuation nasal spray

2.2. Route of administration

Nasal Spray

2.3. Dosage

Two sprays in each nostril twice daily (400micrograms /day).

Once control has been established, it may be possible to maintain control with fewer sprays. A dosage regimen of one spray in each nostril morning and evening has shown to be efficacious in some patients. However, should symptoms recur, patients should revert to the recommended dosage of two sprays into each nostril morning and evening. The minimum dose should be used at which effective control of symptoms is maintained. Total daily administration should not normally exceed eight sprays.

2.4. Frequency

Twice daily administration

2.5. Duration of treatment

Supply can be repeated for up to 6 months if required i.e., duration of hay fever season.

2.6. Maximum or minimum treatment period

For full therapeutic benefit regular use is essential. The co-operation of the patient should be sought to comply with the regular dosing schedule, and it should be explained that maximum relief may not be obtained within the first few applications.

2.7. Quantity to supply

1 x 200 dose nasal spray per supply.

2.8. ▼ black triangle medicines

No

2.9. Legal category

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.

2.10. Is the use out with the SPC?

No.

2.11. Storage requirements

As per manufacturer's instructions

Store below 30 ºC in a cool, dry place. Keep container in the outer carton.

Use within 3 months of first use.

2.12. Additional information

None

3. Adverse reactions

3.1. Warnings including possible adverse reactions and management of these.

Please refer to current BNF, BNF for Children or SPC for full details.

If a patient experiences any side effects that are intolerable or hypersensitivity reactions occur, the medication should be discontinued.

Common side effects include sneezing, unpleasant taste or smell, dry or painful nose or throat, nose bleeds, mild allergic reactions (rash, urticaria, pruritis, erythema).

Very rare side effects include damage to nose, cataracts, glaucoma.

For a full list of side effects, refer to the marketing authorisation holder's Summary of Product Characteristics (SPC). A copy of the SPC must be available to the health professional supplying the medication under this PGD. This can be accessed on **www.medicines.org.uk.**

In the event of severe adverse reaction e.g., swelling of eyes, face, lips or throat, shortness of breath or wheezing, developing of rash or feeling faint, individuals should be advised to seek medical advice immediately.

3.2. Reporting procedure for adverse reactions

Pharmacists should document and report all adverse incidents through their own internal governance systems.

All adverse reactions (actual and suspected) should be reported to the appropriate medical practitioner and recorded in the patient's medical record. Pharmacists should record in their PMR and inform the patient's GP as appropriate.

Where appropriate, healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory

Agency (MHRA) using the Yellow Card reporting scheme. Yellow cards and guidance on their use are available at the back of the BNF or online at **www.mhra.gov.uk/yellowcard.**

3.3. Advice to patient or carer including written information

Written information to be given to individuals:

- Provide manufacturer's consumer information leaflet/patient information leaflet (PIL)

Verbal advice to be given to individuals/parent/carer:

- Advise individual on mode of action, benefits of the medicine, possible side effects and their management.
- Give general advice for managing high pollen count: stay indoors as much as possible, keeping windows and doors shut; avoid cutting grass, large grassy places and camping; shower and wash your hair after being outdoors, especially in the countryside; wear wrap-around sunglasses when outside; keep car windows closed and consider buying pollen filters for car air vents.
- When using nasal spray for first time, the pump should be primed. See PIL for full details.
- Advise patient of nasal spray technique – see PIL for details.
- It may take several days to obtain the full therapeutic effects of the medication.
- If condition worsens or symptoms persist seek further medical advice, initially from the pharmacy.
- Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: **www.mhra.gov.uk/yellowcard.**

3.4. Monitoring

Not applicable

3.5. Follow up

Advise patient if symptoms do not improve after 1 month of regular use or worsening symptoms, they should return to the pharmacy for re-assessment. If patient has exhausted all treatment options available in community pharmacy or is requiring to use for more than 6 months, then refer to GP practice for review.

3.6. Additional facilities

The following should be available when the medication is supplied:

- An acceptable level of privacy to respect patient's rights to confidentiality and safety
- Access to a working telephone
- Access to medical support (this may be via telephone)
- Approved equipment for the disposal of used materials
- Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel
- Access to current BNF (online version preferred)
    - BNF British National Formulary - NICE
    - BNF for Children British National Formulary - NICE
- Access to SmPC/PIL/Risk Minimisation Material:
    - Home - electronic medicines compendium (emc)
    - MHRA Products | Home
    - RMM Directory - (emc)
- Access to copy of current version of this PGD

4. Characteristics of staff authorised under the PGD

4.1. Professional qualifications

Pharmacist with current General Pharmaceutical Council (GPhC) registration.

Under PGD legislation there can be no delegation. Supply of the medication has to be completed by the same practitioner who has assessed the patient under this PGD.

4.2. Specialist competencies or qualifications

Persons must only work under this PGD where they are competent to do so.

All persons operating this PGD must:

- Be familiar with the beclometasone 50 micrograms nasal spray medicine and alert to changes in the manufacturer's product information/summary of product information.
- Have successfully complete the NES Pharmacy e-learning module:

  Seasonal Allergic Rhinitis (Hay Fever) for NHS Pharmacy First Scotland | Turas | Learn

  https://learn.nes.nhs.scot/67704/pharmacy/cpd-resources/seasonal-allergic-rhinitis-hay-fever-for-nhs-pharmacy-first-scotland
- Be able to assess the person's/ parent's/ carer's capacity to understand the nature of the purpose of the medication in order to give or refuse consent.

4.3. Continuing education and training

All practitioners operating under this PGD are responsible for:

- Maintaining their skills, knowledge and their own professional level of competence in this area according to the General Pharmaceutical Council Standards for Pharmacy Professionals
- Ensuring they remain up to date with the use of medications included and be aware of local treatment recommendations.
- Attend approved training and training updates as appropriate.
- Undertake relevant continuing professional development when PGD or NES Pharmacy modules are updated.

