PATIENT GROUP DIRECTION for the Supply of:

Varenicline tablets

By: Accredited Pharmacists/Pharmacy Technicians (under Authorising Person for PGD at the Pharmacy)

In: Community Pharmacies in Barnsley, Calderdale, Doncaster and Sheffield accredited by Yorkshire Smokefree

- It is the responsibility of the professional working under this PGD to verify that the client fulfils the stated criteria for supply of the treatment concerned

- It is not appropriate to have a PGD in place that is infrequently used by health care professionals because of progressive unfamiliarity with its contents. Any healthcare professional that works to a PGD infrequently should consider whether to cease doing so

- Varenicline is a licensed Prescription Only Medicine as defined by the Medicines Act 1968 and Prescription Only Medicines (Human Use) Order 1997

Varenicline is subject to standard MHRA safety monitoring procedures, healthcare professionals are asked to report any adverse reactions via the Yellow Card Scheme

- This PGD takes the place of a Prescription, as defined by The Human Medicines Regulations 2012

- Clinical indications, Contraindications, and Cautions are as set out in the Summary of Product Characteristics

- Inclusion and Exclusion criteria are summarised within the PGD

- "Off Label" use is not supported by the PGD

It is the responsibility of Clinicians issuing varenicline under the PGD to assess patients' suitability against the PGD Inclusion and Exclusion criteria and the SPC Indications/Contraindications. Patients falling outside of these criteria cannot receive varenicline under the PGD.

PGD Review date: 13st November 2027

1. Purpose of the PGD		
For accredited pharmacists/**Pharmacy Technicians (under Authorising Person for PGD at the Pharmacy – see page 14 for definition of this role)** to supply varenicline within its licensed indications as an option for smokers who have expressed a desire to quit smoking and who will be supported and monitored by Yorkshire Smokefree or may be referred to an accredited pharmacy by Yorkshire Smokefree contracted local Stop Smoking Service.		
2. Clinical condition or situation to which this PGD applies		
2.1	Define condition/situation	Tobacco dependence treatment and reduction of nicotine cravings in individuals who smoke and who are willing to seek treatment for tobacco dependence.
2.2	Qualifications & 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 Patient Group Directions.
2.3	Initial training	The registered healthcare professional authorised to operate under this PGD must have: • 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) 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.
2.4	Competency assessment	Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions
2.5	Ongoing training & 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.
2.6	Criteria for inclusion	• Clients over 18 years of age • Informed consent including consent to

		share relevant information with the individual's GP Practice (via local systems), where registered. • Individual agrees to receive advice and treatment from the registered healthcare professional in line with this PGD • Tobacco users identified as sufficiently motivated to quit • Tobacco users who are receiving support to stop smoking with Yorkshire Smokefree or a Yorkshire Smokefree contracted Stop Smoking Service • A medical history is taken and documented to establish that there are no contraindications for treatment with varenicline and that any cautions for use are recorded (see Criteria for exclusion). Refer to Appendix A for *Varenicline voucher*
2.7	Criteria for exclusion	• Consent to treatment refused and/or consent refused to share information with the individual's registered GP Practice • Tobacco users not sufficiently motivated to quit or to use varenicline • Clients under 18 years of age • Individuals receiving varenicline and/or tobacco dependence treatment (i.e. Cytisinicline (Cytisine), Bupropion or Varenicline) from another provider • Sensitivity to varenicline or any of its excipients • Pregnancy/ breastfeeding • Epilepsy or history of fits or seizures • Known or suspected end stage renal disease (CKD stage 5, eGFR <15mL/min/1.73m2) • Individuals unable to absorb oral medications and/or inability to swallow solid oral dosage formulations (i.e. tablets) • Clients who have experienced serious or worrying side effects from a previous course of varenicline – including Stevens-Johnson Syndrome or Erythema Multiforme • Patients on Clozapine excluded from this PGD through community pharmacy (can be looked at separately through service users consultant – prescribed through them with support from YSF)

		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.
2.8	Criteria for cautions [to include consideration of Concurrent medication]	**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. This will be discussed weekly for 4 weeks, then biweekly thereafter and documented by the YSF representative supporting the patient. **Renal impairment** **Ask the client if they have known renal impairment/chronic kidney disease.**

