PGD3917

South Staffordshire & Shropshire Healthcare NHS Foundation Trust

PATIENT GROUP DIRECTION
FOR THE SUPPLY OF PODOPHYLLOTOXIN 0.5% SOLUTION FOR THE TREATMENT OF ANO-GENITAL WARTS

By registered nurses and registered midwives in Integrated Sexual Health Services employed as by South Staffordshire & Shropshire Healthcare Foundation NHS Trust

This Patient Group Direction for use in South Staffordshire & Shropshire Healthcare NHS Foundation Trust and is authorised by:			
Position of Signatory	**Name**	**Signed**	**Date**
Medical Director	Dr Abid Khan	-	
Chief Pharmacist	Cathy Riley		
Director of Quality & Clinical Performance	Therèsa Moyes		
Director of Nursing	Alison Bussey		

The named below, being employees of South Staffordshire & Shropshire Healthcare NHS Foundation Trust are authorised to administer podophyllotoxin 0.5% to patients in Integrated Sexual Health Services under this Patient Group Direction

Name	Job Title	Signed	Date

This Patient Group Direction is operational from: 1st October 2017
Review date: Aug 2019. Expires on 31st Oct 2019
Replaces PGD3216b

Professional Responsibility

All registered nurses and non medical prescribers being employees of South Staffordshire & Shropshire Healthcare NHS Foundation Trust are authorised to supply podophyllotoxin 0.5% solution as specified under this Patient Group direction following demonstration of the competencies below;

Professional Responsibility / Competencies

1. The registered nurse will have undertaken appropriate training in order to carry out clinical assessments of patient that requires treatment according to the indication listed in the PGD
2. Hold a recognised qualification in sexual health skills (ENB 276 or equivalent post-registration qualification/ in- house training/competency in STIs)
3. An introduction to sexual health is not sufficient
4. Has been assessed as competent to provide care and treatment of genital infections
5. Has been assessed as competent to provide GUM care
6. Has been assessed and achieved the required standard in sexual health skills
7. Has undergone regular training and updating in safeguarding vulnerable adults
8. All nurses will have received training in the management and treatment of anaphylactic shock on an annual basis
   Each nurse will keep a record in their professional portfolio of the updates attended during every 12 month period – This information will also form part of the team's annual training plan
   The nurse will have due regard for the NMC Code of Conduct, Scope of Professional Practice and Standards for Medicines Management (Nursing & Midwifery Council)
9. Undertaken appropriate training and possess the competencies for working under PGDs for the supply and administration of medicines
   All registered nurses details and signature must be entered onto the PGD
10. Following administration a record of the date, strength, brand and dose of the medication should be recorded in the clients records and documented in the medicine card with PGD number recorded as authorisation

For full product information, always refer to the latest SPC (Summary of Product Characteristics).

If the anaphylaxis is related to a medication, please remember to report to the CSM, via a Yellow Card Report (http://emc.medicines.org.uk)

Supply/Administration of	Podophyllotoxin 0.5% Solution (Condyline Solution)
Legal Classification	Prescription only Medicine
Black Triangle?	No
Type	Topical Solution
Storage	Supplies will be available from central stock location, pre-labelled with the correct dose and quantity by the pharmacy department. Details of service user name and date of issue must be completed on the label prior to supplying to the patient. Information leaflets must be given. Any relevant documentation must be completed.
Condition to be treated	Topical treatment of condylomata acuminata warts affecting the penis or female external genitalia.
Inclusion Criteria	Individuals who present with external genital warts, non keratinised
Exclusion Criteria	**Personal characteristics** • Individuals under the age of 13 years • Individuals aged under 16 years who are assessed as not competent using Fraser Guidelines • Known or suspected pregnancy • Risk of pregnancy • Breastfeeding • Unable to manage treatment at home **Medication history** • Known allergy to any of the constituents found within the medication or hypersensitivity to podophyllotoxin • Individual has already had an 12 week course of podophyllotoxin (See treatment cycles below) **Medical history** • Nurse cannot accurately determine that the lesions are genital warts • Inflamed, ulcerated or broken skin or open wounds following surgery • Warts on internal mucosal skin (vaginal or anal canal, urethral meatus, cervix) • Extra-genital warts • Warts involving an area greater than $4cm^2$

