Patient Group Direction (PGD)

This PGD authorises community pharmacists to supply varenicline tablets to patients aged 18 years and over who meet the criteria for inclusion under the terms of this document, under the Public Health Service within community pharmacies.

Publication date: 3rd April 2025

NHS Lothian PGD 558 Version 1

Valid from: 26/05/2025

Expiry: 02/04/2028

Version 1.0

Most Recent Changes

Version	Date	Summary of changes
1.0	03/04/2025	• New national specimen PGD produced

Contents

Authorisation

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

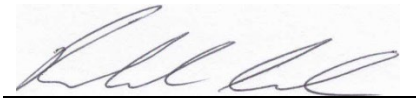
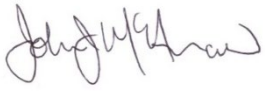
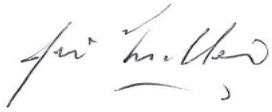
PGD varenicline tablets

This specimen PGD template has been produced in collaboration with the Pharmaceutical Public Health Network to assist NHS Boards in the uniform provision of services under 'Community Pharmacy Public Health Service' banner across NHS Scotland. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The community pharmacist who may supply varenicline tablets under this PGD can do so only as a named individual. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with the General Pharmaceutical Council Standards for Pharmacy Professionals and to ensure familiarity with the manufacturer's product information/summary of product characteristics (SPC) for all medicines supplied in accordance with this PGD.

NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Supply of the medicine must be by the same practitioner who has assessed the patient under the PGD.

This PGD has been approved on behalf of NHS Scotland by NHS 24 by:

Doctor	Dr Ron Cook	Signature	
Pharmacist	Dr John McAnaw	Signature	
NHS Scotland Representative	Mr Jim Miller	Signature	

Approved on behalf of NHS Lothian by:

Medical Director: Ms Tracey Gilles
Director of Pharmacy: Scott Garden
Clinical Governance Lead: Dr Emma Morrison
Date approved: 26/05/2025

Effective from: 26 May 2025

It is the responsibility of the person using the PGD to ensure they are using the most recent issue.

Expiry date: 2nd April 2027

1. Clinical situation

1.1. Indication

Patient wishes to use varenicline as a treatment option under the Community Pharmacy Smoking Cessation service.

1.2. Inclusion criteria

Patient aged 18 years of age and over.

Dependent smoker (i.e. they smoke within 30 minutes of waking up and / or find quitting unaided difficult).

Patient is motivated to stop smoking and agrees to receive appropriate behavioural support provided either by the pharmacy team at point of supply, or Quit Your Way smoking cessation advisors.

Patient is registered with a GP practice in Scotland.

Valid consent to receiving treatment under this PGD and information sharing has been obtained.

1.3. Exclusion criteria

Smokers not sufficiently motivated to quit.

Individuals not willing to engage in weekly monitoring and support.

Known or suspected pregnancy (or planned pregnancy during treatment period).

Breastfeeding.

Hypersensitivity to varenicline or any of the excipients.

Severe renal impairment or end stage renal disease – eGFR <30mL/min/1.73m^2

Previous history of Stevens-Johnson Syndrome or Erythema Multiforme

History of seizures e.g. epilepsy or conditions where seizure threshold may be lowered.

Concomitant use of other smoking cessation therapies or e-cigarettes.

Individuals for whom no valid consent has been received.

1.4. Cautions/need for further advice/ circumstances when further advice should be sought from a prescriber

Renal impairment

- Patients with no known renal impairment can be treated without the requirement to independently check levels of impairment. Determination of "no known renal impairment" can be made by asking patient if GP has advised that they have some degree of renal/kidney function impairment, or if they have ongoing reviews with a renal doctor.
- If there are any patient factors which could indicate an increased risk of renal impairment (e.g., current medication, relevant co-morbidities or age), treatment can be considered in community pharmacy if relevant patient records/blood results can be independently checked e.g., using Clinical Portal. If this is not possible, the patient should be referred to GP).
- No dosage adjustments are required for patients with mild to moderate renal impairment.
- For those with moderate renal impairment who experience adverse effects to varenicline which are not tolerable, dosing may be reduced to 1mg daily.

Diabetes – individuals taking insulin may be supplied with varenicline, however patients should be advised to monitor their blood glucose levels more closely, be vigilant for symptoms of hypoglycaemia and contact their GP or specialist diabetes service if glucose levels change. If the PGD user has any doubts around the ability of the individual to monitor their blood glucose levels, varenicline must not be supplied

under this PGD and the individual should be referred to GP and Quit Your Way Specialist Service.

