Patient Group Direction

For the supply of

Nystatin oral suspension 100,000 units/mL

By registered community pharmacists providing the

NHS Wales Clinical Community Pharmacy Service for

the treatment of oral candidiasis

in Powys Teaching Health Board

Operational from: 1st July 2023

Review Date: 31st March 2026

Version number: 1.0

PGD for the supply of nystatin oral suspension 100,000 units/mL for the treatment of oral thrush by pharmacists delivering the Common Ailment Service component of the Clinical Community Pharmacy Service

Reference:	Nystatin oral suspension 100,000 units/mL 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	24th 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
Dianne Burnett	Main author	National Lead Pharmacist Welsh Medicines Advice Service, Cardiff and Vale UHB
Adam Mackridge	Professional lead CPCAG reviewer	Chair of Community Pharmacy Clinical Advisory Group (CPCAG) and Strategic Lead Pharmacist for Community Pharmacy, Betsi Cadwaladr UHB
Meryl Davies	CPCAG reviewer	Lead Antimicrobial Pharmacist, Primary and Community Care, Public Health Wales
Dr. Federica Faggian	Medical Reviewer	Consultant microbiologist, Cardiff and Vale UHB

Date CPCAG approval of PGD: 3rd July 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...	9/15/2023
Chief Pharmacist for PTHB	Jacqui Seaton	DocuSigned by: Jacqui Seaton 71E8089DE3634C4...	9/18/2023
Clinical Governance Lead for PTHB	Amanda Edwards	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	9/19/2023
Senior Pharmacist Lead for Community Pharmacies, PTHB	Emlyn Pritchard	DocuSigned by: Emlyn Pritchard EB776BA7283F49B...	25/08/2023

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 nystatin oral suspension. ➢ have awareness of the adverse drug reactions associated with nystatin oral suspension. **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. ➢ as registered professionals, be professionally accountable and must work within their competence. A record of any training and competency assessments undertaken must be maintained.

4. Clinical condition

Clinical condition or situation to which this PGD applies	For the treatment of oral thrush in accordance with the community pharmacy Common Ailment Service (CAS) component of the Clinical Community Pharmacy Service (CCPS).
Criteria for inclusion	Nystatin oral suspension can be given to individuals aged 4 weeks and over, presenting with symptoms of oral candidiasis including white spots or plaques in the mouth which can be wiped off leaving behind red patches, (erythema) loss of taste and where miconazole oral gel is unsuitable and: ➢ they have an identified risk factor for oral candidiasis: o dentures o recent antibiotic or steroid treatment o diabetes; treatment can be offered with referral to GP for follow up (see cautions) o excessive mouth wash use o iron, folate or vitamin B12 deficiency o smokers o babies and the elderly o individuals with known immunosuppression except for those listed in the exclusions. For example, individuals taking oral corticosteroids or disease-modifying anti-rheumatic drugs (DMARDs). Treatment can be offered with referral to GP for follow up o individuals with poor health ➢ they have no contraindications to nystatin – see SmPC ➢ where informed consent has been given (patient, parent/guardian, carer)
Criteria for exclusion[2]	Nystatin oral suspension should not be supplied: ➢ to infants less than 4 weeks of age ➢ if the individual has signs of widespread or severe infection e.g. difficulty or pain on swallowing, or retrosternal pain ➢ if the individual is systemically unwell ➢ if the individual has no obvious risk factor outlined in the inclusion criteria and is otherwise healthy ➢ if the individual has a single red or red and white plaque that cannot be rubbed off. (erythroplakia, erythroleukoplakia) ➢ to individuals with known hypersensitivity to nystatin or any of the excipients – see SmPC ➢ to individuals with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption, or sucrase-isomaltase insufficiency; nystatin contains sucrose ➢ to individuals receiving chemotherapy ➢ to individuals with known immunosuppression AND the infection is extensive or severe or there is suspicion that their

[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.