5. Audit trail

5.1. Authorisation of supply

Pharmacists can be authorised to supply the medicine specified in this PGD when they have completed local Board requirements for service registration.

Pharmacists should complete the individual authorisation form contained in the PGD (Appendix 1) and submit to the relevant NHS Health Board prior to using the PGD.

5.2. Record of supply

All records must be clear, legible, contemporaneous and in an easily retrievable format to allow audit of practice.

A Universal Claim Framework (UCF) record of the screening and subsequent supply, or not, of the medicine specified in this PGD should be made in accordance with the NHS Pharmacy First Scotland service specification.

Pharmacists must record the following information, included in the assessment form, in the PMR (either paper or computer based):

- name of individual, address, date of birth / CHI number
- name of GP with whom the individual is registered (if known)
- confirmation that valid consent to be treated under this PGD was obtained (include details of parent/guardian/person with parental responsibility where applicable)
- details of presenting complaint and diagnosis
- details of medicine supplied - name of medicine, batch number and expiry date, with date of supply.

- details of exclusion criteria – why the medicine was not supplied (if applicable)
- advice given, including advice given if excluded or declines treatment under this PGD
- details of any adverse drug reactions and actions taken
- referral arrangements (including self-care)
- signature and printed name of the pharmacist who undertook assessment of clinical suitability and, where appropriate, subsequently supplied the medicine

The patient's GP (where known) should be provided with a copy of the GP notification form for the supply of beclometasone 50micrograms nasal spray, or appropriate referral on the same, or next available working day.

These records should be retained in accordance with national guidance[1] (see page 56 for standard retention periods summary table). Where local arrangements differ, clarification should be obtained through your Health Board Information Governance Lead.

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

1. Scottish Government. *Scottish Government Records Management.* Edinburgh 2020. Available at **SG-HSC-Scotland-Records-Management-Code-of-Practice-2020-v20200602.pdf** (Accessed on 31st March 2023)

6. Additional references

Practitioners operating the PGD must be familiar with:

1. National Institute for Clinical Excellence / Public Health England. Available at: **Allergic rhinitis | Health topics A to Z | CKS | NICE**. (Accessed 31st March 2023)

2. Current edition of British National Formulary (BNF) BNF British National Formulary - NICE, and BNF for children BNF for Children British National Formulary - NICE

3. Marketing authorisation holder's Summary of Product Characteristics. Electronic Medicines Compendium. *Beconase® Aqueous Nasal Spray SPC.* Available **Beconase® Aqueous Nasal Spray - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)** (Accessed 31st March 2023)

7. Individual authorisation (Appendix 1)

PGDs FOR THE SUPPLY OF TREATMENTS FOR SEASONAL ALLERGIC RHINITIS BY COMMUNITY PHARMACISTS UNDER THE "NHS PHARMACY FIRST SCOTLAND" SERVICE

Health Boards to provide authorisation form to pharmacy contractors

8. Version history

Version	Date	Summary of changes
1.0	17/05/2023	New National Specimen PGD produced.

Patient Group Direction (PGD)

This PGD authorises community pharmacists to supply fexofenadine 120mg tablets to patients aged 12 years and over presenting with symptoms of seasonal allergic rhinitis under NHS Pharmacy First Scotland.

Publication date: 17 May 2023

Version 1.0

NHS SCOTLAND

Most Recent Changes

Version	Date	Summary of changes
1.0	17/05/2023	• New National PGD produced

Contents

Authorisation 4

1. Clinical situation 6

2. Description of treatment 8

3. Adverse reactions 10

4. Characteristics of staff authorised under the PGD 12

5. Audit trail 15

6. Additional references 17

7. Individual authorisation (Appendix 1) 18

8. Version history 18

Authorisation

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

PGD fexofenadine 120mg tablets

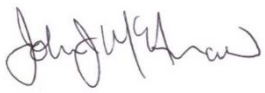
This specimen PGD template has been produced in collaboration with the Primary Care Community Pharmacy Group to assist NHS Boards in the uniform provision of services under 'NHS Pharmacy First Scotland' banner across NHS Scotland. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The community pharmacist who may supply fexofenadine tablets under this PGD can do so only as a named individual. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with the General Pharmaceutical Council Standards for Pharmacy Professionals and to ensure familiarity with the manufacturer's product information/summary of product characteristics (SPC) for all medicines supplied in accordance with this PGD.

NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Supply of the medicine has to be by the same practitioner who has assessed the patient under the PGD.

This PGD has been approved on behalf of NHS Scotland by NHS 24 by:

Doctor (Name / Signature): Dr Laura Ryan 

Pharmacist (Name /Signature): Dr John McAnaw 

NHS Scotland representative (Name / Signature): Mr Jim Miller 

Approved on behalf of NHS……*insert Board*…… by:

Medical Director (Name / Signature) ……..
Director of Pharmacy/Senior Pharmacist (Name / Signature) ……
Clinical Governance Lead (Name / Signature) ……..
Date approved: ……

Effective from: *insert date*

It is the responsibility of the person using the PGD to ensure they are using the most recent issue.

Expiry date: 17 May 2026

1. Clinical situation

1.1. Indication

Relief of symptoms of seasonal allergic rhinitis

1.2. Inclusion criteria

Patients aged 12 years and over with symptoms of seasonal allergic rhinitis:

- **Who have had treatment failure or remain symptomatic despite use of at least two other allergy treatments available over the counter within the last six months.**

  OR

- **Who have required fexofenadine to treat symptoms in previous presentations**.

NB: A combination of other allergy treatment products may be required to obtain acceptable symptom control. However, fexofenadine should not be taken together with other oral antihistamine treatments.

Valid consent to receiving treatment under this PGD has been obtained.

1.3. Exclusion criteria

Patients under 12 years of age.

Previous hypersensitivity to fexofenadine or any excipients (including colouring Allura Red AC Lake which may cause allergic reactions).

Pregnancy.

Breast Feeding.

Individuals for whom no valid consent has been received.

