This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD must be used.

PATIENT GROUP DIRECTION (PGD)

Community pharmacy supply of varenicline tablets as part of the tobacco dependence treatment services across the North-East of England

Version Number 1.2

Change History

Version and date	Change details
Version 1.0 November 2024	New national template *Varenicline National PGD template V1.0 FINAL Oct 2024* published by the Specialist Pharmacy Service (SPS) at https://www.sps.nhs.uk/articles/varenicline-for-smoking-cessation/
Version 1.1 February 2025	**National template adapted for the North-East of England region by:** **Regional North-East England authorisations** Addition of organisational authorisation by the lead local authority, and clinical authorisation by lead clinicians. Addition of list of participating local authority areas that have signed a MOU with the lead local authority and adopted this PGD through their governance processes. **Initial training** Added: *As described in the accompanying pharmacy service specification*, *undertaken appropriate training*. Removed the need for additional local safeguarding training. **Competency assessment** Kept the same format and wording in Appendix A. **Criteria for inclusion** Removed provision of extended regime for a total of 24 weeks treatment. **Criteria for exclusion: Medical** Added patients taking clozapine (very high risk drug) and patients taking the high risk drugs haloperidol or olanzapine; theophylline or aminophylline; erlotinib and riociguat (Note: Addition of haloperidol to the listing of high risk drugs following cross-referencing of information at https://www.sps.nhs.uk/articles/managing-specific-interactions-with-smoking/). Altered patients with known or suspected end stage renal disease to patients with known or suspected renal disease.

Version and date	Change details
	Cautions: Medication related cautions when an individual stops smoking Altered wording to reflect GP practice PharmOutcomes email notification one week prior to client quit attempt. Removed description of additional actions to take where an individual has already stopped smoking (or reduced their tobacco consumption or entered a period of temporary abstinence) prior to presenting for treatment with varenicline. Removed patients taking clozapine (very high risk drug) and patients taking the high risk drugs to exclusions. Added agomelatine to listing of moderate risk drugs, following cross-referencing of information at https://www.sps.nhs.uk/articles/managing-specific-interactions-with-smoking/. Removed description of the development of local protocols to guide prescribing (the signposting to recommended sources of information remains). **Dose and frequency of administration** Removed extended regime dosing. Removed renal dosing regime. **Duration of treatment** Removed extended regime. **Quantity to be supplied** Removed extended regime. Removed renal dosing regime. **Management of and reporting procedure for adverse reactions** Added that the pharmacy will directly notify the stop smoking service adviser if concerns on the supply of varenicline are received from the GP practice. **Records** Text amended to state that the GP practice should be notified within one day of provision via PharmOutcomes email notification. **Appendix B** Alterations made to Appendix B to make it clear which drugs are excluded (with the addition of haloperidol to high-risk drugs), and which moderate risk drugs carry a caution (with the addition of agomelatine), the actions to take, and that the GP practice is informed one week before the client quit attempt by PharmOutcomes email.
Version 1.2 July 2025	**Quantity to be supplied** Addition of reduced dose regime.

National PGD Development Group

Date national PGD template comes into effect:	1 November 2024
Review date of national template:	30 April 2027
Expiry date of national template:	31 October 2027

The national PGD template has been peer reviewed by the smoking cessation Short Life Working Group in accordance with their Terms of Reference. It has been endorsed by the NHSE National Specialty Adviser for tobacco dependency and approved by the SPS Medicines Governance Do Once Programme Board in October 2024.
Note: The working group and approving organisation(s) agreement to the content only applies to the national template and does not extend to any local adaptations made to any of the content which are solely the responsibility of the organisation authorising the PGD. The most up to date version of the national template is available here:
https://www.sps.nhs.uk/home/guidance/patient-group-directions/templates/

