Patient Group Direction (PGD Varenicline: Version 1.0)

The supply of varenicline tablets as part of a tobacco dependence treatment service by community pharmacists

Authorised for use in Torbay Council by (acting as Clinical Governance Lead) Lincoln Sargeant, Director of Public Health in Torbay Local Authority area

Signed Lincoln Sargeant, Director of Public Health, Torbay Council



Date: 25 March 2026

TORBAY COUNCIL

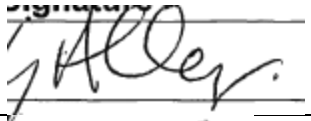
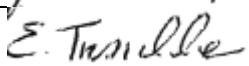
PLYMOUTH CITY COUNCIL

Devon County Council

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Staff involved in the development of this PGD:

	Name	Signature	Date
Physician	Glen Allaway		14.01.2026
Pharmacist	Emma Tresidder		14.01.2026
Specialist in antimicrobial therapy (e.g. Microbiologist or Antimicrobial Pharmacist)	Not applicable		

Date of Implementation: 25 March 2026 **Expiry Date: 25 March 2028**

As part of the development of this PGD we have taken into account all equality and diversity issues. Patients are only excluded from this PGD in line with national guidance or for safety reasons.

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The community pharmacists named below are authorised to supply varenicline as specified under this Patient Group Direction, being employees of

…… (INSERT ORGANISATION NAME)

In signing this document, I confirm the following:

- I have read and understood the above mentioned PGD.
- I agree to practice only within the bounds of my own competence and in accordance with my Code of Professional Conduct.
- I have the qualifications required under the staff characteristics detailed in the PGD
- I am competent to operate under this PGD and able to evidence this
- I agree to administer/supply the above preparations in accordance with this PGD

NAME *(please print)*	**TITLE**	**SIGNATURE**	**AUTHORISING MANAGER** *(please print)*	**MANAGER'S SIGNATURE**	**DATE**

- **Complete additional pages as necessary.**
- **Retain all original signed pages with authorising manager.**

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1. Clinical Condition

Definition of condition/situation	• Tobacco dependence treatment and reduction of nicotine cravings in individuals presenting in pharmacy who smoke and who are willing to seek treatment for tobacco dependence. • Varenicline can be provided as a first-line treatment, based on suitability and preference. Clients do not need to have tried another form of medication to assist with a quit attempt before being prescribed varenicline.
Criteria for inclusion	• Informed consent including consent to share relevant information with the individual's GP Practice and/or external stop smoking service (via local systems), where registered. • Consent to share completion of course or discontinuation of medication due to adverse effects or other reasons with the individual's GP practice and/or external stop smoking service. • Individuals aged 18 years or older • Individuals who smoke identified as having a long-term goal of tobacco abstinence • Individual is willing to continue a course of treatment for (at least) 12 weeks, which includes behavioural support, at locally agreed intervals from their referring tobacco dependence treatment support service. • Individual is sufficiently motivated to stop tobacco use 7-14 days after starting varenicline. • Or: • **Individuals dependent on tobacco motivated to engage in a gradual approach to quitting smoking but who are not able to quit abruptly**. This cohort should reduce smoking during the first 12 weeks of treatment and quit by the end of that treatment period. They should then continue taking varenicline for an additional 12 weeks, (a total of 24 weeks of treatment - extended regimen). • Individual agrees to receive advice and treatment from the registered healthcare professional in line with this PGD
Criteria for exclusion	• Consent to treatment refused and/or consent refused to share information with the individual's registered GP Practice and/or stop smoking service.

- Individuals under 18 years of age
- Individuals receiving varenicline and/or other pharmaceutical tobacco dependence treatment (i.e. NRT, cytisinicline (cytisine) or bupropion) from another provider
- Individuals who have no intention to stop smoking or who are not willing to continue a course of treatment for (at least) 12 weeks and engage in behavioural support.
- Individuals unable to absorb oral medications and/or inability to swallow solid oral dosage formulations (i.e. tablets)
- Known hypersensitivity to varenicline or any of the components within the formulation – see Summary of Product Characteristics
- Previous intolerable adverse effects with varenicline use, that were not managed by dose reduction
- Previous Stevens-Johnson Syndrome or Erythema Multiforme associated with varenicline use
- Known or suspected pregnancy (or pregnancy planned during treatment period) [See NICE NG209 guidance for information on recommended tobacco dependence treatment interventions in pregnant individuals].
- Currently breastfeeding
- History of seizures or conditions known to lower the seizure threshold
- Known or suspected renal impairment
- Current or history of psychiatric disorders. People taking medication for depression/anxiety and related disorders should be referred to their GP or specialist smoking cessation service for monitoring during treatment.
- The metabolism of some drugs will be affected if a patient stops smoking, as cigarette smoke stimulates the cytochrome P450 enzymes (particularly CYP1A2). Patients using these medications should receive treatment through their GP or a specialist treatment service to allow monitoring and dosage adjustment as necessary.
    - Aminophylline
    - Chlorpromazine
    - Clozapine
    - Erlotinib
    - Flecainide
    - Haloperidol
    - Insulin
    - Methadone
    - Mexiletine
    - Olanzapine
    - Riluzole
    - Riociguat
    - Theophylline
    - Warfarin

- This list is not exhaustive. The full list of interactions can be found through the BNF, Stockley's Drug Interactions (where available) and at Managing specific interactions with smoking – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

	If there are any doubts about the individual's suitability for varenicline the registered pharmacist working under this PGD must refer the individual to their GP Practice/appropriate specialist and not initiate or continue treatment under this PGD.
Caution	**The health risks of tobacco dependence are widely acknowledged and the likelihood of experiencing risks from using varenicline is expected to be lower compared to the risk of continuing to smoke.** **Cardiovascular symptoms** Individuals taking varenicline should be instructed to notify their GP practice of new or worsening cardiovascular symptoms and to **seek immediate medical attention if they experience signs and symptoms of myocardial infarction or stroke.** **Neuropsychiatric symptoms** Changes in behaviour or thinking, anxiety, psychosis, mood swings, aggressive behaviour, depression, suicidal ideation and behaviour and suicide attempts have been reported in individuals attempting to quit smoking. **Individuals should be advised to discontinue varenicline immediately and notify their relevant service provider if they experience serious neuropsychiatric symptoms such as agitation, depressed mood, changes in behaviour or thinking, or seek immediate medical advice if they develop suicidal ideation or suicidal behaviour.** **Other cautions** • **Cutaneous reactions:** Individuals reporting hypersensitivity reactions (including angioedema) and/or severe skin reactions (e.g., Stevens Johnson syndrome and Erythema Multiforme) should **discontinue treatment and contact a healthcare provider immediately.** Clinical signs of angioedema include swelling of the face, mouth (tongue, lips and gums), neck (throat and larynx) and extremities. There were rare reports of life-threatening angioedema and skin reactions requiring urgent medical attention identified from post-marketing reports. • **Effects on ability to drive:** Varenicline may cause dizziness, somnolence and transient loss of consciousness, and therefore may influence the ability to drive and use machines. Individuals should be advised not to drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether varenicline affects their ability to perform these activities. • **Alcohol**: There have been post marketing reports of increased intoxicating effects of alcohol in individuals treated with varenicline. A causal relationship between these events and varenicline use has not been established. Individuals should be advised of possible increased intoxicating effects of alcohol when taking varenicline. • **Side effects on treatment cessation:** Up to 3% of individuals report side effects (e.g. increase in irritability, urge to smoke, depression or insomnia) on cessation of varenicline treatment. At the final review appointment, if an individual with a high risk of relapse is experiencing side effects (e.g. irritability because of treatment cessation) refer to their GP Practice or other appropriate specialist for consideration of further/tapering doses.

Action if excluded/ patient refuses medication	• Record reasons for exclusion in the appropriate clinical record and any advice given to the individual along with the action taken (e.g. referred to GP Practice) • Signpost individual back to the referring service, another relevant provider, their GP practice, appropriate specialist, or mental health service as appropriate. • Recommend alternative tobacco dependence interventions if appropriate.

2. Characteristics of Staff

Qualifications required	Community pharmacist currently registered with the General Pharmaceutical Council

Additional requirements	**Initial training:** The registered pharmacist authorised to operate under this PGD must have: • Undertaken appropriate training and successfully completed the competencies to undertake clinical assessment of individuals leading to diagnosis of the conditions listed. • Undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - eLfH PGD elearning programme • Completed locally required training (including updates) as required by the specification. Individuals operating under this PGD must be familiar with the product and alert to changes in the Summary of Product Characteristics (SPC). Individuals operating under this PGD must have access to the PGD and associated online resources. **Competency assessment:** Individuals operating under this PGD must be assessed as competent or complete a self-declaration of competence to operate under this PGD. 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 varenicline - if any training needs are identified these should be discussed with the senior person responsible for authorising individuals to act under the PGD and further training provided as required. **The decision to supply any medication rests with the individual community pharmacist who must abide by the PGD and any associated organisational policies**.

3. Description of Treatment

Name of Medicine, strength and formulation	Varenicline 0.5mg and 1mg tablets
Legal Class	POM (Prescription Only Medicine)
Off label use	There are no off-label uses allowed under this PGD
Storage	• Stock must be securely stored according to organisation medicines policy and in conditions in line with manufacturers Summary of Product Characteristics (SPC), which is available from the electronic Medicines Compendium website: www.medicines.org.uk or MHRA website https://www.gov.uk/guidance/find-product-information-about-medicines . • Do not store above 25°C
Dose to be used (including criteria for use of differing doses)	Days 1 - 3: 500micrograms once a day Days 4 - 7: 500micrograms twice a day Day 8 to end of treatment (up to 12 weeks in total): 1mg twice a day The client should set a date to stop smoking. Varenicline dosing should usually start 1 - 2 weeks before this date. For patients who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment at 1mg twice daily (or reduced dose of 500mcg twice daily if required) may be considered for the maintenance of abstinence. This should be based on discussion with patient where risk of relapse is considered to be high. Patients who require a gradual approach to quitting should reduce smoking during the first 12 weeks of treatment and quit by the end of that treatment period. Patients should then continue taking varenicline at 1mg twice daily (or reduced dose of 500mcg twice daily if required) for an additional 12 weeks for a total of 24 weeks of treatment. Patients who cannot tolerate adverse reactions to varenicline may temporarily or permanently reduce their dose to 500micrograms twice daily. Days 1 - 3: 500micrograms once a day Day 4 to end of treatment: 500micrograms twice daily
Method or route of administration	Oral

Total dose and number of times drug to be given. Details of supply (if supply made)	Instalment 1 – Days 1-14: • Supply appropriately labelled initiation pack containing 11 x 0.5mg tablets and 14 x 1mg tablets. • Where initiation packs are unavailable provide separate appropriately labelled packs containing 11 x 0.5mg tablets and 14 x 1mg tablets. Instalment 2 – Days 15-28: • Supply appropriately labelled pack containing 28 x 1mg tablets • Where a reduced dose is required due to adverse reactions supply appropriately labelled pack containing 28 x 0.5mg tablets Further instalments: • Supply 56 x 1mg tablets in 4-week instalments up to 12 weeks total treatment (extended to 24 weeks if required as detailed above) • Where a reduced dose is required due to adverse reactions supply appropriately labelled packs containing a total of 56 x 0.5mg tablets in 4-week instalments up to 12 weeks total treatment (extended to 24 weeks if required). At the final review appointment, if an individual with a high risk of relapse is experiencing side effects (e.g. irritability because of treatment cessation) refer to their GP Practice or other appropriate specialist for consideration of further/tapering doses.
advice and information to patient/carer including follow-up	• Advise clients of possible side effects of smoking cessation and varenicline therapy. A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website and the BNF The following side effects are listed in the product SPC/BNF as **very common/common** with varenicline (but may not reflect all reported side effects): ○ Abnormal appetite (increased or decreased) ○ Abnormal dreams ○ Asthenia ○ Chest discomfort (chest pain) ○ Constipation ○ Cough, nasopharyngitis ○ Diarrhoea ○ Dizziness ○ Drowsiness ○ Dry mouth ○ Dysgeusia ○ Dyspnea ○ Fatigue ○ Gastrointestinal discomfort (abdominal distension, abdominal pain, dyspepsia, flatulence) ○ Gastrointestinal disorders (including gastroesophageal reflux disease) ○ Headache

- Insomnia
- Joint disorders
- Muscle complaints (arthralgia, myalgia, back pain)
- Nausea
- Oral disorders
- Pain
- Skin reactions (rash, pruritus)
- Sleep disorders
- Toothache
- Vomiting
- Increased body weight

Reassure the individual that these side effects occur mainly at the beginning of treatment and often resolve, without intervention. These symptoms may also be the result of tobacco withdrawal symptoms and not treatment with varenicline.

The cautions section of this PGD should be discussed with the patient prior to treatment. In the event of any severe adverse reaction the individual must be advised to stop treatment immediately and seek urgent medical advice.

- The manufacturer's patient information leaflet (PIL) must be given to the client.
- Give any additional information in accordance with the local service specification and training, including general advice on smoking cessation and treatment adherence
- Explain the dose, frequency and method of administration, including how to use the initiation pack
- Tablets should be swallowed whole with water and can be taken with or without food.
- Where the patient is experiencing nausea, they should be advised to take the tablets with a large glass of water after food.
- Advise individual/carer to return any unused medicines to a pharmacy for disposal: Do not dispose of medicines in the bin, down the sink or toilet.

Client should be followed up at appropriate intervals in line with the service specification for the duration of their treatment

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Specify method of recording supply /administration including audit trail

Adverse drug reactions must be clearly documented and, where appropriate, reported to the Medicines and Healthcare products Regulatory Agency (MHRA) using the yellow card scheme http://yellowcard.mhra.gov.uk

- Record all ADRs in the patient's medical record.
- Report via organisation incident policy.
- It is considered good practice to notify the individual's GP Practice and/or other relevant healthcare providers in the event of an adverse reaction.

Appropriate records must include the following:

- That valid informed consent has been given
- Individual's name, address and date of birth
- Name of GP Practice where individual is registered or record the individual is not

registered with a GP Practice

- Name and GPhC number of pharmacist operating under this PGD
- Specify how the individual has/has not met the criteria of the PGD
- Relevant past and present medical history and medication history
- Name/dose/form/quantity of medicine supplied
- Date and time of supply
- Documentation of cautions as appropriate
- Advice given if individual excluded or declines treatment
- Details of any ADRs/allergy status and actions taken
- The supply must be entered in the Patient Medication Record (PMR)
- That supply was made under a PGD
- Any safety incidents, such as medication errors, near misses and suspected adverse events
- Any additional requirements in accordance with the local authority service specification
- GP Practice to be notified on the day of provision or next working day via usual communication channels
- All records should be kept in line with national guidance. This includes individual data, master copies of the PGD and lists of authorised practitioners.

Records should be signed and dated (or a password-controlled e-records).

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 the local specification.

References used in the development of this PGD:	• Summary of Product Characteristics accessed, www.medicines.org.uk (April 25) • BNF online https://bnf.nice.org.uk/ (accessed April 2025) • NICE, Medicines Practice Guidelines (MPG2), Updated March 2017 https://www.nice.org.uk/guidance/mpg2 • MHRA, yellow card, helping to make medicines safer: http://yellowcard.mhra.gov.uk • National Institute for Health and Care Excellence CKS. Smoking cessation: Which drugs are affected by stopping smoking? Available at: https://cks.nice.org.uk/topics/smoking-cessation/prescribing-information/drugs-affected-by-smoking-cessation/ (accessed April 25) • Specialist Pharmacy Service: Managing specific interactions with smoking. Available at Managing specific interactions with smoking – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice (accessed April 2025) **The following PGDs were used to develop this PGD:** Specialist Pharmacy Service: Varenicline PGD template. 'Varenicline National PGD template V1.0 FINAL Oct 2024' – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice Somerset County Council: Patient Group Direction for the supply of varenicline by community pharmacists. Version 1.7 Nov 2022 SOUTH SOMERSET PRIMARY CARE TRUST NHS Scotland: Patient Group Direction Version 1.0 April 2025 PGD-Varenicline-tablets-Version-1.0-April-2025.pdf

Please refer to the summary of product characteristics for full information

This Patient Group Direction is operational from 25 March 2026 and expires 25 March 2028

Version History

Version	Date	Brief Summary of Change	Owner's Name
1.0	December 2025	Adaptation of SPS template for local use	Emma Tresidder