1.4. Cautions/need for further advice/ circumstances when further advice should be sought from a doctor

Caution in patients with a history of, or ongoing cardiovascular disease – patients should be warned that, antihistamines as a medicine class, have been associated with the adverse reactions, tachycardia and palpitations.

Caution in elderly (although no significant CNS effects noted).

Caution in renal or hepatic impairment (no dosage adjustment necessary).

Concomitant administration with erythromycin or ketoconazole can increase plasma level of fexofenadine but this was not accompanied by any effect on QT interval or increase of adverse reactions.

1.5. Action if excluded

Consider alternative NHS Pharmacy First Scotland treatments (either under PGD or otherwise).

If appropriate, refer to GP practice and document the reason for exclusion and any action taken in Patient Medication Record (PMR).

1.6. Action if patient declines

If appropriate, refer to GP practice and document the reason for declining treatment and advice given in PMR.

2. Description of treatment

2.1. Name of medicine/form/strength

Fexofenadine 120mg film coated tablets

2.2. Route of administration

Oral

2.3. Dosage

One tablet

2.4. Frequency

Once daily (before a meal)

2.5. Duration of treatment

Supply can be repeated for up to 6 months if required i.e., duration of hay fever season.

2.6. Maximum or minimum treatment period

Ongoing need to be assessed before further supply.

Can be stopped after hay fever season is complete.

2.7. Quantity to supply

30 tablets – usual initial supply to assess response.

60 tablets may be given at subsequent supplies if acceptable response is achieved or has been previously achieved.

2.8. ▼ black triangle medicines

No

2.9. Legal category

Prescription Only Medicine (POM)

2.10. Is the use out with the SPC?

No.

2.11. Storage requirements

As per manufacturer's instructions.

Store below 25ºC in a cool, dry place.

2.12. Additional information

None

3. Adverse reactions

3.1. Warnings including possible adverse reactions and management of these.

Please refer to current BNF or SPC for full details

If a patient experiences any side effects that are intolerable or hypersensitivity reactions occur, the medication should be discontinued.

For a full list of side effects, refer to the marketing authorisation holder's Summary of Product Characteristics (SPC). A copy of the SPC must be available to the health professional supplying the medication under this PGD. This can be accessed at **www.medicines.org.uk.**

In the event of severe adverse reaction e.g., swelling of eyes, face, lips or throat, shortness of breath or wheezing, developing of rash or feeling faint, individuals should be advised to seek medical advice immediately.

3.2. Reporting procedure for adverse reactions

Pharmacists should document and report all adverse incidents through their own internal governance systems.

All adverse reactions (actual and suspected) should be reported to the appropriate medical practitioner and recorded in the patient's medical record. Pharmacists should record in their PMR and inform the patient's GP as appropriate.

Where appropriate, healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme. Yellow cards and guidance on their use are available at the back of the BNF or online at **www.mhra.gov.uk/yellowcard.**

3.3. Advice to patient or carer including written information

Written information to be given to individuals:

- Provide manufacturer's consumer information leaflet/patient information leaflet (PIL).

Verbal advice to be given to individuals:

- Advise the individual on mode of action, benefits of the medicine, possible side effects and their management.
- Advise that medication should be taken before a meal.
- Advise if taking aluminium or magnesium containing antacids – leave at least 2 hours between administration of fexofenadine and these medicines.
- Give general advice for managing high pollen count: stay indoors as much as possible, keeping windows and doors shut; avoid cutting grass, large grassy places and camping; shower and wash your hair after being outdoors, especially in the countryside; wear wrap-around sunglasses when outside; keep car windows closed and consider buying pollen filters for car air vents.
- Advise to seek medical advice in the event of a severe adverse reaction.
- If the condition worsens or symptoms persist, seek further medical advice initially from the pharmacy.
- Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme at: **www.mhra.gov.uk/yellowcard.**

3.4. Monitoring

Not applicable

3.5. Follow up

Advise patient if symptoms do not improve after 1 month of regular use or worsening symptoms, return to pharmacy for re-assessment.

If patient has exhausted all treatment options available in community pharmacy or is requiring to use for more than 6 months then refer to GP for review.

3.6. Additional facilities

The following should be available when the medication is supplied:

- An acceptable level of privacy to respect patient's rights to confidentiality and safety
- Access to a working telephone
- Access to medical support (this may be via telephone)
- Approved equipment for the disposal of used materials
- Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel
- Access to current BNF (online version preferred)
    - BNF British National Formulary - NICE
    - BNF for Children British National Formulary - NICE
- Access to SmPC/PIL/Risk Minimisation Material:
    - Home - electronic medicines compendium (emc)
    - MHRA Products | Home
    - RMM Directory - (emc)
- Access to copy of current version of this PGD

4. Characteristics of staff authorised under the PGD

4.1. Professional qualifications

Pharmacist with current General Pharmaceutical Council (GPhC) registration.

Under PGD legislation there can be no delegation. Supply of the medication has to be completed by the same practitioner who has assessed the patient under this PGD.

4.2. Specialist competencies or qualifications

Persons must only work under this PGD where they are competent to do so.

All persons operating this PGD must:

- Be familiar with the fexofenadine medicine and alert to changes in the manufacturer's product information/summary of product information.
- Have successfully complete the NES Pharmacy e-learning module:

  Seasonal Allergic Rhinitis (Hay Fever) for NHS Pharmacy First Scotland | Turas | Learn

  https://learn.nes.nhs.scot/67704/pharmacy/cpd-resources/seasonal-allergic-rhinitis-hay-fever-for-nhs-pharmacy-first-scotland
- Be able to assess the person's capacity to understand the nature of the purpose of the medication in order to give or refuse consent.

4.3. Continuing education and training

All practitioners operating under this PGD are responsible for:

- Maintaining their skills, knowledge and their own professional level of competence in this area according to the General Pharmaceutical Council Standards for Pharmacy Professionals.
- Ensuring they remain up to date with the use of medications included and be aware of local treatment recommendations.
- Attending approved training and training updates as appropriate.
- Undertaking relevant continuing professional development when PGD or NES Pharmacy modules are updated.