Working Group

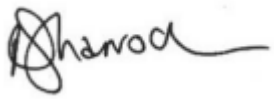
Name	Designation
Anne Joshua	Deputy Director of Pharmacy Commissioning, Primary Care Community Services, NHSE
Katie Evans	Specialist Mental Health Pharmacist and Consultations Lead for College of Mental Health Pharmacy (CMHP)
Roz Gittins	Past President, College of Mental Health Pharmacy (CMHP)
Ciara Ni Dhubhlaing	Past President, College of Mental Health Pharmacy (CMHP)
Emma Bryant	Specialist Pharmacist – Mental Health, SPS Medicines Use and Safety Team
Dr Peter Byrne	Consultant Liaison Psychiatrist Royal London Hospital. Royal College of Psychiatrists Associate Registrar for Public Health
Keith Kendall	Regional Senior Pharmacy Integration Lead – North East and Yorkshire Region
Louise Ross	Clinical Consultant, National Centre for Smoking Cessation and Training
Martyn Willmore	Tobacco Control Senior Programme Manager, Health Improvement: Alcohol, Drugs, Tobacco and Justice Division, DHSC
Dr Debbie Robson	Senior Lecturer in Tobacco Harm Reduction, National Addiction Centre, Addictions Department & NIHR ARC South London, Institute of Psychiatry, Psychology & Neuroscience, King's College London,
Julia Robson	Tobacco Control Programme Manager. Office for Health Improvement and Disparities, Department of Health and Social Care.
Professor Sanjay Agrawal	NHSE National Specialty Adviser for tobacco dependency, Chair RCP of the Tobacco Special Advisory Group, Chair NHSE Tobacco Dependence Stakeholder Group, Consultant in respiratory and critical care medicine University Hospitals of Leicester NHS Trust.
Peter Pratt	National Speciality Adviser for Mental Health Pharmacy, NHS England
Qasim Chowdary	Tobacco Control Manager, DHSC
Rob Hebdon	National Pharmacy Integration Lead, NHS England
Stephen Riley	Deputy North-West Regional Chief Pharmacist – Pharmacy Integration
Jo Jenkins	Associate Director – Medicines Governance, Medicines Use and Safety Division, Specialist Pharmacy Service
Kieran Reynolds (SLWG co-ordinator)	Advanced Specialist Pharmacist – Medicines Governance, Medicines Use and Safety Division, Specialist Pharmacy Service
Tracy Rogers	Director, Medicines Use and Safety Division, Specialist Pharmacy Service

The working group gratefully acknowledge the specialist input of Dr Andy McEwen, Chief Executive, National Centre for Smoking Cessation and Training (NCSCT).

Regional North-East England Authorisations

Date regional PGD template comes into effect:	7 July 2025
Expiry date of regional template:	31 October 2027

This regional PGD has been developed by the following health professionals, using the national SPS template and making the amendments to the national template as described in the Change History.

Clinical authorisation			
Name	**Job title and organisation**	**Signature**	**Date**
Senior doctor Ruth Sharrock	Dr Ruth Sharrock Consultant Respiratory Physician Gateshead NHS Foundation Trust		03/07/25
Senior pharmacist Claire Jones	Public Health Pharmacy Adviser Public Health Team Durham County Council		03/07/25
Senior pharmacist Sue White	Public Health Pharmacy Adviser Public Health Team Gateshead Council		03/07/25
Senior representative of professional group using the PGD Ann Gunning	Head of Services and Support Community Pharmacy North of Tyne		03/07/25

Organisational authorisation

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

It is the responsibility of the organisation that has legal authority to authorise the PGD, and to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

The PGD has been approved for use by Middlesbrough Council as the lead authority.

Organisational authorisation			
Role	**Name**	**Signature**	**Date**
Director of Public Health	Mark Adams		7 July 2025

National SPS guidance at https://www.sps.nhs.uk/articles/patient-group-directions-in-complex-commissioning-scenarios/ states: *Where multiple organisations are involved all parties must be involved in an MOU and a lead commissioner may be identified as agreed. Where a lead commissioner is identified to act to authorise a PGD/s on behalf of other commissioning organisations, it is essential that all involved organisations have the necessary governance processes in place to ensure any authorisations undertaken by the lead organisation are formally noted. This should be reflected in the MOU.*

Middlesbrough Council as the lead authority authorises this PGD for use by community pharmacies in the following local authority areas:

Authorised for use in the following local authority areas
County Durham
Darlington
Middlesbrough
Redcar & Cleveland
Hartlepool
Stockton on Tees
Newcastle
Sunderland
Northumberland
South Tyneside
North Tyneside
Gateshead

It is the responsibility of the provider organisation to ensure that all legal and governance requirements for using the PGD are met.

