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

Patient Group Direction for the Supply of Imiquimod 5% w/w Cream for the Treatment of External Anogenital Warts by Nurses Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

Lead Author: Adapted from the SPS/FSRH National PGD Template by the Medicines Management Specialist Nurse NHSG	**Consultation Group:** See relevant page in the PGD	**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature: 		**Signature:** 
NoS Identifier: NoS/PGD/Imiquimod/ MGPG1170	**Review Date:** June 2023 **Expiry Date:** June 2024	**Date Approved:** June 2021

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 1

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	New PGD adapted from FRSH/SPS national PGD template.	
Date of change	**Summary of Changes**	**Section heading**
March 2021	New NoS PGD adapted from FRSH/SPS national template.	

NoS Identifier: NoS/PGD/Imiquimod/MGPG1170
Keyword(s): PGD Patient Group Direction imiquimod nurse genital anogenital warts

Policy Statement: It is the responsibility of the individual healthcare professionals and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

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.

Document:	Drafted:	March 2021
	Completed:	May 2021
	Approved:	June 2021 (published – August 2021)
	Amended:	

Organisational Authorisations

This PGD is not legally valid until it has had the relevant organisational authorisation.

PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr Ciara Cunningham **Health Board:** NHST **Title:** Consultant Genitourinary Medicine **Contact email:** ciara.cunningham@nhs.scot **Signature:** .....
Senior representative of the professional group who will provide care under the direction	**Name:** Julia Penn **Health Board:** NHSG **Title:** Sexual Health Nurse Manager **Contact email:** julia.penn@nhs.scot **Signature:** .....
Lead author	**Name:** Frances Adamson **Health Board:** NHSG **Title :** Medicines Management Specialist Nurse **Contact email:** frances.adamson@nhs.scot **Signature:** .....
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Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		August 2021

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox		August 2021

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

Name:	Title:
Frances Adamson	**Lead Author:** Medicines Management Specialist Nurse NHSG
Alison Jane Smith	**Pharmacist:** Medicines Management Pharmacist NHSG
Dr Ciara Cunningham	**Medical Practitioner:** Consultant Genitourinary Medicine NHST
Julia Penn	**Senior Representative:** Sexual Health Nurse Manager
Deborah Syme	Team Leader The Corner NHST
Sara Bereridge	Clinical Nurse Specialist Sexual Health NHST
Kimberley MacInnes	Service Manager / Lead Nurse Sexual Health NHSH
Russell Mackay	Principle Pharmacist NHSO
Liam Callaghan	Chief Pharmacist NHSWI

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Clinical indication to which this PGD applies

Definition of situation/ Condition	This Patient Group Direction (PGD) will authorise nurses to supply imiquimod 5% w/w cream to individuals aged 13 years and over for the self-treatment of external anogenital warts (Condyloma acuminate). **NOTE:** For alternate treatment of non-keratinised warts see Podophyllotoxin PGD. This PGD should be used in conjunction with individual Board protocols and the recommendations in the current British Association for Sexual Health and HIV (BASHH) relevant guidelines, recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), and the individual Summary of Product Characteristics (SmPC).
Inclusion criteria	Individuals aged 13 years and over who present with visible external keratinised and non-keratinised anogenital warts. Prior to the supply of the medicine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.
Exclusion criteria	• Individuals under 13 years of age* • Under 16 years of age and judged to be incapable of understanding the nature and possible consequences of procedures or treatment as per Age of Legal Capacity (Scotland) Act 1991. (Commonly referred to as Fraser Guideline) • Individuals 16 years of age and over and assessed as lacking capacity to consent. **Medical history** • Pregnancy • Breastfeeding • Non-keratinised warts where Imiquimod isn't felt to be the best choice of treatment (refer to Podophyllotoxin PGD/ consider other treatment options) • Practitioner cannot accurately determine that the lesions are genital warts • Individual has already not responded to a 16 week course of treatment with imiquimod for current warts • Inflamed, ulcerated or broken skin

