Patient Group Direction

For the supply of

Scheriproct® ointment/suppositories

By registered community pharmacists providing the

NHS Wales Clinical Community Pharmacy Service for the

relief of symptoms associated with haemorrhoids

in Powys Teaching Health Board]

Operational from: 1st July 2023

Review Date: 31st March 2026

Version number: 1.0

PGD for the supply of Scheriproct® ointment/suppositories for the relief of symptoms associated with haemorrhoids by pharmacists delivering the Common Ailment Service component of the Clinical Community Pharmacy Service

Reference:	Scheriproct® ointment/suppositories PGD
Version no:	1.0
Valid from:	1st July 2023
Review date:	31st March 2026
Expiry date:	30th June 2026

Welsh Medicines Advice Service has developed this PGD for local authorisation

Those using this PGD must ensure that it is authorised by the Local Health Board in which they are operating and signed in section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with the Human Medicines Regulations 2012 (HMR2012)[1]. **THE PGD IS NOT LEGAL OR VALID WITHOUT SIGNED AUTHORISATION IN ACCORDANCE WITH HMR2012 SCHEDULE 16 Part 2.**

Authorising organisations must not *alter, amend* or *add* to the *clinical* content of this document. Such action will invalidate the *clinical sign-off* with which it is provided.

As operation of this PGD is the responsibility of service providers, the authorising organisation can decide which staff groups, in keeping with relevant legislation, can work to the PGD.

INDIVIDUAL PRACTITIONERS MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date.

Any queries regarding the clinical content of this PGD should be addressed to: welshmedicines.information@wales.nhs.uk

Change history:

Version number	Change details	Date
1.0	Original PGD template developed	9th February 2023

[1] this includes any relevant amendments to legislation (e.g. 2013 No.235, 2015 No.178 and 2015 No.323).

1. PGD development

This PGD has been developed and peer reviewed by an expert panel and approved by the Community Pharmacy Clinical Advisory Group in accordance with the PGD Policy.

This section MUST REMAIN when a PGD is adopted by an organisation

Expert panel

Name	Position	Designation
Alya Al-Affan	Main author	Formulary and PGD Lead for the Common Ailments Service, Welsh Medicines Advice Service, Cardiff and Vale UHB
Amy David	CPCAG reviewer	Primary Care Pharmacist, Swansea Bay UHB
Richard Evans	CPCAG reviewer	Community Pharmacy Advisor, Aneurin Bevan UHB
Dr Sarah Medlicott	Medical Reviewer	Senior GP Partner on Medicines Management and Expenditure Committee, Cwm Taf Morgannwg UHB

Date CPCAG approval of PGD: 21st June 2023

2. Organisational authorisations

The PGD is not legally valid until it has had the authorisation of the Local Health Board in which the community pharmacy using it operates.

It is the responsibility of the Local Health Board, to ensure that all legal and governance requirements are met. The Local Health Board accepts governance responsibility for the appropriate use of the PGD.

Powys Teaching Health Board authorises this PGD for use by community pharmacies within its area that have been commissioned to provide the Common Ailments Service component of the Clinical Community Pharmacy Service. This authorisation is limited to those pharmacists that meet the requirements set out within the PGD.

Local Health Board approval (legal requirement) as per health board policy			
Role	**Name**	**Sign**	**Date**
Lead Doctor for PTHB	Dr Kate Wright	DocuSigned by: Kate Wright 1F267952823F473...	9/18/2023
Chief Pharmacist for PTHB	Jacqui Seaton	DocuSigned by: Jacqui Seaton 71E8089DE3634C4...	9/18/2023
Clinical Governance Lead for PTHB	Amanda Edwards	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	9/19/2023
Senior Pharmacist Lead for Community Pharmacies PTHB	Emlyn Pritchard	DocuSigned by: Emlyn Pritchard EB776BA7283F49B...	25/08/2023

Local enquiries regarding the use of this PGD may be directed to welshmedicines.information@wales.nhs.uk

Appendix B provides a practitioner listing sheet. Individual practitioners must be listed by name to work to this PGD. Alternative practitioner listing sheets may be used where appropriate in

accordance with local policy, but this should be an individual agreement or a multiple practitioner listing sheet as included at the end of this PGD.

3. Characteristics of Staff

Qualifications and professional registration	This PGD is for use by pharmacists currently registered with the General Pharmaceutical Council (GPhC).
Additional requirements	Pharmacists must: ➢ be employed by, or providing services on behalf of a pharmacy listed in the All Wales Pharmacy Database (AWPD) for the Clinical Community Pharmacy Service. ➢ be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it by completing Appendix B. ➢ be familiar with the medicine and alert to changes in the Summary of Product Characteristics (SmPC). ➢ have access to the Patient Group Direction and associated resources (including the service specification and the clinical guidance document supporting the PGD) and must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs). ➢ be named in the All Wales Pharmacy Database for the Common Ailment component of the Clinical Community Pharmacy Service. ➢ have met the training requirements for the service as set out by HEIW (Health Education and Improvement Wales. ➢ be familiar with the British National Formulary (BNF) and SmPC entries for Scheriproct® ointment/suppositories. ➢ have awareness of the adverse drug reactions associated with Scheriproct® ointment/suppositories. **The pharmacist must be listed by name, under the current version of this PGD that has been issued by the local health board in which area they are operating before working under its authority.**

Ongoing training and competency	Pharmacists must: ➢ undertake regular CPD and maintain own level of competence and knowledge in this clinical area to provide the service. ➢ be aware of any updates made to the products in the SmPC and BNF. ➢ be aware of any updates to relevant national and local guidelines. ➢ as registered professionals, be professionally accountable and must work within their competence. A record of any training and competency assessments undertaken must be maintained.

4. Clinical condition

Clinical condition or situation to which this PGD applies	For the relief of symptoms associated with haemorrhoids in accordance with the community pharmacy Common Ailment Service (CAS) component of the Clinical Community Pharmacy Service (CCPS).
Criteria for inclusion	Scheriproct® ointment/suppositories can be supplied to individuals aged 18 years of age and over presenting with symptoms of pain, irritation and inflammation in haemorrhoids and: ➢ they have no contraindications to Scheriproct® ointment/suppositories – see SmPC ➢ where informed consent has been given (patient, parent/guardian, carer)

Criteria for exclusion[2] (continued over page)	Scheriproct® ointment/suppositories should not be supplied if the pharmacist is unsure of the diagnosis and/or: ➢ if symptoms are associated with a change in bowel habit. ➢ if symptoms include: ○ moderate-severe abdominal pain ○ night-time diarrhoea for several nights ○ unexplained appetite and/or weight loss ○ rectal bleeding or occult bleeding in faeces ○ painful perianal lump/lesion ○ severe pain in the affected area (may be a thrombosed haemorrhoid) ➢ a suspected sexually transmitted infection (STI) ➢ suspected infection (e.g. fever, pus leaking from haemorrhoid) or sepsis: **would require urgent referral** ➢ a second or subsequent episode whereby a diagnosis of haemorrhoids from a GP has not been confirmed (treatment can be provided on first presentation but patients should then be referred to their GP for a confirmed diagnosis) ➢ severe or recurrent symptoms that fall outside the maximum number of treatment episodes in 12 months ➢ non-response to treatment or worsening symptoms, despite using the cream/ointment for 7 days

[2] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required.

Criteria for exclusion (continued)	➢ co-treatment with CYP3A inhibitors (e.g. ritonavir), including cobicistat containing products may increase the risk of systemic side effects therefore the combination should be avoided ➢ pregnant individuals ➢ breastfeeding individuals ➢ to individuals with known hypersensitivity to Scheriproct® ointment/suppositories or any of the excipients – see SmPC ➢ if the pharmacist is unable to undertake an appropriate assessment, in order to determine the need for the medicine and that it would be appropriate for the patient to use it ➢ to individuals who are unable to administer or use the product effectively themselves or who do not have a parent/guardian/carer to administer or apply the medication for them ➢ if individual does not agree to share relevant clinical information

Cautions (including relevant actions to be taken)	Please refer to the SmPC for Scheriproct® ointment/suppositories for full details of special warnings and precautions for use. ➢ Visual disturbance may be reported with systemic and topical corticosteroid use. If an individual presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an optician/ophthalmologist for evaluation of possible causes. These may include: ○ cataract ○ glaucoma ○ rare diseases such as central serous chorioretinopathy (CSCR) ➢ Systemic absorption may occur following the application of topical steroids. Prolonged or excessive use may enhance these effects so use is limited to a maximum of 7 days. ➢ Concurrent use with other corticosteroid preparations, either topically or orally may increase the likelihood of systemic effects. This should be borne in mind if consideration is given to offering Scheriproct® ointment or suppositories. **Scheriproct® ointment** ➢ The excipients (castor oil refined, castor oil hydrogenated,
(continued over page)	

Cautions (including relevant actions to be taken) (continued)	macrogol-400-monoricinoleate and perfume oil chypre) in the ointment may reduce the effectiveness of latex products such as condoms. As a result, an additional contraceptive technique should be utilised whilst using the ointment. ➢ Contains castor oil, castor oil hydrogenated and macrogol 400 monoricinoleate which may cause skin reactions. ➢ Contains fragrance (perfume oil, chypre) with allergens that may cause allergic reactions. **Scheriproct® suppositories** ➢ The excipients (hard fat) in the suppositories may reduce the effectiveness of latex products such as condoms. As a result, an additional contraceptive technique should be utilised whilst using the suppositories. See also drug interactions section below for additional cautions.
Action to be taken if the individual is excluded or declines treatment	➢ Explain the reasons for exclusion to the individual and document in the consultation record. ➢ If the individual declines, record the reason and advise of the consequences of not receiving treatment. Document the advice given alongside details of any referral made and their (patient, parent, guardian) intended actions. ➢ If appropriate, patients may be offered a suitable alternative to Scheriproct® ointment/suppositories from the All Wales Common Ailments Service Formulary. Alternatively, refer the individual to their GP if appropriate and/or provide them with information about further options. ➢ Where there are safeguarding concerns, seek advice from local safeguarding services.
Further advice	➢ Further information can be found in the SmPC, BNF and the All Wales Common Ailments Service Formulary.

5. Description of treatment

Name, strength & formulation of drug	**Scheriproct® ointment** In 1 gram: prednisolone hexanoate 1.9 mg, cinchocaine hydrochloride 5 mg Excipients with known effect: 442.9 mg refined castor oil, 75 mg hydrogenated castor oil, 75 mg macrogol 400 monricinoleate and 0.2 mg perfume oil, chypre **Scheriproct® suppositories** Each suppository contains: prednisolone hexanoate 1.3 mg, cinchocaine hydrochloride 1 mg
Legal category	Prescription Only Medicine (POM)
Black triangle▼	No
Off-label use	No
Route / method of administration	Anal application (ointment). Anal insertion (suppositories).

Dose and frequency of administration	**For individuals aged 18 years of age and over:** Scheriproct® ointment Around the anus: Spread a pea-size amount gently over the skin around and just inside the anus TWICE a day for a MAXIMUM of SEVEN days. Inside the anus: Fill the applicator with ointment and insert one applicator full TWICE a day for a MAXIMUM of SEVEN days. N.B. The ointment may be applied three or four times on the first day to obtain quick relief. Scheriproct® suppositories Insert the whole suppository into the anus ONCE a day, preferably after a bowel movement for a MAXIMUM of SEVEN days. N.B. If discomfort is severe, one suppository can be inserted two or three times a day at the start of treatment to obtain quick relief.
Duration of treatment	This PGD only allows for the duration stated in the dosage schedule above.

Quantity to be supplied/administered	Appropriately labelled pack to provide treatment for a maximum of SEVEN days. Scheriproct® ointment 1 x 30 g pack to provide 7 days treatment at a dose of TWICE daily application (can be used up to four times daily at start of treatment if needed). Scheriproct® suppositories 1 x 12 suppository pack to provide a maximum of 7 days treatment at a dose of ONCE daily insertions (can be used up to three times a day at start of treatment if needed).

