Patient Group Direction

For the supply of

Azelastine hydrochloride 0.1% w/v (140 micrograms/dose) nasal spray

By registered community pharmacists providing the

NHS Wales Clinical Community Pharmacy Service for

the treatment of symptoms of allergic rhinitis

in [Powys Teaching Health Board]

Operational from: 1st July 2023

Review Date: 31st March 2026

Version number: 1.0

PGD for the supply of Azelastine hydrochloride 0.1% w/v (140 micrograms/spray) nasal spray for the treatment of symptoms of allergic rhinitis by pharmacists delivering the Common Ailment Service component of the Clinical Community Pharmacy Service

Reference:	Azelastine hydrochloride 0.1% w/v (140 micrograms/spray) nasal spray PGD
Version no:	1.0
Valid from:	1st July 2023
Review date:	31st March 2026
Expiry date:	30th June 2026

Welsh Medicines Advice Service has developed this PGD for local authorisation

Those using this PGD must ensure that it is authorised by the Local Health Board in which they are operating and signed in section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with the Human Medicines Regulations 2012 (HMR2012)[1]. **THE PGD IS NOT LEGAL OR VALID WITHOUT SIGNED AUTHORISATION IN ACCORDANCE WITH HMR2012 SCHEDULE 16 Part 2.**

Authorising organisations must not *alter, amend* or *add* to the *clinical* content of this document. Such action will invalidate the *clinical sign-off* with which it is provided.

As operation of this PGD is the responsibility of service providers, the authorising organisation can decide which staff groups, in keeping with relevant legislation, can work to the PGD.

INDIVIDUAL PRACTITIONERS MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date.

Any queries regarding the clinical content of this PGD should be addressed to: welshmedicines.information@wales.nhs.uk

Change history:

Version number	Change details	Date
1.0	Original PGD template developed	20th February 2023

[1] this includes any relevant amendments to legislation (e.g. 2013 No.235, 2015 No.178 and 2015 No.323).

1. PGD development

This PGD has been developed and peer reviewed by an expert panel and approved by the Community Pharmacy Clinical Advisory Group (CPCAG) in accordance with the PGD Policy.

This section MUST REMAIN when a PGD is adopted by an organisation

Expert panel

Name	Position	Designation
Alya Al-Affan	Main author	Formulary and PGD Lead for the Common Ailments Service, Welsh Medicines Advice Service, Cardiff and Vale UHB
Adam Mackridge	CPCAG reviewer	Chair of Community Pharmacy Clinical Advisory Group (CPCAG) and Strategic Lead Pharmacist for Community Pharmacy, Betsi Cadwaladr UHB
Rachel James	CPCAG reviewer	Advanced Pharmacist, Community and Practice Development, Hywel Dda UHB
Manjeet Singh	Medical Reviewer	Consultant in Acute Care, Aneurin Bevan UHB

Date CPCAG approval of PGD: 13th June 2023

2. Organisational authorisations

The PGD is not legally valid until it has had the authorisation of the Local Health Board in which the community pharmacy using it operates.

It is the responsibility of the Local Health Board, to ensure that all legal and governance requirements are met. The Local Health Board accepts governance responsibility for the appropriate use of the PGD.

Powys Teaching Health Board authorises this PGD for use by community pharmacies within its area that have been commissioned to provide the Common Ailments Service component of the Clinical Community Pharmacy Service. This authorisation is limited to those pharmacists that meet the requirements set out within the PGD.

Local Health Board approval (legal requirement) as per health board policy			
Role	**Name**	**Sign**	**Date**
Lead Doctor for PTHB	Dr Kate Wright	DocuSigned by: Kate Wright 1F267952823F473...	8/22/2023
Chief Pharmacist for PTHB	Jacqui Seaton	DocuSigned by: Jacqui Seaton 71E8089DE3634C4...	8/24/2023
Clinical Governance Lead for PTHB	Amanda Edwards	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	8/29/2023
Senior Pharmacist Lead for Community Pharmacies, PTHB	Emlyn Pritchard	DocuSigned by: Emlyn Pritchard EB776BA7283F49B...	8/24/2023

Local enquiries regarding the use of this PGD may be directed to welshmedicines.information@wales.nhs.uk

Appendix B provides a practitioner listing sheet. Individual practitioners must be listed by name to work to this PGD. Alternative practitioner listing sheets may be used where appropriate in accordance with local policy, but this should be an individual agreement or a multiple practitioner listing sheet as included at the end of this PGD.