		If there is doubt it may be possible to obtain U&E's through the NHS app or the client can ask for a copy of most recent results through their GP - No dosage adjustment is necessary for clients with mild to moderate renal impairment (egfr >30ml/min). - For clients who disclose moderate renal impairment (egfr 30 – 50ml/min) dosing may be reduced to 1 mg once daily if not tolerating the side effects of the medication. Can be discussed by YSF in weekly follow up. - For clients with severe renal impairment (egfr 15 – 29ml/min) the recommended dose is 1mg once daily (0.5mg for first 3 days) - Based on insufficient clinical experience with Varenicline in clients with end stage renal disease (egfr <15ml/min), treatment is not recommended - **Effect of Smoking Cessation: (Appendix B)** • Cigarette smoke stimulates a liver enzyme responsible for metabolising some medicines in the body, such as theophylline, warfarin, clozapine and insulin, meaning that the metabolism of these medications increases. Clients should be warned that physiological changes resulting from smoking cessation, **with *or without*** treatment with varenicline, may alter the pharmacokinetics or pharmacodynamics of some medicinal products for which dose adjustment may be necessary. **YSF service should enquire if the patient is taking Warfarin, Aminophylline/Theophylline and if so, email a letter to the client's GP/warfarin clinic (if client consents) to see if they would be happy to make dose adjustments and/or monitoring through the period of smoking cessation. YSF service to inform the client that they must contact their GP to inform them that they intend to stop smoking in the next few weeks. If the client agrees to do this the voucher may be issued. The pharmacy professional will make the clinical decision whether to supply varenicline through the PGD bearing in mind the above contact with GP. The pharmacy professional should counsel the client on possible symptoms to be aware of that could indicate a rise in plasma theophylline level i.e. vomiting, dilated pupils, sinus tachycardia and**

		hyperglycaemia. If a supply is made, the GP must be notified of the supply by email within 48 hours. **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.** **High Risk secondary care medicines including Olanzapine, Erlotinib & Riociguat will require informing secondary care consultant if considering stopping smoking to they can ensure they either amend dosages/monitor for side effects once treatment started. This should preferably be completed before sending to community pharmacy.** - If a client is a diabetic on insulin treatment a judgement must be made by YSF/PGD user on their ability to test and manage their blood glucose or for a carer to do it for them. If so they should be advised to monitor their blood glucose levels more closely after stopping smoking and adjust insulin doses as necessary. - When the client stops smoking, metabolism of theophylline/aminophylline is reduced which could cause plasma levels to rise, possibly to toxic levels if the dose is not adjusted. Signs of theophylline toxicity are: - vomiting, dilated pupils, sinus tachycardia and hyperglycaemia - Clients on Warfarin need to have a plan for weekly INR's during the period of smoking cessation and for one month after to ensure dose adjustments are made if necessary to avoid a raised INR - Clients on Olanzapine need authorisation from the consultant and a plan for side effects to be monitored on smoking cessation. A dose reduction prior is not normally advised but may be recommended by the consultant if side effects including dizziness, sedation, hypotension develop. - Clients on Erlotinib from cancer services should not cease smoking without discussion with their consultant. - Clients on Riociguat from pulmonary hypertension specialist should not cease

		smoking without discussion with their specialist. **Please note: 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. Appendix B contains medications with moderate risk of increases on smoking cessation. Appendix C is a list of potential side effects and actions required which is from SPS and NICE guidelines.** **<u>Other Cautions:</u>** • **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.
2.9	Client consent [verbal, written, implied]	Informed consent as stated in the local consent policy, including consent to the use of the PGD, and informing GP of supply of varenicline