5. Audit trail

5.1. Authorisation of supply

Pharmacists can be authorised to supply the medicine specified in this PGD when they have completed local Board requirements for service registration.

Pharmacists should complete the individual authorisation form contained in the PGD (Appendix 1) and submit to the relevant NHS Health Board prior to using the PGD.

5.2. Record of supply

All records must be clear, legible, contemporaneous and in an easily retrievable format to allow audit of practice.

A Universal Claim Framework (UCF) record of the screening and subsequent supply, or not, of the medicine specified in this PGD should be made in accordance with the NHS Pharmacy First Scotland service specification.

Pharmacists must record the following information, included in the assessment form, in the PMR (either paper or computer based):

- name of individual, address, date of birth / CHI number
- name of GP with whom the individual is registered (if known)
- confirmation that valid consent to be treated under this PGD was obtained (include details of parent/guardian/person with parental responsibility where applicable)
- details of presenting complaint and diagnosis
- details of medicine supplied - name of medicine, batch number and expiry date, with date of supply.

- details of exclusion criteria – why the medicine was not supplied (if applicable)
- advice given, including advice given if excluded or declines treatment under this PGD
- details of any adverse drug reactions and actions taken
- referral arrangements (including self-care)
- signature and printed name of the pharmacist who undertook assessment of clinical suitability and, where appropriate, subsequently supplied the medicine

The patient's GP (where known) should be provided with a copy of the GP notification form for the supply of fexofenadine 120mg tablets, or appropriate referral on the same, or next available working day.

These records should be retained in accordance with national guidance[1] (see page 56 for standard retention periods summary table). Where local arrangements differ, clarification should be obtained through your Health Board Information Governance Lead.

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

1. Scottish Government. *Scottish Government Records Management.* Edinburgh 2020. Available at **SG-HSC-Scotland-Records-Management-Code-of-Practice-2020-v20200602.pdf** (Accessed on 31st March 2023)

6. Additional references

Practitioners operating the PGD must be familiar with:

1. National Institute for Clinical Excellence / Public Health England. Available at: **Allergic rhinitis | Health topics A to Z | CKS | NICE**. (Accessed 23rd November 2022)

2. Current edition of British National Formulary (BNF) and BNF for children

3. Marketing authorisation holder's Summary of Product Characteristics. Electronic Medicines Compendium. *Fexofenadine hydrochloride 120mg film-coated tablets SPC.* Available at **Fexofenadine hydrochloride 120mg film-coated Tablets - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)** (Accessed 23rd November 2022)

7. Individual authorisation (Appendix 1)

PGDs FOR THE SUPPLY OF TREATMENTS FOR SEASONAL ALLERGIC RHINITIS BY COMMUNITY PHARMACISTS UNDER THE "NHS PHARMACY FIRST SCOTLAND" SERVICE

Health Boards to provide authorisation form to pharmacy contractors

8. Version history

Version	Date	Summary of changes
1.0	17/03/2023	New National PGD produced.

Patient Group Direction (PGD)

This PGD authorises community pharmacists to supply mometasone furoate 50micrograms/actuation nasal spray to patients aged 3 years and over presenting with symptoms of seasonal allergic rhinitis under NHS Pharmacy First Scotland.

Publication date: 17 May 2023

Version 1.0

NHS SCOTLAND

Most Recent Changes

Version	Date	Summary of changes
1.0	17/05/2023	• New national PGD produced.

Contents

Authorisation 4

1. Clinical situation 6

2. Description of treatment 9

3. Adverse reactions 11

4. Characteristics of staff authorised under the PGD 15

5. Audit trail 17

6. Additional references 19

7. Individual authorisation (Appendix 1) 20

8. Version history 21

Authorisation

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

PGD mometasone furoate 50micrograms/actuation nasal spray

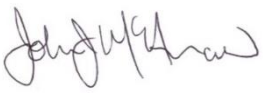
This specimen PGD template has been produced in collaboration with the Primary Care Community Pharmacy Group to assist NHS Boards in the uniform provision of services under 'NHS Pharmacy First Scotland' banner across NHS Scotland. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

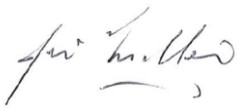
The community pharmacist who may supply mometasone nasal spray under this PGD can do so only as a named individual. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with the General Pharmaceutical Council Standards for Pharmacy Professionals and to ensure familiarity with the manufacturer's product information/summary of product characteristics (SPC) for all medicines supplied in accordance with this PGD.

NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Supply of the medicine has to be by the same practitioner who has assessed the patient under the PGD.

This PGD has been approved on behalf of NHS Scotland by NHS 24 by:

Doctor (Name / Signature): Dr Laura Ryan 

Pharmacist (Name /Signature): Dr John McAnaw 

NHS Scotland representative (Name / Signature): Mr Jim Miller 

Approved on behalf of NHS……*insert Board*…… by:

Medical Director (Name / Signature) ……..
Director of Pharmacy/Senior Pharmacist (Name / Signature) ……
Clinical Governance Lead (Name / Signature) ……..
Date approved: ……

Effective from: *insert date*

It is the responsibility of the person using the PGD to ensure they are using the most recent issue.

Expiry date: 17 May 2026

1. Clinical situation

1.1. Indication

Relief of symptoms of seasonal allergic rhinitis, in adults and children over 3 years of age.

1.2. Inclusion criteria

Patients aged 3 years and older with symptoms of seasonal allergic rhinitis:

- **Who have had treatment failure or remain symptomatic despite use of at least two other allergy treatments available over the counter within the last six months.**

NB: A combination of allergy treatment products may be required to obtain acceptable symptom control. However, mometasone nasal spray should not be used together with other nasal steroid treatments.

Valid consent to receiving treatment under this PGD has been obtained.