3. Characteristics of Staff

Qualifications and professional registration	This PGD is for use by pharmacists currently registered with the General Pharmaceutical Council (GPhC).
Additional requirements	Pharmacists must: ➢ be employed by, or providing services on behalf of a pharmacy listed in the All Wales Pharmacy Database (AWPD) for the Clinical Community Pharmacy Service ➢ be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it by completing Appendix B ➢ be familiar with the medicine and alert to changes in the Summary of Product Characteristics (SmPC). ➢ have access to the Patient Group Direction and associated resources (including the service specification and the clinical guidance document supporting the PGD) and must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs). ➢ be named in the All Wales Pharmacy Database for the Common Ailment component of the Clinical Community Pharmacy Service. ➢ have met the training requirements for the service as set out by HEIW (Health Education and Improvement Wales). ➢ be familiar with the British National Formulary (BNF) and SmPC entries for azelastine hydrochloride 140 micrograms/dose nasal spray. ➢ have awareness of the adverse drug reactions associated with azelastine hydrochloride 140 micrograms/dose nasal spray **The pharmacist must be listed by name, under the current version of this PGD that has been issued by the local health board in which area they are operating before working under its authority.**
Ongoing training and competency	Pharmacists must: ➢ undertake regular CPD and maintain own level of competence and knowledge in this clinical area to provide the service. ➢ be aware of any updates made to the products in the SmPC and BNF.

	➢ be aware of any updates to relevant national and local guidelines A record of training and competence must be maintained in the individual's personal file.

4. Clinical condition

Clinical condition or situation to which this PGD applies	For the treatment of the symptoms of allergic rhinitis in accordance with the community pharmacy Common Ailments Service (CAS) component of the Clinical Community Pharmacy Service (CCPS).
Criteria for inclusion	Azelastine hydrochloride 0.1% w/v (140 micrograms/dose) nasal spray can be given to: Individuals aged 6 years and over, presenting with mild-to-moderate intermittent or mild, persistent symptoms of allergic rhinitis and: ➢ they have no contraindications to azelastine hydrochloride 0.1% w/v (140 micrograms/dose) nasal spray– see SmPC ➢ where informed consent has been given (patient, parent/guardian, carer)
Criteria for exclusion[2]	Azelastine hydrochloride 0.1% w/v (140 micrograms/dose) nasal spray should not be supplied: ➢ to individuals who present with red flag symptoms including: o fever o shortness of breath o recurrent epistaxis o nasal pain ➢ if infective rhinitis is suspected e.g. high fever, extreme tenderness around the eyes or nose ➢ if symptoms are thought to be medication-related e.g. decongestants (rebound congestion), alpha-blockers, ACE inhibitors, beta-blockers, aspirin and NSAIDs as the individual will need a medication review. ➢ if symptoms are thought to be due to a non-allergic cause

[2] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required.

	e.g. chemical, physical, endocrine, food and drink, systemic, structural ➢ if symptoms are refractory to treatment with azelastine nasal spray. ➢ if diagnosis is uncertain ➢ alongside the medication isocarboxazid, phenelzine or tranylcypromine as these are predicted to increase the risk of antimuscarinic adverse effects when given alongside azelastine; concomitant use should be avoided ➢ to individuals with known hypersensitivity to azelastine hydrochloride 0.1% w/v (140 micrograms/dose) nasal spray or any of the excipients – see SmPC. ➢ if the pharmacist is unable to undertake an appropriate assessment, in order to determine the need for the medicine and that it would be appropriate for the patient to use it. ➢ to individuals who are unable to administer or use the product effectively themselves or who do not have a parent/guardian/carer to administer or apply the medication for them. ➢ if individual does not agree to share relevant clinical information.
Cautions (including relevant actions to be taken)	Please refer to the SmPC for Azelastine hydrochloride 0.1% w/v (140 micrograms/dose) nasal spray for full details of special warnings and precautions for use. ➢ Pregnancy and lactation: minimal systemic exposure can be expected following intranasal administration due to the low dose and route of administration. See also drug interaction section below for additional cautions.
Action to be taken if the individual is excluded or declines treatment	➢ Explain the reasons for exclusion to the individual and document in the consultation record. ➢ If the individual declines, record the reason and advise of the consequences of not receiving treatment. Document the advice given alongside details of any referral made and their (patient, parent, guardian) intended actions. ➢ If appropriate, patients may be offered a suitable alternative to Azelastine hydrochloride 0.1% w/v (140 micrograms/dose) nasal

	spray from the All Wales Common Ailments Service Formulary. Alternatively, refer the individual to their GP if appropriate and/or provide them with information about further options. ➢ Where there are safeguarding concerns, seek advice from local safeguarding services.
Further advice	➢ Further information can be found in the SmPC, BNF and the All Wales Common Ailments Service Formulary.

