Patient Group Direction for the supply of aciclovir for the treatment of : Genital Herpes	
Title of patient group direction	Patient group direction for the supply of aciclovir for the treatment of : Genital Herpes
Approved at	NMP/PGD Group
PGD approved / valid from	September 2018
Review date	June 2021
Expiry date	September 2021
Clinical area(s) where PGD applies	York and North Yorkshire Sexual Health services
Identified Lead for monitoring / review and contact details	Alison Chorlton Lead Nurse (ext 5465)
CONSULTATION PROCESS ADOPTED IN DEVELOPING THE PATIENT GROUP DIRECTION (PGD)	
New Document	No
Reviewed Document	Yes
If the PGD is revised what revisions were required and for what reasons e.g. change in medical procedures or change in legislation	Current PGD due for renewal
List of persons involved in the consultation process. (The group must include a sponsoring clinician, a pharmacist and a senior representative of the professional group. The job title and level of consultation should also be listed).	Dr Ian Fairley, Consultant Alison Chorlton, Lead nurse sexual health Elizabeth Clarke, Advanced Nurse Specialist

CLINICAL CONDITION	
Condition	First line management of uncomplicated primary genital herpes infection and/or recurrent episodes
Inclusion criteria	Direct clinical visualization of blisters and/or ulceration of the external genitalia For future outbreaks of patients already diagnosed as having genital herpes
Exclusion criteria	• Patient declines treatment under PGD. • Complicated presentations, e.g. complicated by secondary bacterial infection • Known allergies/hypersensitivity to aciclovir, any constituents of the tablets or valaciclovir • Pregnancy and breastfeeding • Known HIV infection • Immunosuppression • Renal impairment • Patients taking other medications such as aminophylline/ theophylline or tacrolimus. • Reservations/concerns by patient of possible side effects • All must have no contraindications in their medical history to the type of antiviral supplied • Children aged 12 and under Patients age 13-15 who are not Fraser competent
Action if excluded	Refer to medical practitioner/ non-medical prescriber during that clinical session or when next available in clinic. When a medical practitioner is not physically present. Defer treatment and discuss by telephone. If patient presents with an acute presentation and no doctor is available refer for immediate assessment in emergency department/urgent care.
Action for patients not	

wishing to receive care under the PGD	Discuss other options for managing symptoms e.g. salt water bathing, analgesia (see clinical guidelines) or refer to medical practitioner/ non-medical prescriber during that clinical session

DESCRIPTION OF TREATMENT			
Name of Medicine	Aciclovir		
Legal Classification	Licensed, Prescription only Medicine (POM)		
Licensing information	400mg three times daily off label dose		
	Is the medicine licensed for the intended use?	**YES**	
	Does it have a black triangle status?		**NO**
	Does it have a Risk Minimisation Measures (RMM) recommendation		**NO**
Form	Tablets		
Strength	400mg or 200mg		
Dose	400mg 3 times daily for 5 days or 200mg 5 times a day for 5 days.		
Frequency	As above		
Route	Oral		
Total Treatment Quantity	Total of 15 x 400mg tablets (5 day course) or Total of 25 x 200mg tablets (5 day course)		
Interactions with other medicines (This must include all potentially serious interactions listed in the BNF	Probenecid and cimetidine (reduce the renal clearance with aciclovir) Aminophylline and theophylline (increased levels when co-administered with aciclovir) Tacrolimus (risk of nephrotoxicity)		

	Mycophenolate (mycophenolate is predicted to increase the risk of haematological toxicity when given with aciclovir). Ciclosporin-aciclovir does not normally seem to affect ciclosporin concentrations or worsen renal function on concurrent use, but cases of nephrotoxicity and increased ciclosporin concentrations have been reported. See Appendix 1 in British National Formulary (BNF) under aciclovir. If in doubt contact Medicines Information (ext 5960)	
Adverse Reactions (This should include all the common and potentially serious adverse reactions. It is acceptable to state that the BNF should be referred to for further information)	Gastrointestinal upset Fatigue Fever Skin rash Skin irritation Headache Dizziness Photosensitivity For infrequent side effects see BNF	**Treatment of adverse reactions** Advise patient on reporting adverse outcomes or side effects to the appropriate medical practitioner who will provide further advice. Report and refer to consultant-in-charge any serious adverse drug reactions and document in patient's notes York Teaching Hospitals NHS Foundation Trust Datix form to be completed and procedure guidelines followed. Report all serious suspected adverse drug reactions to the MHRA using a yellow card or electronically, even if they are listed above, in the BNF or in the product SPC. Serious reactions are those that are:- fatal, life-threatening, disabling, incapacitating or which result in prolonged hospitalisation and/or are medically significant

