This Patient Group Direction (PGD) must only be used by registered healthcare 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)

Supply of imiquimod 5% w/w cream for the treatment of external anogenital warts in Integrated Sexual Health Services (ISHS) Derbyshire Community Health Services

Version Number 2.0

Change History	
Version and Date	**Change details**
Version 1 February 2021	New template
Version 2.0 July 2023	Reviewed template. No relevant changes to SPC. Updated PGD development group members. Some minor formatting and rewording to align with other sexual health PGDs.

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 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
Andrea Smith	Community pharmacy
Carmel Lloyd	Royal College of Midwives
Chetna Parmar	Pharmacist adviser, Umbrella
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	Chair General Training Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Dr John Saunders	Consultant in Sexual Health and HIV
Dr Kathy French	Pan London PGD working group
Dr Rita Browne	Consultant in Sexual Health and HIV
Dr Sarah Pillai	Associate Specialist
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
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)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Portia Jackson	Pharmacist, Cambridgeshire Community Services
Rosie Furner (Working Group Co-ordinator)	Governance Pharmacist, Medicines Use and Safety, Specialist Pharmacy Service
Vicky Garner	Consultant Midwife British Pregnancy Advisory Service (BPAS)
Sandra Wolper	Associate Director Specialist Pharmacy Service
Tracy Rogers	Director Specialist Pharmacy Service

ORGANISATIONAL AUTHORISATIONS

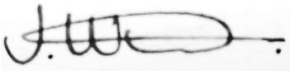
PATIENT GROUP DIRECTION DEVELOPMENT WORKING GROUP

This PGD has been agreed by doctors, and/or expert clinical practitioners, pharmacist and representative healthcare professionals from the trust stated below for use within Integrated Sexual Health Services (ISHS) University of Derby and Burton Teaching Hospitals Foundation Trust (UHDBFT) and Derbyshire Community Health Services Foundation Trust (DCHSFT)

PATIENT GROUP DIRECTION AUTHORISATION

PGD approved by PGD Working Group on *23rd November 2023*

This PGD is authorised for use on behalf of DCHS by the following signatories:

Position of signatory	Name	Signature	Date
Deputy Chief Nurse	Jo Wain		13/12/2023
Head of Medicines Management	Kate Needham		13/12/2023
Medical Director	Dr Ben Pearson		13/12/2023
Lead Clinician	Dr Ade Apoola		13/12/2023

REVIEWED FOR DCHS BY:		
Date	**Name**	**Position**
November 2023	Lisa Walton Dr Ade Apoola	ISHS Specialist Nurse Practitioner ISHS Lead Clinician

PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct. Individual practitioners must declare that they have read and understood the Patient Group Direction and agree to supply/administer medication(s) listed only in accordance with the PGD.

1. Characteristics of staff

Qualifications and professional registration	Current contract of employment within a Local Authority or NHS commissioned service or an NHS Trust/organisation. 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. Individual has undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - eLfH PGD elearning programme 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 advised in the RCN Sexual Health Education directory. The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults. For advice on additional local training requirements see section 4: Characteristics of DCHS ISHS Staff.
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix A) or complete an appropriate self-declaration of competence for relevant testing and/or treatment. • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions
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 age 13 and over who present with external anogenital warts, keratinised and non-keratinised. • Consent given. • Aged 13 years and over. All individuals under the age of 19 years - follow local young person's risk assessment or equivalent local process.
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** • Practitioner cannot accurately determine that the lesions are genital warts • Inflamed, ulcerated or broken skin • Warts on internal mucosal skin (vagina, anal canal, urethral meatus, cervix) • Extra-genital warts • Warts involving area more than 4cm^2 • Individuals with autoimmune conditions, on immunosuppressive treatment, or organ transplant recipients • Individuals who are unable to apply the preparation safely • Imiquimod cream therapy is not recommended until the skin has healed after any previous drug or surgical treatment. • Non-response to a previous 16 week course of imiquimod • Pregnancy • Breastfeeding **Medication history** • Any concurrent interacting medicine(s) – see Section 3 Drug interactions. • Known hypersensitivity or allergy to imiquimod or any other constituent or excipient of the medicine - see Summary of Product Characteristics
Cautions including any relevant action to be taken	• The Summary of Product Characteristics (SPC) advises caution with use of imiquimod cream in uncircumcised men with foreskin associated warts due to reports of phimosis and stricture. • 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.

	• 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). **Safeguarding:** Where there are any safeguarding concerns refer to local policies for safeguarding adults and children and/or seek advice from the safeguarding lead/team in the organisation. Document the concern and outcome in the healthcare record. DCHS: Safeguarding adults and children policies on DCHS SharePoint. DCHS Safeguarding Team: 01773 850000. East Midland's Children and Young People's Sexual Assault Service (EMCYPSAS): 0800 183 0023 (24-hour service). • 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	• If declined ensure individual is aware of the need for treatment and the potential consequences of not receiving 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, 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	Imiquimod 5% w/w cream in 250mg single use sachets
Legal category	POM
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: • Children and adolescents aged 13 years an over. The 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. 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 administration 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 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.
Duration of treatment	• Minimum period of treatment is 4 weeks with review to determine need to continue treatment. • As per BASHH guidelines, review at designated time interval. If response is inadequate, switch to an alternative treatment. • Maximum period of treatment under this PGD is 16 weeks. • Advise to stop treatment once no visible lesions remain.
Quantity to be supplied	• Initial supply of a four week course (12 sachets). • Following review, a maximum supply of sufficient sachets (in full original labelled boxes) to complete full 16 week course.
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
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 www.bnf.org or the product SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
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 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).
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 DCHS Incident Reporting Policy.
Written information and further advice to be given to individual	**Medication:** • 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 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 is 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. • Imiquimod has the potential to exacerbate inflammatory conditions of the skin. • Advise individual that imiquimod can prevent condoms and diaphragms from being fully effective • Advise individual 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 and wearing away of the skin, 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 (SPC). 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.
Follow up treatment	• The individual should be advised to seek medical advice in the event of an adverse reaction.

Records	**Record:**
	• The consent of the individual and
	  ○ If individual is under 13 years of age record action taken
	  ○ If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken.
	  ○ 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
	• Batch number and expiry date of product in line with local procedure
	• 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.

4. Characteristics of DCHS ISHS Staff

Qualifications	A registered nurse working within ISHS who is deemed competent by their clinical line manager and authorised by their professional lead to undertake the clinical assessment of a patients leading to the identification of those suitable for management under this PGD.
Additional Local Training	Has undertaken the local training programme on the process, responsibilities and scope of PGDs. Has undertaken local training based on the use of this PGD. Has undertaken training in recognition of and treatment of anaphylaxis including basic life support in the 12 months. Has undertaken Safeguarding Children Level 3 training in the last 12 months. Has undertaken Safeguarding Adults Level 2 training in the last 3 years.
Continuing Training & Education	Evidence of Continuing Professional Development (CPD) in ISHS nurse role. The nurse should be aware of any change to the recommendations for the medicines listed. It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of individual scope of practice.

5. Key references

Key references (accessed April 2023)	• 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 2015 https://www.bashhguidelines.org/media/1075/uk-national-guideline-on-warts-2015-final.pdf

	• 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 A - Registered health professional authorisation sheet

PGD Name/Version: PGD 208(S) Imiquimod Cream for External Anogenital Warts National Template v2.0

Valid from: 1 February 2024 **Expiry:** 31 January 2027

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

Registered health professional
By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Derbyshire Community Health Services for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager
Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

PGD Authorisation Forms shall be maintained and retained by the Service Manager who is responsible for the safe storage of the records.