	Cautions: • 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. http://www.bashh.org/documents/86/86.pdf
Action if excluded or patient declines	• Refer to appropriate doctor/ independent nurse prescriber • If individual has already had 12 weeks treatment, consider alternative treatment after medical review. (See treatment cycles below) • If individual declines, ensure awareness of the need for treatment, document refusal and refer to appropriate doctor/ independent nurse prescriber
Reasons for seeking further advice from doctor	• Discuss with appropriate doctor/independent nurse prescriber any medical condition or medication of which the nurse is unsure • Should the patient meet any of the exclusion criteria
Administration Route	Topical to genital lesions
Dose	Podophyllotoxin 0.5% Solution in 3.5ml bottle
Administration Schedule	Apply twice daily (every 12 hours) for 3 consecutive days. Then no treatment for 4 days for 4 weeks. This four week cycle may be repeated up to a maximum of two more cycles at weekly if there has been a demonstrable response to the initial treatment i.e. greater than 50% reduction in volume. Only a small area of warts should be treated at any one time. Duration of Treatment: • Maximum of 12 weeks treatment
Warnings/Adverse Reactions	• Local irritation may occur in the first 2-3 days of starting treatment associated with the start of wart necrosis. • Tenderness, itching, erythema, stinging,

	superficial ulceration and balanoposthitis may occur. In most cases the reactions are mild and local irritation decreases after treatment. Refer to current Summary of Product Characteristics (SPC) of relevant product and current British National Formulary (BNF) for full list and further information. In the event of untoward or unexpected adverse reactions: • If necessary seek appropriate emergency advice and assistance • Document in the individual's clinical record and inform appropriate doctor/independent nurse prescriber • Complete incident procedure if adverse reaction is severe (refer to local organisational policy) Use the yellow card system to report serious adverse drug reactions directly to the Medicines and Healthcare products Regulatory Agency (MHRA). Yellow cards are available in the back of the BNF or obtained via Freephone 0808 100 3352 or online at www.yellowcard.mhra.gov.uk.
Advice/Management of Adverse Reactions & Follow-up Action	• Provide Manufacturer's Patient Information Leaflet (PIL) and genital warts information leaflet and discuss • Teach individual how to use the solution safely and effectively • Thoroughly washaffected area with soap and water and dry prior to application • Avoid prolonged contact with healthy skin as it may be harmful • Wash hands thoroughly after use • Women must be advised of the importance of avoiding pregnancy during treatment • Give information about the Human Papilloma virus Women must be advised to immediately stop using podophyllotoxin if there is any risk of pregnancy and return to the clinic for further advice. <u>Follow Up:</u> • There is no follow-up required if the warts have resolved in five weeks. • Change in treatment may be indicated if there is less than 50% response after 5 weeks. Seek

	advice from an appropriate doctor/ independent nurse prescriber
Use in pregnancy and lactation	Not appropriate for PGD
Records	The nurse must ensure the following is documented in the clinical record: • Individuals name, address and date of birth • Attendance date and reason for attendance • Past and current medical history, including drug history • Family history • Any known allergy • Any advice given about the medication including side effects, how to take it and what to do if any concerns • Any referral arrangements • Any supply outside the product licence • The consent of the individual • If the individual is < 16 years of age document competency using Fraser guidelines • Record the name of the medication, number of packs supplied with batch number and expiry date according to local policy and record PGD number • Record any follow up arrangements • Include the signature and designation of the nurse who supplied the medication (follow local procedures for computer records) Additional records required for treatment of ano-genital warts: • Clear dated diagram or documentation of location, description and size of warts