NHS
York and Scarborough Teaching Hospitals
NHS Foundation Trust

This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

PATIENT GROUP DIRECTION (PGD)

Supply of oral aciclovir for the treatment of genital herpes simplex virus (HSV) infections in York & North Yorkshire Sexual Health Services

Version Number 1.0

Change History	
Version and Date	**Change details**
Version 1 February 2021	New template

This Patient Group Direction (PGD) must only be used by registered professionals who have been named and authorised by their organisation to practise under it (See Appendix A). The most recent and in date final signed version of the PGD must be used.

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	22nd February 2021
Review date	July 2023
Expiry date:	31st January 2024

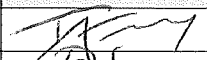
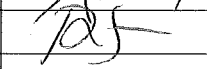
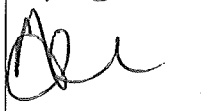
This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by British Association for Sexual Health and HIV (BASHH)/BASHH Bacterial Special Interest Group (BSIG) in February 2021.

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	Pan London PGD working group
Emma Anderson	Centre for Pharmacy Postgraduate Education (CPPE)
Helen Donovan	Royal College of Nursing
Jo Jenkins (Working Group Co-ordinator)	Specialist Pharmacist (PGDs) 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
Sally Hogan	British Pregnancy Advisory Service (BPAS)
Sandra Wolper	Associate Director Specialist Pharmacy Service
Silvia Ceci	Chief Pharmaceutical Officer's Clinical Fellow Specialist Pharmacy Service
Tracy Rogers	Associate Director Specialist Pharmacy Service

ORGANISATIONAL AUTHORISATIONS

The PGD is not legally valid until it has had the relevant organisational authorisations.

Name	Job title and organisation	Signature	Date
Senior doctor	Dr Ian Fairley		16-08-22
Senior pharmacist	Paul Jackson		17/8/22
Senior representative of professional group using the PGD	Alison Chorlton		16.8.22
Person signing on behalf of authorising body	Jennie Booth, Lead Nurse Medicines Management		19.08.2022
	Stuart Parkes, Chief Pharmacist		19/08/2022

PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct. Individual practitioners must declare that they have read and understood the Patient Group Direction and agree to supply/administer medication(s) listed only in accordance with the PGD.

- Trust PGD policy is available via on Staff Room
- An audit must be completed at renewal- see Trust PGD Policy for audit requirements

1. Characteristics of staff

The practitioner should be aware of any change to the recommendations for acyclovir and current guidance from national authorities e.g. the BNF and NICE.

It is the responsibility of the individual to keep up to date with continued professional development and to work within the limitations of their individual scope of practice

Qualifications and professional registration	Current contract of employment within a Local Authority or NHS commissioned service or an NHS Trust/organisation. Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.
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 patient 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. 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 A) or complete an appropriate self-declaration of competence for relevant testing and/or treatment. • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions
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. • Completion of PGD awareness session via Trust Learning HUB
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

2. 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 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 or culture test for the presence of HSV. • Consent given. • Aged 13 years and over. All individual under the age of 19 years - follow local young person's risk assessment or equivalent local process.
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 • 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 • Breastfeeding • Treatment of individuals who are immunosuppressed by other treatment or disease **Medication history** • Any concurrent interacting medicine(s) – see Section 3 Drug interactions. • Known hypersensitivity or allergy to aciclovir, any related antiviral medicines (e.g. famiciclovir, valaciclovir) or any other constituent or excipient of the medicine - see Summary of Product Characteristics
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.

3. Description of treatment

Name, strength & formulation of drug	Aciclovir tablets 200mg or 400mg NB: 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 Or 200mg five times a day
Duration of treatment	5 days.
Quantity to be supplied	Appropriately labelled pack containing 25x200mg tablets or 15x400mg /tablets
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
Drug interactions	All concurrent medications should be reviewed for interactions.

	A detailed list of all drug interactions is available in the BNF or the product SPC
Identification & 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 organisation incident policy.
Written information and further advice to be given to individual	**Medication:** • Give patient 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 sex (including orogenital sex) if lesions are present. o Use condoms with new or uninfected partners. 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, and that they should seek advice from a specialist in GUM for screening. • Offer screening for other STIs as appropriate. • Offer condoms and advice on safer sex practices and possible 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
	  ○ If individual is under 13 years of age record action taken
	  ○ If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken.
	  ○ 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 of medication supplied
	• Date of supply
	• Dose supplied
	• Quantity supplied including batch number and expiry date in line with local procedures.
	• 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)
	
	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.

4. Key references

Key references (accessed February 2020)	• 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 • BASSH 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

Appendix A - Registered health professional authorisation sheet

PGD -Supply of oral aciclovir for the treatment of genital herpes simplex virus (HSV) infections Valid from: March 2022 Expiry: 31st January 2024

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

Registered health professional

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of York & Scarborough Teaching Hospitals NHS Foundation Trust for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

When the expiry date is exceeded, this PGD ceases to be a legal document. Staff authorisation records must be maintained for 8 years if the PGD relates to adults only, 10 years for implants and 25 years after the expiry date if the PGD relates to children