2.10	Action if client excluded	Pharmacies providing Yorkshire Smokefree contracted Stop Smoking Services should offer clients the option of NRT. This might include any of the conditions referred to as exclusion criteria above, but also previously unrecognised co-morbidities. Other pharmacies should direct the client back to Yorkshire Smokefree. Document action in client's medication record (PMR) and 'Inform service provider of the outcome'
2.11	Action if treatment declined by client	Pharmacies providing Yorkshire Smokefree contracted Stop Smoking Services should offer other available smoking cessation options if appropriate. Other pharmacies should direct the client back to Yorkshire Smokefree. Document action in client's medication record (PMR) and inform the Service Provider of the outcome
3. Characteristics of staff		
3.1	Class of healthcare professional for whom PGD is applicable & professional qualifications required	Pharmacist or pharmacy technician registered with General Pharmaceutical Council, working within and for a pharmacy with an agreement with Yorkshire Smokefree to provide varenicline under PGD. It is the responsibility of the individual pharmacist or pharmacy technician to ensure that they and their staff are competent in all aspects of supply of Varenicline. This PGD will only apply whilst the pharmacist or pharmacy technician is employed or contracted/working at the time in an accredited Pharmacy within Barnsley, Calderdale, Doncaster or Sheffield.
3.2	Additional requirements/ specialist qualifications required	Accredited pharmacies will have a suitable private consultation room / area which is available for all client consultations.
3.3	Continued training requirements	The practitioner should be aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of individual scope of practice.
4. Description of treatment		
4.1	Generic name of medicine and form (e.g. tablets)	Varenicline 0.5mg and 1mg tablets
4.2	Legal status POM/P/GSL	POM
	Licensed or unlicensed use	Licensed

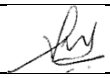
	[If unlicensed state rationale for use]	
4.3	Dose [Where a range is applicable include criteria for deciding on a dose]	**<u>eGFR >30ml/min</u>** **Days 1 – 3:** 0.5 mg (white tablets) once daily **Days 4 – 7:** 0.5 mg twice daily **Day 8 to the end of treatment (up to a maximum of 12 weeks):** 1 mg (light blue tablets) twice daily Note: The quit date is often on day 8 of taking Varenicline. Patients who cannot tolerate the adverse effects of varenicline can have the dose lowered temporarily or permanently to 0.5 mg twice daily (See BNF 4.10.2). **<u>egfr 15-29ml/min:</u>** **Severe renal impairment** **Days 1-3:** 0.5mg (white tablets) OD **Day 4 onwards** 1mg (light blue tablets) OD Clients must attend the same pharmacy for all supplies of Varenicline. In exceptional circumstances e.g. where the pharmacy has a locum who is unable to supply under the PGD the client may access another pharmacy A break in treatment of up to 3 days is permitted, after this Varenicline must not be supplied and the client should be referred back to the local Yorkshire Smokefree service.
4.4	Route / method of administration	Oral
4.5	Total dose and number of times treatment can be administered; state time frame	• Clients should be supplied a 14 day initiation pack and should set a quit date 7 to 14 days after initiation • Clients should be seen by the stop smoking Advisor, weekly for at least 4 weeks after the quit date, then fortnightly. • Clients should be seen by the pharmacist or pharmacy technician at each supply of Varenicline • Treatment plan: -Starter pack – 14 days -Maintenance pack- 14 days -Maintenance pack- 28 days -Maintenance pack- 28 days • The treatment course is up to 12 weeks

4.6	Information on follow-up management	Advise to seek medical advice if more severe reactions to medication occur
4.7	Written/verbal advice for client before/after treatment and management	• Ensure a PIL is provided to the client and advise them to read this prior to starting • Clients should be advised to set a quit date 7 to 14 days after initiation • The major reasons for varenicline failure are: - Unrealistic expectations - Unable to tolerate side-effect of nausea - Insufficient or incorrect use • It is important to make sure that the client understands the following points: 1. The tablets should be swallowed whole with water 2. Varenicline is an effective medication but effort and determination are also necessary 3. It works by acting on the parts of the brain which are affected by nicotine in cigarettes 4. It does not remove all temptation to smoke, but it does make abstinence easier 5. Varenicline is safe, but about a third of clients may experience mild nausea some 30 minutes after taking it. This reaction usually diminishes gradually over the first few weeks and is less troublesome if tablets are taken with or after food. Most clients tolerate it without problems. If client is unable to tolerate due to nausea consider dose reduction or alternative stop smoking product. 6. The patient should be warned that the medication can cause drowsiness 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. 7. Clients should be advised to stop Varenicline and seek prompt medical advice from GP/crisis team/Yorkshire smoke free team/pharmacist if they develop agitation, depressed mood or suicidal thoughts 8. Individuals taking medications detailed within the Cautions section of this PGD should be advised on any required action. 9. Instruct on correct use and daily dose. Use mock product packaging for the explanation. Clients should take varenicline for 7 to 14 days before stopping smoking

