Patient Group Direction for the supply of Imiquimod 5% cream for the treatment of anogenital warts	
Title of patient group direction	**Imiquimod 5% cream**
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 PGD 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).	Dr Ian Fairley Consultant Alison Chorlton – Lead Nurse Sexual Health Elizabeth Clarke Advanced Nurse Specialist

CLINICAL CONDITION	
Condition	Anogenital warts
Inclusion criteria	• Patients who have been diagnosed/observed as having genital warts by a medical practitioner or competent nurse within sexual health services • The wart treatment decision is defined by the BASHH flow chart of management of warts in women/men(2015) **The above criteria reflect the national recommendations made by the British Association for Sexual Health and HIV www.bashh.org.uk**
Exclusion criteria	• Pregnancy or risk of pregnancy or breast feeding • None or unreliable method of contraception if female and sexually active with male during treatment period. • Complicated presentations, e.g. complicated by secondary bacterial infection and/or bleeding frankly, existing inflammatory conditions, ulceration. • No visualization of genital warts or unknown morphology • If only internal or intrameatal genital warts are present • Patients who are receiving immunosuppressive medication. • Broken skin surfaces. • Known allergy or previous adverse reaction to imiquimod or any excipients of the product. • Previously non-responsive to imiquimod treatment. • Patient declines treatment under PGD. • Known HIV positive. • Patient aged 12 or below. • Patients aged 13 to 15 who are not Fraser competent. • Treatment not recommended by the BASHH flow chart of management of warts in women/men(2015)

Action if excluded	• Refer to medical practitioner/prescriber unless there is an appropriate alternative according BASHH flow chart of management of warts in women/men(2015) • 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/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.

DESCRIPTION OF TREATMENT			
Name of Medicine	Imiquimod		
Legal Classification	Prescription only medication (POM)		
Licensing information	Imiquimod cream is licensed for the treatment of genital warts on the external genital and perianal areas in adults Unlicensed under 18, but can be given under specialist supervision		
	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	Cream.		
Strength	5%		
Dose	Apply a thin layer of cream 3 times a week on alternate days, leave on warts for 6 to 10 hours, then wash off. Repeat for up to 4 weeks then review. Dispense as 12 sachet box.		
Frequency	As above		
Route	Topical		
Total Treatment Quantity	12 sachets for each 4 week treatment cycle before review. Maximum treatment course 16 consecutive weeks.		
Interactions with other medicines (This must include all potentially serious interactions listed in the BNF)	• Avoid concurrent use with other treatments for anogenital warts. • Immunosuppressive medication –see exclusion criteria. **If in doubt, contact Medicines Information for advice on York 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)	• Skin irritation, redness and oedema, itching, erosion, excoriation, scabbing. Headache. Influenza-like symptoms, myalgia. • Excessive application can cause ulceration, severe oedema. • If used on foreskin associated warts there is a small risk of paraphimosis	**Treatment of adverse reactions** • Contact the appropriate medical practitioner to gain further advice. • Report and refer to Consultant-in- charge any serious adverse drug reactions and document in patient's records • York Teaching Hospitals NHS Foundation Trust drug AIRs Datix form to be completed and procedure guidelines followed. • Report all serious suspected adverse drug reactions to the Committee on Safety of Medicines using a yellow card, even if they are listed above, in the BNF or in the product SPC.
Advice to Patients: Written and Oral advice (This should include the provision of a patient information leaflet)	• Information regarding aetiology and transmission of wart virus infection and possibility of recurrences; with leaflet. • Information regarding treatment compliance/correct application and side effects; supported by manufacturer's information leaflet. • Advise patient to abstain from sexual intercourse when cream applied and latex weakening if a condom used therefore, not suitable method of contraception when cream is on the skin. • Avoid bathing/showering when cream applied as it will remove the cream. • Advice on the need to use reliable method of	

	contraception for non-treatment days. If female patient and sexually active and if contraception fails, may need emergency contraception. • Advice regarding general hygiene and skin care during treatment. In particular, foreskin associated warts require the patient to follow a daily foreskin hygiene routine. • Advice to patient on reporting adverse outcomes, or side effects. • Advice regarding discussions with partner, management of future episodes of warts if any, and pregnancy/childbirth, including stopping using cream if patient becomes pregnant. • Advise of need to ensure female patients undergo routine cervical cytology screening. • Discuss safer sex in general for future sexual health.
Follow up action	• There is no follow-up required if the warts have resolved four weeks after treatment has finished • If warts still persist after 20 weeks (i.e. 16 weeks treatment course plus four weeks subsequently treatment free) • Change in treatment may also be indicated if the individual is not tolerating the treatment, or if there is a less than 50% response after 8 to 12 weeks. Seek advice from an appropriate doctor/independent non-medical prescriber
Storage	• locked medicines cupboard – store below 25 °C • Locked medicine box or briefcase
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** • Date/time of record entry • Drug name and strength • Dose and form • Route of administration • Time of administration if appropriate • Advice given to patients, including written

	information. • name/job title of staff administering/supplying medicine(and signature if written records) • Details of any adverse drug reactions or side effects • Details of any problems reported with compliance and action advised/taken • Consent to treatment under PGD • That treatment was supplied under a PGD • Any communication with other health care providers
Audit Arrangements	As per current Trust PGD Policy
References	York Department of Genitourinary Medicine Genital Wart Pathway 2015 National guidelines for the management of Anogenital warts 2015 _ www.bashh.org British National Formulary, www.bnf.org.uk The Electronic Medicines Compendium (eMC) http://www.medicines.org.uk/EMC/default.aspx Nursing and Midwifery Council, The Code for nurses and midwives. March 2015 www.nmc.org.uk **(refers to record keeping)**
Competency Requirements (attach any competency frameworks / documents)	Completion of a local Sexual Health training programme for the supply of imiquimod cream under PGD within Sexual Health services. This will require/include: • Clinical competence in the history taking, clinical examination/assessment and genital screening and competent to accurately identify genital wart lesions. • Knowledge base of the interactions of imiquimod with other drugs, and other contra-indications for issuing imiquimod. • Competence in the above will be demonstrated by the undertaking of a local clinical competency based training and assessment programme. • 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. • Evidence of continuing professional development in Sexual Health and/or the Sexual Health nurse role. • Minimum of 6 months experience of working within Sexual Health in the preceding 3 years. • Competence in the use of PGDS. • Trust PGD awareness session or Trust HUB e-learning. • Regular attendance at clinical governance/audit Tri annual day at York Sexual Health Services. *Maintain professional accountability with the Nursing and Midwifery Council (NMC) and ensure continuing professional development.*

AUTHORISATION OF THE PATIENT GROUP DIRECTION (PGD) FOR THE SUPPLY OF: Imiquimod 5% cream for the treatment of anogenital warts

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		31/7/18
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		03.09.2018
Chief Pharmacist / Deputy Chief Pharmacist	Stuart Parkes		3/9/2018

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 Yorclinic 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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