Psychiatric disorders – the use of varenicline in individuals with or without a history of psychiatric disorders was not associated with an increased risk of serious neuropsychiatric adverse events. However, clinicians should be aware of the possible short term exacerbation of underlying psychiatric illness (e.g. depression) in individuals attempting to stop smoking with or without treatment. Individuals should be advised to discontinue varenicline immediately and seek further medical advice 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.

Cardiovascular disease – individuals should be instructed to notify their doctor of new or worsening cardiovascular symptoms and to seek immediate medical attention if they experience signs or symptoms of myocardial infarction or stroke.

Cutaneous reactions – individuals reporting hypersensitivity reactions (including angioedema) and/or severe skin reactions (e.g. Stevens Johnson syndrome) should discontinue treatment and seek further medical advice.

Use of alcohol whilst taking varenicline – 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, but individuals should be advised of possible increased intoxicating effects of alcohol when taking varenicline.

Interactions with other medicines.

- No clinically meaningful drug interactions have been reported with varenicline.
- Physiological changes resulting from smoking cessation (with or without varenicline) may alter the pharmacokinetics or pharmacodynamics of some medicinal products, for which dose adjustment may be necessary.

- Details of drugs affected by stopping smoking are available from the Specialist Pharmacy Services (www.sps.nhs.uk) – managing specific interactions with smoking: **Managing specific interactions with smoking – SPS**
- Individuals taking medications which may be affected by stopping smoking should be advised to inform their prescriber of their quit attempt in case they require dose adjustment or monitoring. This should be established according to the individual circumstances before supply of varenicline. Following this, a notification of supply should be sent by the pharmacist to the GP practice following supply under the PGD.
- For individuals taking **clozapine**, **BEFORE** the supply of varenicline via PGD the pharmacist must inform the prescriber that the patient is making an attempt to stop smoking so that clozapine levels can be monitored. Cautions – see BNF and Summary of Product Characteristics. Varenicline can only be supplied if contact can be made with prescriber prior to initiation and a monitoring plan put in place. See patient information leaflet NHS Lothian Clozapine and Smoking available here: **Clozapine and Smoking**

1.5. Action if excluded

Offer alternative products, if appropriate, or refer to GP Practice or Specialist Quit Your Way Smoking Cessation service.

- Edinburgh : 0131 286 5113
- Midlothian and East Lothian: 0131 537 9914
- West Lothian: 01506 651 829

Document reason for exclusion and any action taken in Patient Medication Record (PMR).

1.6. Action if patient declines

Offer alternative products, if appropriate, or refer to GP Practice or Specialist Quit Your Way Smoking Cessation service using the contact details in section 1.5.

Document that patient declined and any action taken in Patient Medication Record (PMR).

2. Description of treatment

2.1. Name of medicine/form/strength

Varenicline 500 microgram and 1 mg coated tablets

2.2. Route of administration

Oral

2.3. Dosage

Day 1 – 3 of treatment – 500 microgram ONCE daily

Day 4 – 7 of treatment – 500 microgram TWICE daily

Day 8 to the end of the treatment – 1 mg TWICE daily for 11 weeks.

- If adverse effects e.g. nausea are not tolerated, dose can be reduced to 500 microgram TWICE daily.
- In patients with moderate renal impairment, if adverse effects are not tolerated, dose can be reduced to 1 mg ONCE daily.

Maximum single dose – 1 mg, maximum daily dose 2 mg.

2.4. Frequency

As above.

2.5. Duration of treatment

Usually 12 weeks including a 1-week titration period at the start as above.

2.6. Maximum or minimum treatment period

Every attempt should be made to reduce the use of varenicline to zero by the end of **12** weeks.

Individuals may benefit from continuing treatment with varenicline after the initial 12 weeks to assist with the cessation attempt or reduce the risk of relapse.

The pharmacist should assess the patient to determine whether this is appropriate for the individual and refer Quit Your Way smoking cessation advisors to enable continuation of support (see section 1.5 for contact details).

2.7. Quantity to supply

<table>
<tr><th></th><th>Standard treatment</th><th>Intolerable adverse effects at standard dose</th><th>Intolerable adverse effects in moderate renal impairment</th></tr>
<tr><td>Initiation of treatment (Day 1 -14)</td><td colspan="3">11 x 500 microgram plus 14 x 1 mg
(If there are issues procuring the initiation packs, appropriately labelled packs containing 11 x 500 microgram tablets and 14 x 1mg tablets may be supplied)</td></tr>
<tr><td>Remainder of treatment
(Day 15 onwards in weekly instalments)</td><td>14 x 1 mg</td><td>14 x 500 microgram</td><td>7 x 1 mg</td></tr>
</table>

Supply should normally be on a weekly basis. (During initiation period, two weeks supply can be given at once).