		• At the end of treatment, discontinuation of varenicline has been associated with an increase in irritability, urge to smoke, depression, and/or insomnia in up to 3% of clients. The pharmacist or pharmacy technician should inform the client accordingly and discuss or consider the need for dose tapering • No clinically significant drug interactions have been reported
4.8	Communication with client's General Practitioner	In every case when a supply of varenicline is made in accordance with this PGD, the pharmacist or pharmacy technician must inform the client's General Practitioner (GP) of the supply in a timely manner, using 'Notification of first OR further supply of Varenicline through the PGD' (Appendix A). This must not exceed one calendar month. This applies whether the pharmacy is a Yorkshire Smokefree contracted Stop Smoking Service Provider or not.
4.9	Instructions on identifying, managing & reporting adverse drug reactions	For clients experiencing mild adverse effects after dose increase to 1mg twice daily, and where this is interfering with the quit attempt, consider a temporary or permanent dose lowering to 0.5 mg twice daily. (See BNF 4.10.2) Review at next scheduled appointment. Smoking cessation with or without treatment is associated with various symptoms. For example, dysphoria or depressed mood; insomnia, irritability, frustration or anger; anxiety; difficulty concentrating; restlessness; decreased heart rate; increased appetite or weight gain have been reported in clients attempting to stop smoking. No attempt has been made in either the design or the analysis of the Varenicline studies to distinguish between adverse events associated with study drug treatment or those possibly associated with nicotine withdrawal. Clients should be asked at every appointment about their mood. If the client develops suicidal thoughts or behaviour, they should be told to stop treatment and contact their GP immediately. Where the pharmacy is not the client's Yorkshire Smokefree contracted Stop Smoking Service Provider, the pharmacist or pharmacy technician should also inform the Service Provider. If the client, family or care givers have concerns about agitation, depressed mood or changes in behaviour varenicline should be stopped immediately.

		Please refer to current BNF and SPC for full details. Report all Adverse Drug Reactions using the Yellow Card System: https://yellowcard.mhra.gov.uk/
4.10	Arrangements for referral for medical advice	Pharmacist or pharmacy technician must be able to advise client/parent/carer what action to take in the event of the client experiencing any side effects and the most appropriate action (e.g. dose reduction or medical service to contact.
4.11	Precautions, facilities & supplies	Store in a cool dry place. Order supplies from licensed pharmacy wholesalers.
4.12	Specify method of recording supply sufficient to enable audit trail	Pharmacists or pharmacy technician are required to keep a record of the consultation and supply in the Patient Medication Records (PMR). The supply of Varenicline should also be recorded on Quitmanager: • Client's name, address, date of birth and GP details. • Referring Yorkshire Smokefree contracted Stop Smoking Service Provider. • Date supplied and name of the pharmacist or pharmacy technican who supplied the medication. • Reason for inclusion. • Advice given to client. • Details of any adverse drug reaction and actions taken including documentation in the client's medical record via GP (as well as reporting to the CSM using the 'Yellow Card' reporting system.

5. Audit			
The use of this PGD to be monitored by the service in which it is used.			
6. Management			
6.1	This PGD has been written by:		
Job title	Name	Signature	Date
Lead Pharmacist	Patrick Cleary	P.J Cleary	16/12/2024
Health and Wellbeing community manager	Jan Spence	J D Spence	23/09/2025
6.2	This PGD has been approved on behalf of South West Yorkshire Partnership NHS Foundation Trust by:		
Job title	Name	Signature	Date

Medical Director	Subha Thiyagesh		07.10.2025

6.3	Persons permitted to authorise staff they are responsible for to operate this PGD
	Commissioning Manager for the County Council or Deputy

7. References and Sources of Information

- 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/
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- 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/
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- 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
- Specialist Pharmacy Service. Managing specific interactions with smoking; Oct 2023. Available from Managing specific interactions with smoking – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice. [Accessed online: 22/1/24].
- NICE. Which drugs are affected by stopping smoking; Sept 2023. Available from Drugs affected by smoking cessation | Prescribing information | Smoking cessation | CKS | NICE. [Accessed online: 22/1/24].
- NICE. What are the signs and symptoms of drugs commonly involved in poisoning or overdose; March 2022. Available from Signs and symptoms | Diagnosis | Poisoning or overdose | CKS | NICE. Accessed online: 22/1/24].

