NHS
York and Scarborough Teaching Hospitals
NHS Foundation Trust

This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

PATIENT GROUP DIRECTION (PGD)

Supply of podophyllotoxin 0.15% w/w cream or 0.5% w/v solution for the treatment of external ano-genital warts in York & North Yorkshire Sexual Health Services including specialist clinical outreach services

Version Number 1.0

Change History	
Version and Date	**Change details**
Version 1 February 2021	New template

This Patient Group Direction (PGD) must only be used by registered professionals who have been named and authorised by their organisation to practise under it (See Appendix A). The most recent and in date final signed version of the PGD must be used.

Reference Number: v1
Valid from: May 2022
Review date: July 2023
Expiry date: 31st January 2024

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	22nd February 2021
Review date	July 2023
Expiry date:	31st January 2024

This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by British Association for Sexual Health and HIV (BASHH)/BASHH Bacterial Special Interest Group (BSIG) in February 2021.

This section MUST REMAIN when a PGD is adopted by an organisation.

Name	Designation
Ali Grant	Highly Specialist Clinical Pharmacist: HIV, Sexual and Reproductive Health
Alison Crompton	Community pharmacy
Amy Moore	Pharmacist HIV, Sexual and Reproductive Health Kingston Hospital NHS Foundation Trust
Andrea Smith	Community pharmacy
Carmel Lloyd	Royal College of Midwives
Chetna Parmar	Pharmacist adviser, Umbrella
Clare Livingstone	Royal College of Midwives
Deborah Redknapp	English HIV and Sexual Health Commissioners Group (EHSHCG)
Dipti Patel	Local authority pharmacist
Dr Achyuta Nori	Consultant in Sexual Health and HIV
Dr Cindy Farmer	Chair General Training Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Dr John Saunders	Consultant in Sexual Health and HIV
Dr Kathy French	Pan London PGD working group
Dr Rita Browne	Consultant in Sexual Health and HIV
Dr Sarah Pillai	Pan London PGD working group
Emma Anderson	Centre for Pharmacy Postgraduate Education (CPPE)
Helen Donovan	Royal College of Nursing
Jo Jenkins (Working Group Co-ordinator)	Specialist Pharmacist (PGDs) Specialist Pharmacy Service
Jodie Crossman	Specialist Nurse. BASHH SHAN SIG Chair
Jodie Walker-Haywood	Specialist Nurse, BASHH Board Nurse Representative, BASHH SHAN SIG Secretary
Leanne Bobb	English HIV and Sexual Health Commissioners Group (EHSHCG)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Portia Jackson	Pharmacist, Cambridgeshire Community Services
Sally Hogan	British Pregnancy Advisory Service (BPAS)
Sandra Wolper	Associate Director Specialist Pharmacy Service
Silvia Ceci	Chief Pharmaceutical Officer's Clinical Fellow Specialist Pharmacy Service
Tracy Rogers	Associate Director Specialist Pharmacy Service

Name	Job title and organisation	Signature	Date
Senior doctor	Dr Ian Fairley, Lead Consultant YSH		26/05/22
Senior pharmacist	Paul Jackson, Pharmacist		14/6/22
Senior representative of professional group using the PGD	Steve Evans , ANS		7/7/22
Person signing on behalf of authorising body	Jennie Booth, Lead Nurse Medicines Management Stuart Parkes, Chief Pharmacist pp KATE NIXON Dept Chief Pharmacist		04.08.2022 11/8/22

1. Characteristics of staff

Qualifications and professional registration	Current contract of employment within a Local Authority or NHS commissioned service or an NHS Trust/organisation. Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.
Initial training	The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of patient leading to diagnosis of the conditions listed. Recommended requirement for training would be successful completion of a relevant sexual health module/course accredited or endorsed by the BASHH, CPPE, RCN or a university or advised in the RCN Sexual Health Education directory. The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults.
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix A) or complete an appropriate self-declaration of competence for relevant testing and/or treatment. • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions
Ongoing training and competency	• Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required. • Completion of PGD awareness session via Trust Learning HUB
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	• Treatment of external anogenital warts
Criteria for inclusion	• Individuals who present with external non-keratinised anogenital warts. • Consent given. • Aged 13 years and over. All individual under the age of 19 years - follow local young person's risk assessment or equivalent local process.
Criteria for exclusion	• Consent not given. • Individuals under 13 years of age. • Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines. • Individuals 16 years of age and over and assessed as lacking capacity to consent. **Medical history** • Pregnancy • Breastfeeding • Keratinised warts (refer to imiquimod PGD/ consider other treatment options) • Practitioner cannot accurately determine that the lesions are genital warts • Individual has already not responded to a 8 week course of treatment with podophyllotoxin • Concomitant use with other podophyllotoxin containing preparations • Inflamed, ulcerated or broken skin • Open wounds (i.e. following a surgical procedure) or bleeding wounds • Warts on internal mucosal skin (vaginal or anal canal) urethral meatus, cervix • Extra - genital warts • Individuals who are unable to apply the podophyllotoxin preparation safely • Warts involving an area greater than 4 cm^2 **Medication history** • Any concurrent interacting medicine(s) – see Section 3 Drug interactions. • Known hypersensitivity or allergy to podophyllotoxin or any other constituent or excipient of the medicine - see Summary of Product Characteristics
Cautions including any relevant action to be taken	• An individual with impaired cell mediated immunity (e.g. those with HIV or transplant recipients) may respond poorly to treatment and have higher relapse rates. The British Association for Sexual Health and HIV (BASHH) recommends careful follow-up of these individuals – follow up in these patients should be arranged with a specialist. • Counsel women of the importance of avoiding pregnancy during treatment. If women become pregnant during