2.8. ▼ Additional monitoring (formerly black triangle medicines)

No

2.9. Legal category

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.

2.10. Is the use out with the SPC?

No

2.11. Storage requirements

As per manufacturer's instructions.

Store below 25ºC in a cool, dry place

2.12. Additional information

None

3. Adverse reactions

3.1. Warnings including possible adverse reactions and management of these.

Please refer to current BNF or SPC for full details.

Very common side effects (≥ 1 in 10) include nausea*, abnormal dreams, insomnia, headache, nasopharyngitis.

*Nausea – around one third of individuals may experience mild nausea usually about 30 minutes after taking varenicline. This often diminishes gradually over a few weeks and most individuals can tolerate it.

Common side effects (≥ 1 in 100 to < 1 in 10) include bronchitis, sinusitis, changes in appetite, weight gain, drowsiness, dizziness, changes in taste, shortness of breath, cough, rash, pruritis, muscle complaints (arthralgia, myalgia, back pain), gastrointestinal disorders (including reflux, vomiting, constipation, diarrhoea, abdominal distension, abdominal pain, toothache, dyspepsia, flatulence, dry mouth).

Patients with history of psychiatric illness - individuals with a history of psychiatric illness should be monitored closely while taking varenicline. Individuals should be advised to discontinue treatment immediately and seek prompt medical advice if they develop agitation, depressed mood or suicidal thoughts.

Effects on ability to drive and use machines – Varenicline may cause dizziness, somnolence and transient loss of consciousness, and therefore may have minor or moderate influence on the ability to drive and use machines. Patients are advised not to drive, operate complex machinery or engage in potentially hazardous activities until it is known whether this medicinal product affects their ability to perform these activities.

End of treatment – at the end of treatment, discontinuation of varenicline has been associated with increased irritability, urge to smoke and/or insomnia in up to 3% of patients. The pharmacist should inform the patient accordingly.

For a full list of side effects, refer to the marketing authorisation holder's Summary of Product Characteristics (SPC). A copy of the SPC must be available to the health professional supplying the medication under this PGD. This can be accessed on **www.medicines.org.uk.**

If a patient experiences any side effects that are intolerable or hypersensitivity reactions occur, the medication should be discontinued.

In the event of severe adverse reaction e.g., swelling of eyes, face, lips or throat, shortness of breath or wheezing, developing of rash, or feeling faint, individuals should be advised to seek medical advice immediately.

3.2. Reporting procedure for adverse reactions

Pharmacists should document and report all adverse incidents through their own internal governance systems.

All adverse reactions (actual and suspected) should be reported to the appropriate medical practitioner and recorded in the patient's medical record. Pharmacists should record in their PMR and inform the patient's GP as appropriate.

Where appropriate, healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme. Yellow cards and guidance on their use are available at the back of the BNF or online at **www.mhra.gov.uk/yellowcard.**

3.3. Advice to patient or carer including written information

Written information to be given to individuals:

- Provide manufacturer's consumer information leaflet/patient information leaflet (PIL)

- Direct patient to NHS Inform for information (www.nhsinform.scot) on “Quit your way” services available at: **Quit Your Way Scotland | NHS inform**

- Consider displaying QR code with link to NHS Inform on wall of consultation room (see page 22 under References).

Verbal advice to be given to individuals/parent/carer:

- Explain dosage regimen, length of course and possible side effects (including how to manage these and reassurance that side effects occur mainly at the beginning of treatment and often resolve, without intervention. These symptoms may also be the result of tobacco withdrawal and not treatment with varenicline).

- Individuals should set a quit date for 7 to 14 days after initiation of treatment.

- Explain that varenicline should be swallowed whole with water, taken either with or without food (although some evidence shows taking with food reduces the likelihood of nausea occurring).

- Individuals should be warned that varenicline may cause drowsiness – exercise caution when starting treatment and avoid driving or operating machinery or tools if affected.

- Advise to seek further medical advice if any serious adverse effects occur.

    - If they experience serious neuropsychiatric symptoms such as hostility, agitation, depressed mood, changes in behaviour or thinking, suicidal thoughts which they don’t think are related to stopping smoking, individuals should be advised to discontinue varenicline immediately and seek further medical advice.

    - If they experience signs and symptoms of chest pain or stroke like symptoms.