1.3. Exclusion criteria

Patients under 3 years of age.

Hypersensitivity to mometasone furoate or to any of the excipients within the nasal spray.

Nasal blockage in the absence of rhinorrhoea, nasal itch and sneezing.

Unilateral discharge.

Untreated localised infection involving the nasal mucosa e.g., herpes simplex.

Patients with symptoms associated with acute bacterial sinusitis e.g., fever, severe pain, purulent discharge.

Patients who have experienced recent nasal surgery or trauma where healing is not complete.

Pregnancy.

Breast Feeding.

Individuals for whom no valid consent has been received.

1.4. Cautions/need for further advice/ circumstances when further advice should be sought from a doctor

Consult **Mometasone Furoate 50 micrograms/dose Nasal Spray, suspension - (SmPC)** for full list of cautions and special warnings.

- Mometasone furoate nasal spray should be used with caution, if at all, in patients with active or quiescent tuberculous infections of the respiratory tract, or untreated bacterial, fungal or systemic viral infections.

- Patients who are potentially immunosuppressed should be warned about of the risk of exposure to certain infections (e.g., chicken pox, measles) and the importance of obtaining medical advice if such exposure occurs.

- Systemic effects of nasal corticosteroids may occur, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different corticosteroid preparations.

- Potential systemic effects may include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, cataract, glaucoma and more rarely, a range of psychological or behavioural

effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children)

- Visual disturbance – if patient presents with visual disturbances e.g., blurred vision or other visual disturbances, referral to an ophthalmologist should be considered for evaluation of possible causes.

1.5. Action if excluded

Consider alternative NHS Pharmacy First Scotland treatments (either under PGD or otherwise).

If appropriate, refer to GP practice and document the reason for exclusion and any action taken in Patient Medication Record (PMR).

1.6. Action if patient declines

If appropriate, refer to GP practice and document the reason for declining treatment and advice given in PMR.

2. Description of treatment

2.1. Name of medicine/form/strength

Mometasone furoate 50micrograms /actuation nasal spray, suspension

2.2. Route of administration

Nasal Spray

2.3. Dosage

Adults and children aged 12 years and over:

- TWO sprays (50 micrograms/actuation) into each nostril once daily (total dose 200 micrograms).
- Once symptoms are controlled, dose reduction to ONE spray in each nostril (total dose 100 micrograms) may be effective for maintenance.
- If symptoms are inadequately controlled, the dose may be increased to a maximum daily dose of FOUR sprays in each nostril once daily (total dose 400 micrograms). Dose reduction is recommended following control of symptoms.

Children aged 3 – 11 years:

- ONE spray (50 micrograms/actuation) into each nostril once daily (total dose 100 micrograms).

2.4. Frequency

Once daily administration

2.5. Duration of treatment

Supply can be repeated for up to 6 months if required i.e., duration of hay fever season.

2.6. Maximum or minimum treatment period

Mometasone furoate nasal spray demonstrates a clinically significant onset of action within 12 hours after the first dose in some patients with seasonal allergic rhinitis; however, full benefit of treatment may not be achieved in the first 48 hours. Therefore, the patient should continue regular use to achieve full therapeutic benefit.

2.7. Quantity to supply

1 x 140 dose nasal spray per supply.

2.8. ▼ black triangle medicines

No

2.9. Legal category

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.

2.10. Is the use out with the SPC?

No.

2.11. Storage requirements

As per manufacturer's instructions – use within 2 months of first use.

Store below 25ºC in a cool, dry place

2.12. Additional information

None

3. Adverse reactions

3.1. Warnings including possible adverse reactions and management of these.

Please refer to current BNF, BNF for Children or SPC for full details.

If a patient experiences any side effects that are intolerable or hypersensitivity reactions occur, the medication should be discontinued.

Common side effects include headache, sneezing, nose bleeds, sore nose or throat, ulcers in nose, respiratory tract infection.

For a full list of side effects, refer to the marketing authorisation holder's Summary of Product Characteristics (SPC). A copy of the SPC must be available to the health professional supplying the medication under this PGD. This can be accessed on **www.medicines.org.uk.**

In the event of severe adverse reaction e.g., swelling of eyes, face, lips or throat, shortness of breath or wheezing, developing of rash or feeling faint, individuals should be advised to seek medical advice immediately.

3.2. Reporting procedure for adverse reactions

Pharmacists should document and report all adverse incidents through their own internal governance systems.

All adverse reactions (actual and suspected) should be reported to the appropriate medical practitioner and recorded in the patient's medical record. Pharmacists should record in their PMR and inform the patient's GP as appropriate.

Where appropriate, healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme. Yellow cards and guidance on their use are available at the back of the BNF or online at **www.mhra.gov.uk/yellowcard.**

3.3. Advice to patient or carer including written information

Written information to be given to individuals:

- Provide manufacturer's consumer information leaflet/patient information leaflet (PIL)

Verbal advice to be given to individuals/parent/carer:

- Advise the individual on mode of action, benefits of the medicine, possible side effects and their management.
- Give general advice for managing high pollen count: stay indoors as much as possible, keeping windows and doors shut; avoid cutting grass, large grassy places and camping; shower and wash your hair after being outdoors, especially in the countryside; wear wrap-around sunglasses when outside; keep car windows closed and consider buying pollen filters for car air vents.
- When using nasal spray for first time, the pump should be primed. See PIL for full details.

- Advise the individual on nasal spray technique – see PIL for details.
- While an improvement in symptoms may be observed within 12 hours of use, it may take several days to obtain the full therapeutic effects of the medication.
- If conditions worsens or symptoms persist, seek further medical advice initially from the pharmacy. Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: **www.mhra.gov.uk/yellowcard.**

3.4. Monitoring

Not applicable

3.5. Follow up

Advise patient if symptoms do not improve after 1 month of regular use or worsening symptoms, they should return to the pharmacy for re-assessment. If patient has exhausted all treatment options available in community pharmacy or is requiring to use for more than 6 months, then refer to GP practice for review.