5. Description of treatment

Name, strength & formulation of drug	Azelastine hydrochloride 0.1% w/v (140 micrograms/dose) nasal spray
Legal category	Prescription Only Medicine (POM)
Black triangle▼	No
Off-label use	No
Route / method of administration	Intranasal
Dose and frequency of administration	**Adults and children aged 6 years and over:** ONE spray application in each nostril TWICE a day until symptoms resolve.
Duration of treatment	This PGD only allows for the duration stated in the dosage schedule above.
Quantity to be supplied/administered	Appropriately labelled pack to provide treatment for 6 weeks. 1 x 22 mL pack to provide 6 weeks of treatment at a dose of TWICE daily intranasal application.
Drug interactions	➢ The SmPC for azelastine nasal spray states no specific interactions have been studied. ➢ The BNF states since systemic absorption can follow topical application, the possibility of interactions with topical azelastine should be borne in mind: **Contraindication** ➢ Isocarboxazid, phenelzine, tranylcypromine – these are predicted to increase the risk of antimuscarinic adverse

	effects when given alongside azelastine. Manufacturer advises avoid. **Caution** ➢ Betahistine – azelastine is predicted to decrease the effects of betahistine. Prior to offering treatment to an individual, the SmPC and the BNF should be referred to in order to check there are no changes regarding the interaction status of azelastine.
Identification & management of adverse reactions	A detailed list of adverse reactions is available in the SmPC, and the BNF. This list does not reflect all reported side effects. If the patient experiences any of the following they must discontinue treatment: ➢ difficulty breathing or swallowing ➢ swelling of the mouth, face, lips, tongue or throat (severe allergic reaction symptoms) ➢ severe itching of the skin, with a rash or raised lumps, hives or blisters. The following side effects have been reported as: Very common to common (affecting less than 1 in 10 or between 1 in 10 and 1 in 100 patients) ➢ Bitter taste: this may be experienced after administration (often due to incorrect method of application, namely tilting the head too far backwards during administration) which in rare cases may lead to nausea. Uncommon (affecting between 1 in 100 and 1 in 1000 patients) ➢ Mild, transient irritation of the inflamed nasal mucosa may occur with symptoms such as: o stinging o itching o sneezing

	○ epistaxis N.B detailed lists of adverse reactions are available in the SmPC, and the BNF. Prior to issuing medication, please refer to these resources to check that there has been no change to the potential adverse reactions listed above.
Patient or carer advice/follow up	Supply the marketing authorisation holder's patient information leaflet (PIL). **Directions for use** Instructions for preparation if preparation supplied as separate bottle and pump 1) Open the bottle by unscrewing the cap. 2) Place the spray pump nozzle in the bottle and screw the pump onto the bottle. Remove the protective cap. 3) Before first using, squeeze down the collar several times until an even spray emerges. The spray is now ready to use. Instructions for preparation if preparation supplied as attached pump and bottle 1) Remove the protective cap. 2) Before first using, squeeze down the collar several times until an even spray emerges. The spray is now ready to use. How to use the spray Correct technique is very important when using nasal sprays to give the best chance of a satisfactory response to the medication. 1) Blow nose 2) Shake the container well and remove the protective cap. 3) Before the first use, press the pump several times until an even spray emerges. 4) Keeping head straight and looking down, use the right hand for the left nostril and put the nozzle just inside the nose aiming for the outside wall.

(continued over page)	5) Squeeze once while breathing in gently through the nose. Do not sniff. 6) Change hands, then repeat for the other nostril. 7) Wipe the pump nozzle and replace the protective cap. <u>If more nasal spray than recommended is used</u> ➢ This is unlikely to cause any problems. Seek advice from your pharmacist if you are worried.
Patient or carer advice/follow up (continued)	➢ If anyone, especially a child, accidentally drinks the nasal spray solution, contact your pharmacist, doctor or local hospital casualty department immediately. ➢ If you accidentally get nasal spray in your eyes, bathe them with plenty of water. They may sting for a while. <u>If a dose of the nasal spray is missed</u> ➢ Use the spray as soon as you remember, then take the next dose at the usual time. ➢ Do not use a double dose to make up for a missed dose. **Lifestyle advice** ➢ Allergen avoidance (if a specific identified allergen is the cause of symptoms). Examples include: o wearing wraparound sunglasses to protect your eyes from pollen o use hypoallergenic bedding and covers; wash bedding regularly at ≥ 60°C o dust with a damp cloth and use a vacuum with a HEPA filter o do not allow pets in bedrooms and wash them at least once every 2 weeks and groom them outside regularly