Criteria for exclusion	immunosuppressive treatment e.g. DMARDs are causing marked immunosuppression ➢ to individuals who are HIV positive ➢ to individuals with suspected immunosuppression and not currently receiving treatment ➢ if the individual continues to have symptoms despite appropriate treatment for seven days ➢ 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 the product effectively themselves or who do not have a parent/guardian/carer to administer or apply the medication for them ➢ if an individual does not agree to share relevant clinical information
Cautions (including relevant actions to be taken)	Please refer to the SmPC for nystatin oral suspension for full details of special warnings and precautions for use. **Hypersensitivity Reactions** In the event of irritation or sensitisation treatment should be discontinued. In the event of severe acute hypersensitivity reactions, such as anaphylaxis and angioedema, the patient should be advised to consult a doctor immediately. **Skin reactions** In the event of serious skin reactions, e.g. Stevens-Johnson syndrome, the patient should be advised to discontinue treatment at the first appearance of a skin rash and to consult a doctor immediately. **Diabetes** Nystatin contains sucrose. Individuals with diabetes can be supplied with treatment if, in the opinion of the pharmacist, there are no concerns or symptoms suggestive of current poor control. For example, thirst, blurred vision, fatigue etc. Provided there are no alarming features, signs or symptoms, treatment can be supplied. Where treatment is supplied, the individual must be advised to makes an appointment with their diabetic clinic/diabetic nurse for review within 7 days of supply. **Pregnancy** Absorption of nystatin from the gastrointestinal tract is negligible. However, the manufacturer advises that it should be prescribed during pregnancy only if the potential benefits to be derived outweigh the possible risks involved, as it is not known whether nystatin can cause foetal harm when administered to a pregnant woman. Where treatment is supplied, the individual must be advised

Cautions (including relevant actions to be taken) (continued)	to make an appointment with their GP for review within 7 days of supply. **Breast feeding** The manufacturer advises that caution should be exercised when nystatin is prescribed for a breastfeeding woman, as it is not known whether nystatin is excreted in human milk. However, there is extensive experience of safe use in breastfeeding. **Excipients** ➢ Nystatin Oral Suspension contains 0.3 mmol (or 1.3 mg) sodium per 1 mL dose. To be taken into consideration by patients on a controlled sodium diet. ➢ Nystatin Oral Suspension contains sodium metabisulphite (E223) which may rarely cause severe hypersensitivity reactions and bronchospasm. ➢ Nystatin Oral Suspension contains propyl p-hydroxybenzoate and methyl p-hydroxybenzoate which may cause allergic reactions (possibly delayed). ➢ Some nystatin formulations may contain a small amount of ethanol, less than 100 mg per dose.
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 nystatin oral suspension 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. ➢ If the red or red and white plaque cannot be rubbed off, advise the individual to see a dentist.
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	Nystatin oral suspension 100,000 units/mL
Legal category	POM
Black triangle▼	No
Off-label use	No
Route / method of administration	Oral suspension should be used in the mouth.
Dose and frequency of administration	1 mL (100,000 units) suspension dropped into the mouth FOUR TIMES DAILY for SEVEN days. Treatment should be continued for 48 hours after lesions have resolved.
Duration of treatment	This PGD only allows for the duration stated in the dosage schedule above. Treatment should be continued for 48 hours after lesions have resolved.
Quantity to be supplied/administered	Appropriately labelled pack to provide treatment for SEVEN days. 2 x 30 mL pack to provide SEVEN days treatment at a dose of 1 mL FOUR TIMES DAILY. Treatment should be continued for 48 hours after lesions have resolved.
Drug interactions	A detailed list of drug interactions can be found in the SmPC and the BNF. There are no known drug interactions with nystatin oral suspension.
Identification & management of adverse reactions	If the patient experiences any of the following they must discontinue treatment and seek medical help: ➢ 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: ➢ nausea, vomiting, diarrhoea, gastrointestinal stress (with large doses) ➢ rash including urticaria (rarely) ➢ Stevens-Johnson syndrome (rarely) ➢ hypersensitivity and angioedema, including facial oedema) ➢ 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). Inform the individual or their carer: ➢ if they get any side effects, to talk to their doctor, pharmacist or nurse and report any suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) by using the Yellow Card 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 read the medicines for children leaflet on nystatin for *Candida* infections. ➢ to visit the NHS website on nystatin for more information. ➢ to administer the medicine after food or drink; advise individual not to eat or drink for 30 minutes after using the suspension. ➢ to shake the bottle well before use. ➢ to space the doses evenly throughout the day. ➢ to use the dropper to drop the liquid inside the mouth near to the affected area(s) but to not touch the mouth with the dropper. ➢ to swish the suspension around the mouth; the suspension should be kept in contact with the affected area(s) for as long as possible before swallowing. ➢ if they wear dentures, remove them at bedtime. ➢ the treatment should be continued for 48 hours after lesions have resolved. ➢ if individual is immunocompromised or diabetic or pregnant and treatment is supplied, advise that they contact their GP for follow up. ➢ the importance of good dental hygiene. ➢ if they are a smoker, offer advice on smoking cessation. ➢ if they use a steroid inhaler advise the following: o good inhaler technique. o rinsing the mouth with water (or cleaning the teeth) after inhalation to remove drug particles. o use a spacer device to reduce the impaction of particles in the oral cavity. o stepping down the dose of corticosteroid when appropriate and in accordance with the instructions given by their managing healthcare professional. ➢ If the person wears dentures, advise them to: o leave the dentures out for at least 6 hours in each 24 hour period to promote healing of the gums; if the gums are inflamed, they may benefit from the dentures being left out for longer.