3.6. Additional facilities

The following should be available when the medication is supplied:

- An acceptable level of privacy to respect patient's rights to confidentiality and safety
- Access to a working telephone
- Access to medical support (this may be via telephone)
- Approved equipment for the disposal of used materials
- Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel
- Access to current BNF (online version preferred)
    - BNF British National Formulary - NICE
    - BNF for Children British National Formulary - NICE
- Access to SmPC/PIL/Risk Minimisation Material:
    - Home - electronic medicines compendium (emc)
    - MHRA Products | Home
    - RMM Directory - (emc)
- Access to copy of current version of this PGD

4. Characteristics of staff authorised under the PGD

4.1. Professional qualifications

Pharmacist with current General Pharmaceutical Council (GPhC) registration.

Under PGD legislation there can be no delegation. Supply of the medication has to be completed by the same practitioner who has assessed the patient under this PGD.

4.2. Specialist competencies or qualifications

Persons must only work under this PGD where they are competent to do so.

All persons operating this PGD must:

- Be familiar with the mometasone fuorate 50 microgram nasal spray medicine and alert to changes in the manufacturer's product information/summary of product information.
- Have successfully complete the NES Pharmacy e-learning module:

  Seasonal Allergic Rhinitis (Hay Fever) for NHS Pharmacy First Scotland | Turas | Learn

  https://learn.nes.nhs.scot/67704/pharmacy/cpd-resources/seasonal-allergic-rhinitis-hay-fever-for-nhs-pharmacy-first-scotland

- Be able to assess the person's/ parent's/ carer's capacity to understand the nature of the purpose of the medication in order to give or refuse consent.

4.3. Continuing education and training

All practitioners operating under this PGD are responsible for:

- Maintaining their skills, knowledge and their own professional level of competence in this area according to the General Pharmaceutical Council Standards for Pharmacy Professionals
- Ensuring they remain up to date with the use of medications included and be aware of local treatment recommendations.
- Attend approved training and training updates as appropriate.
- Undertake relevant continuing professional development when PGD or NES Pharmacy modules are updated.

5. Audit trail

5.1. Authorisation of supply

Pharmacists can be authorised to supply the medicine specified in this PGD when they have completed local Board requirements for service registration.

Pharmacists should complete the individual authorisation form contained in the PGD (Appendix 1) and submit to the relevant NHS Health Board prior to using the PGD.

5.2. Record of supply

All records must be clear, legible, contemporaneous and in an easily retrievable format to allow audit of practice.

A Universal Claim Framework (UCF) record of the screening and subsequent supply, or not, of the medicine specified in this PGD should be made in accordance with the NHS Pharmacy First Scotland service specification.

Pharmacists must record the following information, included in the assessment form, in the PMR (either paper or computer based):

- name of individual, address, date of birth / CHI number
- name of GP with whom the individual is registered (if known)
- confirmation that valid consent to be treated under this PGD was obtained (include details of parent/guardian/person with parental responsibility where applicable)
- details of presenting complaint and diagnosis
- details of medicine supplied - name of medicine, batch number and expiry date, with date of supply.

- details of exclusion criteria – why the medicine was not supplied (if applicable)
- advice given, including advice given if excluded or declines treatment under this PGD
- details of any adverse drug reactions and actions taken
- referral arrangements (including self-care)
- signature and printed name of the pharmacist who undertook assessment of clinical suitability and, where appropriate, subsequently supplied the medicine

The patient's GP (where known) should be provided with a copy of the GP notification form for the supply of mometasone 50micrograms nasal spray, or appropriate referral on the same, or next available working day.

These records should be retained in accordance with national guidance[1] (see page 56 for standard retention periods summary table). Where local arrangements differ, clarification should be obtained through your Health Board Information Governance Lead.

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

1. Scottish Government. *Scottish Government Records Management.* Edinburgh 2020. Available at **SG-HSC-Scotland-Records-Management-Code-of-Practice-2020-v20200602.pdf** (Accessed on 31st March 2023)

6. Additional references

Practitioners operating the PGD must be familiar with:

1. National Institute for Clinical Excellence / Public Health England. Available at: **Allergic rhinitis | Health topics A to Z | CKS | NICE**. (Accessed 31st March 2023)

2. Current edition of British National Formulary (BNF) BNF British National Formulary - NICE, and BNF for children BNF for Children British National Formulary - NICE

3. Marketing authorisation holder's Summary of Product Characteristics. Electronic Medicines Compendium. *Mometasone furoate 50mcg / actuation Nasal Spray, suspension. SPC.* Available **Mometasone Furoate 50 micrograms/dose Nasal Spray, suspension - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)** (Accessed 31st March 2023)

7. Individual authorisation (Appendix 1)

PGDs FOR THE SUPPLY OF TREATMENTS FOR SEASONAL ALLERGIC RHINITIS BY COMMUNITY PHARMACISTS UNDER THE "NHS PHARMACY FIRST SCOTLAND" SERVICE

Health Boards to provide authorisation form to pharmacy contractors

8. Version history

Version	Date	Summary of changes
1.0	17/05/23	New National Specimen PGD produced.

Patient Group Direction (PGD)

This PGD authorises community pharmacists to supply olopatadine 1mg/ml eye drops to patients aged 3 years and over presenting with symptoms of seasonal allergic conjunctivitis under NHS Pharmacy First Scotland.

Publication date: 17 May 2023

Version 1.0

NHS SCOTLAND

Most Recent Changes

Version	Date	Summary of changes
1.0	17/05/2023	• New national PGD produced.