	• Open wounds (i.e. following a surgical procedure) or bleeding wounds • Imiquimod is not recommended until the skin has healed after any previous drug or surgical treatment • Warts on internal mucosal skin (vaginal or anal canal) urethral meatus, cervix • Extra-genital warts • Individuals who are unable to apply imiquimod preparation safely • Have lesions with a surface area greater than 4cm^2 • Individuals with autoimmune conditions, on immunosuppressive treatment, or organ transplant recipients. **Medication History** • Any concurrent interacting medicine(s) – see Appendix 1 of the current BNF • Known hypersensitivity or allergy to imiquimod or any other constituent or excipient of the medicine - see SmPC • Where there is no valid consent. **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.
Precautions and special warnings	If the individual is less than 16 years of age an assessment based on Fraser Guideline must be made and documented. 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. BASHH recommends careful follow-up of these individuals – follow up in these individuals should be arranged with a specialist.
Action if excluded from treatment	Medical advice must be sought – refer to relevant medical practitioner. Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.

Action if treatment is declined	Inform/refer to the relevant medical practitioner if individual declines treatment. Document that the supply was declined, the reason and advice given in appropriate clinical records. Discuss alternative means of therapy e.g. cryotherapy or podophyllotoxin for non-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.

Description of treatment available under the PGD

Name form and strength of medicine	Imiquimod 5% w/w cream in 250mg single use sachets
Legal status	Imiquimod 5% w/w cream is a Prescription-only Medicine (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. This PGD includes off label use in the following conditions: Children and adolescents aged 13 years an over. Treatment of warts in children and adolescents follows the same principles as in adults, with the same range of treatment options, and is considered specifically in the BASHH guidelines on children and young people. However, use in this age group is outside the terms of the marketing authorisation and constitutes an off-label use. The individual should be informed prior to the supply that the use is off-label.
Dosage/Maximum total dose	Apply 3 times a week on non-consecutive days (example: Monday, Wednesday, and Friday; or Tuesday, Thursday and Saturday) prior to normal sleeping hours. The cream should remain on the skin for 6 to 10 hours.
Frequency of dose/Duration of treatment	Minimum period of treatment is 4 weeks with review to determine need to continue treatment. As per BASHH guidelines, non-responders by 12-16 weeks should be switched to an alternative treatment.

	Maximum period of treatment under this PGD is 4 weeks with further 4 week supplies only allowed following review. Advise to stop treatment once no visible lesions remain.
Maximum or minimum treatment period	Under this PGD the minimum period of treatment is 4 weeks and maximum period of treatment is 16 weeks (4 issues of 4 week treatments under PGD).
Route/Method of administration	Topical to external genitalia.
Quantity to be supplied	Initial supply a four week course (12 sachets). Maximum supply after review of sufficient sachets (in full original labelled boxes) to complete full 16 week course.
Storage requirements	Do not store above 25 °C. Sachets should not be re-used once opened.
Follow-up (if applicable)	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, advise the individual to contact the service for further advice.
Advice (Verbal)	**Medication:** • 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 carefully before and after application of cream. • Avoid contact with the eyes, lips and nostrils • Only apply to affected areas and avoid any application on internal surfaces. • Occlusive dressing should not be used on areas treated with imiquimod cream. • Imiquimod cream should be applied prior to normal sleeping hours. • Imiquimod cream should be applied in a thin layer and rubbed on the clean wart area until the cream vanishes. • Sachets should not be re-used once opened. • During the 6 to 10 hour treatment period, showering or bathing should be avoided. • After this period it is essential that imiquimod cream should be removed with mild soap and water. • Application of an excess of cream or prolonged contact with the skin may result in a severe application site reaction.

