NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Patient Group Direction For The Supply Of Oral Aciclovir For The Treatment Of Genital Herpes Simplex Virus (HSV) Infections By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Lead Author: Adapted from SPS/BASHH/BSIG Template Supply of oral aciclovir for the treatment of genital herpes simplex virus (HSV) infections, Version 2 – Published July 2023		**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**

NoS Identifier: NoS/PGD/Aciclovir/1446	**Review Date:** July 2026 **Expiry Date:** January 2027	**Date Approved by NoS:** 29th April 2024

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 2

Revision History for NoS:

NoS PGD that has been superseded	NoS/PGD/Aciclovir/MGPG1167, Version 1	
Date of change	**Summary of Changes**	**Section heading**
November 2023	Reference to NoS Appendix 1 and 2.	Authorisation
November 2023	Statement added in about nurses being registered by the NMC.	Professional registration
November 2023	Removed SPS advised training and added TURAS NoS PGD training link.	Initial Training
November 2023	Added in statement about capacity under the age of 13 and the legislation statement added.	Criteria for inclusion
November 2023	NICE Competency framework statement removed.	Competency assessment
November 2023	Added clinical systems utilised.	Records
February 2024	Local authority statement removed.	Qualifications and professional registration
April 2024	Added in statement about capacity under the age of 13 and the legislation statement added.	Criteria for inclusion

SPS/BASHH/BSIG most recent changes

Change History	
Version and Date	**Change details**
Version 1 February 2021	New template.
Version 2.0 July 2023	Reviewed template. No relevant changes to SPC. Updated PGD development group members. Some minor formatting and rewording to align with other sexual health PGDs. Removed breastfeeding as exclusion.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Authorisation

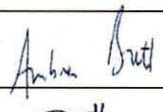
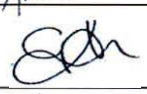
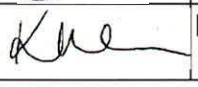
This specimen Patient Group Direction (PGD) template has been produced by SPS/BASHH/BSIG and adapted by North of Scotland PGD Group (NoS) to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may supply medicines under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/Summary of Product Characteristics (SmPC) for all medicines administered 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. Administration/supply of the medicines has to be by the same practitioner who has assessed the patient under the PGD.

All authorised staff are required to read the PGD and sign the Agreement to Administer/supply Medicines under PGD (Appendix 1).

A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.

This PGD has been produced for NoS by:					
Doctor	Ambreen Butt	Signature		Date Signed	20/03/2024
Pharmacist	Gayle Anderson	Signature		Date Signed	07/03/2024
Nurse	Kimberley MacInnes	Signature		Date Signed	07/03/2024

Approved for use within NoS by:

NoS Group Chair	Signature	Date Signed
Lesley Coyle		15/04/2024

Authorised and executively signed for use within NoS by:

NHS Grampian Chief Executive	Signature	Date Signed
Adam Coldwells – Interim Chief Executive		29/04/2024

Version 2 – Approved for NoS from 29th April 2024

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	February 2024
Review date:	July 2026
Expiry date:	January 2027

This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by British Association for Sexual Health and HIV (BASHH)/BASHH Bacterial Special Interest Group (BSIG) in June 2023.

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

Name	Designation
Ali Grant	Highly Specialist Clinical Pharmacist: HIV, Sexual and Reproductive Health
Alison Crompton	Community pharmacy
Amy Moore	Pharmacist HIV, Sexual and Reproductive Health Kingston Hospital NHS Foundation Trust
Andrea Smith	Community pharmacy
Carmel Lloyd	Royal College of Midwives
Chetna Parmar	Pharmacist adviser, Umbrella
Clare Livingstone	Royal College of Midwives
Deborah Redknapp	English HIV and Sexual Health Commissioners Group (EHSHCG)
Dipti Patel	Local authority pharmacist
Dr Achyuta Nori	Consultant in Sexual Health and HIV
Dr Cindy Farmer	Chair General Training Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Dr John Saunders	Consultant in Sexual Health and HIV
Dr Kathy French	Pan London PGD working group
Dr Rita Browne	Consultant in Sexual Health and HIV
Dr Sarah Pillai	Associate Specialist
Emma Anderson	Centre for Pharmacy Postgraduate Education (CPPE)
Heather Randle	Royal College of Nursing
Jo Jenkins	Lead Pharmacist Patient Group Directions and Medicines Mechanisms, Specialist Pharmacy Service
Jodie Crossman	Specialist Nurse, BASHH SHAN SIG Chair
Jodie Walker-Haywood	Specialist Nurse, BASHH Board Nurse Representative, BASHH SHAN SIG Secretary
Leanne Bobb	English HIV and Sexual Health Commissioners Group (EHSHCG)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Portia Jackson	Pharmacist, Cambridgeshire Community Services
Rosie Furner (Working Group Co-ordinator)	Governance Pharmacist, Medicines Use and Safety, Specialist Pharmacy Service
Vicky Garner	Consultant Midwife British Pregnancy Advisory Service (BPAS)
Sandra Wolper	Associate Director Specialist Pharmacy Service
Tracy Rogers	Director Specialist Pharmacy Service