	treatment, they should stop using podophyllotoxin and return to the clinic. • If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented. • If the presenting individual is under 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy (note under 13 years of age excluded from treatment under this PGD). • Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain.
Action to be taken if the individual is excluded or declines treatment	• Record reason for decline in the consultation record. • Explain the reasons for exclusion to the individual and document in the consultation record. • Discuss alternative means of therapy e.g. cryotherapy or imiquimod for keratinised warts, if appropriate, and where required refer the individual to a suitable health service provider and/or provide them with information about further options.

3. Description of treatment

Name, strength & formulation of drug	Podophyllotoxin 0.15% w/w cream - 5g tube **OR** Podophyllotoxin 0.5% w/v solution - 3mL or 3.5mL bottle
Legal category	POM
Route of administration	Topical
Off label use	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 (SPC). This PGD includes off label use in the following conditions: • The Warticon® brand of both cream and solution is not licensed for use in those under 18 years of age Medicines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where medicines have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with pharmacy/Medicines Management. Where a medicine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence.
Dose and frequency of	• Apply twice daily (every 12 hours) for three consecutive days.

administration	• Then no treatment for four days. • Repeat for three to four further weeks depending on product used
Duration of treatment	Maximum period of treatment under this PGD is: • Condyline® solution up to 5 weeks total • Warticon® cream and liquid up to 4 weeks total A second four/five week treatment course may be started under this PGD after review as a separate episode of care.
Quantity to be supplied	Podophyllotoxin Cream 0.15% w/w 1 tube of 5g **OR** Podophyllotoxin solution 0.5% w/v 1 bottle of 3mL or 1 bottle of 3.5mL
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC. Specifically for the product included in this PGD: **Podophyllotoxin solution: Warticon® (containing 0.5% Podophyllotoxin in 3ml)** • Should be stored below 25°C. • Keep container tightly closed when not in use. Contents are flammable. Keep away from fire, flame or heat. • Do not leave Warticon® solution in direct sunlight. **Podophyllotoxin solution: Condyline® (containing 0.5% Podophyllotoxin in 3.5ml)** • Do not store above 25 degrees. • Product is flammable and should be kept away from naked flames, patient information leaflet is provided with the product giving details on the use and handling of the product. • Once opened, the product has a shelf life of 6 weeks.
Drug interactions	All concurrent medications should be reviewed for interactions. A detailed list of all drug interactions is available in the BNF or the product SPC
Identification & management of adverse reactions	A detailed list of adverse reactions is available in the SPC and BNF The following side effects are very common/common with podophyllotoxin: • Application site irritation (including erythema, pruritus, skin burning sensation) The excipients of Warticon® cream include: • Methyl and propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed). • Sorbic acid, stearylalcohol and cetylalcohol which may cause local skin reactions, (e.g. contact dermatitis). • Butyl hydroxyanisole which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

Management of and reporting procedure for adverse reactions	• Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme • Record all adverse drug reactions (ADRs) in the patient's medical record. • Report via organisation incident policy.
Written information and further advice to be given to individual	**Medication (general):** • Give patient information leaflet (PIL) provided with the original pack. Explain mode of action, side effects, and benefits of the medicine • Hands should be washed thoroughly before and after application • Podophyllotoxin preparations should not come into contact with the eyes. If this occurs, the eye should be thoroughly rinsed with water. • Avoid applying the cream to healthy surrounding tissue and open wounds • Occlusive dressings should not be used on areas treated with the cream. • Local irritation may occur on the second or third day of application associated with the start of wart necrosis. In most cases, the reactions are mild. If severe local skin reactions occur (bleeding, swelling, excessive pain, burning, itching) the cream should be washed immediately from the treatment area with mild soap and water, treatment discontinued and the patient advised to seek medical advice. • To avoid smoking, or being near an open flame during application and immediately after using podophyllotoxin solution. **Product specific counselling:** **Warticon® cream- containing podophyllotoxin 0.15%w/w in 5g.** • The affected area should be thoroughly washed with soap and water and dried prior to application. • Using a fingertip, the cream should be applied twice daily morning and evening (every 12 hours) for 3 consecutive days using only enough cream to just cover each wart. The cream should then be withheld for the next 4 consecutive days. • Application to the surrounding normal tissue should be avoided. • Residual warts should be treated with further courses of twice daily applications for three days at weekly intervals, if necessary for a total of 4 weeks of treatment. • Hands should be washed thoroughly after application. **Warticon® solution- containing podophyllotoxin 0. 5%w/v in 3ml.** • The affected area should be thoroughly washed with