Contents

Authorisation 4

1. Clinical situation 6

2. Description of treatment 8

3. Adverse reactions 10

4. Characteristics of staff authorised under the PGD 14

5. Audit trail 15

6. Additional references 17

7. Individual authorisation (Appendix 1) 18

8. Version history 19

Authorisation

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

PGD olopatadine 1mg/ml eye drops

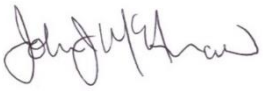
This specimen PGD template has been produced in collaboration with the Primary Care Community Pharmacy Group to assist NHS Boards in the uniform provision of services under 'NHS Pharmacy First Scotland' banner across NHS Scotland. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

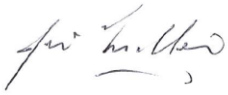
The community pharmacist who may supply olopatadine eye drops under this PGD can do so only as a named individual. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with the General Pharmaceutical Council Standards for Pharmacy Professionals and to ensure familiarity with the manufacturer's product information/summary of product characteristics (SPC) for all medicines supplied in accordance with this PGD.

NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Supply of the medicine has to be by the same practitioner who has assessed the patient under the PGD.

This PGD has been approved on behalf of NHS Scotland by NHS 24 by:

Doctor (Name / Signature): Dr Laura Ryan 

Pharmacist (Name /Signature): Dr John McAnaw 

NHS Scotland representative (Name / Signature): Mr Jim Miller 

Approved on behalf of NHS……*insert Board*…… by:

Medical Director (Name / Signature) ……..
Director of Pharmacy/Senior Pharmacist (Name / Signature) ……
Clinical Governance Lead (Name / Signature) ……..
Date approved: ……

Effective from: *insert date*

It is the responsibility of the person using the PGD to ensure they are using the most recent issue.

Expiry date: 17 May 2026

1. Clinical situation

1.1. Indication

Relief of signs and symptoms of seasonal allergic conjunctivitis

1.2. Inclusion criteria

Patients aged 3 years and older with ocular symptoms of seasonal allergic rhinitis **who have been diagnosed with allergic conjunctivitis.**

AND

Who have had treatment failure or remain symptomatic despite use of at least one other allergy treatment for ocular symptoms available over the counter.

NB: A combination of oral, nasal spray and eye treatment products may be required to obtain acceptable symptom control. However, olopatadine should not be used together with other topical eye treatments for allergic conjunctivitis.

1.3. Exclusion criteria

Patients under 3 years of age.

Patient without a diagnosis of allergic conjunctivitis.

Previous hypersensitivity to olopatadine or to any of the excipients.

Pregnancy.

Patient of child-bearing ability not using effective contraception.

Breast Feeding.

Current treatment with olopatadine which exceeds 4 months in duration.

Individuals for whom no valid consent has been received.

1.4. Cautions/need for further advice/circumstances when further advice should be sought from a doctor/optometrist

Caution in previous frequent or prolonged use of olopatadine in patients with dry eyes.

Compromised cornea.

Red eye caused by another reason e.g., accompanied by purulent discharge, altered visual acuity, wearing of contact lenses, chemical exposure, anticoagulation.

1.5. Action if excluded

Seek advice from local optometrist. Document the reason for exclusion and any action taken in Patient Medication Record (PMR).

1.6. Action if patient declines

If appropriate, refer to optometrist and document the reason for declining treatment and advice given in PMR.

2. Description of treatment

2.1. Name of medicine/form/strength

Olopatadine 1mg/ml eye drops

2.2. Route of administration

Topical ocular administration

2.3. Dosage

One drop into affected eye(s)

2.4. Frequency

Twice daily (Eight hourly)

2.5. Duration of treatment

Until resolution of symptoms (e.g., red, itchy, gritty, watery discharge, swollen eyelids).

2.6. Maximum or minimum treatment period

MAXIMUM treatment period in total – FOUR months (28 days per individual bottle).

2.7. Quantity to supply

One 5ml bottle per supply

2.8. ▼ black triangle medicines

No

2.9. Legal category

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.

2.10. Is the use out with the SPC?

No.

2.11. Storage requirements

As per manufacturer's instructions

Store below 25ºC in a cool, dry place

2.12. Additional information

None

3. Adverse reactions

3.1. Warnings including possible adverse reactions and management of these.

Please refer to current BNF or SPC for full details

If a patient experiences any side effects that are intolerable or hypersensitivity reactions occur, the medication should be discontinued.

For a full list of side effects, refer to the marketing authorisation holder's Summary of Product Characteristics (SPC). A copy of the SPC must be available to the health professional supplying the medication under this PGD. This can be accessed on **www.medicines.org.uk**

Common side effects include headache, distortion in the sense of taste (dysgeusia), eye pain, eye irritation, dry eye, abnormal sensation in eyes, nasal dryness and fatigue.

Other less common side effects include: rhinitis, dizziness, hypoaesthesia, corneal erosion, corneal epithelium defect, corneal epithelium disorder, punctate keratitis, keratitis, corneal staining, eye discharge, photophobia, blurred vision, visual acuity reduced, blepharospasm, ocular discomfort, eye pruritis, conjunctival follicles, conjunctival disorder, foreign body sensation in eyes, lacrimation increased, eyelids pruritis, erythema of eyelid, eyelid oedema, eyelid disorder, ocular hyperaemia

In the event of severe adverse reaction individuals should be advised to seek medical advice.

3.2. Reporting procedure for adverse reactions

Pharmacists should document and report all adverse incidents through their own internal governance systems.

All adverse reactions (actual and suspected) should be reported to the appropriate medical practitioner and recorded in the patient's medical record. Pharmacists should record in their PMR and inform the patient's GP/optometrist as appropriate.

Where appropriate, healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme. Yellow cards and guidance on their use are available at the back of the BNF or online at **www.mhra.gov.uk/yellowcard.**

3.3. Advice to patient or carer including written information

Written information to be given to individuals:

- Provide manufacturer's consumer information leaflet/patient information leaflet (PIL).