- Discuss the major reasons for varenicline treatment failure:

- Unrealistic expectations
- Lack of preparation for the potential for the tablets to cause nausea.
- Insufficient or incorrect use
- Insufficient psychological support.

3.4. Monitoring

Carbon monoxide (CO) monitoring should be carried out at Weeks 1, 4 and 12, but ideally every week.

3.5. Follow up

Varenicline should be supplied weekly along with motivational support for the individual.

Smoking status should be checked each week.

Follow up and smoking status should be carried out at 4 and 12 weeks, and recorded on the Pharmacy Care Record (PCR).

3.6. Additional facilities

The following should be available when the medication is supplied:

- An acceptable level of privacy to respect patient's rights to confidentiality and safety.
- Access to a working telephone.
- Access to medical support (this may be via telephone or email).
- Approved equipment for the disposal of used materials.
- Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel.
- Access to current BNF (online version preferred)
    - BNF British National Formulary - NICE
- Access to SmPC/PIL/Risk Minimisation Material:
    - Home - electronic medicines compendium (emc)
    - MHRA Products | Home
    - RMM Directory - (emc)
- Access to Specialist Pharmacy Service resource
    - https://www.sps.nhs.uk/
- Access to copy of current version of this PGD.

4. Characteristics of staff authorised under the PGD

4.1. Professional qualifications

Pharmacist with current General Pharmaceutical Council (GPhC) registration.

Under PGD legislation there can be no delegation. Supply of the medication must be completed by the same practitioner who has assessed the patient under this PGD.

4.2. Specialist competencies or qualifications

Persons must only work under this PGD where they are competent to do so.

All persons operating under this PGD must:

- Be familiar with varenicline medicine and alert to changes in the manufacturer's product information/summary of product information.
- Have successfully completed the following NES Pharmacy e-learning modules:

  NHS Scotland Smoking Cessation service NHS Scotland Smoking Cessation service | Turas | Learn

- Ensure they understand their professional and legal responsibilities when working under a PGD **Overview | Patient group directions | Guidance | NICE**
- Ensure they are competent in the use of PGDs (see NICE Competency framework for healthcare professionals using PGDs **Tools and resources | Patient group directions | Guidance | NICE**)

Continuing education and training

All practitioners operating under this PGD are responsible for:

- Maintaining their skills, knowledge, and their own professional level of competence in this area according to the General Pharmaceutical Council Standards for Pharmacy Professionals.
- Ensuring they remain up to date with the use of medications included.
- Attending approved training and training updates as appropriate.
- Ensuring that they have an under
- Undertake relevant continuing professional development when PGD or NES Pharmacy modules are updated.

5. Audit trail

5.1. Authorisation of supply

Pharmacists can be authorised to supply the medicine specified in this PGD when they have completed local Board requirements for service registration.

Pharmacists should complete the authorisation form contained in the PGD (Appendix 1)

5.2. Record of supply

All records must be clear, legible, contemporaneous and in an easily retrievable format to allow audit of practice.

A Universal Claim Framework (UCF) record of the screening and any subsequent supply of the medicine specified in this PGD should be made in accordance with the Community Pharmacy Public Health Service - Smoking Cessation service specification.

Pharmacists must record the following information, included in the varenicline patient assessment form, in the PMR (either paper or computer based):

- name of individual, address, date of birth / CHI number
- name of GP with whom the individual is registered
- confirmation that valid consent to be treated under this PGD was obtained (include details of parent/guardian/person with parental responsibility where applicable)
- details of medicine supplied - name of medicine, batch number and expiry date, with date of supply
- details of exclusion criteria – why the medicine was not supplied (if applicable)

- advice given, including advice given if excluded or declines treatment under this PGD
- details of any adverse drug reactions and actions taken
- referral arrangements (including self-care)
- name of the pharmacist who undertook assessment of clinical suitability and, where appropriate, subsequently supplied the medicine.

The patient's GP should be provided with a copy of the GP notification form for the supply of varenicline tablets, or appropriate referral if unsuitable for treatment with varenicline in community pharmacy on the same, or next available working day.

Details of the supply should also be recorded in the Pharmacy Care Record (PCR) to ensure correct payment for delivery of the Smoking Cessation service.

These records should be retained in accordance with national guidance[1] (see page 56 for standard retention periods summary table). Where local arrangements differ, clarification should be obtained through your Health Board Information Governance Lead.

All records of the drug(s) specified in this PGD will be filed with the normal records of medicines in each service. A designated person within each service will be responsible for auditing completion of drug forms and collation of data.