	soap and water, and dried prior to application. • Warticon® should be applied twice daily, morning and evening (every 12 hours) for 3 consecutive days. The treatment should then be withheld for the next 4 consecutive days. • Application to the surrounding normal tissue should be avoided. • If residual warts persist, this 3-day treatment may be repeated weekly until there is no visible wart tissue or for a total of 4 weeks of treatment. • Warticon® solution should be applied to the warts with the applicator supplied with the solution. • Due to the flammable nature of Warticon® solution, patients should avoid smoking or being near an open flame during application and immediately after use. • The solution should be allowed to dry before opposing skin surfaces are returned to their normal position. • Warticon® solution is flammable and should be kept away from naked flames. A patient information leaflet is provided with the product giving details on the use and handling of the product. **<u>Condyline® solution- containing podophyllotoxin 0. 5%w/v in 3.5ml.</u>** • Apply twice daily for three days directly to the warts. Allow to dry after treatment. • Use the applicator provided, applying not more than 50 applicators-full for each treatment. • This three day treatment may be repeated, if necessary, at weekly intervals for a total of five weeks of treatment. Only a small area or number of warts should be treated at any one time. Care must be taken to avoid application to healthy tissue. • Condyline® is flammable and should be kept away from naked flames. A patient information leaflet is provided with the product giving details on the use and handling of the product. **Condition:** • Individuals diagnosed with anogenital warts should be offered information (verbal, written and/or digital) about their diagnosis and management • Counsel women of the importance of avoiding pregnancy during treatment. If women become pregnant during treatment, they should stop using podophyllotoxin and return to the clinic. • Sexual contact should be avoided soon after application and until the skin has healed. This is because of a possible irritant effect on the partner • Advise that as per BASHH guidelines, a change in therapy is indicated if either the patient is not tolerating the current treatment, or there is less than a 50% response to the current treatment by 4 to 5 weeks – individual should be advised reviewed by the clinic.

	• Offer screening for other STIs as appropriate. • Offer condoms and advice on safer sex practices and possible need for screening for sexually transmitted infections (STIs • Where treatment not supplied via a sexual health clinic ensure the individual has contact details of local sexual health services.
Follow up treatment	• The individual should be advised to seek medical advice in the event of an adverse reaction. • If symptoms worsen and/or are unresolved after completing the course, counsel patient to return to the clinic for further advice.

Records	**Record:**
	• The consent of the individual and
	  o If individual is under 13 years of age record action taken
	  o If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken.
	  o If individual over 16 years of age and not competent, record action taken
	• If individual not treated under PGD record action taken
	• Name of individual, address, date of birth
	• GP contact details where appropriate
	• Relevant past and present medical and sexual history, including medication history.
	• Examination or microbiology finding/s where relevant.
	• Any known allergies and nature of reaction
	• Name of registered health professional
	• Name of medication supplied
	• Date of supply
	• Dose supplied
	• Quantity supplied including batch number and expiry date in line with local procedures.
	• Advice given about the medication including side effects, benefits, and when and what to do if any concerns
	• Advice given, including advice given if excluded or declines treatment
	• Details of any adverse drug reactions and actions taken
	• Any referral arrangements made
	• Any supply outside the terms of the product marketing authorisation
	• Recorded that supplied via Patient Group Direction (PGD)
	
	Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy.
	
	All records should be clear, legible and contemporaneous.
	
	A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

4. Key references

Key references (accessed February 2020)	• Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2 • BASHH UK National Guidelines on the Management of Anogenital Warts 2015 https://www.bashhguidelines.org/media/1075/uk-national-guideline-on-warts-2015-final.pdf • Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines

Appendix A - Registered health professional authorisation sheet

PGD Supply of podophyllotoxin 0.15% w/w cream or 0.5% w/v solution for the treatment of external anogenital warts
Valid from: May 2022 **Expiry: January 2024**

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

Registered health professional

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of York & Scarborough Teaching Hospitals NHS Foundation Trust for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD. When the expiry date is exceeded, this PGD ceases to be a legal document. Staff authorisation records must be maintained for 8 years if the PGD relates to adults only, 10 years for implants and 25 years after the expiry date if the PGD relates to children