This patient group direction (PGD) must only be used by registered health 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)

For the administration or supply of

Podophyllotoxin 0.15% cream

By registered health care professionals for

External ano-genital warts, non-keratinised (First line treatment)

Throughout the Manx Care and those contracted by the Manx Care where appropriate within practice

PGD NUMBER 63

1. Change history

Version number	Change details	Date
1	Original PGD ratified	June 2021
2	Addition of age wording, plus minor wording amendments	February 2022

2. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care PGD website FAQs

3. PGD development

Refer to the NICE PGD competency framework for people developing PGDs

Job Title & organisation	Name	Signature	Date
Author of the PGD			
Member of the PGD working group			

4. PGD authorisation

Refer to the NICE PGD competency framework for people authorising PGDs

Job Title	Name	Signature	Date
Medical Director			
Chief Pharmacist/ Pharmaceutical Adviser			
Senior Paramedic			
Director of Nursing			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)			

5. PGD adoption by the provider

Refer to the NICE PGD competency framework for people authorising PGDs

Job title and organisation	Signature	Date	Applicable or not applicable to area

6. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the NICE PGD competency framework for health professionals using PGDs

	Requirements of registered Healthcare professionals working under the PGD
Qualifications and professional registration	• Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy • Pharmacists must be practising in Manx Care authorised premises i.e. contracted pharmacy premises
Initial training	• Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria • Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD • Local training in the use of PGDs
Competency assessment	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGDs
Ongoing training and competency	The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years

7. Clinical Conditions

Clinical condition or situation to which this PGD applies	Individuals who present with external anogenital warts, non-keratinised for first line treatment
Inclusion criteria	• Individuals who present with external anogenital warts, non-keratinised • Aged 13 years and over. All individual under the age of 19 years - follow local young person's risk assessment or equivalent local process
Exclusion criteria	• 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 • Risk of pregnancy or breast feeding • Keratinised warts – see Imiquimod PGD • Females not currently on a reliable form of contraception • Known allergy or hypersensitivity to podophyllotoxin • Individual has already had a 4 week course of podophyllotoxin • Inflamed, ulcerated or broken skin • Warts on internal mucosal skin (vaginal or anal canal, urethral meatus, cervix) • Extra genital warts • Warts involving an area greater than $4cm^2$
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 • Avoid normal skin • Avoid open wounds • Keep away from face • Very irritant to eyes
Arrangements for referral for medical advice	Patient should be referred to a more experienced clinical practitioner for further assessment
Action to be taken if patient excluded	Patient should be referred to a more experienced clinical practitioner for further assessment
Action to be taken if patient declines treatment	• A verbal explanation should be given to the patient on: the need for the medication and any possible effects or potential risks which may occur as a result of refusing treatment • This information must be documented in the patients' health records • Any patient who declines care must have demonstrated capacity to do so • Where appropriate care should be escalated

8. Details of the medicine

Name, form and strength of medicine	Podophyllotoxin 0.15% cream
Legal category	Prescription Only Medicine (POM)
Indicate any off-label use (if relevant)	None
Route/method of administration	Topical
Dose and frequency	Apply cream (enough to cover each wart) TWICE daily for 3 consecutive days then take a four day break. Continue this regime for a maximum of 4 weeks or sooner if warts resolve
Quantity to be administered and/or supplied	Supply: 1 original pack (5g tube) Administered: 1 dose
Maximum or minimum treatment period	Maximum of 4 weeks
Storage	Room temperature
Adverse effects	• balanoposthitis • skin irritation such as tenderness, itching, erythema, stinging and superficial ulceration
Records to be kept	The administration of any medication given under a PGD must be recorded within the patient's medical records

9. Patient information

Verbal/Written information to be given to patient or carer	• Verbal information must be given to patients and or carers for all medication being administered under a PGD • Where medication is being supplied under a PGD, written patient information leaflet must also be supplied • A patient information leaflet is available on request
Follow-up advice to be given to patient or carer	If symptoms do not improve or worsen or you become unwell, seek medical advice immediately

10. Appendix A

References
1. British National Formulary (BNF) available online: https://bnf.nice.org.uk 2. Nursing and Midwifery "The code" available online: https://www.nmc.org.uk 3. Current Health Care Professions Council standards of practice 4. General Pharmaceutical Council standards 5. The General Optical Council 6. Electronic medicines compendium available online: https://www.medicines.org.uk 7. BASHH guidelines

11. Appendix B

Health professionals agreed to practice
• Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor • A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves