

Patient Group Direction

For the supply of

Benzoyl peroxide 5% gel

By community pharmacists providing the

NHS Wales Clinical Community Pharmacy Service for

the treatment of **acne vulgaris**

in **Powys Teaching Health Board**

Operational from: 1st July 2023

Review Date: 31st March 2026

Version number: 1.0

*PGD for the supply of benzoyl peroxide 5% gel for acne vulgaris as part of the
Community Pharmacy Common Ailment Service
Valid from: 01st July 2023 Expiry Date: 30th July 2026*

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Valid from 01/07/2023
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PGD for the supply of benzoyl peroxide 5% gel for the treatment of acne vulgaris by pharmacists delivering the Common Ailment Service component of the Clinical Community Pharmacy Service

Reference: Benzoyl peroxide 5% gel 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	13 th January 2023

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

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1. PGD development

This PGD has been developed and peer reviewed by an expert panel and approved by the Community Pharmacy Clinical Advisory Group (CPCAG) 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. Ceri Todd	Medical Reviewer	Group Medical Director, Primary Care, Therapies Service, Swansea Bay UHB

Date CPCAG approval of PGD: 1st June 2023

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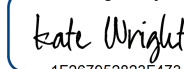
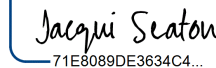


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2. Organisational authorisations

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:  1F267952823F473...	8/22/2023
Chief Pharmacist for PTHB	Jacqui Seaton	DocuSigned by:  71E8089DE3634C4...	8/24/2023
Clinical Governance Lead for PTHB	Amanda Edwards	DocuSigned by:  74A4E51A42E9473...	8/29/2023
Senior Pharmacist Lead for Community Pharmacies, PTHB	Emlyn Pritchard	DocuSigned by:  EB776BA7283F49B...	8/24/2023

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.

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3. Characteristics of Staff

Qualifications and professional registration	<p>This PGD is for use by pharmacists currently registered with the General Pharmaceutical Council (GPhC).</p>
Additional requirements	<p>Pharmacists must:</p> <ul style="list-style-type: none"> ➤ 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 benzoyl peroxide 5% gel. ➤ have awareness of the adverse drug reactions associated with benzoyl peroxide 5% gel. <p>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.</p>
Ongoing training and competency	<p>Pharmacists must:</p> <ul style="list-style-type: none"> ➤ 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

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	<ul style="list-style-type: none"> ➤ as registered professionals, be professionally accountable and must work within their competence <p>A record of training and competence must be maintained in the individual's personal file.</p>
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4. Clinical condition

Clinical condition or situation to which this PGD applies	For the treatment of acne vulgaris in accordance with the community pharmacy Common Ailments Service (CAS) component of the Clinical Community Pharmacy Service (CCPS).
Criteria for inclusion	<p>Benzoyl peroxide 5% gel can be supplied to:</p> <p>Individuals aged 12 years and over, presenting with symptoms of mild to moderate acne where:</p> <ul style="list-style-type: none"> ➤ other options in the pathway, prescribed or non-prescribed, are unsuitable or ineffective ➤ an individual is pregnant or breastfeeding ➤ the individual has no contraindications to benzoyl peroxide 5% gel – see SmPC ➤ informed consent has been given (patient, parent/guardian, carer)
Criteria for exclusion²	<p>Benzoyl peroxide 5% gel should not be supplied:</p> <ul style="list-style-type: none"> ➤ if the pharmacist is unsure of the diagnosis ➤ to individuals with severe, extensive or persistent symptoms ➤ to individuals with signs of an untreated bacterial, viral or fungal infection of the skin (if infected lesions are present) ➤ to individuals with mild to moderate acne where one first line treatment has been trialled and is ineffective ➤ to individuals with moderate to severe acne with a large number of inflammatory lesions (especially if there are nodules or cysts present) ➤ to individuals already receiving acne treatment from a healthcare provider, particularly if the medication is tretinoin,

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.

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(continued over page)	<p>isotretinoin or tazarotene; concomitant application of these with benzoyl peroxide may reduce their efficacy and increase irritation</p> <ul style="list-style-type: none"> ➤ to individuals presenting with fever, arthralgia or who appear systemically unwell (urgent same day referral) ➤ to individuals where oral therapies have previously been used for acne ➤ to individuals where other medication the individual is taking may be contributing to acne
Criteria for exclusion (continued)	<ul style="list-style-type: none"> ➤ when acne of any severity is causing or contributing to psychological distress ➤ to individuals with known hypersensitivity to benzoyl peroxide 5% gel 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)	<p>Please refer to the SmPC for benzoyl peroxide 5% gel for full details of special warnings and precautions for use.</p> <ul style="list-style-type: none"> ➤ For external use only. ➤ Exercise caution when applying the drug to the neck and other sensitive areas. ➤ The gel may cause swelling or blistering of the skin. Discontinue use immediately if this occurs. ➤ The gel may bleach hair or coloured fabrics so contact with hair, fabrics, furniture and carpeting should be avoided. ➤ As benzoyl peroxide can cause increased sensitivity to light, sunlamps should not be used and deliberate/prolonged exposure to sun should be avoided or minimised.

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	<ul style="list-style-type: none"> ➤ Should only be used in pregnant or breastfeeding individuals if clearly indicated. ➤ If the gel has been recommended to a breast-feeding individual, it must not be applied to the chest in order to avoid accidental transfer to the infant. ➤ Ingredients within benzoyl peroxide gel e.g. propylene glycol (E1520) may cause skin irritation. Refer to the SmPC of the product to highlight excipients that may be irritant. <p>See also drug interactions section below for additional cautions.</p>
Action to be taken if the individual is excluded or declines treatment (continued over page)	<ul style="list-style-type: none"> ➤ 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
Action to be taken if the individual is excluded or declines treatment (continued)	<p>given alongside details of any referral made and their (patient, parent, guardian) intended actions.</p> <ul style="list-style-type: none"> ➤ If appropriate, patients may be offered a suitable alternative to benzoyl peroxide 5% gel 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	<ul style="list-style-type: none"> ➤ Further information can be found in the SmPC, BNF and the All Wales Common Ailments Service Formulary

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5. Description of treatment

Name, strength & formulation of drug	Benzoyl Peroxide 5% gel
Legal category	Pharmacy only (P)
Black triangle ▼	No
Off-label use	Yes (PIL suggests only using if the individual's doctor has said it's ok) Where a drug 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 license.
Route / method of administration	Topical. For external cutaneous use only.
Dose and frequency of administration	For individuals aged 12 years and over: Apply thinly ONCE daily, to the entire affected area before bed. If tolerated, application frequency can be increased to TWICE daily (morning and evening). N.B. Frequency should be reduced if there is irritation, i.e. back to once daily or once every two days until the skin adjusts to the product.
Duration of treatment	Up to 12 weeks' treatment. This PGD only allows for the duration stated in the dosage schedule above.
Quantity to be supplied/administered	Appropriately labelled pack(s) to provide treatment for 12 weeks: up to 4 x 30 g packs OR up to 2 x 60 g packs to provide 12 weeks' treatment at the dose and duration of dosing schedule. N.B. Only one tube at a time should be opened, as once seal is broken the shelf life is 2 months.
Drug interactions	<ul style="list-style-type: none"> ➤ The SmPC for benzoyl peroxide 5% gel states no interaction studies have been performed. However, medicines with desquamative, irritant and drying effects should not be used concurrently with benzoyl peroxide gel. ➤ There are no interactions listed in the BNF.

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	Both the BNF and the SmPC should be checked prior to supply of the medication to ensure there are no changes to the interaction section.
Identification & management of adverse reactions	<p>A detailed list of adverse reactions is available in the SmPC, and the BNF. This list does not reflect all reported side effects.</p> <p>If the patient experiences any of the following they must discontinue treatment:</p> <ul style="list-style-type: none"> ➤ 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. <p>The following side effects have been reported as:</p> <p><u>Very common to common</u> (affecting between 1 in 10 and 1 in 100 patients)</p> <ul style="list-style-type: none"> ➤ Dryness, erythema, peeling, burning sensation, pruritus, skin pain and stinging, skin irritation (irritant contact dermatitis) <p><u>Uncommon</u> (affecting between 1 in 100 and 1 in 1000 patients)</p> <ul style="list-style-type: none"> ➤ Allergic contact dermatitis <p><u>Not known</u> (cannot be estimated from the available data)</p> <ul style="list-style-type: none"> ➤ Swelling face and allergic reactions, including application site hypersensitivity and anaphylaxis <p>N.B. Detailed lists of adverse reactions are available in the SmPC, and the BNF. Prior to issuing medication, please refer to these resources to check that there has been no change to the potential adverse reactions listed above.</p>
Patient or carer advice/follow up	<p>Supply the marketing authorisation holder's patient information leaflet (PIL).</p> <p>Medication</p> <ul style="list-style-type: none"> ➤ Treatment takes time to work (typically about 4 weeks)