Registered Health Professional Authorisation Sheet

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

Individual practitioners must be authorised by name to work to this PGD. Appendix A provides a registered health professional authorisation sheet.

1. Characteristics of staff

Qualifications and professional registration	Current contract of employment within a Local Authority or NHS commissioned service or an NHS Trust/organisation. Registered healthcare professional listed in the legislation as able to practice under PGDs.
Initial training	The registered healthcare professional authorised to operate under this PGD must have: • As described in the accompanying pharmacy service specification, undertaken appropriate training 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 training (including updates) in safeguarding vulnerable adults. 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 complete a self-declaration of competence to operate under this PGD (see authorisation record sheet in Appendix A). • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions
Ongoing training and competency	• Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required. • Organisational PGD and/or medication training as required by employing Trust/organisation.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.	

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Tobacco dependence treatment and reduction of nicotine cravings in individuals who smoke and who are willing to seek treatment for tobacco dependence.

Criteria for inclusion	• Informed consent including consent to share relevant information with the individual's GP Practice (via local systems), where registered • Individuals aged 18 years or older • Individuals who smoke identified as having a long-term goal of tobacco abstinence • Individuals sufficiently motivated to stop tobacco dependence 7-14 days after starting varenicline. • Individual is willing to continue a course of treatment for 12 weeks, which includes behavioural support, at agreed intervals from their referring tobacco dependence treatment support service. • Individual agrees to receive advice and treatment from the registered healthcare professional in line with this PGD
Criteria for exclusion	**Individual** • Consent to treatment refused and/or consent refused to share information with the individual's registered GP Practice • Individuals under 18 years of age • Individuals receiving varenicline and/or tobacco dependence treatment (i.e. cytisinicline (cytisine) or bupropion) from another provider • Individuals who have no intention to stop smoking • Individuals who report they are not sufficiently motivated to stop smoking or who are not willing to continue a course of treatment for 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) **Pharmaceutical** • 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 **Medical** • Individuals taking clozapine (very high risk drug – see Appendix B) • Individuals taking haloperidol or olanzapine, theophylline or aminophylline, erlotinib and riociguat (high risk drugs – see Appendix B) • 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 disease If there are any doubts about the individual's suitability for varenicline the registered healthcare professional working under this PGD must refer the individual to their GP Practice/appropriate specialist and not initiate or continue treatment under this PGD.
Cautions including any relevant action to be taken	**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. **Individuals with current or past history of psychiatric disorders** The health benefits of treatment for tobacco dependence are widely acknowledged and any opportunity to stop smoking should be widely supported. However, treatment for tobacco dependence, with or without pharmacotherapy, has been associated with the short-term exacerbation of underlying psychiatric illness (e.g., depression). 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. **Medication related cautions when an individual stops smoking** Physiological changes resulting from smoking cessation, (with or without treatment with varenicline), may alter the pharmacokinetics or pharmacodynamics of some medicinal products, for which dosage adjustment may be necessary. As ingredients in tobacco smoke induce CYP1A2, smoking cessation may result in an increase of plasma levels of CYP1A2 substrates. Before supplying varenicline, PGD users must first establish (using the information presented below) if there is a potential interaction due to a change in smoking status and inform the

	individual of this. The individual should be informed that their GP practice will be notified via email 1 week before their quit attempt (i.e. the client will set a quit date on day 8-14 of the initiation pack). This email describes the interacting medicine(s) and the actions that the client has been advised to take so that any relevant monitoring and/or dose adjustments can be carried out by the individual/their health care professional. The PGD user must **ensure** the service provider who prescribes any interacting medicine to any individual supplied with varenicline under this PGD are aware of the individual's intention to stop smoking **AND** that a plan is in place re: monitoring and dose adjustments, if required. If the individual is unwilling to share information between services, varenicline must not be supplied under this PGD and the individual should be referred to an appropriate alternative service provider, as per local arrangements. If it is **not possible to inform** the prescriber(s) of the interacting medicine(s) of the individual's intention to stop smoking **so that any relevant monitoring and/or dosage adjustments can be carried out** by the individual/their health care professional, varenicline **must not be** supplied under this PGD and the individual should be **referred** to an appropriate alternative service provider. If individuals **relapse and start smoking again**, they are **required to notify all healthcare practitioners** involved in their care (so that any appropriate monitoring and/or dose adjustments can be actioned). They must be advised of this responsibility and ensure that this information is communicated. The impact of smoking cessation on the following medicines have been classified as: - **Very high risk** (risk of death AND dosage adjustments required) see Criteria for exclusion for clozapine. - **High risk** (narrow therapeutic index drug and potential toxicity OR rapid dosage adjustments required) see Criteria for exclusion for haloperidol or olanzapine, theophylline or aminophylline, erlotinib and riociguat. - **Moderate risk** (increased risk of adverse effects +/- dosage amendments required). **This list is not exhaustive and these risk categories are provided as a guide and should not act as a substitute for the PGD user's own clinical judgement.** **HIGH RISK:** see Appendix B ○ Insulin ○ Warfarin