- **It is the responsibility of the Authorising Person to keep this list up to date and in a safe place for reference.** Any healthcare professionals who no longer meets the competency requirements or leave the service or practice must be removed from the list; likewise, any new healthcare professionals meeting the competency requirements should be added to the list in order to work under the Patient Group Direction.

- The Authorising Person is only expected to confirm that the Healthcare Professionals meets the minimum training and competency requirements under this PGD. It is the responsibility of the Healthcare Professional themselves and their Professional Body to ensure that they are fit to practice.

- This Patient Group Direction is to be read, agreed to and signed by all healthcare professionals it applies to. The original signed copy should be retained by the Authorised Person with responsibility for PGDs within the pharmacy. A copy should be retained by each pharmacist or pharmacy technician .

- **I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work under it within my professional code of conduct**

Healthcare Professionals permitted to supply or administer under this PGD				
Name & job title of Healthcare Professional	Signature	Authorised Person with responsibility for PGDs: Commissioning Manager or Deputy	Signature	Date approved

Appendix A:

Notification of FIRST supply of Varenicline to your patient through the Varenicline PGD

Patient Name	
Address	
Date of Birth	

Dear Doctor

I have supplied the following stop smoking medication to your patient named above, through the South West Yorkshire NHS Foundation Trust/Yorkshire Smokefree Patient Group Direction for the Supply of Varenicline Tablets of which I am an accredited Pharmacist/pharmacy technician.

Varenicline starter pack x 1

PGD Requirements

	Yes	No
1. Aged 18 or above		
2. Tobacco dependent and motivated to quit		
3. Agreed to behavioural support during course of Varenicline		
4. Is the client currently pregnant or breastfeeding		
Does the client have history of:		
5. End stage renal disease (efgr <15ml/min)		
6. Epilepsy or history of fits or seizures		
7. Sensitivity to varenicline or excipients, or serious side effects from previous course of varenicline		
Clients must answer YES to Qs 1-3 to be eligible **If clients answer YES to any of Qs 4-7 they are NOT eligible for varenicline through the PGD**		

Pharmacist/Pharmacy Technician Name **Date of supply**

Name and Address of Pharmacy

Notification of FURTHER supply of Varenicline to your patient through the Varenicline PGD

Patient Name	
Address	
Date of Birth	

Dear Doctor

I have supplied the following stop smoking medication to your patient named above, through the South West Yorkshire NHS Foundation Trust/Yorkshire Smokefree Patient Group Direction for the Supply of Varenicline Tablets of which I am an accredited Pharmacist/ pharmacy technician.

Varenicline Maintenance Pack 28 x 1 mg bd	
Varenicline Maintenance Pack 28 x 0.5 mg bd	

Pharmacist/Pharmacy Technician Name

Date of supply

Name and Address of Pharmacy

Notification of FURTHER supply of Varenicline to your patient through the Varenicline PGD

Patient Name	
Address	
Date of Birth	

Dear Doctor

I have supplied the following stop smoking medication to your patient named above, through the South West Yorkshire NHS Foundation Trust/Yorkshire Smokefree Patient Group Direction for the Supply of Varenicline Tablets of which I am an accredited Pharmacist/pharmacy technician.

Varenicline Maintenance Pack 56 x 1 mg bd	
Varenicline Maintenance Pack 56 x 0.5 mg bd	

Supply: …. Of 2.

Pharmacist/Pharmacy Technician Name

Date of supply

Name and Address of Pharmacy

Appendix B: Drug-smoking Interactions:

High risk:

Medication	Impact of smoking cessation	Possible adverse effects	Action	When to implement action
Olanzapine	Metabolism of olanzapine is reduced.	Increased risk of adverse events of olanzapine (e.g. dizziness, sedation, hypotension).	Ensure the service provider who prescribes olanzapine to any individual supplied with varenicline under this PGD are aware of the individual's intention to stop smoking **before** varenicline is supplied.	Prior to varenicline supply
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.	Service users advised to increase monitoring of BM's and followed up at appointments. Advised contact GP/diabetes team if any issues develop with high or low BM's
Theophylline or aminophylline	Metabolism of theophylline and aminophylline are reduced.	Could cause plasma theophylline levels to rise, possibly to toxic levels	The PGD user must inform the individual's prescriber of their intention to stop smoking and agree subsequent additional monitoring by the prescriber **before** the individual is supplied with varenicline.	Prior to varenicline supply

