

Patient Group Direction for the Supply of Aciclovir Tablets for the Treatment of Genital Herpes Simplex Infection by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

Lead Author: Adapted from the SPS/FSRH National PGD Template by the Medicines Management Specialist Nurse NHSG	Consultation Group: See relevant page in the PGD	Approver: NoS PGD Group Authorisation: NHS Grampian
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Signature: 		Signature: 
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NoS Identifier: NoS/PGD/Aciclovir/MGPG 1167	Review Date: June 2023 Expiry Date: June 2024	Date Approved: June 2021
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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 1

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	New PGD adapted from FRS/SPS national PGD template and supersedes NHSH 05_22_V5 and NHST Patient Group Direction for the Supply of Aciclovir 400mg.	
Date of change	Summary of Changes	Section heading
March 2020	New NoS PGD adapted from FRS/SPS national PGD and NHSH, NHST existing PGDs.	

NoS Identifier:

NoS/PGD/Aciclovir/MGPG1167

Keyword(s):

PGD Patient Group Direction aciclovir genital herpes simplex sexual health nurse

Policy Statement: It is the responsibility of the individual healthcare professionals and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

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.

Document:

Drafted:

March 2021

Completed:

May 2021

Approved:





June 2021 (published – August 2021)

Amended:


Organisational Authorisations

This PGD is not legally valid until it has had the relevant organisational authorisation.


PGD Developed/Reviewed by;

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Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		August 2021

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox		August 2021

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

Name:

Title:

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Lead Pharmacist NHSO

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Clinical indication to which this PGD applies

<p>Definition of situation/ Condition</p>	<p>This Patient Group Direction (PGD) will authorise approved healthcare professionals as detailed in the characteristics of staff authorised to work under this PGD to supply aciclovir tablets to individuals aged 13 year and over for the treatment of genital infection with herpes simplex virus (HSV).</p> <p>This PGD should be used in conjunction with the individual Board protocols and the recommendations in the current British Association for Sexual Health and HIV (BASHH) relevant guidelines, British National Formulary (BNF), British National Formulary for Children (BNFC), and the individual Summary of Product Characteristics (SmPC).</p>
<p>Inclusion criteria</p>	<ul style="list-style-type: none"> • Individuals aged 13 years and over. • 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. <p>Prior to the supply of the medicine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.</p>
<p>Exclusion criteria</p>	<ul style="list-style-type: none"> • Individuals under 13 years of age* • Under 16 years of age and judged to be incapable of understanding the nature and possible consequences of procedures or treatment as per Age of Legal Capacity (Scotland) Act 1991. (Commonly referred to as Fraser Guideline) • Individuals 16 years of age and over and assessed as lacking capacity to consent. <p>Medical history</p> <ul style="list-style-type: none"> • 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

	<ul style="list-style-type: none"> • 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 <p>Medication history</p> <ul style="list-style-type: none"> • Any concurrent interacting medicine(s) – Check Appendix 1 of current edition of the British National Formulary (BNF) for full list of interacting medicines • Known hypersensitivity or allergy to aciclovir, any related antiviral medicines (e.g. famciclovir, valaciclovir) or any other constituent or excipient of the medicine - see SmPC • Where there is no valid consent. <p>Note: Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain.</p> <p>*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.</p>
<p>Precautions and special warnings</p>	<p>If the individual is less than 16 years of age an assessment based on Fraser Guideline must be made and documented.</p>
<p>Action if excluded from treatment</p>	<p>Medical advice must be sought – refer to relevant medical practitioner.</p> <p>Document the reason for exclusion under the PGD and any action taken in the individual’s appropriate clinical records.</p>
<p>Action if treatment is declined</p>	<p>Inform/refer to the relevant medical practitioner if individual declines treatment.</p> <p>Document that the supply was declined, the reason and advice given in appropriate clinical records.</p>

Description of treatment available under the PGD

Name form and strength of medicine	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 status	Aciclovir tablets are a Prescription-only Medicine (POM). In accordance with the MHRA all medicines supplied under a PGD must either be from over-labelled stock, or be labelled appropriately in accordance with the regulatory body guidelines for the labelling of medicines for the professional providing the supply. 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 (SmPC). This PGD includes an off label dosage regime of 400mg three times a day. This is outside the terms of the marketing authorisation. The individual should be informed prior to the supply that the use is off-label.
Dosage/Maximum total dose	400mg three times a day.
Frequency of dose/Duration of treatment	400mg three times a day for 5 days.
Maximum or minimum treatment period	Aciclovir should be taken for the maximum duration of 5 days.
Route/Method of administration	Oral.
Quantity to be supplied	Supply 30x 200mg Tablets OR Supply 15x 400mg Tablets
Storage requirements	Do not store above 25°C
Follow-up (if applicable)	Individuals should be advised to seek medical advice in the event of an adverse reaction or if symptoms persist.

