NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Patient Group Direction For The Supply Of Podophyllotoxin For The Treatment Of External Genital Warts By Nurses Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Lead Author: Adapted from SPS/BASHH PGD Supply of Podophyllotoxin 0.15% W/W Cream Or 0.5% W/V Solution For The Treatment Of External Anogenital Warts, Version 2.2 – Published – July 2024		**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature: 		**Signature:** 
NoS Identifier: NoS/PGD/Podophyllotoxin/ 1452	**Review Date:** July 2026 **Expiry Date:** January 2027	**Date Approved by NoS:** 5th of April 2024 (Amended September 2024)

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 2.2 (Amended September 2024)

Revision History for NoS:

NoS PGD that has been superseded	NoS/PGD/Podophyllotoxin/1452, Version 2.1	
Date of change	**Summary of Changes**	**Section heading**
November 2023	Reference to NoS Appendix 1 and 2.	Authorisation
November 2023	Statement added in about nurses being registered by the NMC.	Professional registration
November 2023	Removed SPS advised training and added TURAS NoS PGD training link added.	Initial Training
November 2023	Added in statement about capacity under the age of 13 and the legislation statement added.	Criteria for inclusion
November 2023	Note added about contacting child protection if child under 12 presents.	Criteria for exclusion
November 2023	NICE Competency framework statement removed.	Competency assessment
November 2023	Added clinical systems utilised.	Records
January 2024	Changed age 19 to age 18 for clarity when following local young person's risk assessment.	Criteria for inclusion
March 2024	NoS over label supply statement added.	Legal Category

SPS/BASHH most recent changes

Change History	
Version and Date	**Change details**
Version 1 February 2021	New template
Version 2.0 July 2023	Reviewed template. Updated PGD development group members. Reviewed SPC and one additional statement in exclusion criteria. Some minor formatting and rewording to align with other sexual health PGDs.
Version 2.1 October 2023	Removed references to Condyline® product which has been withdrawn. Updated membership PGD development group.
Version 2.2 July 2024	Updated exclusion criteria to remove keratinised warts to reflect updated BASHH guidance. Added information on application, HPV vaccine, and patient information leaflet. Updated references. Updated SLWG.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Authorisation

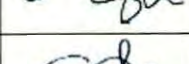
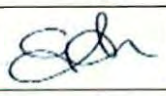
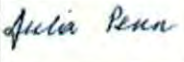
This specimen Patient Group Direction (PGD) template has been produced by SPS/BASHH and adapted by North of Scotland PGD Group (NoS) to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may supply medicines under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/Summary of Product Characteristics (SmPC) for all medicines supplied in accordance with this PGD.

NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Supply of the medicines has to be by the same practitioner who has assessed the patient under the PGD.

All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1).

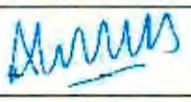
A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.

This PGD has been produced for NoS by:					
Doctor	Dr Ciara Cunningham	Signature		Date Signed	05/09/2024
Pharmacist	Gayle Anderson	Signature		Date Signed	05/09/2024
Nurse	Julia Penn	Signature		Date Signed	05/09/2024

Approved for use within NoS by:

NoS Group Chair	**Signature**	**Date Signed**
Lesley Coyle		02/10/2024

Authorised and executively signed for use within NoS by:

NHS Grampian Chief Executive	**Signature**	**Date Signed**
Adam Coldwells – Interim Chief Executive		05/10/2024

Version 2.2 – Approved for NoS from 5th October 2024

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	February 2024
Review date	July 2026
Expiry date:	January 2027

This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group (SLWG) 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 June 2023.

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
Carmel Lloyd	Royal College of Midwives
Chetna Parmar	Pharmacist adviser, Umbrella
Tanya Lane	Designate Clinical Excellence Lead for Contraception and Sexual Health, Registered Nurse, MSI Reproductive Choices
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	Vice President, Professional Learning and Development Faculty of Sexual and Reproductive Healthcare (FSRH)
Dr Rachael Jones	Consultant in HIV and Genito-urinary Medicine, Chelsea and Westminster NHS Foundation Trust
Norah O'Brien	National Programme Manager, Programme Delivery and Service Improvement, UKSHA
Deborah Shaw	National Programme Manager, Programme Delivery and Service Improvement, UKSHA
Dr Rita Browne	Consultant in Sexual Health and HIV
Emma Anderson	Centre for Pharmacy Postgraduate Education (CPPE)
Heather Randle	Royal College of Nursing
Jo Jenkins	Lead Pharmacist Patient Group Directions and Medicines Mechanisms, Specialist Pharmacy Service
Margaret Kingston	Consultant Physician Genitourinary Medicine, Associate Medical Director, Manchester University NHS Foundation Trust and BASHH representative
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)

Name	Designation
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Portia Jackson	Lead Pharmacist iCaSH, Cambridgeshire Community Services
Rosie Furner (Working Group Co-ordinator)	Specialist Pharmacist - Patient Group Directions and Medicines Mechanisms, Specialist Pharmacy Service
Elaine Scott	Senior Quality Matron British Pregnancy Advisory Service (BPAS)
Kalpesh Thakrar	Lead Pharmacist British Pregnancy Advisory Service (BPAS)
Sandra Wolper	Associate Director Specialist Pharmacy Service
Tracy Rogers	Director Specialist Pharmacy Service