Drug interactions	The SmPC for both Scheriproct® ointment and Scheriproct® suppositories highlights: **Contraindication** (under remit of PGD) Co-treatment with CYP3A inhibitors (e.g. ritonavir), including cobicistat containing products, is expected to increase the risk of systemic effects. Under the remit of this PGD, the combination should be avoided. **Cautions** Concurrent use with other corticosteroid preparations, either topically or orally may increase the likelihood of systemic effects. ➢ There are no interactions currently listed in the BNF. Prior to offering treatment to an individual, the SmPC and the BNF should be referred to in order to check there are no changes regarding the interaction status of the products.
Identification & management of adverse reactions (continued over page)	A detailed list of adverse reactions is available in the SmPC, and the BNF. This list does not reflect all reported side effects. If the patient experiences any of the following they must discontinue treatment: ➢ difficulty breathing or swallowing ➢ swelling of the mouth, face, lips, tongue or throat (severe allergic reaction symptoms) ➢ severe itching of the skin, with a rash or raised lumps, hives or blisters

Identification & management of adverse reactions (continued)	The following side effects have been reported as: Not known (cannot be estimated from the available data) ➢ Blurred vision

Patient or carer advice/follow up	Supply the marketing authorisation holder's patient information leaflet (PIL). **Directions for use of Scheriproct® ointment/suppositories** Scheriproct® ointment 1) Gently but thoroughly wash the anal area before use of ointment and dry gently with a soft towel. 2) Wash and dry hands before use. If the ointment is to be used **around** the anus: ○ squeeze a pea-sized amount on to the top of your finger and gently spread it over the skin around and just inside the anus; do not rub it in. If the ointment is to be used **inside** the anus: ○ screw the separate applicator completely onto the tube; do not use the applicator if it is damaged. ○ squeeze the tube until the applicator is full of ointment; the amount of ointment in the applicator is one dose. ○ insert the applicator very carefully into the anus until the whole length of the applicator is inside; while squeezing the tube gently, carefully withdraw the applicator. 3) After each use, clean the applicator externally with a paper towel, then remove the remaining product in the applicator with a cotton swab and clean it again with a paper towel. Rinse the applicator under warm water for about 1 minute and dry the applicator externally with a paper towel. 4) Wash and dry hands after use. Scheriproct® suppositories 1) Gently but thoroughly wash the anal area and dry gently with a soft towel. 2) Wash and dry hands.
(continued over page)	

Patient or carer advice/follow up (continued) (continued over page)	3) Remove the foil covering from the suppository before use (finding the small tear in the foil packet will aid opening). 4) Insert one suppository into the anus far enough so that it doesn't slip out. ○ If the suppository has softened prior to insertion (due to warm temperature) they can be hardened by putting them into cold water while still in the foil covering. ○ To make insertion easier, either stand with one foot raised on a chair or squat down. 5) Wash and dry hands after use. **Treatment advice** ➢ Treatments only provide symptomatic relief and do not cure haemorrhoids. ➢ Advice from the GP should be sought if this is the first presentation, if symptoms are not relieved following one week of treatment or if there is any concern regarding symptoms including: ○ tummy pain that doesn't go away quickly. ○ diarrhoea (watery poo) at night for several nights. ○ unexplained weight loss. ○ bleeding or severe pain from the anus. ○ lasting change in toilet habit. ○ painful lump or other change around the anus. ○ recurrent piles. ➢ Seek advice from your GP or call 111 urgently if: ○ you have piles and your temperature is very high, or you feel hot and shivery and generally unwell. ○ you have pus leaking from your piles. ○ worsening symptoms. ➢ If there is extreme pain, a lot of blood, or bleeding that does not stop go to A&E or call 999.