Characteristics of staff

Qualifications and professional registration	Registered nurses and midwives as recognised by the Nursing and Midwifery Council (NMC).
Initial training	The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of an individual leading to diagnosis of the conditions listed. Recommended requirement for training would be successful completion of a relevant sexual health module/course accredited or endorsed by the BASHH, CPPE, RCN or a university or advised in the RCN Sexual Health Education directory. Have undertaken NoS PGD module training on TURAS Learn. The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults.
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix 1 and Appendix 2) or complete an appropriate self-declaration of competence for relevant testing and/or treatment.
Ongoing training and competency	• Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required. • Organisational PGD and/or medication training as required by employing Trust/organisation.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Treatment of genital infection with herpes simplex virus (HSV).
Criteria for inclusion	• An individual clinically diagnosed with HSV by history and visual recognition of painful genital blisters and/or ulcers. **OR** • An individual with a positive polymerase chain reaction (PCR) test and current blisters or ulcers clinically consistent with HSV. • Consent given. • Aged 13 years and over*. All individuals under the age of 18 years - follow local young person's risk assessment or equivalent local process. • An individual under 16 years of age may give consent for the supply of acyclovir, provided they understand fully the benefits and risks involved. The individual should be encouraged to involve a parent/guardian, if possible, in this decision. Where there is no parental involvement and the individual indicates that they wish to accept the supply, supply should proceed, if the healthcare professional deems the individual to have the legal capacity to consent. The Age of Legal Capacity (S) Act 1991, s2 (4) states that 'a person under the age of 16 years shall have legal capacity to consent on their own behalf to any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner attending them, they are capable of understanding the nature and possible consequences of the procedure or treatment'.
Criteria for exclusion	• Consent not given. • Individuals under 13 years of age. • Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines. • Individuals 16 years of age and over and assessed as lacking capacity to consent.

	Medical history • An individual who has reported 6 or more episodes of genital herpes within the last 12 months - refer to a prescriber to discuss potential requirement for suppressive therapy. • An individual in whom the current episode started more than 5 days ago. • Individual with known severe renal impairment (eGFR <10mL/min). • Where there has been a failure to respond to aciclovir treatment. • An individual who is systemically unwell or has a generalized rash. • An individual with severe local secondary infection. • Pregnancy. • Treatment of individuals who are immunosuppressed by other treatment or disease. **Medication history** • Any concurrent interacting medicine(s) – see Drug interactions. • Known hypersensitivity or allergy to aciclovir, any related antiviral medicines (e.g. famciclovir, valaciclovir) or any other constituent or excipient of the medicine - see Summary of Product Characteristics. ***Children under the age of 13 years should not be treated under this PGD. (The child protection team must be contacted for children of 12 years and under who present having had sexual intercourse). For those aged 13-16 years consider child protection team referral for these individuals if appropriate and according to local Board protocols.**
Cautions including any relevant action to be taken	• If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented. • If the presenting individual is under 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy (note under 13 years of age excluded from treatment under this PGD). • Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain.

Action to be taken if the individual is excluded or declines treatment	• If declined ensure individual aware of conservative measures which can be taken to relieve symptoms. • Explain the reasons for exclusion to the individual and document in the consultation record. • Record reason for decline in the consultation record. • Refer the individual to a suitable health service provider if appropriate and/or provide them with information about further options.

Description of treatment

Name, strength and formulation of drug	Aciclovir tablets 200mg or 400mg **Note:** The treatments in this PGD are written according to national guidance, however the healthcare professional should also refer to the local formulary or other local supporting guidance for selection of the most appropriate preparation for the individual.
Legal category	POM
Route of administration	Oral
Off label use	Best practice advice is given by BASHH and is used as the reference guidance in this PGD and may vary from the Summary of Product Characteristics (SPC). This PGD includes an off label dosage regime of: • 400mg three times a day Medicines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where medicines have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with pharmacy/Medicines Management. Where a medicine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence.