1. Scottish Government. *Scottish Government Records Management.* Edinburgh 2020. Available at **SG-HSC-Scotland-Records-Management-Code-of-Practice-2020-v20200602.pdf** (Accessed 19th December 2023)

6. Additional references

Practitioners operating the PGD must be familiar with:

1. National Institute for Health and Care Excellence (NICE). Varenicline for smoking cessation. . Available at **Overview | Varenicline for smoking cessation | Guidance | NICE** (Accessed 2 April 2025)

2. BMJ. Risk of neuropsychiatric adverse events associated with varenicline: systematic review and meta-analysis. 2015; 350; h1109. Available at: **Risk of neuropsychiatric adverse events associated with varenicline: systematic review and meta-analysis | The BMJ** (Accessed 2 April 2025)

3. Specialist Pharmacy Services. Managing specific interactions with smoking. Available at: **Managing specific interactions with smoking – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice** (Accessed 2 April 2025)

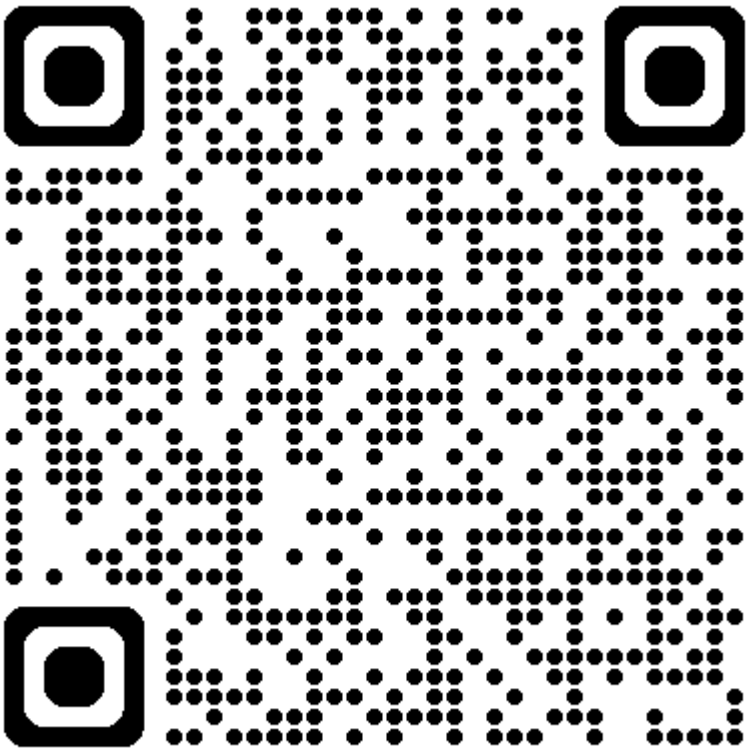
4. Current edition of British National Formulary (BNF) BNF British National Formulary - NICE,

5. Marketing authorisation holder's Summary of Product Characteristics. Electronic Medicines Compendium. *Varenicline. SmPC.* Available at **Home - electronic medicines compendium (emc)** (Accessed 2 April 2025)

6. NHS 24. NHS Inform Stopping Smoking. Available at: **Stopping smoking | NHS inform** (Accessed 26 March 2025)

7. NHS Lothian Clozapine and Smoking patient information leaflet Available at **Clozapine and Smoking** (accessed 8 May 2025)

NHS Inform – Stopping Smoking



7. Individual authorisation (Appendix 1)

PGD FOR THE SUPPLY OF VARENICLINE TABLETS BY COMMUNITY PHARMACISTS UNDER THE "COMMUNITY PHARMACY PUBLIC HEALTH" SERVICE

This PGD does not remove professional obligations and accountability.

- It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with the General Pharmaceutical Council Standards for Pharmacy Professionals.

- The professional must ensure familiarity with the marketing authorisation holder's Summary of Product Characteristics for medicines administered / supplied in accordance with this PGD.

- The decision to supply/administer any medication rests with the individual professional who must abide by the criteria within the PGD

- The PGD is not legally valid if it is out of date or does not have the necessary authorisation signatures on page four

- Authorised staff should be provided with an individual copy of the clinical content of the PGD and a copy of the document showing their authorisation.

- This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.

CONTRACTOR CODE:	

AUTHORISED PRACTITIONER LIST:

I have read and understood the Patient Group Direction and agree to use it and acknowledge that it is my responsibility to maintain my knowledge, skills and competencies through CPD. I wish to operate in and agree to provide varenicline tablets only in accordance with the specific PGD.

NAME	SIGNATURE	GPhC REGISTRATION	DATE

8. Version history

Version	Date	Summary of changes
1.0	03/04/2025	• New National Specimen PGD produced.