Patient or carer advice/follow up (continued)	○ clean dentures by brushing and then soaking them in a disinfectant solution (for example chlorhexidine or hexetidine) overnight; the dentures can be soaked in any solution marketed to sterilize baby's bottles (providing the dentures contain no metal). ○ Allow the dentures to air-dry after disinfection; this also kills adherent *Candida*. ○ brush the mucosal surface regularly with a soft brush. ○ see a dentist to correct ill-fitting dentures.
Records	The consultation details including any medication supplied under the 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 onto the Choose Pharmacy as soon as practically possible following the consultation. If the patient is excluded, and any specific advice that has been given, a record of the reason for exclusion 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 24 February 2023]
- Summary Product Characteristics (SmPC). Available from: https://www.medicines.org.uk/emc [accessed 24 February 2023]
- Patient Group Directions. Medicines practice guideline [MPG2]. Updated March 2017. Available from: http://www.nice.org.uk/guidance/mpg2/resources [accessed 24 February 2023]
- General Pharmaceutical Council. In Practice: Guidance on Consent. Revised June 2018. Available from: https://www.pharmacyregulation.org [accessed 24 February 2023]
- General Pharmaceutical Council. In Practice: Guidance on Confidentiality. Revised June 2018. Available from: https://www.pharmacyregulation.org [accessed 24 February 2023]
- All Wales Medicines Strategy Group. All Wales Common Ailments Formulary. February 2018. Available from: https://awttc.nhs.wales [accessed 24 February 2023]
- National Institute for Health and Care Excellence: Clinical Knowledge Summaries. *Candida* – oral. Last revised May 2022. Available from: https://cks.nice.org.uk [accessed 24 February 2023]
- Specialist Pharmacy Service. Lactation Safety Information: Nystatin. For oropharyngeal use. Reviewed 4th August 2020. Available from: https://www.sps.nhs.uk [accessed 24 February 2023]
- Yellow Card Reporting. Available from: http://yellowcard.mhra.gov.uk [accessed 24 February 2023]
- NHS 111 Wales Health A-Z. Available from: https://111.wales.nhs.uk [accessed 24 February 2023]
- NHS Medicines A-Z. Available from: https://www.nhs.uk [accessed 24 February 2023]

Appendix B: *Healthcare Professionals Agreement to Practice*

Authorisation for the use of the Patient Group Direction for the supply of:
Nystatin by community pharmacists under the Clinical Community Pharmacy Service,
Common Ailment Service (oral candidiasis) 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