Patient or carer advice/follow up (continued)	**Lifestyle advice** Keep stools soft, and don't strain on the toilet. The following may help: ○ eat plenty of fibre (e.g. fruit and vegetables, cereals, and wholegrain bread); increasing dietary intake should be done gradually to minimise flatulence and bloating. ○ try to maintain a healthy weight; losing weight is recommended if indicated (e.g. BMI > 25 kg/m^2). ○ drink plenty of fluids, ideally water; avoid too much alcohol, caffeine and sugary drinks. ○ avoid painkillers that contain codeine as it can cause constipation; avoid non-steroidal anti-inflammatory drugs (NSAIDS), if there is rectal bleeding (in which case you would need to make an appointment to discuss with your GP). ○ exercise regularly as per recommended guidelines. ○ do not delay going to the toilet. ➢ Ensure good perianal hygiene (may wish to use damp wipes rather than dry paper; pat dry rather than rub around bottom). ➢ A warm bath or applying an ice pack wrapped in a towel to the area may help ease discomfort. ➢ External haemorrhoids may be gently pushed back inside. **Signposting** Inform the individual or carer for both preparations: ➢ if they get any side effects, to talk to their doctor, or pharmacist or nurse and report any suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) by using the Yellow Card reporting scheme. This includes any possible side effects not listed in the PIL. ➢ to seek medical advice if their condition deteriorates and/or they become systemically unwell. ➢ to read the PIL before taking the medication. ➢ to visit the NHS website on haemorrhoids for more information.

Records	The consultation details including any medication supplied under this PGD must be recorded in Choose Pharmacy at the time of the consultation. Where the Choose Pharmacy platform is not available, temporary records must be made using the paper-based consultation record. Paper based records must be transferred into Choose Pharmacy as soon as practically possible following the consultation. If the patient is excluded, a record of the reason for exclusion and any specific advice that has been given must be documented within the consultation notes.

Appendices

Appendix A: *Key references*

- British National Formulary (BNF) – current edition. Available from: https://bnf.nice.org.uk/ [accessed 20 March 2023]
- Summary Product Characteristics (SmPC). Available from: https://www.medicines.org.uk/emc/ [accessed 20 March 2023]
- Patient Group Directions. Medicines practice guideline [MPG2]. Updated March 2017. Available from: http://www.nice.org.uk/guidance/mpg2/resources [accessed 20 March 2023]
- General Pharmaceutical Council. In Practice: Guidance on Consent. Revised June 2018. Available from: https://www.pharmacyregulation.org [accessed 20 March 2023]
- General Pharmaceutical Council. In Practice: Guidance on Confidentiality. Revised June 2018. Available from: https://www.pharmacyregulation.org [accessed 20 March 2023]
- All Wales Medicines Strategy Group. All Wales Common Ailments Formulary. February 2018. Available from: https://awttc.nhs.wales [accessed 20 March 2023]
- National Institute for Health and Care Excellence: Clinical Knowledge Summaries: Hameorrhoids. Last revised July 2021. Available from: https://cks.nice.org.uk [accessed 02 May 2023]
- Yellow Card Reporting. Available from: http://yellowcard.mhra.gov.uk [accessed 20 March 2023]
- NHS 111 Wales Health A-Z. Available from: https://111.wales.nhs.uk [accessed 20 March 2023]
- NHS Medicines A-Z. Available from: https://www.nhs.uk [accessed 20 March 2023]

Appendix B: *Healthcare Professionals Agreement to Practice*

Authorisation for the use of the Patient Group Direction for the supply of: Scheriproct® ointment/suppositories by community pharmacists under the Clinical Community Pharmacy Service, Common Ailment Service (haemorrhoids) commissioned by Powys Teaching Health Board]

Patient Group Directions do not remove inherent professional obligations or accountability.

Once completed and approved, health professionals wishing to use the PGD must sign up to the PGD for the local health board in which they will be providing services. Only pharmacists who are accredited in line with the National Service Specification can operate under the PGD.

This Patient Group Direction is to be read, agreed and signed by all registered healthcare professionals authorised to operate the PGD. By signing this document, the professional operating the PGD confirms that they have read and understood the content of this PGD and are willing and competent to work under it within their professional code of conduct. One copy should be given to each named pharmacist and a signed copy must be kept within the pharmacy by the nominated member of staff with responsibility for PGDs. This will usually be the Superintendent Pharmacist or Responsible Pharmacist.

Name and address of pharmacy:

For registered professional

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work under it within my professional code of conduct.

Name of registered pharmacist	Signature	GPhC number	Date