Dose and frequency of administration	400mg three times a day.
Duration of treatment	5 days.
Quantity to be supplied	Appropriately labelled pack/s containing 30 x 200mg tablets **or** 15 x 400mg
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
Drug interactions	The following interactions are identified as severe (red) interaction by the BNF. Where it is known an individual is concurrently taking one of the following medicines aciclovir must not be supplied under this PGD and the individual referred to a prescriber: • Ciclosporin, tacrolimus or mycophenolate • Aminophylline or theophylline A detailed list of all drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Identification and management of adverse reactions	A detailed list of adverse reactions is available in the SPC and BNF The following side effects are very common/common with aciclovir: • abdominal pain • diarrhoea • dizziness • fatigue • fever • headache • nausea • photosensitivity reaction • vomiting.
Management of and reporting procedure for adverse reactions	• Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme. • Record all adverse drug reactions (ADRs) in the patient's medical record. • Report via DATIX.

Written information and further advice to be given to individual	**Medication:** • Give manufacturer information leaflet (PIL) provided with the original pack. Explain mode of action, side effects, and benefits of the medicine. **Condition:** • Individuals diagnosed with HSV should be offered information (verbal, written and/or digital) about their diagnosis and management. • Explain that anti-viral therapy does not alter the natural history of the disease in that the frequency or severity of subsequent occurrences remains unaltered. Symptoms improve (reduce in frequency and severity) with time and can be well controlled. • Explain that transmission can occur when there are no symptoms (asymptomatic shedding), but the risk is higher when symptomatic. Advise the person to: o Avoid sexual contact until the lesions have healed. o Explain that condoms cannot completely prevent transmission, due to close skin contact or contact with infected secretions during foreplay. o Advise people who are concerned about transmitting genital herpes to long-term partners that their partner may already be infected even if they do not have symptoms. • Offer screening for other STIs as appropriate. • Offer condoms and advice on safer sex practices and need for screening for sexually transmitted infections (STIs). • Where treatment not supplied via a sexual health clinic ensure the individual has contact details of local sexual health services.
Follow up treatment	• The individual should be advised to seek medical advice in the event of an adverse reaction or if symptoms persist.
Records	**Record:** • The consent of the individual and: o If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken o if individual over 16 years of age and not competent, record action taken • If individual not treated under PGD record action taken • Name of individual, address, date of birth • GP contact details where appropriate

	• Relevant past and present medical and sexual history, including medication history • Examination or microbiology finding/s where relevant. • Any known allergies and nature of reaction • Name of registered health professional • Name and form of medication supplied • Date of supply • Dose supplied • Quantity supplied • Batch number and expiry date of product in line with local procedure • Advice given about the medication including side effects, benefits, and when and what to do if any concerns • Advice given, including advice given if excluded or declines treatment • Details of any adverse drug reactions and actions taken • Any referral arrangements made • Any supply outside the terms of the product marketing authorisation • Recorded that supplied via Patient Group Direction (PGD) Depending on the clinical setting where supply is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: • NaSH – Sexual Health Electronic Patient Record • BadgerNet – Digital Maternity Notes • HEPMA • Individual's GP records if appropriate • Individual service specific systems. Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy. All records should be clear, legible and contemporaneous. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

Key references

Key references (accessed April 2023)	• Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2 • BASHH National Guidelines on the management of genital herpes https://www.bashhguidelines.org/current-guidelines/genital-ulceration/anogenital-herpes-2014/ • Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines

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Appendix 1 - Healthcare Professional Agreement to Supply Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to supply the medicine(s) contained within the following Patient Group Direction:

Patient Group Direction For The Supply Of Oral Aciclovir For The Treatment Of Genital Herpes Simplex Virus (HSV) Infections By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles - Version 2

I have completed the appropriate training to my professional standards enabling me to supply the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 2 - Healthcare Professionals Authorisation to Supply Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to supply the medicine(s) under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to supply the medicine(s) under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that supply is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.
Patient Group Direction For The Supply Of Oral Aciclovir For The Treatment Of Genital Herpes Simplex Virus (HSV) Infections By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles - Version 2
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

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Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**