	MODERATE RISK: see Appendix B ○ Agomelatine ○ Chlorpromazine ○ Flecainide ○ Fluvoxamine ○ Melatonin ○ Methadone ○ Mexiletine ○ Riluzole ○ Ropinirole Resources to help guide prescribers make any required dosage changes required in response to smoking cessation (and individuals re-starting smoking) include: - Considering drug interactions with smoking - Managing specific interactions with smoking - Individual drug SPCs: accessible via: ○ Electronic medicines compendium ○ MHRA - Young AH, Taylor D, Barnes TRE. The Maudsley Prescribing Guidelines in Psychiatry. John Wiley & Sons, Ltd.; 2021. Print ISBN: 9781119772224 https://onlinelibrary.wiley.com/doi/book/10.1002/9781119870203 **Other cautions** • **Cutaneous reactions:** Individuals reporting hypersensitivity reactions (including angioedema) and/or severe skin reactions (e.g., Stevens Johnson syndrome) should discontinue treatment and contact a healthcare provider immediately. Although rare, these reactions have been 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 to be taken if the individual is excluded	• 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.
Action to be taken if the individual or carer declines treatment	• Document the reason for why the individual declined and any advice given to the individual along with any action taken (e.g. referred to smoking cessation service). • Any individual who declines treatment should be signposted back to the referring service, another relevant provider, their GP Practice, appropriate specialist or mental health service as appropriate. • Recommend alternative smoking cessation interventions if appropriate
Arrangements for referral for medical advice	Refer to the referring service, another relevant provider, an individual's GP Practice, appropriate specialist or mental health service as appropriate.

3. Description of treatment

Name, strength & formulation of drug	Varenicline 0.5mg and 1mg tablets
Legal category	Prescription Only Medicine (POM)
Route / method of administration	Orally, swallowed whole with water
Indicate any off-label use (if relevant)	**Temperature variations** Medicines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions the pharmacist must ensure the medicine remains pharmaceutically stable and appropriate for use if it is to be issued. Where medicines have been assessed by a pharmacist in accordance with national or specific product recommendations/manufacturer advice as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected medicines for use lies with the pharmacist.
Dose and frequency of administration	Individuals should set a quit date for 7 to 14 days after initiation of varenicline treatment. **<u>Standard regimen</u>** **Days 1 to 3**: 0.5mg once daily **Days 4 to 7**: 0.5mg twice daily **Days 8 onwards (to complete 12 week course)**: 1mg twice

	daily† until a total of 12 weeks' treatment has been taken. † ***Intolerance of higher dose (1mg twice daily) of varenicline:*** *for individuals who cannot tolerate the adverse effects (e.g. nausea) of the higher dose of varenicline, and where this is interfering with the attempt to quit, the dose may be reduced temporarily or permanently to 0.5mg twice daily. This reduction should be agreed with the individual and the PGD user. Dose reductions should be initiated at review points for repeat supply. If there are any concerns the individual should be signposted back to the referring service, another relevant provider, their GP Practice, appropriate specialist or mental health service as appropriate.* **Tapering dose** Tapering doses are not permitted under this PGD – if potentially indicated refer to an appropriate prescriber.
Duration of treatment	Maximum of 12 weeks permitted for the standard regimen.
Quantity to be supplied	**Standard regimen (to complete 12-week course):** • **Initiation (Days 1 to 14):** Appropriately labelled initiation pack‡ containing 11 x 0.5mg tablets and 14 x 1mg tablets • **Maintenance (Day 15 onwards):** Appropriately labelled packs of 28 x 1mg tablets can be supplied in instalments to a total of 12 weeks' therapy (i.e. 5 installments of 28 x 1mg tablets). ‡ *If there are issues procuring the initiation packs, appropriately labelled packs containing 11 x 0.5mg tablets and 14 x 1mg tablets may be supplied, noting if supplied other than by a registered pharmacist these must be obtained from a licensed pre-packing unit, as per NICE guidance.* **For the standard regimen where higher dose (1mg twice daily) of varenicline is not tolerated and dose reduced to 0.5mg twice daily:** Appropriately labelled packs of 28 x 0.5mg tablets can be supplied in instalments to a total of 12 weeks' therapy. **Tapering dose (for individuals at high risk of relapse and experiencing side effects)**: Supply not permitted under this PGD: refer to GP Practice or other appropriate specialist for consideration of further/tapering doses.
Storage	Stock must be securely stored according to organisation medicines policy and in conditions in line with SPC, which is available from the electronic Medicines Compendium website
Drug interactions	**Drug-drug interactions:** Whilst the product SPC states that no clinically significant drug-drug interactions exist with varenicline, all concurrent medications must be checked for interactions in case of

	updated SPC advice. Where a clinically significant drug interaction is identified the individual should be referred to an appropriate clinician for consideration of suitability. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website **Drug-smoking interactions:** Physiological changes resulting from smoking cessation, with or without treatment with varenicline, may alter the pharmacokinetics or pharmacodynamics of some medicinal products, for which dosage adjustment may be necessary. As smoking induces CYP1A2, smoking cessation may result in an increase of plasma levels of CYP1A2 substrates. Refer to Cautions section for specific advice. For further advice see: Considering drug interactions with smoking Managing specific interactions with smoking Individuals should be reviewed at each collection point to ensure that any relevant monitoring has been carried out by the individual/their health care professional noting specifically the detail given in Cautions section, and Appendix B.
Identification & management of adverse reactions	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. In the event of a severe adverse reaction (including cutaneous reactions or exacerbation of known psychiatric illness: See Individuals with current or past history of psychiatric disorders for further information), the individual must be advised to stop treatment immediately and seek urgent medical advice.
Management of and reporting procedure for adverse reactions	• Healthcare professionals and individuals/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme • Record all adverse drug reactions (ADRs) in the individual's clinical record. • Report and document in accordance with 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. • The pharmacy should directly notify the stop smoking service adviser if concerns on the supply of varenicline are received back from the GP practice.
Written information to be given to individual or carer	• Provide marketing authorisation holder's patient information leaflet (PIL) provided with the product. • Give any additional information in accordance with the local service specification.
Advice/follow up treatment	**Pharmaceutical** • Explain the dose, frequency and method of administration, including how to use the initiation pack. • The individual/carer should be advised to read the PIL. • Inform the individual/carer of possible side effects and their management. • The individual/carer should be advised to seek medical advice in the event of a serious adverse reaction. • The tablets should be swallowed whole with water, they can be taken either with or without food. There is some evidence that taking with food reduces the likelihood of nausea.

	• Individuals should be warned that the medicine may make them sleepy and not to drive or operate machinery/tools if affected. Individuals should exercise caution before driving or using machinery until they are reasonably certain that varenicline does not adversely affect their performance. Occupational risk should be highlighted, as appropriate.
	
	Medical/Psychological
	• Individuals taking varenicline, or any other treatment for tobacco dependence, should be advised to discontinue treatment and seek prompt medical advice if they develop agitation, depressed mood, or suicidal thoughts (MHRA/CHM advice) and also to contact the PGD user or the tobacco dependence services.
	• Advise on actions to be taken by individuals with a history of mild to moderate mental health disorders and if their symptoms worsen i.e., discontinue treatment and report to the GP Practice and PGD user as soon as possible.
	• Tobacco dependence treatment may lead to a change in blood glucose levels. Individuals with diabetes should be advised to be vigilant for signs of hypo/hyperglycaemia and, where usually monitored, be advised to monitor blood glucose more frequently.
	• Individuals taking medications detailed within the Cautions section of this PGD should be advised on any required action.
	• Individual 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.
	
	Individual
	• Individuals should set a quit date for 7 to 14 days after initiation of varenicline treatment.
	• Discuss the major reasons for varenicline failure which are:
	  ○ Unrealistic expectations;
	  ○ Lack of preparation for the potential for the tablets to cause nausea;
	  ○ Insufficient or incorrect use;
	  ○ Insufficient support from a trained tobacco dependence advisor.
	• Further information that may support adherence as part of shared decision making:
	  ○ Varenicline works by acting on the parts of the brain which are affected by nicotine in cigarettes.
	  ○ Varenicline does not remove all temptation to smoke, but it does make abstinence easier (“it takes the edge off the discomfort”).
	  ○ Approximately one third of individuals may experience mild nausea around 30 minutes after taking varenicline. This reaction usually diminishes gradually over the first few weeks, and most people

	tolerate it without problems. If this occurs, advise the individual to return for consideration of dosage reduction or if severe, individuals should be referred to their G.P. ○ Tobacco dependence treatment with or without medication is associated with various symptoms (e.g. irritability, poor sleep etc.). Individuals should be made aware that they may experience any of these side effects and on discontinuation of therapy, but it is not clear whether the effects are linked to therapy or to nicotine withdrawal. Advise this is a short-term treatment for long-term benefit. ○ Possible physical changes on stopping smoking, e.g. weight gain and how to manage this. ○ Outline the expectations of both the individual and the PGD user with reference to the ongoing treatment and future appointments. ○ Details of next consultation with the PGD user. • 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.
Records	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 of registered healthcare professional operating under this PGD • Declaration, professional registration (e.g. NMC, GPhC) number and name of registered healthcare professional who supplied the medication • 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 within 1 day of supply via PharmOutcomes email notification • Details of any drug-smoking interactions, monitoring required and any actions taken

	• 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 local policy.**

4. Key references

Key references	• Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • National Institute for Health and Care Excellence (2013). Overview | Patient group directions | Guidance | NICE | Updated March 2017 Available at: https://www.nice.org.uk/Guidance/MPG2 [• National Institute for Health and Care Excellence (2007). Overview | Varenicline for smoking cessation | Guidance | NICE. Available at: https://www.nice.org.uk/guidance/ta123 • Specialist Pharmacy Service (2023). Considering drug interactions with smoking. Available at: https://www.sps.nhs.uk/articles/considering-drug-interactions-with-smoking/ • Specialist Pharmacy Service (2023). Managing specific interactions with smoking. Available at: https://www.sps.nhs.uk/articles/managing-specific-interactions-with-smoking/ • Medicines and Healthcare products Regulatory Agency (2014). Smoking and smoking cessation: clinically significant interactions with commonly used medicines. GOV.UK. Available at: https://www.gov.uk/drug-safety-update/smoking-and-smoking-cessation-clinically-significant-interactions-with-commonly-used-medicines • 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/ • West R, Evins AE, Benowitz NL, Russ C, McRae T, Lawrence D, St Aubin L, Krishen A, Maravic MC, Anthenelli RM. (2018). Factors associated with the efficacy of smoking cessation treatments and predictors of smoking abstinence in EAGLES. Addiction (Abingdon, England), 113(8), pp.1507–1516. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6055735/ • National Centre for Smoking Cessation and Training (NCSCT) (2024). Varenicline. Available at: https://www.ncsct.co.uk/library/view/pdf/NCSCT-Generic-varenicline.pdf • National Centre for Smoking Cessation and Training (NCSCT). NHS Standard Treatment Plan (STP) for Inpatient Tobacco Dependence in Mental Health Hospitals. Available at:

	https://www.ncsct.co.uk/publications/STP-inpatient-mental-health • Agrawal S, Evison M, Ananth S, Fullerton D, McDill H, Perry M, Pollington J, Restick L, Spencer E, Vaghela A. (2024) Medical management of inpatients with tobacco dependency. *Thorax*; **79:**3-11. Available at: https://thorax.bmj.com/content/thoraxjnl/79/Suppl_1/3.full.pdf

Appendix A: Registered health professional authorisation sheet

PGD Name: Community pharmacy supply of varenicline tablets as part of the tobacco dependence treatment services across the North-East of England
Version: 1.2
Valid from: 7 July 2025
Expiry: 31 October 2027
Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

Registered health professional

By signing this patient group direction, you are indicating that you agree to its contents and that you will work within it.
Patient group directions do not remove inherent professional obligations or accountability.
It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

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

Authorising manager

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

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.
This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.
This information should be retained according to organisation PGD policy.

