

**Patient Group Direction for the supply of :  
podophyllotoxin 0.5% solution or 0.15% cream for the treatment of anogenital warts-  
primary and recurrent**

<b>Title of patient group direction</b>	Patient Group Direction for the supply of: podophyllotoxin 0.5% solution or 0.15% cream for the treatment of anogenital warts- primary and recurrent
<b>Approved at</b>	NMP/PGD Group
<b>PGD approved / valid from</b>	September 2018
<b>Review date</b>	June 2021
<b>Expiry date</b>	September 2021
<b>Clinical area(s) where PGD applies</b>	York and North Yorkshire Sexual Health services
<b>Identified Lead for monitoring / review and contact details</b>	Alison Chorlton Lead Nurse

**CONSULTATION PROCESS ADOPTED IN DEVELOPING THE PATIENT GROUP DIRECTION (PGD)**

<b>New Document</b>	No
<b>Reviewed Document</b>	Yes
<b>If the PGD is revised what revisions were required and for what reasons e.g. change in medical procedures or change in legislation</b>	Current PGD due for renewal June 2018
<b>List of persons involved in the consultation process.</b> (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 Alison Chorlton – Lead Nurse Sexual Health Elizabeth Clarke Advanced Nurse Specialist

## CLINICAL CONDITION

<b>Condition</b>	Penile warts or those affecting external female genitalia
<b>Inclusion criteria</b>	<ul style="list-style-type: none"> <li>• Patients who have been diagnosed/observed as having genital warts by a medical practitioner or competent nurse within sexual health services</li> <li>• The wart treatment decision is defined by the BASHH flow chart of management of warts in women/men(2015)</li> </ul> <p style="text-align: center;"><b>The above criteria reflect the national recommendations made by the British Association for Sexual Health and HIV <a href="http://www.bashh.org.uk">www.bashh.org.uk</a></b></p>
<b>Exclusion criteria</b>	<ul style="list-style-type: none"> <li>• Pregnancy, risk of pregnancy or breast feeding</li> <li>• None or unreliable method of contraception if female and sexually active with male during treatment period.</li> <li>• Complicated presentations, e.g. complicated by secondary bacterial infection and/or frank bleeding, co-existing inflammatory conditions, ulceration.</li> <li>• No visualization of genital warts.</li> <li>• Unknown morphology.</li> <li>• Broken skin surfaces.</li> <li>• Warts over 4cm<sup>2</sup> total area</li> <li>• Known allergy or previous adverse reaction to podophyllin or podophyllotoxin.</li> <li>• Patient declines treatment under PGD.</li> <li>• Known HIV positive.</li> <li>• If only internal or intrameatal genital warts are present</li> <li>• Perianal warts (as not licensed)</li> <li>• Patient aged 12 or below.</li> <li>• Patients aged 13 to 15 who are not Fraser competent.</li> <li>• If the treatment is not recommended by the BASHH flow chart of management of warts in women/men(2015)</li> </ul>

<p><b>Action if excluded</b></p>	<ul style="list-style-type: none"> <li>• Refer to Medical Practitioner unless there is an appropriate alternative according to the BASHH flow chart of management of warts in women/men(2015)</li> <li>• There may be occasions when a medical practitioner is not physically present within the department. Discuss by telephone where possible or refer to a non-medical prescriber.</li> </ul>
<p><b>Action for patients not wishing to receive care under the PGD</b></p>	<p>Refer to medical practitioner or non-medical prescriber during clinical session</p> <p>When a medical practitioner/NMP is not physically present within the department defer treatment until after telephone discussion with a medical practitioner</p>