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 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.	Prior to varenicline supply
Erlotinib	Metabolism of erlotinib is reduced.	Rapid dose reduction required upon smoking cessation.	Ensure the service provider who prescribes erlotinib to any individual supplied with varenicline under this PGD are aware of the individual's intention to have tobacco dependence treatment and the dose is adjusted accordingly **before** varenicline is supplied.	Prior to varenicline supply
Riociguat	Metabolism of riociguat is reduced.	Increased risk of adverse effects of riociguat (e.g. dizziness, headache, nausea, diarrhoea).	Ensure the service provider who prescribes riociguat 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 **before** varenicline is supplied.	Prior to varenicline supply

Moderate risk:

Medication	Impact of smoking cessation	Possible adverse effects	Action	When to implement action
Chlorpromazine	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).	Will be assessed on a weekly basis in the first 4 weeks, asking if any new side effects or concerns
Flecainide				
Fluvoxamine				
Haloperidol				
Methadone				
Mexiletine				
Melatonin				
Riluzole				
Ropinirole				

Appendix C: List of medications affected by stop smoking and potential signs and symptoms (derived from SPS & NICE guidelines)

	Action required & Urgency
Theophylline	Aim to reduce dose by 25-30% over first week. Monitor the patient closely for signs of toxicity (vomiting, restlessness, agitation, dilated pupils, hyperglycaemia, hyperglycaemia, tachycardia, haematemesis, convulsions, hypokalaemia and ventricular arrythmias). Any signs of toxicity arrange urgent admission to acute hospital.
Erlotinib	Smoking cessation should not commence without seeking specialist advice first.
Warfarin	Service monitoring warfarin (GP or warfarin clinics) should be contacted prior to stopping smoking. Risk of bleeding increased due to rising INR. Recommended weekly INR through smoking cessation period until stable. As it is longer acting medication it is prudent to continue monitoring weekly for up to a month or until INR levels appear stabilised. Advice patient to consult yellow book on the signs of increased bleeding and seek urgent assessment should these signs develop.
Olanzapine	Specialist contacted prior to stopping smoking. Be alert for adverse effects such as dizziness, sedation, hypotension. If concern about side effects then a dose reduction of up to 25% may be required.
Haloperidol	Be alert for adverse effects such as dizziness, sedation, extra-pyramidal effects, anti-cholinergic effects, arrythmias. If concerns do ECG and reduce dose by 25%.
Chlorpromazine	Be alert for adverse effects such as dizziness, sedation, extra-pyramidal effects, tachycardia, arrythmia, hypothermia, hypotension, respiratory depression, seizures. If concerns do ECG and reduce dose.
Fluvoxamine	Monitor for side effects such as nausea, tremor and nystagmus. If side effects, consider dose reduction.
Agomelatine	Monitor for side effects such as nausea, dizziness and sedation. If side effects, consider dose reduction
Methadone	Monitor for signs of opiate toxicity such as drowsiness, respiratory depression, pinpoint pupils, hypotension and loss of consciousness. Reduce dose if needed. Patient likely to get supplies from substance misuse teams who can help with any queries/advice on dose.
Melatonin	Drowsiness, headache and dizziness can increase. If occurs reduce dose.

Cinacalcet	While not expected to cause major changes it is advised to seek advice from the specialist who initiated (likely renal). May need to monitor parathyroid levels.
Mexiletine	Monitor for side effects such as nausea, tremor and hypertension. Any concerns contact specialist who manages the drug.
Riluzole	Monitor for side effects of drowsiness, headache and dizziness. Discuss with specialist involved (likely neurology)
Riociguat	Need to contact specialist initiator (likely pulmonary hypertension specialist) prior to stopping smoking. Levels increase by up to 60%. Monitor for nausea, diarrhoea, dizziness and headache.
Ropinirole	Monitor for side effects of nausea and dizziness. May need to adjust dose if necessary (Parkinsons disease).
Pifenidone	Seek advice from specialist initiator (likely respiratory) as trials suggest increased levels of up to 50%. Monitor for sings of hepatic toxicity. Need LFT's.
Flecainide	Monitor for side effects such as dizziness and visual disturbances, levels can increase up to 50%, consider dose reduction.