Patient Group Direction for the administration and / or supply of for the treatment of : Lidocaine 2.5% with prilocaine 2.5%for the topical analgesia during genital herpes outbreaks	
Title of patient group direction	Lidocaine 2.5% with Prilocaine2.5% for topical analgesia during genital herpes outbreaks
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 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 PGDs due for renewal June 2018
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).	Alison Chorlton, Lead Nurse sexual health Dr Ian Fairley, Consultant Elizabeth Clarke, Advanced Nurse Specialist

CLINICAL CONDITION	
Condition	For use as local anaesthesia for genital pain from ulceration associated with primary and recurrent episodes of herpes
Inclusion criteria	Patients who have visible genital lesions
Exclusion criteria	• Pregnant, or risk of pregnancy • Allergy to lidocaine and prilocaine, amide type anaesthetics or components of the cream • Anaemia • Patients with metabolic condition glucose-6-phosphate dehydrogenase deficiency or congenital or idiopathic methaemoglobinaemia • Taking medication containing sulphonamides • Recently received anaesthetic or medicine to treat irregular heartbeat • Reservations/concerns by patient of possible side effects • All must have no contraindications in their medical history to the type of medication supplied • Patient declined treatment under PGD. • Patients age 12 or below. • Patients age 13-15 who are not Fraser competent
Action if excluded	• Refer to medical practitioner/non-medical prescriber that clinical session or when next available in clinic. • As there may be occasions when a medical practitioner is not physically present within the department, discuss by telephone where possible with medical practitioner.
Action for patients not wishing to receive care under the PGD	• Refer to medical practitioner/non-medical prescriber that clinical session or when next available in clinic. As there may be occasions when a medical practitioner is not physically

	present within the department, discuss by telephone where possible with medical practitioner first, and defer treatment until after this discussion. • Discuss other options for managing symptoms of genital ulceration e.g. salt water bathing

DESCRIPTION OF TREATMENT			
Name of Medicine	Lidocaine 2.5% with prilocaine 2.5%		
Legal Classification	Prescription only medication		
Licensing information			
	Is the medicine licensed for the intended use?	It is not listed for topical anaesthesia for use on infected/broken skin, however it is commonly prescribed in sexual health for this use and patients are advised to apply a small amount, as there is an increased risk of absorption on unbroken skin.	**NO**
	Does it have a black triangle status?		**NO**
	Does it have a Risk Minimisation Measures (RMM) recommendation		**NO**
Form	Topical Cream		
Strength	Lidocaine 2.5% Prilocaine 2.5%		
Dose	Thinly apply topically to affected area		
Frequency	Apply up to 4 times a day.		
Route	Topical		
Total Treatment Quantity	One 5 gram tube		
Interactions with other medicines (This must include all potentially serious interactions listed in the BNF)	• Prilocaine in high doses may cause an increase in methaemoglobin plasma levels particularly in conjunction with methaemoglobin-inducing agents, e.g. sulphonamides, acetanilid, aniline dyes, benzocaine, chloroquine, dapsone, metoclopramide, naphthalene, nitrates and nitrites, nitrofurantoin, nitroglycerin, nitroprusside, pamaquine, para-aminosalicylic		

	acid, phenacetin, phenobarbital, phenytoin, primaquine, quinine. • With large doses of topical anaesthetics, consideration should be given to the risk of additional systemic toxicity in patients receiving other local anaesthetics or agents structurally related to local anaesthetics, since the toxic effects are additive. • Specific interaction studies with lidocaine/prilocaine and anti-arrhythmic drugs class III (e.g. amiodarone) have not been performed, but caution is advised • Drugs that reduce the clearance of lidocaine (e.g. cimetidine or betablockers) may cause potentially toxic plasma concentrations when lidocaine is given in repeated high doses over a long time period. Such interactions should therefore be of no clinical importance following short-term treatment with lidocaine (e.g., lidocaine/prilocaine cream) at recommended doses. **If in doubt, contact Medicines Information for advice tel 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)	Skin reactions: Burning or itching sensation Redness Swelling Paleness at point of application **Uncommon** Tingling sensation where cream applied **Very rarely** Red dots at application site	**Treatment of adverse reactions** This is a transient side effect. Discontinue use if becomes severe Discontinue use if becomes severe

	(petechiae) Irritation to eyes if eye exposed For infrequent side effects see BNF Refer to manufacturer's patient information leaflet. Severe allergic reactions occur in rare cases (including anaphylaxis)	 Seek immediate medical advice
Advice to Patients: Written and Oral advice (This should include the provision of a patient information leaflet)	• Salt water bathing to keep ulcers clean • The use of antivirals / lidocaine/prilocaine cream for symptom control • Discuss risk of sexual transmission and need for abstinence from sex during herpes episodes • Potential discomfort from any preparation applied to a broken mucosa • That transmission may occur as a result of asymptomatic viral shedding • The possible benefits of condoms in reducing transmission • Pregnancy issues with herpes infections. • Manufacturer's patient information leaflet to be supplied • Advise patient can contact NHS 111 or Emergency Department if serious, out of clinic working hours • For information and advice during working hours, patient to be advised to contact sexual health • Wash hands after use	
Follow up action		

	For patients who have genital ulcers they should return to clinic if the ulcers don't resolve at two weeks
Storage	• locked medicines cupboard – store below 25 °C • Locked briefcase for outreach use
Records to be Kept	Document the following in the patients notes: • Any reason for exclusion, including action taken • If the patient has refused treatment under the PGD, any advice given or cautions taken • That the drug had been administered under a PGD • Date and time of administration • Name, form, strength and dose of drug administered • 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 (patients casenotes, letters etc) • Any communication with other health care professionals • If the patient is pregnant her treatment must be documented in her maternity (green) notes or her GP written to. The record must be signed by the nurse responsible for the administration.
Audit Arrangements	As per current Trust PGD Policy
References	National guidelines for the management of Herpes Simplex Virus (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 Remove 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 lidocaine 2.5% with prilocaine 2.5% 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 administration of lidocaine 2.5% with prilocaine 2.5% • Knowledge base of the interactions of lidocaine 2.5% with prilocaine 2.5%with other drugs, and other exclusions and contra-indications for issuing EMLA as demonstrated by written competency assessment sheets • 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 Nurse Sexual health or Advanced Nurse Specialist, who will both fully competent and either practising as an independent prescriber themselves, or practicing in accordance with this PGD until independent prescriber status is attained. • Receiving Clinical Supervision and/or review of case notes by one of the above Senior Nurses, or medical practitioner, on an ongoing basis • Commitment to continuing professional development identified through Clinical Supervision and appraisal • Evidence of continuing professional development in sexual health.

	• 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 a trust/clinic PGD awareness session or Trust HUB e-learning

AUTHORISATION OF THE PATIENT GROUP DIRECTION (PGD) FOR ADMINISTRATION AND SUPPLY OF: Lidocaine 2.5% with Prilocaine 2.5%for the topical analgesia during genital herpes outbreaks

PGD Development / Review Team – responsible for PGD content

Title	Name	Signature	Date
Lead Author	Alison Anderson		10.07.18
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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