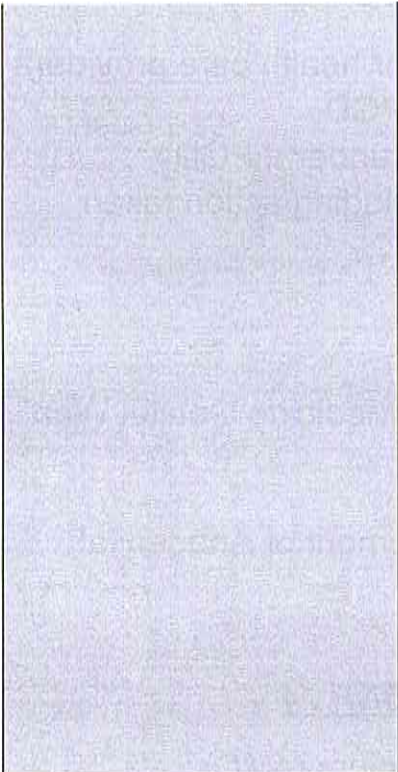
**DESCRIPTION OF TREATMENT**

<b>Name of Medicine</b>	Podophyllotoxin solution/ podophyllotoxin cream		
<b>Legal Classification</b>	Prescription only medication (POM)		
<b>Licensing information</b> Podophyllotoxin solution and cream are licensed for the treatment of genital warts on the penis or female external genitalia	<b>Is the medicine licensed for the intended use?</b>	<b>YES</b>	
	<b>Does it have a black triangle status?</b>		<b>NO</b>
	<b>Does it have a Risk Minimisation Measures (RMM) recommendation</b>		<b>NO</b>
<b>Form</b>	Cream or solution		
<b>Strength</b>	0.5% solution 0.15% cream		
<b>Dose</b>	Enough cream/solution to just cover each wart		
<b>Frequency</b>	<p>Applied twice daily for 3 consecutive days, then 4 days without treatment.</p> <p>Treatment is repeated weekly up to a maximum of four weeks in total (Warticon) or 5 weeks (Condyline solution). The treatment must then be reviewed in accordance with the BASHH flow chart of management of warts in women/men(2015)</p>		
<b>Route</b>	Topical		
<b>Total Treatment Quantity</b>	<p>3.5mL Condyline solution pack or 3mL Warticon solution pack alternatively One tube of 5g Warticon cream</p> <p>Maximum treatment of 4 weeks with Warticon or 5 weeks for Condyline.</p>		
<b>Interactions with other medicines</b> (This must include all potentially serious interactions listed in the BNF)	<ul style="list-style-type: none"> <li>• Avoid concurrent use with other treatments for anogenital warts</li> <li>• No known interactions with other medicinal products</li> </ul>		

<p><b>Adverse Reactions</b> (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)</p>	<ul style="list-style-type: none"> <li>• Burning, itching and soreness</li> <li>• Skin irritation, redness and oedema, erosion, excoriation, scabbing.</li> <li>• Avoid contaminating normal skin and open wounds, keep away from face, very irritant to eyes</li> <li>• Excessive application can cause severe systemic toxicity including gastro-intestinal, renal, haematological and central nervous system effects.</li> </ul>	<p><b>Treatment of adverse reactions</b></p> <ul style="list-style-type: none"> <li>• Transient side effects which should resolve without treatment. If not resolving or cause severe discomfort then contact a medical practitioner</li> <li>• . Wash off any cream/solution and contact the appropriate medical practitioner to gain further advice.</li> <li>• Report and refer to Consultant-in-charge any serious adverse drug reactions and document in patient's records.</li> <li>• York Teaching Hospitals NHS Foundation Trust drug AIRs Datix form to be completed and procedure guidelines followed.</li> <li>• 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</li> </ul>
<p><b>Advice to Patients: Written and Oral advice</b> (This should include the provision of a patient information leaflet)</p>	<ul style="list-style-type: none"> <li>• Information regarding aetiology and transmission of wart virus infection and possibility of recurrences; with leaflet.</li> <li>• Infection and possibility of recurrences; with leaflet.</li> <li>• Information regarding treatment compliance/correct application and side effects; supported by drug information leaflet.</li> </ul>	

	<ul style="list-style-type: none"> <li>• Advise patient to abstain from sexual intercourse when cream or solution applied.</li> <li>• Latex weakening if a condom used therefore, not a suitable method of contraception when cream is on the skin.</li> <li>• Avoid bathing/showering when cream applied as it will remove the cream.</li> <li>• Advise on the need to use reliable method of contraception for non-treatment days if the patient is female and sexually active. Also, if contraception fails they may need emergency contraception.</li> <li>• Advice regarding general hygiene and skin care during treatment.</li> <li>• Advice to patient on reporting adverse out comes or side effects.</li> <li>• Advice regarding discussions with partner, the management of future episodes of warts, and pregnancy/childbirth, including stopping using treatment if patient becomes pregnant.</li> <li>• Advise of need for routine cervical cytology screening when due.</li> <li>• Discussion on safer sex</li> <li>• Hands should be thoroughly washed after application of treatment</li> </ul>
<b>Follow up action</b>	Clinical review in 4 weeks if needed
<b>Storage</b>	<ul style="list-style-type: none"> <li>• locked medicines cupboard – store below 25 °C</li> <li>• In locked medicine box or locked briefcase</li> </ul>
<b>Records to be Kept</b>	<p><b>The following minimum details need to be documented in full in patient's records in relation to initiating treatment under PGD</b></p> <ul style="list-style-type: none"> <li>• Date/time of record entry</li> <li>• Drug name and strength</li> <li>• Dose and form</li> <li>• Route of administration</li> <li>• Time of administration if appropriate</li> <li>• Advice given to patients, including written information</li> <li>• Name/job title of staff administering/supplying medicine(and signature if written records)</li> <li>• Details of any adverse drug reactions or side effects</li> <li>• Details of any problems reported with compliance</li> </ul>

	<p>and action advised/taken</p> <ul style="list-style-type: none"> <li>• Any communication with other health care providers</li> <li>• Consent to treatment under PGD.</li> <li>• That treatment was supplied under a PGD</li> <li>• Any reason for exclusion, including action taken</li> </ul>
<p><b>Audit Arrangements</b></p>	<p>As per current Trust PGD Policy</p>
<p><b>References</b></p>	<p>York Department of Genitourinary Medicine Genital Wart Pathway 2015</p> <p>National guidelines for the management of Anogenital warts 2015  <a href="http://www.bashh.org">www.bashh.org</a></p> <p>British National Formulary (2018) <i>BNF 74</i></p> <p>The Electronic Medicines Compendium (eMC)  <a href="http://www.medicines.org.uk/EMC/default.aspx">http://www.medicines.org.uk/EMC/default.aspx</a></p> <p>Nursing and Midwifery Council, The Code for nurses and midwives. March 2015  <a href="http://www.nmc.org.uk">www.nmc.org.uk</a> <b>(refers to record keeping)</b></p> <p>Nursing and Midwifery Council, Standards for Medicines Management, 2007, minor updates 2015  <a href="http://www.nmc.org.uk">www.nmc.org.uk</a> <i>Remae.</i></p>
<p><b>Competency Requirements</b>  (attach any competency frameworks / documents)</p>	<p>Completion of a local Sexual Health training programme for the supply of podophyllotoxin under PGD within Sexual Health services. This will require/include:</p> <ul style="list-style-type: none"> <li>• Clinical competence in the history taking, clinical examination/assessment and genital screening and competent to accurately identify genital wart lesions.</li> <li>• Knowledge base of the interactions of podophyllotoxin with other drugs, and other contra-indications for issuing podophyllotoxin</li> <li>• Competence in the above will be demonstrated by the undertaking of a local clinical competency based training and assessment programme</li> <li>• 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.</li> </ul>




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- 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 in Sexual Health in the preceding 3 years.
  - Completion of the Trust PGD awareness session or Trust HUB e-learning.
  - Competence in the use of PGDS.
  - Regular attendance and participation in the tri-annually educational clinical governance/audit day at York Sexual Health Services.

Maintain professional accountability with the Nursing and Midwifery Council (NMC) and ensure continuing professional development.

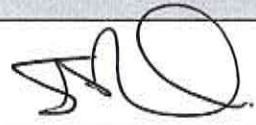



**AUTHORISATION OF THE PATIENT GROUP DIRECTION (PGD) FOR  
ADMINISTRATION/SUPPLY OF: Podophyllotoxin 0.5% solution or 0.15% cream for the  
treatment of anogenital warts- primary and recurrent**

**PGD Development / Review Team – responsible for PGD content**

Title	Name	Signature	Date
Lead Author	ANSON Aherum		30.8.18
Clinical Director Lead Approval	Dr Ian Fairley		30/8/18
Directorate Pharmacy Lead Approval	Paul Jackson		3/9/18

**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		03/09/2018

**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**

<b>Ward / Department</b>	Sexual Health
<b>Professionals to whom this Patient Group Direction applies</b>	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:***

<b>Name (Capitals)</b>	<b>Sign</b>	<b>Job Title</b>	<b>Authorising Manager</b>	<b>Date</b>

**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.**

<b>Author:</b>	Jennie Booth, Lead Nurse Medicines Management Carol Belt, Principal Pharmacy Technician Stuart Parkes, Deputy Chief Pharmacist
<b>Owner:</b>	NMP/PGD Group
<b>Date of issue:</b>	December 2017
<b>Version:</b>	2
<b>Approved by</b>	NMP/PGD Group
<b>Review date:</b>	December 2020