	• If significant local skin reaction occurs lengthen the period of rest days for a cycle by a further day. If the reaction doesn't settle stop treatment and contact clinic/healthcare provider. • Advise patient that imiquimod can prevent condoms and diaphragms from being fully effective • Advise patient that unprotected sexual contact should be avoided soon after application because of the possible irritant effect on the partner. **Condition:** • Individuals diagnosed with anogenital warts should be offered information (verbal, written and/or digital) about their diagnosis and management • There is no data on the use of imiquimod in pregnancy. If women become pregnant during treatment, they should stop using imiquimod and return to the clinic. • Advise regarding general hygiene and skin care during treatment. • Uncircumcised men with warts under the foreskin should pull the foreskin back each day and wash underneath it. If daily washing under the foreskin is not carried out, tightness of the foreskin may occur. Early signs of tightness include swelling, or difficulty in pulling back the foreskin. If these symptoms occur, advise to stop the treatment immediately and contact GP. • Response to treatment may be slow and median time to wart clearance was 8-12 weeks (SmPC). • Offer screening for other sexually transmitted infections (STIs) as appropriate. • Offer condoms and advice on safer sex practices and possible need for screening for STIs. Where treatment is not supplied via a sexual health clinic ensure the individual has contact details of local sexual health services.
Identifying and managing possible adverse reactions	The following side effects are very common/common with imiquimod: • Application site pain and pruritus • Application site burning and irritation • Fatigue • Myalgia • Nausea • Headache The excipients methyl hydroxybenzoate (E218) and propyl hydroxybenzoate (E216) may cause allergic reactions

	(possibly delayed). Cetylalcohol and stearylalcohol may cause local skin reactions (e.g. contact dermatitis). **This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.** **BNF/BNFC**: https://www.bnf.org/products/bnf-online/ **SmPC/PIL/Risk Minimisation Material:** https://www.medicines.org.uk/emc/ http://www.mhra.gov.uk/spc-pil/index.htm https://www.medicines.org.uk/emc/rmm-directory If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Report any severe reactions using the Yellow Card System. https://yellowcard.mhra.gov.uk/
Facilities and supplies required	The following are to be available at sites where the medicine is to be supplied: • Appropriate storage facilities • An acceptable level of privacy to respect individual's right to confidentiality and safety • Access to a working telephone • Access to medical support (this may be via the telephone) • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • Condoms • A copy of this current PGD in print or electronically.

Characteristics of staff authorised to supply medicine(s) under PGD

Professional qualifications	Registered nurses as recognised by the Nursing and Midwifery Council (NMC).
Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual's capacity to understand the nature and purpose of the medicine supply in order to give or refuse consent • Aware of current treatment recommendations and be competent to discuss issues about the medicine with the individual

	• Having undertaken appropriate training to carry out clinical assessment of individuals identifying that treatment is required according to the indications listed in the PGD. • Competent to undertake supply of the medicine • Competent to work under this PGD.
Ongoing training and competency	**All professionals working under this PGD must:** • Have undertaken PGD training as required/set out by each individual Health Board • Maintain their skills, knowledge and their own professional level of competence in this area according to their Code of Professional Conduct • Have knowledge and familiarity of the following; ○ SmPC for the medicine(s) to be supplied in accordance with this PGD.
Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above. Maintain up to date record of all staff authorised to supply the medicine(s) specified in this direction.

Documentation

Authorisation of supply	Nurses working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to supply/administer the medicine(s) specified in this PGD by their Professional Line Manager/Consultant/Practice GPs. All authorised staff are required to read the PGD and sign the Agreement to Supply 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.
Record of supply	An electronic or paper record for recording the screening of individuals and the subsequent supply, or not of the medicine(s) specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum:

	• Date and time of supply • Individuals name and DOB • Exclusion criteria, record why the medicine was not supplied (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, dose, form, route of the medicine supplied • Advice given, including advice given if excluded or declined treatment under this PGD • Signature and name in capital letters of the healthcare professional who supplied the medicine • Record of any adverse effects (advise individuals GP/relevant medical practitioner). 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 • Individual's GP records if appropriate • Individual service specific systems.
Audit	All records of the medicine(s) specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines supplied under a PGD.
References	Electronic Medicines Compendium http://www.medicines.org.uk Aldara 5% Cream – Date of revision of text January 2017, accessed 23/03/21. British National Formulary and British National Formulary for Children https://www.bnf.org/products/bnf-online/ accessed 23/03/21. 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

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

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:

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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 he or she is 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 he or she understands and is 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 his or her individual code of professional practice and conduct.
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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

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Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**