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(continued over page)	<ul style="list-style-type: none"> ➤ Apply the product sparingly after washing the skin with a mild cleanser then gently pat the skin dry. ➤ Avoid contact with the eyes, mouth, angles of the nose or mucous membranes, and areas of irritated/broken skin due to the risk of sensitisation. If the preparation enters the eye, wash thoroughly with water.
Patient or carer advice/follow up (continued)	<ul style="list-style-type: none"> ➤ Treatment may cause increased sensitivity to sunlight. Avoid too much sun and UV light, and wear sunscreen. ➤ A mild burning sensation on first application and some reddening and peeling of the skin within a few days is expected. <ul style="list-style-type: none"> ○ A sudden increase in peeling in the first few weeks is not harmful and occurs in most patients. Discontinuing treatment for 1-2 days should relieve symptoms. ○ If severe irritation occurs, individuals should be directed to use the medication less frequently, to temporarily discontinue use or to discontinue use altogether. ➤ If skin is sensitive, start at a lower frequency (e.g. three times per week), increasing to daily as tolerated. ➤ Seek medical advice if the acne does not start to improve within 6 weeks, or sooner if it becomes worse. ➤ Excessive application will not increase efficacy but may increase the risk of skin irritation. ➤ Benzoyl peroxide gel should not be applied on damaged skin due to the risk of sensitisation. ➤ Use concomitant topical acne therapy (e.g. face washes/scrubs) with caution, especially peeling, desquamating, or abrasive agents, as possible cumulative irritancy may occur. ➤ Do not smoke or go near flames - risk of severe burns. Fabric (clothing, bedding etc.) that has been in contact with the cream burns more easily. Washing clothing and bedding may not totally remove it. ➤ Benzoyl peroxide may bleach hair and coloured fabrics including clothing, towels and bed linen so care to avoid contact of the gel with these materials should be taken. Hands should be washed thoroughly after use of the gel.

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(continued over page)	<ul style="list-style-type: none"> ➤ If any unexpected and/or troublesome side effects occur, encourage the individual to talk to their doctor, pharmacist or nurse. 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 Acne for more information.
Patient or carer advice/follow up (continued)	Lifestyle <ul style="list-style-type: none"> ➤ Acne is not caused by poor hygiene. Avoid over-cleaning the skin (which may cause dryness and irritation). ➤ Try not to pick or squeeze spots because this usually aggravates them and may cause scarring. ➤ Use a non-alkaline (skin pH neutral or slightly acidic) synthetic detergent cleansing product twice daily on acne-prone skin. ➤ If dry skin is a problem, use a fragrance-free water-based emollient. ➤ Shower as soon as possible after exercise as sweat can irritate acne. ➤ Wash hair regularly and avoid letting it fall across the face. ➤ There is not enough evidence to support specific diets for treating acne but maintain a healthy diet is important for general health and well-being. ➤ Avoid using heavy make-up/ cosmetics. Avoid oil-based comedogenic skin care products, make-up and sunscreens. If make-up is used, it should be removed at the end of the day.
Records	<p>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</p>

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	consultation notes. All records should be clear, legible and contemporaneous.
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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. Acne vulgaris. Last revised June 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]

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Appendix B: *Healthcare Professionals Agreement to Practice*

Authorisation for the use of the Patient Group Direction for the supply of:
Benzoyl peroxide 5% gel by community pharmacists under the Clinical Community Pharmacy
Service, Common Ailment Service (acne vulgaris) 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

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