Advice to Patients: Written and Oral advice (This should include the provision of a patient information leaflet)	• Information regarding aetiology and transmission of herpes infection and possibility of recurrences; with leaflet • Information regarding treatment compliance and side effects; supported by drug information leaflet • Advice regarding infectivity and condom use as well as future asymptomatic shedding • Advice regarding general hygiene and skin care and use of analgesics if required • Advice regarding discussions with partner, management of future episodes if any and pregnancy/childbirth • Advice regarding avoiding any form of sexual contact until fully healed • Discussion regarding safer sex in general for future sexual health • Review in 5 days if still symptomatic or if severe episodes • Review in two weeks to offer full STI screening if unable to undertake at initial visit • Offer opportunity of a telephone consultation or to return to discuss diagnosis further if result is positive and patient requires further information and/or support
Follow up action	Telephone the results in two weeks if patient does not need to return for further screening, and only after full discussion of implications of provisional diagnosis of herpes infection.
Storage	Locked medicines cupboard – store below 25 °C Locked briefcase for outreach use
Records to be Kept	**The following minimum details need to be documented in full in patient's records in relation to initiating treatment under PGD** • Written and oral advice given • Date • Drug name and strength • Dose, form and quantity supplied • Route of administration

	• Time of administration if appropriate • Advice given to patients • Signature of staff administering/supplying medicine • Details of any adverse drug reactions or side effects • Form of documentation (patient's case notes, letters etc.) • Any communication with other health care professionals • That aciclovir was supplied under a PGD • The outcome of the compliance discussion needs to be recorded in full in the patient's notes
Audit Arrangements	As per current Trust PGD Policy
References	National guidelines for the management of herpes (2014) British Association for Sexual Health and HIV, www.bashh.org Nursing and Midwifery Council, The Code for nurses and midwives. March 2015 www.nmc.org.uk **(refers to record keeping)** Nursing and Midwifery Council, Standards for Medicines Management, 2007, minor updates 2015 www.nmc.org.uk The British National Formulary, www.bnf.org.uk
Competency Requirements (attach any competency frameworks / documents)	Completion of a local sexual health training programme for the administration of aciclovir under PGD within sexual health services. This will require/include: • Clinical competence in sexual history taking, the clinical examination/assessment and genital screening required to enable the accurate diagnosis and treatment of herpes. • Knowledge base of the interactions of aciclovir with other drugs, and other exclusions and contra-indications for issuing aciclovir

	• Competence in the above will be demonstrated by the undertaking of a local clinical competency based training and assessment programme, evidenced by completion of theoretical study including e-learning and clinical experience within sexual health. • Assessment will be undertaken by the Lead Sexual Health nurse or designated PGD assessor, who will both be fully competent and either practising as an independent prescriber themselves, or practicing in accordance with this PGD. • Receiving Clinical Supervision and/or audit of case notes on an ongoing basis • Commitment to continuing professional development identified through Clinical Supervision and appraisal • Evidence of continuing professional development in sexual health • 5 study days or the equivalent in hours, of study related to the field of sexual health; every 3 years. • Regular attendance and participation in the tri annual educational clinical governance • Maintain professional accountability with the Nursing and Midwifery Council (NMC) and ensure continuing professional development. • Attendance at Trust/clinic PGD awareness session or trust HUB e-learning

AUTHORISATION OF THE PATIENT GROUP DIRECTION (PGD) supply of Aciclovir for the treatment of : Genital Herpes

PGD Development / Review Team – responsible for PGD content

Title	Name	Signature	Date
Lead Author	Alison Chorlton		10 7 18
Clinical Director Lead Approval	Ian Fairley		1/8/18
Directorate Pharmacy Lead Approval	Paul Jackson		21/8/18

PGD Approved by the NMP/PGD Group

Title	Name	Signature	Date
NMP Lead / Lead Nurse Medicines Management	Jennie Booth		24.08.2018
Chief Pharmacist / Deputy Chief Pharmacist	Stuart Parkes		24/8/18

Authorisation to work within the PGD

This patient group direction must be agreed to and signed by all health care professionals involved in its use.

The PGD must be easily accessible in the clinical setting.

Notes to the NMP/PGD Authorising staff

- Do not proceed unless this document carries the signatures of the development / review team (Lead Author, Lead Clinical Director and Directorate Lead Pharmacy)
- You are responsible for fulfilling the legal requirement that a senior person from the profession ensures that only fully competent, qualified and trained professionals operate under this PGD
- Using a PGD is not a form of prescribing

Staff authorised to work under this PGD	
Ward / Department	Sexual Health
Professionals to whom this Patient Group Direction applies	Qualified nurses who work within sexual health and have completed the agreed training programme

I confirm that I have read and understood the content of this patient group direction and that I am willing and competent to work under it within my professional code of conduct when working for this Trust:

Name (Capitals)	Sign	Job Title	Authorising Manager	Date
This is to be completed when the PGD has been approved	This is to be completed when the PGD has been approved	This is to be completed when the PGD has been approved	This is to be completed when the PGD has been approved	This is to be completed when the PGD has been approved

When the review date is exceeded, this PGD ceases to be a legal document	
TEMPLATE DOCUMENTATION CONTROL	
The template documentation control refers to the PGD template not the completed PGD. **Do not alter this section.**	
Author:	Jennie Booth, Lead Nurse Medicines Management Carol Belt, Principal Pharmacy Technician Stuart Parkes, Deputy Chief Pharmacist
Owner:	NMP/PGD Group
Date of issue:	February 2018
Version:	3
Approved by	NMP/PGD Group
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