(continued over page)	○ regularly wash your pet's bedding and clean any furniture they've been on ○ avoid drying clothes outside when pollen count high ○ keep your home dry and well-ventilated; resolve any damp/condensation issues ➢ Provision of information and support e.g. for hay fever, signposting to the Allergy UK website (https://www.allergyuk.org/types-of-allergies/hayfever/) **Signposting** Inform the individual or carer: ➢ if they get any side effects, to talk to their doctor, or pharmacist or nurse and report any suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) by using the Yellow Card
Patient or carer advice/follow up (continued)	reporting scheme. This includes any possible side effects not listed in the PIL ➢ to seek medical advice if their condition deteriorates and/or they become systemically unwell. ➢ to read the PIL before taking the medication ➢ to visit the NHS website on allergic rhinitis for more information ➢ individuals should return to the pharmacy if symptoms do not improve after initial treatment as there are other options within CAS that may be suitable to trial. ➢ if fever, shortness of breath, recurrent epistaxis or nasal pain occurs, the individual should seek review with their GP.
Records	The consultation details including any medication supplied under this PGD must be recorded in Choose Pharmacy at the time of the consultation. Where the Choose Pharmacy platform is not available, temporary records must be made using the paper-based consultation record. Paper based records must be transferred into Choose Pharmacy as soon as practically possible following the consultation. If the patient is excluded, a record of the reason for

	exclusion and any specific advice that has been given must be documented within the consultation notes.

Appendices

Appendix A: *Key references*

- British National Formulary (BNF) – current edition. Available from: https://bnf.nice.org.uk/ [accessed 20 March 2023]
- Summary Product Characteristics (SmPC). Available from: https://www.medicines.org.uk/emc/ [accessed 20 March 2023]
- Patient Group Directions. Medicines practice guideline [MPG2]. Updated March 2017. Available from: http://www.nice.org.uk/guidance/mpg2/resources [accessed 20 March 2023]
- General Pharmaceutical Council. In Practice: Guidance on Consent. Revised June 2018. Available from: https://www.pharmacyregulation.org [accessed 20 March 2023]
- General Pharmaceutical Council. In Practice: Guidance on Confidentiality. Revised June 2018. Available from: https://www.pharmacyregulation.org [accessed 20 March 2023]
- All Wales Medicines Strategy Group. All Wales Common Ailments Formulary. February 2018. Available from: https://awttc.nhs.wales [accessed 20 March 2023]
- National Institute for Health and Care Excellence: Clinical Knowledge Summaries. Allergic rhinitis. Last revised December 2022. Available from: https://cks.nice.org.uk [accessed 02 May 2023]
- Yellow Card Reporting. Available from: http://yellowcard.mhra.gov.uk [accessed 20 March 2023]
- NHS 111 Wales Health A-Z. Available from: https://111.wales.nhs.uk [accessed 20 March 2023]
- NHS Medicines A-Z. Available from: https://www.nhs.uk [accessed 20 March 2023]

Appendix B: *Healthcare Professionals Agreement to Practice*

Authorisation for the use of the Patient Group Direction for the supply of:
Azelastine hydrochloride 0.1% w/v (140 micrograms/dose) nasal spray
by community pharmacists under the Clinical Community Pharmacy Service,
Common Ailment Service (allergic rhinitis) commissioned by
[Powys Teaching Health Board]

Patient Group Directions do not remove inherent professional obligations or accountability.

Once completed and approved, health professionals wishing to use the PGD must sign up to the PGD for the local health board in which they will be providing services. Only pharmacists who are accredited in line with the National Service Specification can operate under the PGD.

This Patient Group Direction is to be read, agreed and signed by all registered healthcare professionals authorised to operate the PGD. By signing this document, the professional operating the PGD confirms that they have read and understood the content of this PGD and are willing and competent to work under it within their professional code of conduct. One copy should be given to each named pharmacist and a signed copy must be kept within the pharmacy by the nominated member of staff with responsibility for PGDs. This will usually be the Superintendent Pharmacist or Responsible Pharmacist.

Name and address of pharmacy:

For registered professional

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work under it within my professional code of conduct.

Name of registered pharmacist	Signature	GPhC number	Date