



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

### Imiquimod 5% Cream

By registered health care professionals for

### External Anogenital warts

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

## PGD NUMBER 33

### 1. Change history

Version number	Change details	Date
1	Original PGD ratified	June 2021

## 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
<b>Qualifications and professional registration</b>	<ul style="list-style-type: none"> <li>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</li> <li>Pharmacists must be practising in Manx Care authorised premises i.e. contracted pharmacy premises</li> </ul>
<b>Initial training</b>	<ul style="list-style-type: none"> <li>Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria</li> <li>Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD</li> <li>Local training in the use of PGDs</li> </ul>
<b>Competency assessment</b>	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGDs
<b>Ongoing training and competency</b>	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

<b>Clinical condition or situation to which this PGD applies</b>	Individuals who present with external anogenital warts, keratinized and non-keratinized
<b>Inclusion criteria</b>	Individuals who present with external anogenital warts, keratinized and non-keratinized
<b>Exclusion criteria</b>	<ul style="list-style-type: none"> <li>• Known or suspected pregnancy</li> <li>• Risk of pregnancy</li> <li>• Breastfeeding</li> <li>• Known allergy to any of the constituents found within the medication or hypersensitivity to Imiquimod.</li> <li>• Non-responsive to previous 16 week course of Imiquimod</li> <li>• Inflamed, ulcerated or broken skin</li> <li>• Warts on internal mucosal skin (vaginal or anal canal, urethral meatus, cervix)</li> <li>• Extra-genital warts</li> <li>• Warts involving an area greater than 4cm<sup>2</sup></li> <li>• Individuals with autoimmune conditions, on immunosuppressive treatment, or organ transplant recipients</li> </ul>
<b>Cautions (including any relevant action to be taken)</b>	<ul style="list-style-type: none"> <li>• Autoimmune disease</li> <li>• avoid broken skin</li> <li>• avoid contact with eyes, lips and nostrils</li> <li>• avoid open wounds</li> <li>• immunosuppressed patients</li> <li>• The summary of product characteristics (SPC) advises caution with the use of Imiquimod Cream in uncircumcised with foreskin associated warts due to reports of phimosis and stricture. BASHH however, states that Imiquimod use in uncircumcised men is safe</li> </ul>
<b>Arrangements for referral for medical advice</b>	Patient should be referred to a more experienced clinical practitioner for further assessment
<b>Action to be taken if patient excluded</b>	Patient should be referred to a more experienced clinical practitioner for further assessment
<b>Action to be taken if patient declines treatment</b>	<ul style="list-style-type: none"> <li>• 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</li> <li>• This information must be documented in the patients' health records</li> <li>• Any patient who declines care must have demonstrated capacity to do so</li> <li>• Where appropriate care should be escalated</li> </ul>

## 8. Details of the medicine

<b>Name, form and strength of medicine</b>	Imiquimod 5% cream
<b>Legal category</b>	Prescription Only Medicine (POM)
<b>Indicate any <u>off-label use</u> (if relevant)</b>	None
<b>Route/method of administration</b>	Topical
<b>Dose and frequency</b>	<ul style="list-style-type: none"> <li>Apply thinly at night, Three times a week ( example: Monday Wednesday and Friday or Tuesday, Thursday and Saturday) prior to normal sleeping hours</li> <li>The cream should remain on the skin for 6 to 10 hours</li> </ul>
<b>Quantity to be administered and/or supplied</b>	Up to 48 sachets (16 weeks supply)
<b>Maximum or minimum treatment period</b>	48 sachets (16 weeks treatment) One episode of care
<b>Storage</b>	Room temperature
<b>Adverse effects</b>	<ul style="list-style-type: none"> <li>Appetite decreased</li> <li>Arthralgia</li> <li>Asthenia</li> <li>Headache</li> <li>Increased risk of infection</li> <li>Lymphadenopathy</li> <li>Myalgia</li> <li>Nausea</li> <li>Pain</li> </ul>
<b>Records to be kept</b>	The administration of any medication given under a PGD must be recorded within the patient's medical records

## 9. Patient information

<b>Verbal/Written information to be given to patient or carer</b>	<ul style="list-style-type: none"> <li>Verbal information must be given to patients and or carers for all medication being administered under a PGD</li> <li>Where medication is being supplied under a PGD, written patient information leaflet must also be supplied</li> <li>A patient information leaflet is available on request</li> </ul>
<b>Follow-up advice to be given to patient or carer</b>	If symptoms do not improve or worsen or you become unwell, seek medical advice immediately

## 10. Appendix A

References
<ol style="list-style-type: none"><li>1. British National Formulary (BNF) available online: <a href="https://bnf.nice.org.uk">https://bnf.nice.org.uk</a></li><li>2. Nursing and Midwifery (2018) "The code" available online: <a href="https://www.nmc.org.uk">https://www.nmc.org.uk</a></li><li>3. Current Health Care Professions Council standards of practice</li><li>4. General Pharmaceutical Council standards</li><li>5. The General Optical Council</li><li>6. Electronic medicines compendium available online: <a href="https://www.medicines.org.uk">https://www.medicines.org.uk</a></li><li>7. <a href="https://www.bashh.org/guidelines">https://www.bashh.org/guidelines</a></li></ol>

## 11. Appendix B

Health professionals agreed to practice
<ul style="list-style-type: none"><li>• Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor</li><li>• 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</li></ul>