

**Patient Group Direction for the administration of :Cryotherapy for the treatment of anogenital warts or anogenital molluscum contagiosum**

<b>Title of patient group direction</b>	Liquid Nitrogen Topical application
<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
<b>CONSULTATION PROCESS ADOPTED IN DEVELOPING THE PATIENT GROUP DIRECTION (PGD)</b>	
<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

<b>CLINICAL CONDITION</b>	
<b>Condition</b>	Anogenital warts or anogenital molluscum contagiosum
<b>Inclusion criteria</b>	<ul style="list-style-type: none"> <li>• Patient who has been diagnosed/observed as having external genital/perianal warts and/or anogenital molluscum contagiosum by a medical practitioner or competent nurse within sexual health</li> <li>• The wart treatment decision is defined by the BASHH flow chart of management of warts in women/men(2015)</li> </ul>
<b>Exclusion criteria</b>	<ul style="list-style-type: none"> <li>• Complicated presentations, e.g. complicated by secondary bacterial infection and/or bleeding frankly.</li> <li>• No visualization of genital /perianal warts/molluscum contagiosum.</li> <li>• Unknown morphology.</li> <li>• Broken skin surfaces.</li> <li>• Co-existing inflammatory skin conditions.</li> <li>• Large affected areas.</li> <li>• Known allergy to nitrogen/cryotherapy.</li> <li>• Patient declines treatment under PGD.</li> <li>• Treatment not advised by the BASHH flow chart of management of warts in women/men(2015)</li> <li>• Patient aged 12 or below.</li> <li>• Patients aged 13 to 15 who are not Fraser competent</li> <li>• Cervical warts should not be treated within the service</li> </ul>
<b>Action if excluded</b>	<ul style="list-style-type: none"> <li>• Refer to medical practitioner/prescriber unless there is an appropriate alternative according to BASHH flow chart of management of warts in women/men(2015)</li> <li>• As there may be occasions when a medical practitioner is not physically present within the department, discuss by telephone where possible with medical practitioner.</li> </ul>
<b>Action for patients not wishing to receive care under</b>	<ul style="list-style-type: none"> <li>• Refer to medical practitioner that clinical</li> </ul>

the PGD

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 is possible.

DESCRIPTION OF TREATMENT			
<b>Name of Medicine</b>	Liquid Nitrogen		
<b>Legal Classification</b>	Medical device		
<b>Licensing information</b>  Liquid nitrogen is marketed for use in cryotherapy.	<b>Is the medicine licensed for the intended use?</b>	<b>YES</b>	Liquid nitrogen filled Cryogun is a licensed medical device intended for freezing warts/lesions
	<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>	Liquid		
<b>Strength</b>	N/A		
<b>Dose</b>	2 freeze thaw cycles keeping the lesion frozen for 20 seconds, to genital/perianal wart or molluscum, with halo of 2mm to surrounding tissue.		
<b>Frequency</b>	Repeat once every 7 to 10 days.		
<b>Route</b>	Topical		
<b>Total Treatment Quantity</b>	Review treatment option every 4 weeks (i.e. after 4 treatments). Treat warts until lesion gone/ molluscum until lesion scabbed.		
<b>Interactions with other medicines</b> (This must include all potentially serious interactions listed in the BNF)	Avoid concurrent use with other treatments for anogenital warts  <b>If in doubt discuss with medical practitioner</b>		

<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>• Skin irritation, redness and oedema.</li> <li>• Scarring and hyper/hypo pigmentation may occur very rarely.</li> <li>• Ulceration may occur which penetrates the dermis</li> </ul>	<p><b>Treatment of adverse reactions</b></p> <ul style="list-style-type: none"> <li>• Contact the medical practitioner to gain further advice.</li> <li>• Report and refer to Consultant-in-charge any serious adverse 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> </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>• Advise that an intense burning may be experienced for 5-10 minutes after application.</li> <li>• Advice to abstain from sexual intercourse or to use a condom whilst warts are visible.</li> <li>• Advice regarding general hygiene and skin care during treatment.</li> <li>• Advice that salt water bathing may be of benefit to some patients following treatment.</li> <li>• Discussion of safer sex in general for future sexual health.</li> <li>• Advice to patient on reporting adverse outcomes, or side effects.</li> <li>• Advise of the need to ensure female patients diagnosed with anogenital warts undergo routine cervical cytology screening when due only.</li> </ul>	
<p><b>Follow up action</b></p>	<p>See weekly and review treatment option every 4 weeks</p>	
<p><b>Storage</b></p>		

	Well ventilated, locked room, for the storage of the Liquid nitrogen.
<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</li> <li>• Dose and form</li> <li>• Route of administration</li> <li>• Time of administration if appropriate</li> <li>• Advice given to patients</li> <li>• Name/job title of staff administering/supplying medicine (and signature if written records)</li> <li>• Details of any adverse reactions or side effects</li> <li>• Details of any problems reported with compliance and action advised/taken</li> <li>• Any communication with other health care providers</li> <li>• If the patient is pregnant her start of treatment must be documented in her maternity (green) notes or her GP written to this need only to be completed on the patient's first visit.</li> <li>• Document that cryotherapy was administered under a PGD</li> <li>• Document consent to PGD</li> <li>• Any reason for exclusion, including action taken</li> <li>• If the patient has refused treatment under the PGD, any advice given or cautions taken</li> </ul>
<b>Audit Arrangements</b>	As per current Trust PGD Policy
<b>References</b>	<ul style="list-style-type: none"> <li>• <u>British Association of Sexual Health and HIV (2015) <i>United Kingdom National Guideline on the Management of Anogenital warts</i> <a href="http://www.bashh.org/documents/86/86.pdf">http://www.bashh.org/documents/86/86.pdf</a> accessed 03.03.2015</u></li> <li>• <u><a href="https://cks.nice.org.uk/molluscum-contagiosum#!scenario">https://cks.nice.org.uk/molluscum-contagiosum#!scenario</a></u></li> </ul>

	<ul style="list-style-type: none"> <li>• British National Formulary 74, 2018 <a href="http://www.bnf.org.uk">www.bnf.org.uk</a></li> <li>• The Electronic Medicines Compendium (eMC) <a href="http://www.medicines.org.uk/EMC/default.aspx">http://www.medicines.org.uk/EMC/default.aspx</a></li> <li>• 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><u>refers to record keeping</u></b>)</li> <li>• Nursing and Midwifery Council, Standards for Medicines Management 2007, minor updates 2015, <a href="http://www.nmc.org.uk">www.nmc.org.uk</a></li> </ul>
<p><b>Competency Requirements</b> (attach any competency frameworks / documents)</p>	<p>Completion of a local Sexual Health training programme for the administration of Cryotherapy 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 for the safe use of cryotherapy and contraindications to use.</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> <li>• Receiving Clinical Supervision and/or audit of case notes on an ongoing basis.</li> <li>• Evidence of continuing professional development in Sexual Health and/or the Sexual Health nurse role.</li> <li>• Minimum of 6 months experience of working in Sexual Health in the preceding 3 years.</li> <li>• Competence in the use of PGDS.</li> <li>• Trust PGD awareness session or Trust HUB e-learning.</li> <li>• Regular attendance and participation in the Tri-annually educational clinical</li> </ul>




governance/audit day at York Sexual Health Services.

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





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

Title	Name	Signature	Date
Lead Author	Adrian Chapman		10-7-18
Clinical Director Lead Approval	JAN FAIRLE		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		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**

<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>
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.**

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