	<p>Individuals who have not had a full sexually transmitted infection (STI) screen (or who did not have HSV diagnosed in a sexual health clinic) should be advised to attend an appropriate service for a full STI screen.</p>
<p>Advice written and verbal</p>	<p>Medication:</p> <ul style="list-style-type: none"> • Give patient information leaflet (PIL) provided with the original pack. Explain mode of action, side effects, and benefits of the medicine. <p>Condition:</p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ Avoid sex (including orogenital sex) if lesions are present. ○ 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. ○ 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 STIs. <p>Where treatment not supplied via a sexual health clinic ensure the individual has contact details of local sexual health services.</p>
<p>Identifying and managing possible adverse reactions</p>	<p>The following side effects are very common/common with aciclovir:</p> <ul style="list-style-type: none"> • abdominal pain • diarrhoea • dizziness • fatigue • fever • headache

	<ul style="list-style-type: none"> • nausea • photosensitivity reaction • vomiting. <p>This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.</p> <p>BNF/BNFC: https://www.bnf.org/products/bnf-online/</p> <p>SmPC/PIL/Risk Minimisation Material: https://www.medicines.org.uk/emc/ http://www.mhra.gov.uk/spc-pil/index.htm https://www.medicines.org.uk/emc/rmm-directory</p> <p>If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.</p> <p>Report any severe reactions using the Yellow Card System. https://yellowcard.mhra.gov.uk/</p>
<p>Facilities and supplies required</p>	<p>The following are to be available at sites where the medicine is to be supplied:</p> <ul style="list-style-type: none"> • Appropriate storage facilities • An acceptable level of privacy to respect individual’s right to confidentiality and safety • Access to a working telephone • Access to medical support (this may be via the telephone) • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • Condoms • A copy of this current PGD in print or electronically.

Characteristics of staff authorised to supply medicine(s) under PGD

<p>Professional qualifications</p>	<p>Registered nurses and midwives as recognised by the Nursing and Midwifery Council (NMC).</p>
<p>Specialist competencies</p>	<p>Approved by the organisation as:</p> <ul style="list-style-type: none"> • Competent to assess the individual’s capacity to understand the nature and purpose of the medicine supply in order to give or refuse consent • Aware of current treatment recommendations and be competent to discuss issues about the medicine with the individual

	<ul style="list-style-type: none"> • Having undertaken appropriate training to carry out clinical assessment of individuals identifying that treatment is required according to the indications listed in the PGD • Competent to undertake supply of the medicine • Competent to work under this PGD.
Ongoing training and competency	<p>All professionals working under this PGD must:</p> <ul style="list-style-type: none"> • Have undertaken PGD training as required/set out by each individual Health Board • Maintain their skills, knowledge and their own professional level of competence in this area according to their Code of Professional Conduct • Have knowledge and familiarity of the following; <ul style="list-style-type: none"> ○ SmPC for the medicine(s) to be supplied in accordance with this PGD.
Responsibilities of professional manager(s)	<p>Professional manager(s) will be responsible for;</p> <p>Ensuring that the current PGD is available to all staff providing care under this direction.</p> <p>Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.</p> <p>Maintain up to date record of all staff authorised to supply the medicine(s) specified in this direction.</p>

Documentation

Authorisation of supply	<p>Nurses working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to supply/administer the medicine(s) specified in this PGD by their Professional Line Manager/Consultant/Practice GPs.</p> <p>Midwives working within NHS Tayside ONLY can be authorised to administer the medicine(s) specified in this PGD by their Professional Line Manager/Consultant/Practice GPs.</p> <p>All authorised staff are required to read the PGD and sign the Agreement to Supply Medicines Under PGD (Appendix 1).</p> <p>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.</p>
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<p>Record of supply</p>	<p>An electronic or paper record for recording the screening of individuals and the subsequent supply, or not of the medicine(s) specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum:</p> <ul style="list-style-type: none"> • Date and time of supply • Individuals name and DOB • Exclusion criteria, record why the medicine was not supplied (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, dose, form, route of the medicine supplied • Advice given, including advice given if excluded or declined treatment under this PGD • Signature and name in capital letters of the healthcare professional who supplied the medicine • Record of any adverse effects (advise individuals GP/relevant medical practitioner). <p>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:</p> <ul style="list-style-type: none"> • NaSH – Sexual Health Electronic Patient Record • BadgerNet – Digital Maternity Notes • Occupational health systems • Individual service specific systems.
<p>Audit</p>	<p>All records of the medicine(s) specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines supplied under a PGD.</p>
<p>References</p>	<p>Electronic Medicines Compendium http://www.medicines.org.uk Aciclovir 200mg Tablets (Wockhardt Brand) – Date of revision of text 21/09/16, accessed 24/03/21.</p> <p>Aciclovir 400mg Tablets (Wockhardt Brand) – Date of revision of text 21/09/16, accessed 24/03/21.</p> <p>British National Formulary and British National Formulary for Children https://www.bnf.org/products/bnf-online/ accessed 24/03/21.</p> <p>BASSH National Guidelines on the management of genital herpes https://www.bashhguidelines.org/current-guidelines/genital-ulceration/anogenital-herpes-2014/</p>



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:

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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: _____

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 he or she is 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 he or she understands and is 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 his or her individual code of professional practice and conduct.

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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