Verbal advice to be given to individuals:

- Advise individual on mode of action, benefits of the medicine, possible side effects and their management.
- Give general advice for managing high pollen count: stay indoors as much as possible, keeping windows and doors shut; avoid cutting grass, large grassy places and camping; shower and wash your hair after being outdoors, especially in the countryside; wear wrap-around sunglasses when outside; keep car windows closed and consider buying pollen filters for car air vents.
- Wearers of contact lenses should remove lenses prior to application of olopatadine eye drops and wait at least 15 minutes after instillation before re-inserting lenses.
- In case of concomitant therapy with other topical ocular medicines, an interval of 10 minutes should be allowed between successive applications. Eye ointments should be administered last.

- Demonstrate the best way to self-administer eye drops.
- Vision may be blurred for a few minutes after instillation – if affected, the patient should not drive or operate hazardous machinery.
- Advise that there might be mild stinging on instillation of drops.
- Treatment with olopatadine should be for a maximum of four months at a time.
- In patients of childbearing potential, effective contraception is required whilst using olopatadine.
- Olopatadine contains benzalkonium chloride which may cause eye irritation.
- Advise to seek medical advice in the event of a severe adverse reaction.
- If the condition worsens or symptoms persist, seek further advice from an optometrist.
- Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: **www.mhra.gov.uk/yellowcard.**

3.4. Monitoring

Not applicable

3.5. Follow up

None

If patient is requiring to use for longer than 4 months, then refer to optometrist/GP for review.

3.6. Additional facilities

The following should be available when the medication is supplied:

- An acceptable level of privacy to respect patient's rights to confidentiality and safety
- Access to a working telephone
- Access to medical support (this may be via telephone)
- Approved equipment for the disposal of used materials
- Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel
- Access to current BNF (online version preferred)
    - BNF British National Formulary - NICE
    - BNF for Children British National Formulary - NICE
- Access to SmPC/PIL/Risk Minimisation Material:
    - Home - electronic medicines compendium (emc)
    - MHRA Products | Home
    - RMM Directory - (emc)
- Access to copy of current version of this PGD

4. Characteristics of staff authorised under the PGD

4.1. Professional qualifications

Pharmacist with current General Pharmaceutical Council (GPhC) registration.

Under PGD legislation there can be no delegation. Supply of the medication has to be completed by the same practitioner who has assessed the patient under this PGD.

4.2. Specialist competencies or qualifications

Persons must only work under this PGD where they are competent to do so.

All persons operating this PGD must:

- Be familiar with the olopatadine 1mg/ml eye drop medicine and alert to changes in the manufacturer's product information/summary of product information.
- Have successfully complete the NES Pharmacy e-learning module:

  Seasonal Allergic Rhinitis (Hay Fever) for NHS Pharmacy First Scotland | Turas | Learn

  https://learn.nes.nhs.scot/67704/pharmacy/cpd-resources/seasonal-allergic-rhinitis-hay-fever-for-nhs-pharmacy-first-scotland
- Be able to assess the person's/ parent's/ carer's capacity to understand the nature of the purpose of the medication in order to give or refuse consent.

4.3. Continuing education and training

All practitioners operating under this PGD are responsible for:

- Maintaining their skills, knowledge and their own professional level of competence in this area according to the General Pharmaceutical Council Standards for Pharmacy Professionals
- Ensuring they remain up to date with the use of medications included and be aware of local treatment recommendations.
- Attend approved training and training updates as appropriate.
- Undertake relevant continuing professional development when PGD or NES Pharmacy modules are updated.

5. Audit trail

5.1. Authorisation of supply

Pharmacists can be authorised to supply the medicine specified in this PGD when they have completed local Board requirements for service registration.

Pharmacists should complete the individual authorisation form contained in the PGD (Appendix 1) and submit to the relevant NHS Health Board prior to using the PGD.

5.2. Record of supply

An electronic or paper record must be completed to allow audit of practice. All records must be clear, legible, contemporaneous and in an easily retrievable format.

Pharmacists must record the following information, included in the assessment form, in the PMR (either paper or computer based):

- name of individual, address, date of birth / CHI number

- name of GP with whom the individual is registered (if known)
- confirmation that valid consent to be treated under this PGD was obtained (include details of parent/guardian/person with parental responsibility where applicable)
- details of presenting complaint and diagnosis
- details of medicine supplied - name of medicine, batch number and expiry date, with date of supply.
- details of exclusion criteria – why the medicine was not supplied (if applicable)
- advice given, including advice given if excluded or declines treatment under this PGD
- details of any adverse drug reactions and actions taken
- referral arrangements (including self-care)
- signature and printed name of the pharmacist who undertook assessment of clinical suitability and, where appropriate, subsequently supplied the medicine

The patient's GP (where known) should be provided with a copy of the GP notification form for the supply of olopatadine 1mg/ml eye drops, or appropriate referral on the same, or next available working day.

These records should be retained in accordance with national guidance[1] (see page 56 for standard retention periods summary table). Where local arrangements differ, clarification should be obtained through your Health Board Information Governance Lead.

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

1. Scottish Government. *Scottish Government Records Management.* Edinburgh 2020. Available at **SG-HSC-Scotland-Records-Management-Code-of-Practice-2020-v20200602.pdf** (Accessed on 31st March 2023)

Additional references

Practitioners operating the PGD must be familiar with:

1. National Institute for Clinical Excellence / Public Health England. Available at: **Allergic rhinitis | Health topics A to Z | CKS | NICE**. (Accessed 31st March 2023)

2. Current edition of British National Formulary (BNF) and BNF for children

3. Marketing authorisation holder's Summary of Product Characteristics. Electronic Medicines Compendium. *Olopatadine 1mg/ml eye drops, Solution SPC.* Available at **Olopatadine 1 mg/ml Eye drops, Solution - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)** (Accessed 31st March 2023)

7. Individual authorisation (Appendix 1)

PGDs FOR THE SUPPLY OF TREATMENTS FOR SEASONAL ALLERGIC RHINITIS BY COMMUNITY PHARMACISTS UNDER THE "NHS PHARMACY FIRST SCOTLAND" SERVICE

Health Boards to provide authorisation form to pharmacy contractors

8. Version history

Version	Date	Summary of changes
1.0	17/05/2023	New National PGD produced.