1. Characteristics of staff

Qualifications and professional registration	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 an individual 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 as advised in the RCN Sexual Health Education directory. Have undertaken NoS PGD module training on TURAS Learn. 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 1 and Appendix 2) or complete an appropriate self-declaration of competence for relevant testing and/or treatment.
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. • Organisational PGD and/or medication training as required by employing Trust/organisation.
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 anogenital warts, keratinised and non-keratinised. • Consent given. • Aged 13 years and over. All individual under the age of 18 years - follow local young person's risk assessment or equivalent local process. • Individuals under 16 years of age may give consent for the supply of podophyllotoxin, provided they understand fully the benefits and risks involved. The individual should be encouraged to involve a parent/guardian, if possible, in this decision. Where there is no parental involvement and the individual indicates that they wish to accept the supply, supply should proceed, if the healthcare professional deems the individual to have the legal capacity to consent. The Age of Legal Capacity (S) Act 1991, s2 (4) states that 'a person under the age of 16 years shall have legal capacity to consent on their own behalf to any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner attending them, they are capable of understanding the nature and possible consequences of the procedure or treatment.
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** • Known or suspected pregnancy. • Breastfeeding. • Practitioner cannot accurately determine that the lesions are genital warts. • Individual has already not responded to an 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 4cm^2. **Medication history** • Known hypersensitivity or allergy to podophyllotoxin or any other constituent or excipient of the medicine - see Summary of Product Characteristics **Note:** Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain. *Children under the age of 13 years should not be treated under this PGD. (The child protection team must be contacted for children of 12 years and under who present having had sexual intercourse). For those aged 13-16 years consider child protection team referral for these individuals if appropriate and according to local Board protocols.
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 individuals 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. • All individuals of child bearing potential should be advised to use contraception, and seek advice if they become pregnant whilst using podophyllotoxin products – see section written information and further advice to be given to individual). • 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). • Inability to stay away from open or naked flames (e.g. smokers): due to risk of severe burns. • 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 0.5% w/v solution - 3mL bottle **OR** Podophyllotoxin 0.15% w/w cream - 5g tube
Legal category	POM In accordance with the MHRA all medicines supplied under a PGD must either be from over-labelled stock, or be labelled appropriately in accordance with the regulatory body guidelines for the labelling of medicines for the professional providing the supply.
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. • Use in the treatment of external perianal warts.

	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 supply 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 administration	• Apply twice daily (every 12 hours) for three consecutive days. • Then no treatment for four days. • Repeat for three to four further weeks depending on product used (see below for maximum duration). • Podophyllotoxin solution is preferred over the cream formulation at easy to reach sites. • Podophyllotoxin 0.15% cream may be used for the treatment of external perianal warts (off label use).
Duration of treatment	Maximum period of treatment under this PGD is: • Podophyllotoxin cream and solution 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. Advise to stop treatment once no visible lesions remain.
Quantity to be supplied	Podophyllotoxin solution 0.5% w/v 1 bottle of 3mL **OR** Podophyllotoxin Cream 0.15% w/w 1 tube of 5g
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.
Drug interactions	Whilst there are no clinically significant interactions listed within this PGD all concurrent medications should be reviewed for interactions. A detailed list of all drug interactions is available in the BNF or the product SPC. Seek advice from an appropriate clinician/Medicines Advisory Service if required.
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, stearyl alcohol and cetyl alcohol 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 individuals/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 individual's clinical record. • Report via organisation incident policy.

Written information and further advice to be given to individual	**Medication (general):** • Give manufacturer 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. Advise that petroleum jelly may be applied to healthy skin adjacent to lesions to limit damage from inadvertent contact with podophyllotoxin solution. If used, instruct individuals not to smoke or go near naked flames due to risk of severe burns. • 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 individual 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, individuals 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 manufacturer 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. Written patient information leaflets are available from, e.g. BASHH, NHS website, for example wart_pil_screen_v_2018.pdf (bashh.org) • Counsel females of the importance of avoiding pregnancy during treatment. If a female become pregnant during treatment, they should stop using podophyllotoxin and return to the clinic. • Avoid sexual contact without condoms 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 individual 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 to attend the clinic for review.

	• 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. • Advise or offer HPV vaccination to eligible individuals, either with or without pre-existing AGW, in accordance with national guidance.
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 individual 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. Depending on the clinical setting where supply is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: • NaSH – Sexual Health Electronic Patient Record • BadgerNet – Digital Maternity Notes • HEPMA • Individual's GP records if appropriate Individual service specific systems.

4. Key references

Key references (accessed April 2023, and May 2024)	• 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 2024 British association for sexual health and HIV national guideline for the management of anogenital warts in adults (2024) (bashh.org) • 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 • MHRA: Emollients: new information about risk of severe and fatal burns with paraffin-containing and paraffin-free emollients (2018) Emollients: new information about risk of severe and fatal burns with paraffin-containing and paraffin-free emollients - GOV.UK (www.gov.uk)

Appendix 1 - Healthcare Professional Agreement to Supply Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to supply the medicine(s) contained within the following Patient Group Direction:

Patient Group Direction For The Supply Of Podophyllotoxin For The Treatment Of External Genital Warts By Nurses Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles – Version 2.2

I have completed the appropriate training to my professional standards enabling me to supply the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 2 - Healthcare Professionals Authorisation to Supply Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to supply the medicine(s) under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to supply the medicine(s) under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that supply is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.
Patient Group Direction For The Supply Of Podophyllotoxin For The Treatment Of External Genital Warts By Nurses Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles – Version 2.2
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

Patient Group Direction For The Supply Of Podophyllotoxin For The Treatment Of External Genital Warts By Nurses Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles – Version 2.2					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**