Appendix B: Drug-smoking interactions

VERY HIGH RISK:

Medication	Impact of smoking cessation	Possible adverse effects	Action	When to implement action
Clozapine	Metabolism of clozapine is reduced. Lower doses of clozapine needed.	Risk of significant adverse effects, including death and seizures, in individuals who abruptly stop smoking whilst taking clozapine, without dose adjustments.	Patients taking Clozapine are excluded	Patients taking Clozapine are excluded

Useful information:

- MHRA/CHM Drug Safety Update: clozapine and other antipsychotics: monitoring blood concentrations for toxicity
- Managing the risks associated with patients prescribed clozapine

HIGH RISK:

Medication	Impact of smoking cessation	Possible adverse effects	Action	When to implement action
Insulin	May affect insulin resistance and enhance insulin sensitivity.	Increased risk of hypoglycemia.	Individuals on insulin may be supplied with varenicline but must be advised to monitor their blood glucose levels closely and of the symptoms of hypoglycemia. 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 an appropriate care provider.	Prior to quit attempt. i.e. patient advised on actions to take and GP practice informed via PharmOutcomes notification on the supply of the initiation pack (which is 1 week before the patient will stop smoking on day 8-14 of the initiation pack).
Warfarin	Metabolism of warfarin is reduced.	Increased risk of adverse effects of warfarin (i.e. bleeding).	Individuals on warfarin may be supplied with varenicline but must advise the INR clinic of their intention	Prior to quit attempt. i.e. patient advised on actions to take and GP practice informed via PharmOutcomes

Medication	Impact of smoking cessation	Possible adverse effects	Action	When to implement action
			to stop smoking using varenicline. A blood test should be arranged with the clinic as per their instructions. The pharmacist should check the individual's yellow book on every scheduled consultation ensuring that their INR is being checked regularly, and that it is within the individual's normal range. If the individual is unwilling to disclose this information, varenicline must not be supplied under this PGD and the individual should be referred to an appropriate care provider.	notification on the supply of the initiation pack (which is 1 week before the patient will stop smoking on day 8-14 of the initiation pack).
Haloperidol or Olanzapine	Metabolism of haloperidol and olanzapine are reduced.	Increased risk of adverse events (e.g. dizziness, sedation, hypotension).	Patients taking Haloperidol or Olanzapine are excluded	Patients taking Haloperidol or Olanzapine are excluded
Theophylline or aminophylline	Metabolism of theophylline and aminophylline are reduced.	Could cause plasma theophylline levels to rise, possibly to toxic levels if the dose of theophylline/aminophylline is not adjusted.	Patients taking Theophylline or Aminophylline are excluded	Patients taking Theophylline or Aminophylline are excluded
Erlotinib	Metabolism of erlotinib is reduced.	Rapid dose reduction required upon smoking cessation.	Patients taking Erlotinib are excluded	Patients taking Erlotinib are excluded
Riociguat	Metabolism of riociguat is reduced.	Increased risk of adverse effects of riociguat (e.g. dizziness, headache, nausea, diarrhoea).	Patients taking Riociguat are excluded	Patients taking Riociguat are excluded

MODERATE RISK:

Medication	Impact of smoking cessation	Possible adverse effects	Action	When to implement action
Agomelatine Chlorpromazine Flecainide Fluvoxamine Methadone Mexiletine Melatonin Riluzole Ropinirole	Metabolism of medication is reduced	Increased risk of adverse effects (see below for further information)	Individuals taking any of the following medicines should be informed of the increased risk of adverse effects when stopping smoking. Ensure the service provider who prescribes any of these interacting medicines to any individual supplied with varenicline under this PGD are aware of the individual's intention to stop smoking and the dose is adjusted accordingly prior to stopping smoking, (if required).	Prior to quit attempt. i.e. patient advised on actions to take and GP practice informed via PharmOutcomes notification on the supply of the initiation pack (which is 1 week before the patient will stop smoking on day 8-14 of the initiation pack).

Useful information:

- Managing specific interactions with smoking
- Individual drug Summary of Product Characteristics (SPC): accessible via:
  - Electronic medicines compendium
  - MHRA